

# **Freedom or Free-for-All in Irish Healthcare?**

Establishing Improved Patient and Consumer Protection Mechanisms in the  
Irish Complementary and Alternative Medicine Sector

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CLAIRE LOUISE O'LEARY





## SUMMARY

Complementary and alternative therapies (CAM), defined by the Cochrane Collaboration, among others, as “a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period”, have become increasingly popular in Ireland, presenting a challenge for conventional healthcare providers and for those upon whom the duty falls, or should fall, to protect the public from harm, by assessing the safety, efficacy and quality of CAM products and services available on the Irish market.

There is a growing emphasis on choice in healthcare, undoubtedly influenced by various widely-publicised controversies undermining public confidence in authority and in conventional healthcare, by the increasing ease with which information, accurate and inaccurate, is disseminated, by freedom of movement, ideas, and practices, and by higher levels of education and disposable wealth. However, the array of CAM therapies available to Irish consumers is vast, there is very limited high quality scientific evidence supporting the efficacy of most of the available therapies for most conditions and there is little by way of effective legal or ethical safeguards to prevent physical, psychological or financial harm to those who opt to use them, despite impassioned political rhetoric, the establishment of working groups, European guidance in the late 1990s in the form of two Resolutions on non-conventional medicine and commissioned reports in the early to mid-2000s recommending improvements in the regulation of the CAM sector. Existing general consumer protection mechanisms, most notably those addressing unfair and misleading practices in consumer transactions, have fallen short of their expected effect, with something of a blind-spot in respect of CAM, leaving misleading claims unchecked and highly visible in the marketplace at the time of writing.

The implications of this lack of appropriate and effective regulation take in issues of the right to bodily integrity, freedom of expression, public health protection, the conflicting constitutional rights of the child and the family unit, choice and access in healthcare and medical ethics. They are not limited to concerns of direct or immediate physical harm or issues of consumer rights, though it is argued that the consumer protection mechanism presents a workable and relatively inexpensive initial step in the introduction of a purpose-built CAM regulatory regime. Longer-term recommendations, focussing *inter alia* on public education, seeking consensus with media outlets on the importance of accurate and responsible reporting in matters of healthcare and science (called for in the Leveson Report in 2012), the establishment of one or more registers for CAM practitioners, enhanced requirements for the treatment of children using CAM and review of the oppressive use of defamation law to chill discourse in the fields of healthcare and science may prove complex, resource intensive and unpopular in some quarters. Nonetheless, if they are likely to meet the broad objective

of improving consumer protection in the CAM sector, they merit sincere consideration. It is argued that creating a strengthened form of the voluntary regulatory regime currently in place, as recommended by the National Working Group on the Regulation of Complementary Therapists in 2005, or working towards voluntary European harmonisation by adopting measures similar to neighbouring jurisdictions as recommended by the Parliamentary Assembly of the Council of Europe in their 1999 Resolution, may not provide sufficient protection for Irish consumers of CAM. The existing model of voluntary self regulation, however robust, is not an appropriate method of regulation for a sector in which no mandatory standards for education, training or practice exist and to whom general legal principles of consumer protection do not appear to apply. European calls for voluntary harmonisation of standards based on the practices of neighbouring Member States only work where similar traditions and cultures of CAM practice exist. In the UK, our nearest neighbour and, at least at the time of writing, fellow Member State, there is significant recognition of CAM and some statutory regulation and integration of a number of CAM therapies into the public health system, despite ongoing high-level debate, official acknowledgement that the evidence supporting the use of many CAM therapies is weak or absent, and politically and administratively difficult attempts to roll back public funding for these inefficacious therapies. It is demonstrably not in the interests of Irish regulators or of Irish consumers to emulate this chaotic situation simply to further the European objectives on free movement.

Instead, it is argued that Ireland, which has gained significant international recognition for its contribution in the STEM sector in recent years, must show leadership, basing future regulation on the best available evidence gleaned from high quality international research, and not on populist, sensationalist and, at times, anti-capitalist rhetoric, no matter how politically expedient. Any such system must have the flexibility to change the classification of a particular CAM therapy based on new evidence, this being a fundamental principle of the scientific process.

The increased popularity of CAM in Ireland has not been matched by increased research, surveillance, or acknowledgement of CAM by the State. The inadequacy of the response has crystallised risk to consumers, has created a fertile environment for charlatanry and has undoubtedly failed to attenuate the concerns of the Parliamentary Assembly in 1999 in respect of variable standards for CAM products and services between Member States. Immediate change is required to ameliorate some, if not all, of these issues. This may, it is argued, come in statutory form, mandating the registration of all those who wish to practice CAM and prescribing minimum standards for education and training, professional practice, and disclosure in obtaining informed consent, and putting in place appropriate, transparent, and publicly accessible grievance procedures. Alternatively, a novel model of Government Sponsored Self-Regulation, similar to that considered in Australia, might provide a more moderate and less confrontational approach to enhancing standards for the sector. By ensuring that minimum standards are established, consumer protection can be increased while informed choice in Irish healthcare is preserved.

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## INDEX OF ABBREVIATIONS

|        |                                                                 |
|--------|-----------------------------------------------------------------|
| ACI    | Acupuncture Council of Ireland                                  |
| AFPA   | Acupuncture Foundation Professional Association                 |
| AHPRA  | Australian Health Products Regulatory Agency                    |
| ASA    | Advertising Standards Agency of Ireland                         |
| BAI    | Broadcasting Association of Ireland                             |
| CAI    | Chiropractic Association of Ireland                             |
| CAM    | Complementary and alternative medicine                          |
| CCPC   | Competition and Consumer Protection Commission                  |
| CDC    | US Centre for Disease Control                                   |
| DCYA   | Department of Children and Youth Affairs                        |
| DOH    | Department of Health                                            |
| ECHR   | European Convention on Human Rights                             |
| ECtHR  | European Court of Human Rights                                  |
| EMA    | European Medicines Agency                                       |
| EU     | European Union                                                  |
| FDA    | US Food and Drug Administration                                 |
| GSSR   | Government Sponsored Self-Regulation                            |
| HPRA   | Health Products Regulatory Authority                            |
| HSE    | Health Service Executive                                        |
| ICCPR  | International Covenant on Civil and Political Rights            |
| ICESCR | International Covenant on Economic, Social and Political Rights |
| IMB    | Irish Medicines Bureau                                          |
| ISH    | Irish Society of Homeopaths                                     |
| MHRA   | UK Medicines and Healthcare products Regulatory Agency          |
| NCCAM  | US National Centre for Complementary and Alternative Medicine   |

|        |                                                             |
|--------|-------------------------------------------------------------|
| NCCIH  | US National Centre for Complementary and Integrative Health |
| NHMRC  | Australian National Health and Medical Research Council     |
| NHS    | UK National Health Service                                  |
| NIH    | US National Institutes for Health                           |
| NMBA   | National Midwifery Board of Australia                       |
| NRS    | National Rules Scheme                                       |
| OCI    | Osteopathic Council of Ireland                              |
| PA     | Product Authorisation                                       |
| PRTCM  | Professional Register of Traditional Chinese Medicine       |
| RFI    | Reiki Federation of Ireland                                 |
| SRS    | Simplified Registration Scheme                              |
| TCHM   | Traditional Chinese Herbal Medicine                         |
| TFEU   | Treaty on the Functioning of the European Union             |
| THMPRS | Traditional Herbal Medicinal Product Registration Scheme    |
| UN     | United Nations                                              |
| UNCRC  | United Nations Convention on the Rights of the Child        |
| WHO    | World Health Organisation                                   |
| WMA    | World Medical Association                                   |
| GMC    | UK General Medical Council                                  |
| SLAPP  | Strategic lawsuit against public participation              |



## INTRODUCTION

In spite of the advances in modern conventional medicine, complementary and alternative medicine (hereafter “CAM”),<sup>1</sup> which is almost entirely unregulated in Ireland, continues to gain popularity.<sup>2</sup> The reasons for the allure of these therapies are almost as varied as the individual CAM therapies themselves, from the perception that they are safer or more efficacious than a conventional therapy,<sup>3</sup> to the sense of empowerment and control over their healthcare experienced by consumers or users of these therapies.<sup>4</sup> Other attributes of CAM espoused by its consumers or patients are that its various therapies:

- (a) are holistic<sup>5</sup>;
- (b) are natural<sup>6</sup>;
- (c) permit more time to be spent with the patient than conventional therapy<sup>7</sup>; and
- (d) provide greater coalescence with the patient’s own values.<sup>8</sup>

So positive is the consumer perception of CAM, in fact, that to burden it with a novel regulatory regime may be considered both unnecessary and draconian. However, despite its significant popularity, there is limited scientific evidence in support of many of the claims made by those

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<sup>1</sup> The term ‘CAM’, though a convention in much of the available literature, refers to two ostensibly distinct groups of therapies: those used alongside conventional medicine (complementary therapies) and those used instead of conventional medicine (alternative therapies). It is not this delineation per se that creates complexity and confusion, but rather the fact that consumers do not always use the individual therapies as such a delineation might suggest; one person’s complementary therapy is another’s alternative. This was reinforced in early feedback from the small empirical study undertaken as part of this thesis. For this reason, the use of ‘CAM’ as a collective term and by reference to convention, was deemed the most appropriate approach for this thesis.

<sup>2</sup> Muhammad Raza, ‘Alternative treatment approaches in epilepsy: Mini-review’ (2011) 5(4) *Clinical and Experimental Medicine* 189. See also Mohammed Siahpush, ‘Postmodern values, dissatisfaction with conventional medicine and popularity of alternative therapies’ (1998) 34(1) *Journal of Sociology* 58; Susan Butler and others, ‘Use of complementary and alternative medicine among men with prostate cancer in a rural setting’ (2011) 36(6) *Journal of Community Health* 1004.

<sup>3</sup> Diane M Shumay and others, ‘Why some cancer patients choose complementary and alternative medicine instead of conventional treatment’ (2001) 50(12) *Journal of Family Practice* 1067. See also, Robert Oldendick and others, ‘Population-based survey of complementary and alternative medicine usage, patient satisfaction, and physician involvement’ (2000) 93(4) *Southern Medical Journal* 375; Edzard Ernst, ‘The role of complementary and alternative medicine’ (2000) 321 *British Medical Journal* 1133.

<sup>4</sup> Frank Riessman, ‘Alternative health movements’ (1994) 24(3) *Social Policy* 53, 57.

<sup>5</sup> Sherri A Olsen, ‘A review of complementary and alternative medicine (CAM) by people with multiple sclerosis’ (2009) 16(1) *Occupational Therapy International* 57, 60.

<sup>6</sup> For 46% of participants in the questionnaire carried out as part of this thesis, the fact that the CAM therapy or therapies used or procured were perceived as being natural was influential in their choice. See Chapter 6.

<sup>7</sup> Aslak Steinsbekk and Laila Launsø, ‘Empowering the cancer patient or controlling the tumor? A qualitative study of how cancer patients experience consultations with complementary and alternative medicine practitioners and physicians, respectively’ (2005) 4(2) *Integrative Cancer Therapies* 195, 198.

<sup>8</sup> John A Astin, ‘Why patients use alternative medicine’ (1998) 279(19) *Journal of the American Medical Association* 1548, 1553.

providing or promoting CAM, a situation which creates risks for consumers or patients relying on them, in whole or in part. It is this fundamental issue that is at the core of this thesis.

## OBJECTIVES

This thesis aims to determine how best to protect consumers of CAM<sup>9</sup> from harm, while maintaining choice in healthcare.

It is divided into three sections. The chapters in Section A (Chapters 1 and 2) set out the social and legal context for healthcare generally and for CAM specifically in Ireland. The chapters in Section B (Chapters 3, 4 and 5) provide detailed analyses of three key areas of relevance in assessing the need for regulation: consumer protection, the protection of children in the CAM setting and the interaction between the CAM sector and free expression. Finally, Section C, encompassing Chapters 6 and 7, contains a short empirical study undertaken as part of this thesis, and the conclusion of the thesis overall.

Chapter 1 begins by providing definitions of ‘medicine’, ‘conventional medicine’, and ‘CAM’, which are surprisingly complex, as their meanings are dependent upon on location, background, social context, and personal health beliefs. It goes on to consider the current legal statuses of both conventional medicine and CAM by comparing their regulatory mechanisms. This is dealt with as a preliminary issue as, although this thesis focusses primarily on CAM, comparative reference, both positive and negative, is made to conventional medicine throughout. It is also necessary to question, at various points, the ethical propriety of particular systems and behaviours and so it was important to select an appropriate ethical foundation for any recommended regulatory change. Principlism, as espoused by Beauchamp and Childress<sup>10</sup> and which is both simple and all-encompassing,<sup>11</sup> was considered most appropriate for this particular undertaking.

Chapter 2 examines the reasons behind the popularity of CAM and the role it plays for consumers in Ireland and elsewhere. In proposing reforms, it would be most convenient to focus exclusively on the negative aspects of CAM, emphasising only the risks for consumers. However, to dismiss the benefits experienced by these consumers, and, indeed, the significant harm visited upon consumers by conventional medicine, would not only provide an unfair and imbalanced analysis, but would lead to a disproportionately heavy-handed approach to any model regulation.

The chapter examines three broad categories of influence for consumers opting to use CAM products or services: “push factors”, being general or individual negative experiences in conventional

---

<sup>9</sup> For the purpose of this thesis, the term ‘consumer’ will include patients, ie all users of CAM and not merely purchasers.

<sup>10</sup> Tom Beauchamp and James F Childress, *Principles of Biomedical Ethics* (Oxford University Press 2009).

<sup>11</sup> Though not particularly clear on hierarchy, which is of little assistance when two of the feted principles are in conflict.

medicine; “pull factors”, being those inherent or perceived positive characteristics of CAM that attract consumers; and other societal influences which affect the dissemination of information in respect of health and healthcare. The chapter concludes that, despite the benefits afforded by some aspects of CAM and its practitioners, the notable lack of supporting evidence for many of the claims made by its proponents and the apparent consumer protection, ethical, and fundamental rights issues raised by CAM demand detailed examination.

Chapter 3 describes the interaction between CAM and consumer law. This requires an examination of *inter alia* the Sale of Goods Act 1893, the Sale of Goods and Supply of Services Act 1980 and the Unfair Commercial Practices Directive<sup>12</sup> (implemented by the Consumer Protection Act 2007). A central theme of this thesis, consumer protection is undermined by the disparity between many of the claims made in the marketing of CAM and by its proponents, and the evidence available in support of those claims. The involvement of regulated professions in the sale of CAM products presents particular difficulties, not only for consumers, but for the reputation of the professions in question. Conflict between the statutory Code of Conduct for pharmacists in Ireland<sup>13</sup> and day-to-day practice itself seems to suggest a lack of effective oversight and enforcement, risking further distrust among consumers in respect of a sector mired in controversy.

Chapter 4 analyses the implications for the use of CAM by children. Despite the lack of evidence in support of safety or efficacy for many of the claims made, countless well-meaning parents opt for CAM remedies for common childhood ailments<sup>14</sup> like teething pain,<sup>15</sup> but also for more serious health conditions.<sup>16</sup> This raises questions in respect of the welfare of the child and the interaction between the collective constitutional right of the family to autonomy<sup>17</sup> and the natural and imprescriptible rights of the child.<sup>18</sup> Though the courts have traditionally come down heavily on the side of the parent,<sup>19</sup> the State may intervene, provided that such intervention is shown to be reasonable and proportionate.<sup>20</sup> With this in mind, it is necessary to examine the roles of the legislature and the courts in protecting those without the capacity to consent to treatments with uncertain safety<sup>21</sup> or efficacy.

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<sup>12</sup> Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/7/EC and 2002/65/EC and Regulation No 2006/2004 [2005] OJ L149/22.

<sup>13</sup> Pharmaceutical Society of Ireland, ‘Code of Conduct for Pharmacists’ (PSI 2009).

<sup>14</sup> Evonne Low and others, ‘Complementary and alternative medicine use in Irish paediatric patients’ (2008) 177(2) *Irish Journal of Medical Science* 147. See also Michael H Cohen and Kathi J Kemper, ‘Complementary therapies in pediatrics: A legal perspective’ (2005) 115(3) *Pediatrics* 774. 6.7% of participants in the survey undertaken as part of this thesis had procured CAM products or services for use by a person under the age of 18. See Chapter 6.

<sup>15</sup> Lisa Markman, ‘Teething: Facts and fiction’ (2009) 30(8) *Pediatric Review* 59.

<sup>16</sup> Kara M Kelly, ‘Complementary and alternative medical therapies for children with cancer’ (2004) 40(14) *European Journal of Cancer* 2041.

<sup>17</sup> *McGee v Attorney General* [1974] 1 IR 284 (SC). See also *North Western Health Board v HW* [2001] 3 IR 622 (SC), 623.

<sup>18</sup> The Irish Constitution, Art 42A.1.

<sup>19</sup> *Lobe v Minister for Justice, Equity and Law Reform* [2003] 1 IR 1 (SC), 159 (Hardiman J), “A decision about a child’s medical treatment is *prima facie* within the authority of his family”.

<sup>20</sup> *Ryan v The Attorney General* [1965] IR 294 (SC) and *Re Matrimonial Home Bill* [1994] 1 IR 305 (SC), 313.

<sup>21</sup> Dáil Deb 11 May 2005, vol 602, col 15653.

There are also ethical issues arising from the provision of such treatments and these must be considered in any future regulatory change.

Chapter 5 addresses commentary in respect of CAM. The protections afforded to commercial and non-commercial expression under Art 10 ECHR and under Art 40.6.1° vary in their stringency, with non-commercial commentary afforded significantly more latitude. Much of the information disseminated to consumers in respect of healthcare is through non-commercial material, in broadcast media, print media, film,

and, most significantly, online. The strenuousness with which such material is protected has created significant risk to public health. Chapter 5 examines both existing and potential harms arising as a result of this undoubtedly worthy but nonetheless problematic unwillingness to limit objectively harmful discourse, and seeks alternatives in the form of voluntary policy changes and amended industry codes of practice.

Chapter 6 sets out, in detail, the results of a short, non-scientific questionnaire, distributed as part of the research undertaken for this thesis. The objective of the research was to obtain data that was contemporary, Irish, and relevant to the specific consumer focus of the thesis, most of which was otherwise unavailable. The data provides evidence of consumer sentiment towards CAM, general levels of use of CAM and procurement of CAM for a minor, frequency of use, favoured modalities and on what bases a participant determined a treatment to be safe or efficacious. Overall, the data highlighted confusion among participants, reinforcing the need for clarification and enhancement of the available consumer protection measures, to ensure that healthcare decision-making be informed. The information gleaned from the questionnaire contributes some domestic context to each of the preceding chapters and their analyses, while also informing the conclusion in Chapter 7.

Chapter 7 provides the conclusion to this thesis. Having briefly assessed the potentially applicable pathways for regulation, it sets out three potential approaches for would-be regulators.

The first and least resource-intensive of the recommendations in this thesis involves the use of existing consumer protection mechanisms, requiring stronger and more consistent enforcement on the parts of relevant authorities, such as the Competition and Consumer Protection Commission (CCPC).<sup>22</sup> The limited invasiveness of this approach and its lack of novelty may help to avoid the worst of the potential political backlash, but its benefits and impact are limited accordingly.

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<sup>22</sup> Competition and Consumer Protection Commission (CCPC) <[www.ccpc.ie/](http://www.ccpc.ie/)> accessed 21 September 2016.

The second recommendation is to combine the strengthened consumer protection enforcement in the first with novel provisions, including *inter alia*: the introduction of mandatory registration for all those who wish to provide CAM services; the establishment of two novel registers, with criteria for entry onto one or the other based primarily on the best available evidence on relative risk and benefit for the relevant therapy and the education and training of the registrant; restriction of claims permissible by practitioners; stricter requirements for obtaining informed consent; amendment of labelling requirements for medicinal products for human use; enforced prohibition on sales of CAM products with unproven safety or efficacy in pharmacies<sup>23</sup>; reform of licencing requirements for medicinal products for human use; implementation of a public information and education campaign; restriction on the use of CAM for children; and changes in codes of practice and policies for healthcare reporting. It seems unlikely, however, that this approach would find favour among legislators or the electorate, creating novel and heavy-handed restrictions where once there were none. As a third option, a final, moderate approach is described.

Though indirect risk and consumer risk are, on the best available evidence, consistently present based on the lack of demonstrated efficacy and safety of many CAM products for many conditions, the direct physical or psychological risk tends to arise from particular techniques or practices undertaken as part of CAM treatment overall. These might include, for example, the use of high velocity thrusts on the cervical spine, the administration of a substance by injection or the use of allergens to create tolerance in allergic patients. By restricting the use of these practices to those who are appropriately skilled, qualified and subject to oversight in accordance with novel but minimally invasive legislation addressing the sector, together with measures addressing the consumer issues and improving public health and research education to ensure that patients and consumers understand the nature and limits of what they are choosing.

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<sup>23</sup> These should not be available for sale in general, but according to the Pharmaceutical Society of Ireland, ‘Code of Conduct for Pharmacists’ (PSI 2009), Principle 1, “In order to comply with his or her obligations under this Principle, the pharmacist should: Not purchase or supply any product, including a medicinal product, where there is reason to doubt its safety, efficacy or quality or where a product may impose a hazard to a patient’s health or wellbeing”. Despite this, products with no proven efficacy are available in pharmacies across the country. See Chapter 3.

It is difficult to predict which of these, if any, might prove useful in an improved consumer protection scheme. Some, or even many, of these recommendations would likely encounter resistance, both from consumers, who may value their virtually unlimited choice in healthcare, and from providers and proponents of CAM, but there is, at a minimum, food for thought here. The various agencies with responsibility for, for example, retail (CCPC), advertising (Advertising Standards Agency of Ireland (ASAI)), health (Health Service Executive (HSE)), child welfare (Department of Children and Youth Affairs) and medicinal products for human use (Health Products Regulatory Authority (HPRA)) among others, have consciously or otherwise failed to utilise their considerable powers to ensure that consumers receive the safe and effective healthcare they require, expect and pay for. To an extent, this is understandable. The complexities in defining and isolating the specific problems arising from CAM have become clear as this research has advanced.<sup>24</sup> However, the protection of consumers, particularly in matters of healthcare, cannot continue to be subjugated to addressing more popular or less complex and contentious issues, or to a perception of freedom that does not exist in the absence of full information disclosure in respect of risks and benefits.

#### **A NOTE ON EVIDENCE OF BENEFIT AND RISK**

Legislative change must be supported by evidence. The evidence of efficacy relied upon throughout this thesis is weighted heavily in favour of empirical studies and, where possible, on systematic reviews and meta-analyses sourced from the Cochrane Library among other reliable sources. Where these were not available, individual double blind, randomised controlled trials were preferred. Preference for these types of evidence was based on the hierarchy of evidence set out by the Oxford Centre for Evidence-Based Medicine in 2011.<sup>25</sup> In this hierarchy, which categorises the standard of evidence required according to the type of information sought, where evidence as to the efficacy of, or risk associated with a therapy is required, systematic reviews of randomised controlled trials are identified as the most reliable sources of evidence, followed by randomised trials or observational studies with dramatic effect.<sup>26</sup> Unfortunately, as set out extensively in the preceding chapters, there is limited evidence of this calibre favouring efficacy for most CAM therapies for most conditions. The reasons for this vary, from funding difficulties to disregard of existing research with unfavourable outcomes, leading to low volumes of data overall. It has been argued by some proponents of CAM that the methods of assessing efficacy used in conventional medicine may be difficult to apply or may not be appropriate for use in assessing the efficacy of CAM, due to the use

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<sup>24</sup> This complexity has also been proffered as a reason for the lack of a pan-European definition for CAM. See Torkel Falkenberg and others, 'Towards a pan-European definition of complementary and alternative medicine--a realistic ambition?' (2012) 19(Suppl 2) *Forschende Komplementärmedizin* 6.

<sup>25</sup> OCEBM Levels of Evidence Working Group, 'The Oxford 2011 Levels of Evidence' (2011) Oxford Centre for Evidence-Based Medicine. For a detailed explanation of this hierarchy, see Peter McNair and Gwyn Lewis, 'Levels of Evidence in Medicine' (2012) 7 *International Journal of Sports Physical Therapy* 474.

<sup>26</sup> See also, David Evans, 'Hierarchy of evidence: A framework for ranking evidence evaluating healthcare interventions' (2003) 12 *Journal of Clinical Nursing* 77, for a slightly different approach to hierarchy.

of multiple therapies at the same time, individualisation of therapies, the importance of the therapist to the outcome, placebo or expectation effects, the different outcomes valued, and the difficulties of assessing manual treatments.<sup>27</sup> Consequently, CAM proponents often choose to rely on studies of lower quality or, commonly, on anecdotal evidence. This is considered an unreliable form of evidence, though, as set out in Chapter 2 and as evidenced in the short empirical study set out in Chapter 6, it is powerful in its effect on consumer or patient behaviour.<sup>28</sup>

However, Tamayo et al<sup>29</sup> take an alternative view, finding that,

A variety of different research designs need to be used to answer the variety of questions that are important in CAM. However, research designs do not have to be reinvented since appropriate methodologies can normally be found in the diverse branches of medical research ... Within conventional research methodology ... it is possible to find many rigorous tools to evaluate the efficacy and safety of interventions and innovative or “alternative” methodologies may be necessary only in isolated circumstances. Expert methodologists have concluded that established methodologies (i.e., experimental trials, observational epidemiology, social survey research) and data-analytic procedures (ie, analysis of variance, logistic regression, multivariate modeling techniques) are quite satisfactory for addressing the majority of study questions related to alternative medicine, from clinical research on therapeutic efficacy to basic science research on mechanisms of pathogenesis and recovery.<sup>30</sup>

This is promising if taken on board by prospective researchers. The lack of high quality data does not only impact those seeking meaningful evidence of efficacy but also those attempting to assess overall risk. A significant problem arises from the lack of contemporaneous data or any semblance of a system for recording adverse events attributable to the use of CAM therapies in Ireland, making comprehensive domestic analysis impossible. Case reports and analyses of the risks associated with CAM originating in other Western jurisdictions, particularly for the better-established therapies, are available, but none claim to be able to provide an accurate incidence rate for any therapy. Such data is urgently needed to provide some guidance to regulators on the level of regulation required. However, though the incidence of adverse events arising out of CAM cannot be accurately assessed at this time,<sup>31</sup> the events themselves, details of many of which have been obtained through systematic

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<sup>27</sup> Institute of Medicine, Board on Health Promotion and Disease Prevention, Committee on the Use of Complementary and Alternative Medicine by the American Public, *Complementary and Alternative Medicine in the United States* (National Academies Press 2005) 123.

<sup>28</sup> Anecdotal evidence may also owe some of its power to the availability heuristic, described as the propensity for estimating the likelihood of something based on how easy or difficult it is to retrieve related information from long term memory. The mind attributes more importance to that which is easily accessible. The more colourful and descriptive something is, the easier it is to retrieve. Anecdotes fulfil this role, whereas data, even of the highest quality, is often unengaging, encouraging retention of the anecdotal information and not the better-quality evidence. See Alison G Harvey, *Cognitive Behavioural Processes Across Psychological Disorders: A Transdiagnostic Approach to Research and Treatment* (Oxford University Press 2004) 153-154.

<sup>29</sup> Carmen Tamayo and others, ‘Research Methodology: Evaluating Complementary and Alternative Therapies’ (2002) 36 *Drug Information Journal* 535.

<sup>30</sup> *ibid* 538-539.

<sup>31</sup> Edzard Ernst, ‘Manipulation of the cervical spine: A systematic review of case reports of serious adverse events, 1995-2001’ (2002) 176 *Medical Journal of Australia* 376, “Serious adverse events after cervical spine

reviews of the existing data and are interspersed throughout this thesis, cannot be disregarded. It may be difficult to justify increased regulation on this basis alone. However, the established consumer risks, indirect risks and direct risks together justify reconsideration of and action to improve the existing lackadaisical regime.

Encouraging the embrace of existing, established research methodologies by CAM proponents could significantly increase the volume of high quality data on the various aspects of CAM germane to the development of regulation.

With this said, it is apt to provide a brief overview of research methodology, before turning to Chapter 1.

## RESEARCH

Having undertaken an initial literature review, the following became apparent:

- i. There was little by way of Irish medical research on CAM;
- ii. There was virtually nothing by way of Irish legal research on CAM;
- iii. There was and there continues to be a chasm between claims made by many CAM practitioners and providers in Ireland and the best-available evidence, leaving consumers at risk of physical, psychological and financial harm;
- iv. General consumer protective measures already in place have not been utilised to their full extent in respect of CAM;
- v. Bolstered voluntary self-regulation may not be sufficient to protect consumers from harm within the CAM sector – instead, statutory regulation may be required to put in place minimum standards for education and training, professional and ethical practice, and to appropriately limit scope of practice based on the best available evidence.

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manipulation continue to be reported. As the incidence of these events is unknown, large and rigorous prospective studies of cervical spine manipulation are needed to accurately define the risks". See also, Joseph I Boullata and Angela M Nace, 'Safety issues with herbal medicine' (2000) 20 *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy* 257, 267, "While claims of therapeutic benefit are evaluated for each herbal medicine, and with the possibility that a number of these products may broaden drug therapy choices, caution must be maintained until complete safety profiles are available. Besides avoiding them in pregnancy, lactation, and childhood, herbal agents should be avoided by patients with serious conditions without consulting a pharmacist or physician. The products should be combined with each other as well as with prescription and OTC agents with great caution", Malcolm W Chan and others, 'Safety of Acupuncture: Overview of Systematic Reviews' (2017) 7 *Scientific Reports* 3369, 3372, "In general, the results show that both minor and serious adverse events can occur from the use of acupuncture ... However, all the reviews have suggested that adverse events are rare and often minor. Although serious complications were rare, they require significant attention as mortalities are associated with these adverse events. There was insufficient data to determine which body sites or whether patient predispositions were associated with these events, but it is clear that patients can be at great risk".



From initiating research in 2011, my methodology has included:

- i. Establishment of aggregated searches on Google Scholar and other academic sites under the terms “complementary medicine”, “alternative medicine”, “complementary and alternative medicine”, “alternative therapy” and “complementary therapy”. These sent results approximately every two days, from which I selected the most pertinent material;
- ii. Manual digital searches for relevant legal and medical academic papers and through Westlaw, Justis, LexisNexis, HeinOnline, the National Center for Biotechnology Information (NCBI), and through the Trinity Library;
- iii. Prioritisation of systematic reviews from the Cochrane Collaboration, an independent global health research organisation.<sup>32</sup> Where no Cochrane review was available, PubMed, Google Scholar and individual publisher databases were searched for relevant material. In the interest of obtaining high-quality clinical evidence, randomised, double-blind, placebo-controlled trials were sought, though not always successfully;
- iv. Construction and dissemination of a questionnaire, the purpose of which was to determine the public understanding of CAM and to assess its level of usage.<sup>33</sup> This sought to determine broadly whether consent given for CAM treatment is truly informed, which would, in turn, inform discussion on the potential risk to public health, a key factor in any debate on regulation;
- v. Interaction with government departments, regulatory agencies, and relevant academics to develop ideas in greater detail;
- vi. Contact with staff in the Centre for Research on Adaptive Nanostructures and Nanodevices (CRANN), to request materials analysis of a sample homeopathic product, obtained from an established, royal-chartered homeopathic dispensary in London, although this did not come to fruition; and
- vii. Consultations with Dr Michael O’Toole, Associate Professor of Global Health at the Centre for Global Health and Dr Helen Sheridan, Professor of Natural Product Chemistry and Head of the Natural Product Drug Discovery Group at the School of Pharmacy and Pharmaceutical Sciences, both at Trinity College Dublin.

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<sup>32</sup> Cochrane Collaboration, ‘About Us’ (2016) <[www.cochrane.org/about-us](http://www.cochrane.org/about-us)> accessed 10 September 2016. For further information, see Iain Chalmers, ‘The Cochrane Collaboration: Preparing, maintaining, and disseminating systematic reviews of the effects of health care’ (1993) 703 *Annals of the New York Academy of Sciences* 156.

<sup>33</sup> The questionnaire received the approval of the Arts, Humanities and Social Sciences (AHSS) Ethics Committee on 3 May 2016.

## ISSUES ENCOUNTERED DURING RESEARCH

- i. While myriad data are available on the merits and demerits of the various CAM therapies, many of the research papers addressing these therapies are biased, with poor methodology, manipulated outcomes or selective publication of positive results. These issues are certainly not specific to CAM and have been recognised as a significant problem in conventional academic medicine.<sup>34</sup> For this reason, systematic reviews have been used, where available, to limit bias.
- ii. Although several public agencies, CAM practitioners and representative bodies were contacted in the course of research, responses were inconsistent in their content, helpfulness and response time, with no responses to date from the CAM sector.<sup>35</sup> This represented a significant difficulty for establishing a balanced and accurate representation of industry perspective. To this end, past reports and surveys undertaken in Ireland were reviewed, with the results extrapolated, insofar as was possible, for use in this research.
- iii. The lack of domestic guidance made contextualising analysis and recommendations difficult, as other jurisdictions vary wildly in their perception, acknowledgement and integration of CAM and were, as such, suboptimal reference points.<sup>36</sup>

Similar challenges will likely be faced by future researchers, though societal sentiment may shift sufficiently to encourage freer dialogue with those in the sector and to facilitate the reasoned development of guidelines.

Nonetheless, having addressed these preliminary issues, we turn, finally, to Chapter 1.

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<sup>34</sup> This is also discussed at length in Chapter 2.

<sup>35</sup> The CCPC, the Health and Social Care Professionals Council (CORU), and the Advertising Standards Agency of Ireland (ASAI) helpfully provided information on their internal processes, which were not always described on their websites.

<sup>36</sup> See Chapter 7.

## **SECTION A**



## CHAPTER 1

### MEDICINE, ETHICS AND A CHANGING HEALTHCARE LANDSCAPE

#### INTRODUCTION

The use of complementary and alternative medicine (CAM) in Ireland is widespread and significant.<sup>1</sup> The embrace of CAM may reflect a general movement towards a broader definition of medicine or healthcare, or it may reflect a partial or complete rejection of the orthodoxy.<sup>2</sup> At present, and in stark contrast to conventional medicine, there is an absence of effective legal controls on the provision of CAM services and products generally and an inadequate regime of regulation, European in origin, for homeopathic and traditional herbal medicinal products for human use.<sup>3</sup> Numerous factors may be responsible for this, from perceived complexity or resourcing issues to the fear of public backlash. Whatever the reasons, the notable popularity of CAM has not been sufficient to motivate regulators to establish an appropriately rigorous regulatory framework to protect consumers from physical, psychological, or financial harm arising from these treatments.

The fundamental aim of this thesis is to highlight the deficiencies in the system of regulation currently in place for CAM, before presenting recommendations for change. In attempting to introduce change to an established system, however unsatisfactory, it is necessary to first acknowledge and define its parameters and the relevant domains therein. Medicine, defined broadly below, bifurcates, for the purpose of this thesis, into conventional medicine and CAM. This nomenclature, though suboptimal,<sup>4</sup> reflects the approach taken in most literature, where these terms form the convention.

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<sup>1</sup> Sinead M Murphy and others, 'Counting the cost of complementary and alternative therapies in an Irish neurological clinic' (2008) 15 *European Journal of Neurology* 1380. As part of the questionnaire disseminated in the course of research for this thesis, respondents were asked if they had ever used or procured a CAM therapy. 48.9% stated that they had. This represents a lifetime prevalence. However, this is significant because physical, psychological or financial harm may result from a single use or procurement. See Chapter 6.

<sup>2</sup> It may also reflect some combination of the two. See Mandreker Bahall and Mark Edwards, 'Perceptions of complementary and alternative medicine among cardiac patients in South Trinidad: A qualitative study' (2015) 15 *BMC Complementary and Alternative Medicine* 99. The authors refer to these as "pull factors" and "push factors". For a detailed analysis of these, see Chapter 2.

<sup>3</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 in respect of homeopathic medicinal products and Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L136/85 in respect of traditional herbal medicinal products for human use. Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965] OJ L022/0369, art 1(2) defines medicinal product as "Any substance or combination of substances presented for treating or preventing disease in human beings or animals; Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product".

<sup>4</sup> The acronym 'CAM' fails to acknowledge the difference in usage between complementary and alternative medicine. Although many therapies may be used as a complementary therapy or as an alternative therapy,

Conventional medicine and CAM operate under different etheas, within different professional cultures and under different societal expectations, though both have ostensibly the same broad goals of treating ills and improving health, and it is undoubtedly instructive to examine the way in which both are regulated in Ireland, the ethical principles that inform decision-making and the relevant jurisprudence for the practice of each. By so doing, it will be possible to determine the extent of the protections in place within the existing system of regulation for conventional medicine, whether this system might be successfully transplanted onto the CAM sector, or whether a novel, sector-specific approach would provide an appropriate level of protection for the dignity and for the physical, psychological and financial wellbeing of consumers.

Part I of this chapter sets out the relevant definitions of medicine, conventional medicine and CAM, detailing the social and legal context in which conventional medicine and CAM operate and identifying a number of deficiencies, particularly in the regulation of CAM. It is to the examination and remediation of these that this thesis will be addressed.

Part II considers the ethical principles guiding healthcare practice generally, and their importance in promoting high standards of behaviour among practitioners. The provision of CAM products and services, which have limited or no high quality evidence in support of their efficacy for most medical conditions, raises issues in respect of: (a) patient autonomy, where this information is not disclosed to the patient before treatment; (b) beneficence and non-maleficence, where there is uncertainty in respect of the balance of risk and benefit for a CAM therapy for a particular condition, or where the balance favours risk over benefit; and (c) justice and allocation of resources, in respect of the public funding of CAM research, which is necessary to enable regulators to understand and establish an appropriate scope of practice for each therapeutic modality, but which may be considered unethical and unjustifiable where ample research has already been undertaken on a particular therapy, with no efficacy established for any condition.<sup>5</sup>

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depending on the choice of the consumer, others should be used exclusively as either a complementary or an alternative therapy. Some herbal remedies, for example, have known interactions with conventional medicinal products, and, where used, should only be considered as an alternative, where the best available evidence suggests that it is safe and efficacious. See Yang T Chua and others, 'Interaction between warfarin and Chinese herbal medicines' (2015) 56(1) Singapore Medical Journal 11 and Adriane Fugh-Berman, 'Herb-drug interactions' (2000) 355(9198) Lancet 134, "Concurrent use of herbs may mimic, magnify, or oppose the effect of drugs". Reiki, if used, should only be used as a complementary therapy, as there is a lack of high quality evidence supporting its exclusive use for any medical condition. See National Centre for Complementary and Integrative Health (NCCIH), 'Reiki: In depth' (2015) <<https://nccih.nih.gov/health/reiki/introduction.htm>> accessed 26 September 2016. The term 'CAM' in this respect, may contribute to confusion and risk for consumers. However, it is asserted that the dichotomy and the apparent lack of its acknowledgement in use of the acronym 'CAM' to bundle both modes of use together is of limited significance in the context of this thesis, which calls for the same standards of evidence of safety and efficacy for all therapies made available on the Irish market, the practical implementation of which should include a profile of potential interactions in the case of medicinal products for human use.

<sup>5</sup> See, for example, NHS Choices, 'Homeopathy' (2015) <[www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx](http://www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx)> accessed 10 September 2016.

Simply by addressing these ethical issues, regulators will effectively ameliorate many of the core concerns addressed throughout this thesis: that consumers are put at risk of harm (beneficence/non-maleficence) by unfair or misleading claims made by CAM practitioners or proponents, or by failure on the part of the practitioner to disclose risks or lack of efficacy in obtaining consent (autonomy), which often have little by way of high quality scientific evidence supporting them.

Chapter 1 concludes that the lack of regulation for CAM in Ireland has created risks for consumers and that, although transposition of the conventional regulatory framework onto CAM is untenable, statutory regulation in other forms may be necessary to protect consumers from harm.

With this said, we begin by considering the definition of medicine and the natures of its two relevant sub-divisions, being conventional medicine and CAM.

## PART I

### CONTEXTUALISING MEDICINE

#### 1. MEDICINE

*Medicine n.*

1. *the science or practice of the diagnosis, treatment, and prevention of disease.*
2. *the science or practice of nonsurgical methods of treating disease.*
3. *any drug or preparation used for the treatment or prevention of disease, particularly a drug that is taken by mouth.*<sup>6</sup>

Many descriptions of medicine exist, from Hippocrates' rather simple but pragmatic portrayal of it as being "... the complete removal of the distress of the sick, the alleviation of the more violent diseases and the refusal to undertake to cure cases in which the disease has already won the mastery, knowing that everything is not possible to medicine",<sup>7</sup> to the rather more expansive depiction provided by Bivins, as

... compris[ing]beliefs as well as facts, experiences as well as knowledge, expectations as well as effects. It is an interpretative as well as a descriptive and prescriptive discipline. As such, the persistence and success of a medical system is invariably contingent, not only on its therapeutic effects, but on the historical and cultural climate within which it operates and to which it responds.<sup>8</sup>

Though both are accurate, Bivins' definition appears to align more closely with the holistic approach most often associated with CAM, though featuring more prominently in conventional medicine as the limitations of the purely reductive approach to medicine are acknowledged.<sup>9</sup> However, although the term 'medicine' might reasonably refer to either conventional medicine or to CAM, colloquially, it refers to conventional medicine. It is helpful to consider conventional medicine, its social status and the strength and quality of legal controls in the sector, before comparing these, later on, with these same factors in the CAM sector, highlighting the disparity between the two and providing a solid point of reference for regulators seeking to establish a novel scheme for CAM.

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<sup>6</sup> Tanya McFerran, *A Dictionary of Nursing* (OUP Oxford 2014) 325.

<sup>7</sup> IM Lonie and others (trs), *Hippocratic Writings* (Penguin Books Ltd 2005) 140. This definition is adhered to still. See Lorry R Frankel, *Ethical dilemmas in pediatrics: Cases and commentaries* (Cambridge University Press 2005) 135.

<sup>8</sup> Roberta Bivins, *Alternative Medicine?* (Oxford University Press 2007) x.

<sup>9</sup> For a discussion of the reductive approach in conventional medicine, see Chapter 2.



## 2. CONVENTIONAL MEDICINE

The US National Centre for Complementary and Integrative Health (NCCIH, formerly NCCAM), which forms part of the National Institutes of Health, defines conventional medicine, (also called Western medicine), as being “medicine practiced by holders of M.D. (medical doctor) ... degrees and by allied health professionals, such as physical therapists, psychologists, and registered nurses”.<sup>10</sup> Similarly, in Ireland, conventional medicine is practiced by medical doctors, possessing an accredited and recognised medical degree<sup>11</sup> and who are registered with the Medical Council<sup>12</sup> and subject to the rules, regulations and disciplinary mechanisms of such.<sup>13</sup>

Conventional medicine in Ireland is statutorily self-regulated, features heavily in socio-political debate and has amassed a significant and multifaceted jurisprudence. In a constant state of evolution, it consistently seeks less invasive methods and more effective treatments with lower doses and fewer side effects.<sup>14</sup> Although diverting, the behaviour and superstition prescribed by antiquity are of diminishing importance, as conventional medicine moves towards an evidence-based paradigm.<sup>15</sup>

### 2.1 SOCIAL CONTEXT AND REGULATORY FRAMEWORK

Given Bivens’ broad definition of medicine and the key role played by the biopsychosocial model in softening the harder edges of conventional medicine,<sup>16</sup> it is important to understand the social context in which conventional medicine and CAM are located.

According to Salter,<sup>17</sup> the medical profession, society and state form a co-dependent relationship, (Figure 1) with society receiving medical care from the state via the medical profession, the state gaining popularity in society and the ability to delegate health services to

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<sup>10</sup> US National Centre for Complementary and Integrative Health (NCCIH), ‘CAM Basics’ (2012) 1 <[https://nccih.nih.gov/sites/nccam.nih.gov/files/D347\\_05-25-2012.pdf](https://nccih.nih.gov/sites/nccam.nih.gov/files/D347_05-25-2012.pdf)> accessed 29 September 2016.

<sup>11</sup> Medical Practitioners Act 2007, s 88(6)(a) and Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22, art 21(1).

<sup>12</sup> Medical Practitioners Act 2007, s 37.

<sup>13</sup> Health and Social Care Professionals Act 2005, s 4(1), provides a list of other designated professions found in the realm of conventional medicine, suggesting that, like the definition provided by the NCCIH, conventional medical practices are not solely within the remit of registered doctors. This negates any potential argument that any treatment provided other than by a doctor is ‘complementary’ to conventional medicine.

<sup>14</sup> Rory Watson, ‘European agency prepares for new rules to improve drug safety’ (2012) *British Medical Journal* 344. See also Nigel Hawkes, ‘Clinical grade stem cells are created by scientists in London’ (2011) *British Medical Journal* 343.

<sup>15</sup> David L Sackett and others, ‘Evidence based medicine: what it is and what it isn’t: it’s about integrating individual clinical expertise and the best external evidence’ (1996) 312(7023) *British Medical Journal* 71. Department of Health and Children, *Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance* (Stationery Office 2008) 11, para 13.

<sup>16</sup> For detail on the application of the biopsychosocial model, see Chapter 2.

<sup>17</sup> Brian Salter, *The New Politics of Medicine* (Palgrave Macmillan 2004) 6-7. See also Dietrich Rueschemeyer D, *Lawyers and Their Society: A Comparative Study of the Legal Profession in Germany and in the United States* (Harvard University Press 1973) 13.

the medical profession and the medical profession receiving the trust of society and the privilege of self-regulation from the state. (Figure 2).

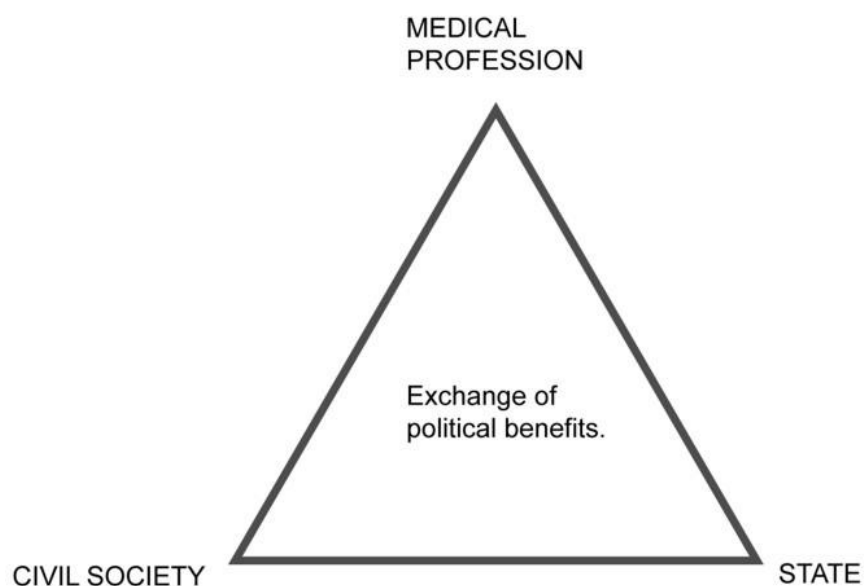


Figure 1 - The triangular relationship between the state, civil society and the medical profession – Brian Salter, *The New Politics of Medicine* (Palgrave Macmillan 2004).

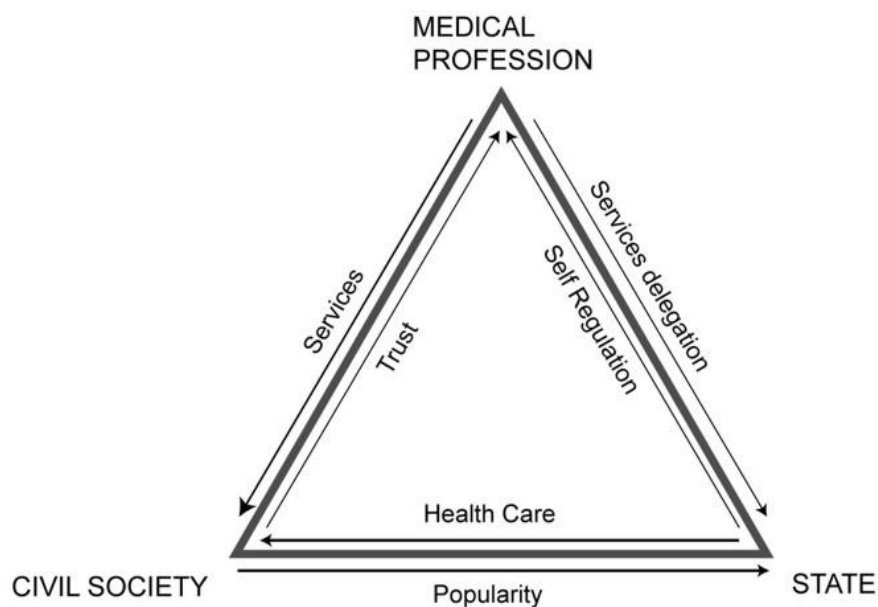


Figure 2 - The exchange of political benefits between the state, civil society and the medical profession, in detail – Brian Salter, *The New Politics of Medicine* (Palgrave Macmillan 2004), illustration by Colum O'Keeffe.

Trust is fundamental in such a system. Without this, Salter's fragile homeostasis breaks down and patients search for something preferable. Trust is established by setting and maintaining high standards in education, training and practice, by acting in good faith, and by ensuring, insofar as it is possible, transparency, accessibility and fairness for those with grievances. To this end, the Medical Council, established by the Medical Practitioners Act 1978<sup>18</sup>:

- i. Ensures the highest standards of medical training and education in the Republic of Ireland;
- ii. Maintains the Register of Medical Practitioners<sup>19</sup>;
- iii. Promotes good medical practice and oversees doctors' continuing professional development; and
- iv. Investigates complaints against medical doctors.<sup>20</sup>

The formalisation of these elements creates predictability, ensuring that patients know what they can expect from a doctor trained or registered in Ireland and to what standards they have been and will be held, and can be contrasted with those established for CAM practitioners at a later point.

## 2.2 EDUCATION AND TRAINING

The Medical Council is responsible for accrediting undergraduate education,<sup>21</sup> based upon the standards of the World Federation for Medical Education.<sup>22</sup> Having completed their undergraduate degree, medical graduates must complete their intern year,<sup>23</sup> and undertake postgraduate qualification.<sup>24</sup> Throughout the medical practitioner's professional career, he or she must undertake professional competence assessment and continuing professional development.<sup>25</sup> Madden<sup>26</sup> cites the 2008 *Report of the Commission on Patient Safety*,<sup>27</sup> which observed that, "health professionals can no longer be regarded as trained for life",<sup>28</sup> upon qualification.<sup>29</sup> This recently-introduced lifelong education improves patient safety and ensures that the domestic medical community keeps apace of international best practice.

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<sup>18</sup> Medical Practitioners Act 1978, s 6.

<sup>19</sup> *ibid* s 26.

<sup>20</sup> Medical Council, 'About Us' (2016) <[www.medicalcouncil.ie/About-Us](http://www.medicalcouncil.ie/About-Us)> accessed 3 October 2016.

<sup>21</sup> Medical Practitioners Act 2007, s 88 (1) and (2).

<sup>22</sup> World Health Organisation (WHO)/World Federation for Medical Education (WFME), 'Guidelines for Accreditation of Basic Medical Education' (WHO/WFME 2005).

<sup>23</sup> Medical Practitioners Act 2007, s 88(3).

<sup>24</sup> *ibid* s 88(4).

<sup>25</sup> *ibid* s 91(1).

<sup>26</sup> Deirdre Madden, *Medical Law in Ireland* (Kluwer Law International 2011).

<sup>27</sup> Department of Health and Children (n 15)

<sup>28</sup> *ibid* 7, para 9.

<sup>29</sup> Deirdre Madden (n 26) 36.

## 2.3 REGISTRATION

Medical practitioners in Ireland must be registered with the Medical Council. Under s 37 of the Medical Practitioners Act 2007, “an unregistered medical practitioner shall not (a) practise medicine,<sup>30</sup> or (b) subject to section 50, advertise the practitioner’s services as a medical practitioner”. Where a practitioner practices while unregistered,<sup>31</sup> falsely claims to be registered,<sup>32</sup> or misrepresents the division in which they are registered,<sup>33</sup> that practitioner, if convicted, is liable to a fine or imprisonment or both.<sup>34</sup> The Register contains information on the qualifications held by the registered practitioner, when they qualified, and the division to which they are registered. Vitally, this is accessible by members of the public, providing a measure of transparency in what may appear to be an opaque and intimidating system.

## 2.4 GRIEVANCES AND OVERSIGHT

Consistency in oversight and the maintenance and improvement of standards appear central to the objectives of the Medical Council. Section 57 of the Medical Practitioners Act 2007 provides for a grievance procedure and sets out a number of grounds for complaint, which range from the broad and all-embracing charge of poor professional performance,<sup>35</sup> to conviction of the practitioner for an indictable offence.<sup>36</sup> Complaints are initially referred for hearing by the Preliminary Proceedings Committee, where a decision is made as to whether further action is required.<sup>37</sup> If so, the case is referred to the Fitness to Practice Committee,<sup>38</sup> who may impose one of a number of sanctions ranging from a written admonishment<sup>39</sup> or a fine<sup>40</sup> to cancelling of the practitioner’s registration.<sup>41</sup> If a practitioner is considered by the Medical Council to be a risk to public safety, whether or not a complaint has been made about him or her, the Council may make an *ex parte* application to court for an order of immediate suspension of the practitioner’s registration, until a hearing by the Fitness to Practice

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<sup>30</sup> This raises the question of the use of the term “complementary and alternative *medicine*”, its appropriateness in an Irish context and the potential to cause confusion among consumers. This was observed during early testing of the questionnaire described in Chapter 6.

<sup>31</sup> Medical Practitioners Act 2007, s 41(1)(a).

<sup>32</sup> *ibid* s 41(1)(b).

<sup>33</sup> *ibid* s 41(1)(c).

<sup>34</sup> *ibid* s 41(5).

<sup>35</sup> *ibid* s 57(1)(b), “Poor professional performance” in relation to a medical practitioner, is defined in s 2 of the 2007 Act as being “failure by the practitioner to meet the standards of competence (whether in knowledge and skill or the application of knowledge and skill or both) that can reasonably be expected of medical practitioners practising medicine of the kind practised by the practitioner”.

<sup>36</sup> *ibid* s 57(1)(g).

<sup>37</sup> *ibid* s 59.

<sup>38</sup> *ibid* s 63.

<sup>39</sup> *ibid* s 71(a).

<sup>40</sup> *ibid* s 71(b).

<sup>41</sup> *ibid* s 71(f).

Committee takes place.<sup>42</sup> Fitness to Practise Inquiry Notifications are published by the Medical Council and are accessible by the public.<sup>43</sup> The accreditation, oversight and grievance mechanisms contribute to the protection of public safety while also ensuring that the reputation of the profession itself does not fall into disrepute. The statutory nature of the Medical Council encourages public confidence in the conventional medical profession although its self-regulatory status is of little assistance in this respect.

## 2.5 ROOM FOR IMPROVEMENT

While contributing significantly to human health, conventional medicine is not without its problems. The medical profession is notable for its culture of paternalism.<sup>44</sup> This unquestioned authority, described perfectly in the 2006 *Report on the Lourdes Hospital Inquiry*<sup>45</sup> as an “incredibly pervasive culture of acceptance and acquiescence of consultant activity”,<sup>46</sup> historically resulted in low levels of accountability, with serious consequences leading to several high profile investigations.<sup>47</sup> A number of similarly damaging financial, legal and religious controversies have contributed to the rising level of public mistrust of the professions,<sup>48</sup> which is exacerbated where professions are self-regulated, a situation which affords a profession the right to control access, the supply of services<sup>49</sup> and the level of oversight, creating a monopoly. Not only this, but the relatively closed ranks of the sector have created a perception of inaccessibility for those with grievances, though, as set out above, detailed systems of reporting are in place. According to a 2006 report by the Medical Council, entitled *Managing Complaints about Doctors*,<sup>50</sup> at the end of the complaints process, complainants in general had negative perceptions of the Council, viewing it as an organisation that protects doctors and not patients.<sup>51</sup> Add to this the sector’s close alliance with the pharmaceutical sector, whose history of corruption has been well-documented, and consumer reticence is not only understandable, but quite rational.

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<sup>42</sup> *ibid* s 60(1).

<sup>43</sup> Medical Council, ‘Fitness to Practise Inquiry Notifications’ (2016) <[www.medicalcouncil.ie/Public-Information/Inquiry-Notifications/Fitness-to-Practise-Notifications/](http://www.medicalcouncil.ie/Public-Information/Inquiry-Notifications/Fitness-to-Practise-Notifications/)> accessed 10 September 2016.

<sup>44</sup> Brian Salter (n 17) 31.

<sup>45</sup> Department of Health and Children, *The Lourdes Hospital Inquiry, An Inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda: Report of Judge Maureen Harding Clarke SC* (Stationery Office 2006).

<sup>46</sup> *ibid* 155, para 1.1.

<sup>47</sup> *ibid*. See also Department of Health and Children, *Report of Dr Deirdre Madden on Post Mortem Practice and Procedures* (Stationery Office 2005).

<sup>48</sup> Denis A Cusack, ‘Ireland: Breakdown of trust between doctor and patient’ (2000) 356 *Lancet* 1431.

<sup>49</sup> Brian Salter (n 17) 13.

<sup>50</sup> Siobhan McCarthy, Hannah McGee and Ciaran O’Boyle, *Managing Complaints about Doctors: Stakeholder Perspectives of the Role of the Medical Council in Ireland* (Medical Council 2006).

<sup>51</sup> *ibid* 9.

With one of the Council's aims being to promote the profession of conventional medicine, this loss of public confidence is not insignificant and could constitute a contributing factor for the exodus towards the CAM sector.<sup>52</sup> Consumer confidence cannot be maintained where consumers perceive a system that is stacked against them.

It appears that, in spite of the ostensibly sturdy conventional medical regulatory framework, quite some work is required before it can be declared an exemplary system of governance. Nonetheless, this suboptimal system provides strictly enforced legal minimum standards for entry, education, training, professional practice and ethical behaviour. The same cannot be said for CAM at this time.

### 3. CAM

According to the Cochrane Collaboration<sup>53</sup> CAM is defined as “a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period.”<sup>54</sup>

The politically dominant health system of Ireland is that which is provided by the State, that is, the services provided in public hospitals and through primary care services. Practices found in such settings are not complementary or alternative. This also applies to treatments provided in a conventional medical setting other than by a doctor.<sup>55</sup>

Describing CAM as a remainder, being what is left behind after conventional medicine is taken away, seems unfair and does not provide much by way of definition, but then, such a broad variety of therapies and subdivisions of therapies and philosophies appears to defy simple characterisation. Nonetheless, Donal Ó Mathúna<sup>56</sup> puts forth a number of helpful criteria for determining what is a CAM therapy:

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<sup>52</sup> As part of the questionnaire disseminated during the course of research for this thesis, respondents were asked why they chose to use or procure a CAM therapy. 19% of respondents stated that they were wary of conventional medicine or were aware of significant harm caused by it. See Chapter 6.

<sup>53</sup> For further information on the Cochrane Collaboration, see Iain Chalmers, ‘The Cochrane Collaboration: Preparing, maintaining, and disseminating systematic reviews of the effects of health care’ (1993) 703 *Annals of the New York Academy of Sciences* 156.

<sup>54</sup> Definition of *complementary and alternative medicine* developed at a 1997 conference of the United States Office for Alternative Medicine of the National Institutes of Health and subsequently adopted by the Cochrane Collaboration and the Ministerial Advisory Committee on Complementary and Alternative Medicine.

<sup>55</sup> Health and Social Care Professionals Act 2005, s 4(1). Interestingly, some private hospitals have introduced acupuncture into their physiotherapy services, though it is not available through public centres. See Bonn Secours Hospital Cork, ‘Acupuncture Cork’ (2016) <[www.bonsecours.ie/acupuncture](http://www.bonsecours.ie/acupuncture)> accessed 30 September 2016.

<sup>56</sup> Donal Ó Mathúna, *Alternative Medicine* (Zondervan 2007).

- i. The therapy has been rejected by conventional medicine;
- ii. A holistic approach is favoured in therapy delivery;
- iii. The therapy has a spiritual element; and
- iv. There is an absence of high quality scientific evidence to support its assertions.<sup>57</sup>

These criteria, combined with the definition provided by the Cochrane Collaboration, also help to outrule common-sense lifestyle interventions, such as exercise and diet modification.

Having reviewed Ó Mathúna's criteria, it is also necessary to categorise the therapies. The sheer number and variety of therapies are undoubtedly intimidating for researchers and would-be regulators, and a streamlined categorisation provides accessibility and ease of referral.

CAM therapies are, according to Arcangelo<sup>58</sup> divided into five domains:

- i. Alternative medical systems (complete systems of theory and practice such as Traditional Chinese Medicine);
- ii. Mind-body interventions (techniques with the aim of enhancing the mind's ability to affect the body, such as meditation and biofeedback);
- iii. Biologically based therapies (therapies involving the use of natural substances to heal, such as homeopathy or herbalism);
- iv. Manipulation and body-based therapies (therapies based on movement of joints and body parts, such as chiropractic, osteopathy or massage);
- v. Energy therapies (therapies involving the use of energy fields, such as magnet therapy, crystal therapy, colour therapy, or reiki).<sup>59</sup>

This subdivision allows consumers to focus on one particular category of therapy, making healthcare decision-making somewhat less overwhelming, which is critical because, as noted in Chapter 3, the choice of which therapy the consumer should seek out for a particular condition lies exclusively with him or her, without the initial advice or referral of a generalist, as is the case in conventional medicine.

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<sup>57</sup> *ibid* 20.

<sup>58</sup> Virginia P Arcangelo and Andrew M Peterson, *Pharmacotherapeutics for Advanced Practice: A Practical Approach* (Lippincott Williams & Wilkins 2005).

<sup>59</sup> *ibid* 96.

### 3.1 SOCIAL CONTEXT AND REGULATORY FRAMEWORK

CAM in Ireland is a private endeavour, making it something of a luxury. A global systematic review by Ernst<sup>60</sup> found that the most frequent users of CAM therapies were affluent, tertiary educated, middle aged, Caucasian women, a finding with which a 2010 Irish study<sup>61</sup> agreed. The Irish study also found that those with a lower standard of education had a much lower uptake of CAM than those with third-level education. Unsurprisingly, those with higher incomes were more likely to avail of CAM than the less well-off<sup>62</sup> and despite the marginalisation of the CAM sector by conventional medicine generally,<sup>63</sup> which is, as mentioned above, moving towards evidence-based practice, and as the power in conventional medicine shifts from doctor to patient,<sup>64</sup> integration of CAM therapies into large general practices<sup>65</sup> and private hospitals is becoming more commonplace.<sup>66</sup>

### 3.2 EDUCATION AND TRAINING/ REGISTRATION/ GRIEVANCES AND OVERSIGHT

CAM in Ireland operates within a framework of voluntary self-regulation. Training and educational programmes are provided to aspiring CAM practitioners by a number of general and specialist private educational institutions. Having completed a qualification, practitioners may be eligible to register with one of the independent representative bodies for their chosen specialisation. Prospective members must normally agree to comply with codes of practice. Once registered, practitioners may use the letters of their representative body and, depending on the body in question, may provide reimbursable therapies to clients with private health insurance from participating health insurance providers. Consumers may feel assured by this ostensibly clear educational and training pathway, a practitioner's membership of a representative body and its association with health insurance providers. However, the situation is a lot less clear than it first appears.

For example:

- i. CAM practitioners in any discipline are not required to have any particular training or education in order to practice;

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<sup>60</sup>Edzard Ernst, 'Prevalence of use of CAM: A systematic review' (2000) 78(2) Bull WHO 253.

<sup>61</sup> Patricia Fox and others, 'Complementary alternative medicine (CAM) use in Ireland: A secondary analysis of SLAN data' (2010) 18(2) Complementary Therapies in Medicine 95, 97.

<sup>62</sup> *ibid.*

<sup>63</sup> Matthew Leach, *Clinical Decision Making in Complementary and Alternative Medicine* (Elsevier Health Sciences 2010) 151.

<sup>64</sup> Marie R Haug and Bebe Lavin, 'Practitioner or patient - who's in charge?' (1981) 22 Journal of Health and Social Behavior 212. Haug and Lavin recommend a move to a consumerist stance in healthcare, where the doctor performs the obligations of the service provider and the patient plays the role of the buyer.

<sup>65</sup> Slievemore Clinic, 'Our Clinics' (2016) <[www.slievemore-clinic.com/](http://www.slievemore-clinic.com/)> accessed 30 September 2016.

<sup>66</sup> Bonn Secours Hospital Cork (n 55).



- ii. Curricula are not standardised and vary in length, detail and clinical experience gained by the student;
- iii. If a qualification is obtained, practitioners are not required to obtain registration in order to practice;
- iv. There may be more than one representative body for any particular therapy<sup>67</sup>;
- v. Codes of practice, with which prospective members must agree to abide, vary between organisations and are not consistently accessible by the general public.

The level of risk unknowingly undertaken by consumers seeking a CAM practitioner in Ireland should be of concern to regulators. Consumers may encounter a provider who is wholly unqualified or a provider with poor quality education or training in their chosen modality, they may not have recourse to a grievance mechanism where their practitioner is not a member of a representative body, or they may be subject to an ineffective or opaque grievance mechanism, where one is in place. In the event that a serious complaint results in removal of the practitioner in question from their chosen register, that practitioner may continue to practice as before, albeit without using the letters of their former representative body. A search of numerous CAM representative bodies found no mechanism through which the public could check previous upheld complaints against practitioners, though, of course, this does not mean that such a facility does not exist.<sup>68</sup> With transparency a core element in establishing trust in a practitioner, in a therapy and in a sector, this might be considered an area for improvement for those providing and representing CAM.

### 3.2.1 GRIEVANCES IN THE COURTS

Where there arises a grievance, which is insufficiently addressed by the CAM practitioner or their representative body, resort may be had to the courts. Where negligence is alleged, determination of the appropriate standard to be applied may not be straightforward. Scant jurisprudence addressing the principles of negligence pertaining to CAM practitioners in Ireland leaves prospective plaintiffs, defendants, and commentators somewhat in the dark. Fundamentally, the courts must determine what standard is applicable in assessing the reasonableness of the CAM practitioner: the ordinary negligence standard, being the behaviour of the reasonable man in the given circumstances,<sup>69</sup> or the professional standard, being the behaviour of the reasonable

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<sup>67</sup> For example, an acupuncturist may be a member of the Acupuncture Council of Ireland, the Acupuncture Foundation Professional Association and/or the Professional Register of Traditional Chinese Medicine. They may also opt not to register with a representative body.

<sup>68</sup> See Chapter 3.

<sup>69</sup> *McComiskey v. McDermott* [1974] IR 75 (SC), 89 (Henchy J).

practitioner of equal status and specialism, principles for which were set out in clear terms by Finlay CJ in *Dunne v National Maternity Hospital*.<sup>70</sup> The *Dunne* principles are as follows:

1. The true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is whether he has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care.
2. If the allegation of negligence against a medical practitioner is based on proof that he deviated from a general and approved practice, that will not establish negligence unless it is also proved that the course he did take was one which no medical practitioner of like specialisation and skill would have followed had he been taking the ordinary care required from a person of his qualifications.
3. If a medical practitioner charged with negligence defends his conduct by establishing that he followed a practice which was general, and which was approved of by his colleagues of similar specialisation and skill, he cannot escape liability if in reply the plaintiff establishes that such practice has inherent defects which ought to be obvious to any person giving the matter due consideration.
4. An honest difference of opinion between doctors as to which is the better of two ways of treating a patient does not provide any ground for leaving a question to the jury as to whether a person who has followed one course rather than the other has been negligent.
5. It is not for a jury (or for a judge) to decide which of two alternative courses of treatment is in their (or his) opinion preferable, but their (or his) function is merely to decide whether the course of treatment followed, on the evidence, complied with the careful conduct of a medical practitioner of like specialisation and skill to that professed by the defendant.<sup>71</sup>

The professional negligence standard is broadly and necessarily protective of the conventional medical professional, who is “considered to expound and exercise difficult skills of fundamental importance to society, whose cultivation required ... elaborate specialist education and training and whose practice was guided by ethical imperatives”.<sup>72</sup> To demand that conventional practitioners accept the significant risk of litigation associated with normal practice under standard negligence principles would be unreasonable and likely to deter prospective entrants, creating further problems for

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<sup>70</sup> *Dunne v National Maternity Hospital* [1989] IR 91 (SC). The standard developed in Ireland *inter alia* through the cases of *Daniels v Heskins* [1954] IR 73 (SC) and *O'Donovan v Cork County Council & ors* [1967] IR 173 (SC).

<sup>71</sup> *Dunne v National Maternity Hospital* (n 70) 109.

<sup>72</sup> John Healy, *Medical Malpractice Law* (Round Hall/Thomson Reuters 2009) 277-278.

the future of the health service. Importantly, the professional standard also represents recognition that the court may not be best placed to judge complex matters of medicine and, for this reason, expert evidence of general and approved practice and divergence from it is of fundamental significance in determining the reasonableness of the defendant medical professional's behaviour in the circumstances. However, the deference to external professional standards by the courts should, by rights, be limited in applicability, particularly given the importance of protecting consumers and patients in transactions where there is an inherent imbalance in power and knowledge.

Though there is little by way of Irish jurisprudence addressing the applicable standard for CAM practitioners, it was addressed in the English case of *Shakoor v Situ*,<sup>73</sup> involving the treatment of a patient for a benign skin condition using Traditional Chinese Herbal Medicine (TCHM), to which he developed an unexpected and fatal reaction. Livesey QC saw fit to apply the standard of the reasonably competent practitioner of the particular art (in this case, TCHM) who is practising in accordance with the standards required in that jurisdiction. Although this appears similarly deferential to the conventional professional standard, he acknowledged that this was a lower standard, noting that patients or consumers could not choose to reject conventional care but subsequently demand the same standards.<sup>74</sup> Livesey QC nonetheless found that such practitioners had a duty keep abreast of the relevant information on risk available in conventional medical literature,<sup>75</sup> in line with established standards in domestic medicine and law.

It is argued that the professional negligence standard set out in detail in *Dunne v National Maternity Hospital* ought not be considered applicable to claims against CAM practitioners, who do not fit the existing narrow criteria of 'professional' at the present time in Ireland.<sup>76</sup> In addition, it is questionable whether the modified standard applied in *Shakoor v Situ* would be consistently applied in the same way in Irish courts at the present time, where the courts may have difficulty in finding cohesive and established standards pertaining to entry, education and professional practice for many CAM therapies in Ireland. Reference or deference to such standards would be difficult.

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<sup>73</sup> *Shakoor v Situ* [2001] 1 WLR 410. For a detailed analysis of the case, see Margaret Fordham, 'The standard of care applicable to practitioners of alternative medicine' (2001) 11 Singapore Journal of Legal Studies 1. The English professional negligence standards developed *inter alia* through the cases of *Bolam v Friern Hospital* [1957] 2 All ER 118, *Whitehouse v Jordan* [1981] 1 All ER 267 (HL), *Maynard v West Midlands* [1985] 1 All ER 635 (HL) and *Bolitho v City & Hackney Health Authority* [1997] 4 All ER 771.

<sup>74</sup> *ibid* 416.

<sup>75</sup> *ibid* 417.

<sup>76</sup> The application of the professional standard to mechanics in the case of *Hughes v JJ Power Ltd & Collier Ltd* [1988] IEHC 34 has been considered questionable by some commentators. See John Healy (n 72) 288. The author argues that "it is very much to be doubted that principle and policy should support the extension of the special professional standard rules to other occupations subsequently treated or self-styled as professions".

It is further argued that while the *Dunne* principles ought not be applicable in cases addressing CAM practitioners, the inherent defects element might nonetheless be considered as persuasive in applying the ordinary negligence standard. Where a CAM practice has minimal or no high-quality evidence supporting efficacy or where the risk-benefit profile based on the best available evidence does not favour treatment of a patient, the practice might reasonably be considered to be inherently defective. This was not accepted in *Shakoor*, where the court was unwilling to find that the condition in question (benign lipomata) could definitively not be treated by TCHM, as some evidence was presented that it could.<sup>77</sup> However, this may not apply equally to all CAM therapies, particularly those such as homeopathy, which have a widely-documented lack of supportive evidence of efficacy. A general practice of advising patients to stop taking their conventional medication or to avoid attending their conventional physician may also be considered inherently defective. In light of the requirement to keep abreast of relevant conventional literature provided in *Shakoor*, courts in Ireland may opt to impose a similar requirement on domestic CAM practitioners, decreasing the likelihood of a successful defence based on ignorance of risks or a poor risk-benefit profile already recognised by conventional medicine.<sup>78</sup>

### 3.3 ROOM FOR IMPROVEMENT

Though legislative frameworks exist to provide substance-specific safety and quality assurance in respect of, for example, homeopathic<sup>79</sup> and herbal<sup>80</sup> remedies,<sup>81</sup> CAM is, at present, almost entirely unregulated in Ireland and untested in Irish courts, depriving would-be legislators of any judicial guidance in respect of their legal standing and the standard to which practitioners should be held.

This regulatory vacuum leaves the public vulnerable to physical, psychological and financial harm, providing as it does for *inter alia* the propagation of misinformation in respect of optimal care.<sup>82</sup> Notwithstanding this apparently-clear red flag, CAM treatments are increasingly sought

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<sup>77</sup> As is noted throughout this thesis, research may be of variable quality and the quality of the evidence presented in support of the efficacy of TCHM for benign lipomata was not addressed in the decision.

<sup>78</sup> In *Shakoor*, the inherent defects element was found to have potential application, though, in this case, it was not considered relevant, as the patient was deemed to have suffered from an extremely rare idiosyncratic reaction that would not have been avoidable even with testing prior to administration of the herbal medicinal product and monitoring after. Given the rarity of such an adverse event, the TCHM practitioner in this case was not found to be negligent in failing to provide a warning of it.

<sup>79</sup> Directive 2001/83/EC (n 3).

<sup>80</sup> Directive 2004/24/EC (n 3).

<sup>81</sup> Though it is argued that these are also inadequate, failing to require scientific evidence of efficacy and failing to consider the potential harm for consumers using inefficacious therapies. See Chapter 3.

<sup>82</sup> Katja Schmidt and Edzard Ernst, 'Assessing websites on complementary and alternative medicine for cancer' (2004) 15(5) *Annals of Oncology* 734, 735-736. See also Edzard Ernst, 'Alternative treatments for breast cancer' (2012) 68 *European Journal of Clinical Pharmacology* 453.

out for minor and major ailments.<sup>83</sup> In 2002, the then Minister for Health, Micheál Martin, spoke at the launch of the *Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland*.<sup>84</sup> He noted the need for regulation of the sector and that

...[P]rotection of the public must clearly be at the heart of effective regulation of any activity. As far as complementary therapists are concerned, there is an overriding requirement to ensure that the general public are properly informed so that they can be confident that a practitioner providing a service is competent to do so.<sup>85</sup>

Despite this recognition and the publication of a subsequent report recommending unified and cohesive voluntary self-regulation of the sector in 2005,<sup>86</sup> no substantial move towards enforceable regulation has been made. The overwhelming variety of CAM therapies is perhaps among the reasons why the CAM sector operates within a system of voluntary self-regulation – to establish a mechanism of regulation that provides the stringency to protect users of all therapies while accommodating the peculiarities of each in the name of consumer choice is an overwhelming task. Voluntary self-regulation, though cost effective, does not provide the ethical, therapeutic or consumer safeguards owed to the public in matters of health. It is, nonetheless, the status quo and so optimisation is essential in lieu of larger reforms. These reforms, if any, must be informed by consideration of healthcare ethics.

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<sup>83</sup> Patricia Fox and others (n 61).

<sup>84</sup> Tim O’Sullivan, ‘Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland’ (Stationery Office 2002).

<sup>85</sup> Speech by Micheál Martin, TD, at the Launch of the Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland, 14 November 2002.

<sup>86</sup> Teri Garvey, *Report of the National Working Group on the Regulation of Complementary Therapists to the Minister for Health and Children* (Stationery Office 2005).

## PART II

### ETHICAL CONSIDERATIONS

*The actions of conventional medical practitioners must be consistent with the law and with the expectations of the society in which they practice.*<sup>87</sup>

#### A NOTE ON SCOPE

A thorough examination of the ethical implications of CAM practice would provide sufficient material for a thesis in its own right. For the purpose of this thesis, however, it is necessary and appropriate to limit discussion to those issues that are most relevant: the deficiency of accurate information provided to consumers in obtaining their consent to treatment and the existing lack of evidence in support of the safety and efficacy of many CAM therapies. Both conventional medicine and CAM create an imbalance in power between the patient or consumer and the practitioner and it is argued that, irrespective of the presence or absence of a statutory basis, the onus of ethical practice, ensuring that the best interests of the patient are prioritised in the context of treatment, rests equally on conventional and CAM practitioners.

The adoption of an appropriate ethical framework for use in addressing the ethical considerations arising throughout this thesis is a necessary initial consideration. The principlist approach, espoused by Beauchamp and Childress,<sup>88</sup> was chosen for this purpose.

#### 4. BIOMEDICAL ETHICS: A PRINCIPLIST APPROACH

According to the British Medical Association, the principles of biomedical ethics are actively utilised in clinical decision making.<sup>89</sup> It is argued that any proposed general standard of care for CAM practitioners be founded on these same ethical principles.

Beauchamp and Childress<sup>90</sup> principlist approach, espousing the four principles of respect for autonomy,<sup>91</sup> non-maleficence,<sup>92</sup> beneficence,<sup>93</sup> and justice<sup>94</sup>, is one of many potentially applicable

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<sup>87</sup> British Medical Association, *Medical Ethics Today: The BMA's Handbook of Ethics and Law* (John Wiley & Sons 2012) 12.

<sup>88</sup> Tom Beauchamp and James F Childress, *Principles of Biomedical Ethics* (Oxford University Press 2009).

<sup>89</sup> British Medical Association, *Medical Ethics Today: The BMA's Handbook of Ethics and Law* (John Wiley & Sons 2012) 12.

<sup>90</sup> Tom Beauchamp and James F Childress (n 88).

<sup>91</sup> *ibid* 99.

<sup>92</sup> *ibid* 149.

<sup>93</sup> *ibid* 197.

<sup>94</sup> *ibid* 240.

ethical philosophies.<sup>95</sup> However, the arguments in favour of the principlist approach, being, among others, its ability to locate all resolvable quandaries of medical ethics within one or more of the four principles, made, not only by Beauchamp and Childress, but by Gillon,<sup>96</sup> and, most recently, by Macklin,<sup>97</sup> remain the most compelling. While a criticism of those opposed to principlism is the lack of a hierarchy for application of the principles, it has been argued that respect for autonomy should be “first among equals”.<sup>98</sup> This reflects the increasing momentum away from the traditional paternalistic model of medicine, noted above, and towards an embrace of self-determination.

#### 4.1 RESPECT FOR AUTONOMY

*Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages.*<sup>99</sup>

Respect for autonomy acknowledges the right of the competent patient to eschew objectively beneficial medical treatment for any reason or none and, conversely, to choose to undergo a dangerous or inefficacious treatment.<sup>100</sup> Its relevance in the analysis of CAM cannot be overestimated.<sup>101</sup>

Consent to medical treatment is a legal expression of autonomy.<sup>102</sup> Valid consent, described in the National Consent Policy<sup>103</sup> and by Stone may be considered to have three elements:

- i. the provision of adequate information;
- ii. competence to consent; and
- iii. voluntariness.<sup>104</sup>

<sup>95</sup> For an overview of the differing approaches and a comparative analysis, see Udo Schüklenk and Jacinta Kerin, ‘Bioethics: Philosophical Aspects’ in Paul B Baltes (ed), *International Encyclopedia of the Social & Behavioral Sciences* (Pergamon 2001) 1195–1201.

<sup>96</sup> Raanan E Gillon, ‘Ethics needs principles—four can encompass the rest—and respect for autonomy should be “first among equals”’ (2003) 29 *Journal of Medical Ethics* 307. See also, Raanan E Gillon, ‘Medical ethics: Four principles plus attention to scope’ (1994) 309 *British Medical Journal* 184.

<sup>97</sup> Ruth Macklin, ‘Can one do good medical ethics without principles?’ (2015) 41 *Journal of Medical Ethics* 75.

<sup>98</sup> Raanan E Gillon (2003) (n 96).

<sup>99</sup> *Schloendorff v The Society of New York Hospital* (1914) 211 N.Y.125, 129-30 (Cardozo J).

<sup>100</sup> National Consent Advisory Group, *National Consent Policy* (HSE 2014) 30.

<sup>101</sup> For a detailed exploration of the limits of personal medical autonomy in Ireland, with particular reference to duty to others, see Rachel O’Sullivan, ‘The patient’s duties to others: Limitations to the principle of autonomy in healthcare decision making’ (2015) 14 *Cork Online Law Review* 7.

<sup>102</sup> Omprakash V Nandimath, ‘Consent and medical treatment: The legal paradigm in India’ (2009) 25 *Indian Journal of Urology* 343.

<sup>103</sup> National Consent Advisory Group (n 100) 23.

<sup>104</sup> Julie Stone, *An Ethical Framework for Complementary and Alternative Therapists* (Routledge 2002) 157. This is also described in Tom Beauchamp and James F Childress, *Principles of Biomedical Ethics*, (4th rev edn, Oxford University Press Inc 1994) 99, “Personal autonomy encompasses, at a minimum, self-rule that is free from both controlling interference by others and from certain limitations such as inadequate understanding that prevents meaningful choice”.

Each is briefly described, both in general and with specific reference to their relevance for CAM.

#### 4.1.1 ADEQUATE INFORMATION

Although it may be argued that the direct and indirect risks and benefits inherent in the use of any CAM therapy are understood and freely undertaken by consumers when the therapy is sought out by them,<sup>105</sup> patient autonomy is heavily reliant on the quality of the information proffered by the provider, just as in conventional medicine. Without relevant, current and accurate information, the consumer cannot act autonomously. This is at the core of considerations of autonomy and consent in CAM.

Consent may be undermined in circumstances where:

- (a) Consumers are not fully informed of the known risks of treatment<sup>106</sup>;
- (b) Consumers are not fully informed of a lack of proven efficacy of treatment<sup>107</sup>;
- (c) Consumers are misled as to the risks or benefits of comparative conventional care<sup>108</sup>; or
- (d) The practitioner overstates his or her own diagnostic or therapeutic competence.<sup>109</sup>

Without obtaining informed consent, practitioners infringe upon the consumer's constitutional right to bodily integrity,<sup>110</sup> the right to self-determination protected under Art 8 ECHR,<sup>111</sup> and risk civil and criminal legal action.<sup>112</sup> Vindication of the consumer's right to autonomy and their constitutional right to bodily integrity in the course of medical treatment requires the disclosure of all information that would be considered material to the reasonable patient and to the particular patient in the decision-making

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<sup>105</sup> Julie Stone (n 104).

<sup>106</sup> Edzard Ernst, Michael H Cohen and Julie Stone, 'Ethical problems arising in evidence based complementary and alternative medicine' (2004) 30 *Journal of Medical Ethics* 156, 158.

<sup>107</sup> Edzard Ernst, 'Ethics of complementary medicine: Practical issues' (2009) 59 *British Journal of General Practice* 517, 517-518.

<sup>108</sup> Lois Downey and others, 'Pediatric vaccination and vaccine-preventable disease acquisition: Associations with care by complementary and alternative medicine providers' (2010) 14 *Maternal and Child Health Journal* 922, 927.

<sup>109</sup> Edzard Ernst, Michael H Cohen and Julie Stone (n 106) 157.

<sup>110</sup> The Irish Constitution, Art 40.3.1°, as established in *Ryan v Attorney General* [1965] IR 294 (SC).

<sup>111</sup> Katri Lõhmus, *Caring Autonomy: European Human Rights Law and the Challenge of Individualism* (Cambridge University Press 2015) 16.

<sup>112</sup> *Walsh v Family Planning Services* [1992] 1 IR 496 (SC); *Re (a Ward of Court) withholding medical treatment* (No 2) [1996] 2 IR 79 (SC), 156 (Denham J).



process.<sup>113</sup> This has been held, in cases involving conventional medicine, to include the disclosure of effects that are particularly common or particularly grave, and might, therefore, influence the decision made by the patient.<sup>114</sup> It is argued that these same guidelines for disclosure should also apply to CAM, albeit with the additional requirements to disclose the absence of scientific evidence in support of efficacy for a particular condition, where relevant, to prospective consumers enabling them to provide better-informed consent on that basis.

The National Consent Policy also provides guidance and recommendations for information to be provided to patients in obtaining consent<sup>115</sup>:

The amount of information to be provided about an intervention will depend on the urgency, complexity, nature and level of risk associated with the intervention. Choosing whether to undergo or to forego medical investigation and treatment ... often requires the service user to balance the potential risks and benefits of both approaches. In these circumstances, service users need adequate information about:

- (a) Their diagnosis and prognosis including any uncertainties about the diagnosis or prognosis<sup>116</sup> [for CAM, this may refer to diagnosis within the particular therapeutic paradigm, causing confusion for consumers accustomed to conventional medicine and difficulties for regulators or courts faced with determining whether a diagnosis provided by a CAM practitioner was appropriate based on medical principles (headache caused by eye-strain) or, for example, on vitalist principles (headache caused by liver Yang and Qi disharmonies)<sup>117</sup>]
- (b) Options for treating or managing the condition, including the option not to treat
- (c) The purpose of any proposed intervention and what it will involve

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<sup>113</sup> *Geoghegan v Harris* [2000] 3 IR 536 (HC) (Kearns J), citing *Canterbury v Spence* (1972) 464 F. 2d 772, 788, on materiality, “A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summons discussion with the patient. There is no bright line separating the significant from the insignificant; the answer in each case must abide a rule of reason”. The reasonable patient test is now applicable in Irish law.

<sup>114</sup> *ibid.*

<sup>115</sup> Practitioners must also respect the wishes of the patient in relation to the information provided, although basic information on their diagnosis, risks and benefits should be given, in a way that is easily understandable by the patient. See Medical Council, *A Guide to Professional Conduct and Ethics for Registered Medical Professionals* (8th edn, Medical Council 2016) 16.

<sup>116</sup> Some codes of practice for CAM disciplines prohibit “medical diagnosis” of any condition if the practitioner is not also a conventional medical practitioner. Some internal inconsistencies exist, however, where a member may not diagnose a medical condition, but must be able to recognise conditions that are outside the scope of their skill or training and refer a patient to another practitioner, including a medical practitioner, accordingly. Clearly, this requires the use of diagnostic skills, including those outside the particular CAM paradigm. See Irish Society of Homeopaths, ‘Code of Ethics and Practice’, Rules of Practice 3 and 4 <<http://irishhomeopathy.ie/wp-content/uploads/2016/06/Code-of-Ethics.pdf>> accessed 20 January 2011 (link not currently active).

<sup>117</sup> Remy R Coeytaux, Wunian Chen, Catherine E Lindemuth and others, ‘Variability in the diagnosis and point selection for persons with frequent headache by traditional Chinese medicine acupuncturists’ (2006) 12(9) *Journal of Alternative and Complementary Medicine* 863, 870.

- (d) The potential benefits, risks and the likelihood of success of a proposed intervention, as well as that of any available alternative
- (e) Whether a proposed investigation or treatment is experimental or part of a research project
- (f) If relevant, that costs will have to be paid and how and where information about these costs may be obtained.<sup>118</sup>

While most CAM therapies may be considered relatively low-risk and elective, and where, in conventional medicine, the information required to be disclosed to patients in order to obtain valid consent for minor treatments is relatively limited, the provision, as standard, of information in line with these recommendations by all CAM practitioners for all therapies would significantly improve the quality of the consent obtained in the sector. Allied to this, however, is a more complex problem.

Although CAM providers undoubtedly take their clinical and ethical responsibilities seriously, convinced of the accuracy of the information they dispense, in very many cases and as noted throughout this thesis, there exists a chasm between that information and the best available evidence. These honestly held beliefs may not be open to change, despite ethical, legal, public health and consumer implications, making the availability of a source of legible, high quality and current information on the safety and efficacy of therapies for potential CAM users an important early consideration for regulators.

#### 4.1.2 COMPETENCE

*The law of consent is based on the assumption that people have rational decision-making capacity. Although competent adults are, in theory, free to make irrational decisions, the presumption is that, given the appropriate information and absence of coercive influences, rational people make rational decisions.*<sup>119</sup>

Consumers of CAM, though presumed competent, rely upon the skill (competence) of the provider to assess their competence to consent to a particular aspect of their care, and, where the competence of the consumer is in question, to facilitate supported decision-making, or to pause care temporarily for assessment.<sup>120</sup> This may not be within the skill-set of a CAM practitioner, given the variation in standards and scope of

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<sup>118</sup> National Consent Advisory Group (n 100) 24.

<sup>119</sup> Julie Stone (n 104) 162.

<sup>120</sup> National Consent Advisory Group (n 100) 29, “Best practice and international human rights standards favour “supported decision-making” where possible. This requires that efforts must be made to support individuals in making decisions for themselves where this is possible”.

education in CAM modalities and the lack of minimum standards in Ireland at present. This uncertainty introduces a further element of risk for consumers, whose competence to consent may be compromised at any point during the course of treatment.

### **4.1.3 VOLUNTARINESS**

For consent to be valid, it must be given freely and not subject to duress.<sup>121</sup> Stone emphasises the need for CAM therapists to avoid urging patients to accept treatment against their wishes, as illness may deprive some consumers of their autonomy, rendering them unusually suggestible. In addition, the therapist-consumer dynamic creates a power and knowledge imbalance, contributing to the potential for undue influence over consumer decision-making. There is no doubt that this is also an issue in conventional medicine, where similar dynamics are established.

The primary importance of consumer autonomy in healthcare and the need to protect both the consumer and the practitioner requires, not only that changes be made within the sector itself, but that resources be provided to improve public education and science and health literacy, in line with the recommendations set out in Chapter 7.

## **4.2 BENEFICENCE AND NON-MALEFICENCE**

The principles of beneficence and non-maleficence, encompassing the assertion that the healthcare provider must assess the risk of a therapy before providing or recommending it for a patient, balancing it with the potential for benefit, together provide the ethical origins of the risk-benefit analysis utilised in modern conventional healthcare. This analysis is central to conventional medical practice, as patients are at a significant disadvantage, usually with limited knowledge of and access to clinical information and without clinical experience. The same approach should be applicable in CAM, though this raises the significant problem of evidence.

For many CAM therapies, the best available evidence either demonstrates a lack of efficacy, or does not demonstrate efficacy beyond the placebo effect.<sup>122</sup> As against this, some therapies carry risk of direct harm, while other therapies, such as homeopathic remedies, may be

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<sup>121</sup> *ibid* 28.

<sup>122</sup> Howard Brody, 'The lie that heals: The ethics of giving placebos' (1982) 97 *Annals of Internal Medicine* 112, 113, "The placebo effect is the change in the patient's condition that is attributable to the symbolic import of the healing intervention rather than to the intervention's specific pharmacologic or physiologic effects". Gotzsche disagrees, asserting that it is not possible to accurately define "placebo effect". See Peter C Gotzsche, 'Is there logic in the placebo?' (1994) 344(8927) *Lancet* 925, 926.

physically inert, but may harm indirectly when used in place of conventional therapies with established safety and efficacy. Where a treatment is inefficacious and carries risk, the balance is unfavourable to the patient and the treatment should not be carried out. This determination must be made on the basis of high quality scientific evidence. Gillon summarises the obligation thus:

The obligation to provide net benefit to patients also requires us to be clear about risk and probability when we make our assessments of harm and benefit. Clearly, a low probability of great harm such as death or severe disability is of less moral importance in the context of non-maleficence than is a high probability of such harm, and a high probability of great benefit such as cure of a life-threatening disease is of more moral importance in the context of beneficence than is a low probability of such benefit. We therefore need empirical information about the probabilities of the various harms and benefits that may result from proposed health care interventions. This information has to come from effective medical research, which is also therefore a *prima facie* moral obligation.<sup>123</sup>

Though CAM practitioners undoubtedly act in good faith, there is not currently enough high quality research demonstrating a favourable risk-benefit profile for many CAM therapies, for the conditions claimed. The continued marketing of these products and services in the face of such uncertainty should be of significant concern to regulators. Though it is hoped that further research will support the safety and efficacy of the many available CAM therapies (as consumers already derive significant benefit from the broader context of CAM therapy, encompassing the environment and the time and attention afforded to them), regulators must act based on existing evidence, enforcing consumer protection measures already in place to limit unsubstantiated claims.

In addition, the education and training standards for CAM providers are inconsistent. Titles such as ‘homeopath’ or ‘chiropractor’ are not protected under Irish or European law, and can be used by anyone who wishes to establish a practice, regardless of their background. Ernst et al<sup>124</sup> express serious concern about the implications of this and its effect on the ability of the therapist to abide by the principle of non-maleficence.<sup>125</sup> Clearly, a shortcoming on the part of the therapist in this respect may have potentially grave repercussions for a patient injured by injudicious, unskilled or dangerous practice and the status and treatment of the CAM sector must be altered to reflect this,<sup>126</sup> until a suitable minimum general standard of safe practice can be established.

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<sup>123</sup> Raanan E Gillon (n 96).

<sup>124</sup> Edzard Ernst, Michael H Cohen and Julie Stone (n 106).

<sup>125</sup> *ibid* 157.

<sup>126</sup> This starkness of the comparison with the conventional medical regime in this respect is apparent in the emphasis placed on evidence-based practice and safety in Department of Health and Children (n 15) 11, where

### 4.3 JUSTICE

In respect of CAM, the primary issues of justice arise from allocation of resources and of access to grievance procedures. With the latter addressed above, it is apt to provide a brief overview of the former, which is, in reality, a hypothetical problem in Ireland under the current regime. CAM services are not currently publicly funded in Ireland and it is not argued that they should be. However, it is important to consider the implications of publicly funding research on CAM, which may discover novel applications for CAM therapies, may detect efficacy where none has been found previously, but may also waste public funds and raise questions of ethical propriety, by continuing to undertake research in areas which have already been extensively researched with limited or no positive outcome.

#### 4.3.1 PUBLIC FUNDING OF CAM RESEARCH

Despite the need for substantiation mentioned above, there must come a point at which enough research has been done to arrive at a conclusion on the therapeutic value of a product or procedure. In 2010, the House of Commons Science and Technology Committee in *Evidence Check 2: Homeopathy – Fourth Session Report* found:

Research funding is limited and highly competitive. The Government should continue its policy of funding the highest quality applications for important scientific research determined on the basis of peer review<sup>127</sup>

There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious. Competition for research funding is fierce and we cannot see how further research on the efficacy of homeopathy is justified in the face of competing priorities<sup>128</sup>

It is also unethical to enter patients into trials to answer questions that have been settled already.<sup>129</sup>

The panel recommended the cessation of funding provision for research of homeopathy on these bases.

The funding of such research is not currently a significant issue in Ireland, where studies addressing CAM within the public health sphere tend to have a conventional medical

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its authors stated, “The Commission is of the view that supporting evidence-based practice is a critical element of a health system which is to deliver safe and high quality care”.

<sup>127</sup> House of Commons Science and Technology Committee, *Evidence Check 2: Homeopathy – Fourth Session Report 2009 – 2010* (London, Stationery Office 2010), para 63.

<sup>128</sup> *ibid* para 77.

<sup>129</sup> *ibid* para 78.

basis.<sup>130</sup> However, research is very much needed to inform the appropriate regulation of CAM and, while some treatment modalities, like homeopathy, have provided no substantive evidence of benefit, many others legitimately require further assessment across a wide range of conditions.

Consideration must be given to existing and potential ethical issues in analysing future changes in the CAM sector, to improve the protection of consumer dignity and bodily integrity and to ensure that potentially efficacious therapies are not unduly dismissed by association with those found, through exhaustive research, to have limited or no efficaciousness.

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<sup>130</sup> Patricia Fox and others (n 61). See also, Evonne Low and others, 'Complementary and alternative medicine use in Irish paediatric patients' (2008) 177(2) *Irish Journal of Medical Science* 147 and Sinead M Murphy and others (n 1).

## CONCLUSION

It is not the intention of this thesis to venerate conventional medicine as the one true source of health care. As is demonstrated in Chapter 2, conventional medicine is riddled with idiosyncrasies, inadequacies and failures, all of which have contributed much to the harm suffered by its consumers. Nor is it intended to denigrate CAM and its practitioners or providers, who contribute much to their consumers' experience of wellbeing. Nonetheless, the many flaws of conventional medicine do not make those of CAM more acceptable. The entry criteria, education and training standards, ethical framework and oversight and grievance mechanisms in conventional medicine, while suboptimal in many ways, at least acknowledge the risk borne by both the provider and the receiver of medical care and facilitate investigation of complaints and, where necessary, appropriate censure. By contrast, the absence of any specific statutory standards for education, training or practice for CAM practitioners in Ireland and the clear reluctance on the part of regulators to establish a suitably protective regime give the impression of a system of medicine with minimal or no risk and therefore without the need for regulation, an understandably attractive proposition for consumers.<sup>131</sup> However, this rather naïve evaluation of safety based on perceived regulatory insouciance, the lack of standardisation in education and training, insufficiently evidence-based practice, and the inconsistent provision of accessible and transparent grievance procedures for CAM disciplines<sup>132</sup> create unnecessary risk for consumers and point to failures in oversight and enforcement in existing consumer protection law within the CAM sector.

It is argued that the wholesale transposition of conventional medical regulation onto the CAM sector would unduly restrict patient choice in healthcare in Ireland and would make CAM in Ireland unsustainable. However, a number of changes are certainly required to protect consumers from physical, psychological or financial harm, focussing on the areas noted above. The ethical principles applicable in conventional medicine should also be applied to CAM, with particular emphasis on disclosure of risks and benefits and informed consent, providing a level of predictability for consumers and for practitioners across the healthcare spectrum.

CAM clearly forms a significant and growing part of the Irish healthcare tapestry. Determining the reasons for its popularity and the weighting of various influences in consumer decision-making between the CAM and conventional sectors may assist regulators in optimising a novel regulatory regime. It is to these influences that we now turn.

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<sup>131</sup> For 31% of CAM users, the fact that the CAM therapy in question was perceived as being safe was influential in their choice to use it. 7% of users based their perception of safety on the fact that CAM products and services are freely available in Ireland. See Chapter 6.

<sup>132</sup> For the purpose of sourcing reports on grievance proceedings, the websites of five prominent CAM representative associations (Irish Society of Homeopathy, Acupuncture Council of Ireland and Chiropractic Association of Ireland, Osteopathic Council of Ireland and Reiki Federation of Ireland) were searched for the words, “report”, “disciplin”, “disciplinary”, “grievance”, “complaint” and “fitness”. No relevant results were returned.





## CHAPTER 2

### FACTORS INFLUENCING CONSUMER CHOICE IN CONVENTIONAL MEDICINE AND CAM

#### INTRODUCTION

Consumer decision-making in the realm of healthcare is multifaceted and complex, particularly where consumers are faced with multiple systems of medicine, many of which clash in their ethos and practice. In order to optimally protect consumers from products or services that may harm them physically, psychologically or financially, directly or indirectly, and to improve the quality of healthcare overall, it is necessary to understand the factors influencing the decision-making process. It is useful, in this respect, to briefly review the relevant data on rates of CAM use and on the predominant users.

The most recent statistics on CAM usage come from a systematic review in the UK,<sup>1</sup> which found an average one-year prevalence (use of a CAM therapy in the past year) of 26.3% and a lifetime prevalence (CAM use over lifetime) of 44% in surveys considered by the panel to be methodologically sound. However, these data, while indicative of the popularity of CAM, are perhaps not of direct relevance in Ireland, due to the social differences between Ireland and the UK, and the regulation and integration of some CAM disciplines into the broader healthcare service provided by the state there. CAM has an established, if contentious, locus in society in the UK. It currently has no such status in Ireland.

A series of SLAN (National Survey of Lifestyles, Attitudes and Nutrition) studies carried out in Ireland<sup>2</sup> found increasing use of CAM services between 1998 (with a prevalence of 20%) and 2002 (with a prevalence of 27%),<sup>3</sup> though, due to its age, one cannot reasonably extrapolate from this data to gain insight into current usage. More recent Irish studies<sup>4</sup> are nonetheless based on this relatively old data, suggesting that more up-to-date research is required to inform national policy.<sup>5</sup>

Existing Irish and international research concurs on the profile of the predominant CAM user, and this was neatly summarised by Widder et al,<sup>6</sup> who found, “Overall, the typical CAM user tends to be female, middle aged, and college-educated, with lower perceived health and a higher level of spirituality (seeking answers and understanding to ultimate questions regarding life and its meaning

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<sup>1</sup> Paul Posadzki and others, ‘Prevalence of use of complementary and alternative medicine (CAM) by patients/consumers in the UK: systematic review of surveys’ (2013) 13(2) *Clinical Medicine* 126, 127.

<sup>2</sup> Patricia Fox and others, ‘Complementary alternative medicine (CAM) use in Ireland: A secondary analysis of SLAN data’ (2010) 18(2) *Complementary Therapies in Medicine* 95.

<sup>3</sup> *ibid* 97.

<sup>4</sup> *ibid* 95. See also, Kah Poh Loh and others, ‘Medical students’ knowledge, perceptions, and interest in complementary and alternative medicine’ (2012) 19 *Journal of Alternative and Complementary Medicine* 360.

<sup>5</sup> As part of the research undertaken for this thesis, a short questionnaire was distributed, seeking to obtain data on contemporary CAM use in Ireland. The results are set out in Chapter 6.

<sup>6</sup> Rebecca M Widder and Douglas C Anderson, ‘The appeal of medical quackery: A rhetorical analysis’ (2015) 11(2) *Research in Social and Administrative Pharmacy* 288.

and relationship with the sacred)”.<sup>7</sup> The authors found that CAM users tended to have conditions without a clear, straightforward or effective treatment path in conventional medicine, and that they also tended to have chronic health problems.<sup>8</sup> Such users may be somewhat disillusioned with conventional medicine or may be seeking to supplement their treatment and, once part of the CAM system, they may be “more susceptible to its lure because the rhetoric of these movements appears to be targeted at them”.<sup>9</sup> Developing an understanding of the lure of CAM may assist conventional practitioners in refining the manner and content of their communication and practice to better fit the particular needs of the patient within the conventional realm. A similar approach must be taken by regulators. This chapter aims to contribute to that understanding.

The popularity of CAM in Ireland is clearly not unfounded. In many ways, CAM fills the void that exists in Irish healthcare, providing the compassion and dignity that patients may no longer expect from conventional care, notwithstanding that conventional medicine has been known to proclaim its superiority, dismissing CAM as worthless.<sup>10</sup> This chapter examines some of the many potential reasons for consumers replacing conventional medicine, in whole or in part, with CAM.

The chapter begins by acknowledging the popularity of CAM, focussing briefly on the reasons for its popularity in particular demographics.

In Part I, the embrace of CAM as a rejection of conventional medicine is examined. Negative experiences of conventional medicine as a rationale for the wholesale abandonment of conventional medicine in favour of CAM is not as common as one might expect<sup>11</sup> and many consumers and patients use CAM alongside conventional medicine.<sup>12</sup> However, it nonetheless remains a key motivation for alteration in service use. In attempting to acknowledge the inadequacies contributing to the shift in consumer sentiment, two broad areas receive attention:

1. Corporate profiteering in healthcare; and
2. Social context and systemic failures.

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<sup>7</sup> *ibid* 289.

<sup>8</sup> *ibid* 290.

<sup>9</sup> *ibid* 295.

<sup>10</sup> Anthony W Fox, ‘Complementary medicines’ in Lionel D Edwards, Anthony W Fox and Peter D Stonier (eds), *Principles and Practice of Pharmaceutical Medicine* (Wiley 2011) 399.

<sup>11</sup> Institute of Medicine, *Complementary and Alternative Medicine in the United States* (National Academies Press 2005) 54-55.

<sup>12</sup> Maria T Chao, Christine Wade and Fredi Kronenberg, ‘Disclosure of complementary and alternative medicine to conventional medical providers: Variation by race/ethnicity and type of CAM’ (2008) 100(11) *Journal of the National Medical Association* 1341.

The profit motivation underlying corruption in conventional medicine features heavily in media coverage of health controversies<sup>13</sup> and, tellingly, in material issued by those promoting CAM.<sup>14</sup> While media reports often focus on the misbehaviour of a particular company or institution, it is not uncommon for later investigations to discover that misleading or unethical practices permeated the lifespan of a product from its preliminary research stage through drug development, clinical trials, academic and industry journal publication, wider media publication and product licencing, to marketing and prescribing, post-marketing surveillance and eventual recall. The involvement of a number of separate commercial and regulatory entities, rather than ‘one bad apple’, ought to be of significant concern to patients and lawmakers alike. By way of example, two short case studies are provided, the first on rofecoxib, a COX-2 inhibitor sold as Vioxx for the treatment of arthritis, among other conditions, and the second on the antidepressant paroxetine, sold as Seroxat in Ireland and Paxil in the US. Each study demonstrates different deceptive and fraudulent practices engaged in by various elements of the conventional healthcare establishment, resulting in substantial human harm and loss of life.

Part I then goes on to examine two Irish healthcare controversies, which also gave rise to significant human suffering in the absence of a profit motivation, demonstrating the harm caused by lapses in oversight, by sub-optimal administration and by the insinuation of non-medical and social influences into medical practice. The administration of infected blood products came about through systemic flaws in the processes of the National Blood Transfusion Board, while the inappropriately widespread and unnecessary performance of the symphysiotomy procedures in Irish maternity hospitals between 1944 and 1984 was driven, in part, by the significant influence of the Roman Catholic church, and went unchallenged due to the ingrained culture of paternalism and deference in Irish hospitals and other institutions at that time.

Matters such as these have proven catastrophic to the health and lives of the patients involved and have shaken trust in healthcare overall. However, patient sentiment has not changed for these newsworthy reasons alone. In fact, many patients simply feel that they are, if not mistreated, then

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<sup>13</sup> Richard Anderson, ‘Pharmaceutical industry gets high on fat profits’ *BBC News* (6 November 2014) <[www.bbc.com/news/business-28212223](http://www.bbc.com/news/business-28212223)> accessed 18 September 2016; Adam Lusher, ‘Big Pharma and governments are ‘turning a blind eye to corruption’, report claims’ *The Independent* (1 June 2016) <[www.independent.co.uk/news/world/politics/big-pharma-and-governments-are-turning-a-blind-eye-to-corruption-report-claims-a7059871.html](http://www.independent.co.uk/news/world/politics/big-pharma-and-governments-are-turning-a-blind-eye-to-corruption-report-claims-a7059871.html)> accessed 18 September 2016; ‘Infamous US drug entrepreneur arrested on suspicion of fraud’ *The Irish Times* (17 December 2015) <[www.irishtimes.com/business/health-pharma/infamous-us-drug-entrepreneur-arrested-on-suspicion-of-fraud-1.2469826](http://www.irishtimes.com/business/health-pharma/infamous-us-drug-entrepreneur-arrested-on-suspicion-of-fraud-1.2469826)> accessed 18 September 2016; Andrew Ward, ‘Big pharma struggles to balance transparency and profits’ *The Irish Times* (18 April 2014) <[www.irishtimes.com/big-pharma-struggles-to-balance-transparency-and-profits-1.1765592](http://www.irishtimes.com/big-pharma-struggles-to-balance-transparency-and-profits-1.1765592)> accessed 18 September 2016.

<sup>14</sup> Stephen Blendell ‘Unhealthy business - Big Pharma: Unhealthy for patients, economy, science and democracy’ <[www.mayohomeopathy.ie/index.php/unhealthy-business-drug-companies/](http://www.mayohomeopathy.ie/index.php/unhealthy-business-drug-companies/)> accessed 18 September 2016; Alliance for Natural Health, ‘ANH Feature: Being made sick for the sake of corporate profits’ (2012) <<http://anhinternational.org/2012/04/19/anh-feature-being-made-sick-for-the-sake-of-corporate-profits/>> accessed 18 September 2016.

perhaps simply not treated with the kindness, empathy or attention that they may have expected from conventional care. Here, CAM provides an attractive solution.

In Part II, the positive contribution made by CAM to the consumer experience of wellbeing is explored. The holistic approach taken by many CAM practitioners is an apparent antithesis to the ostensibly reductionist approach attributed to conventional medicine. While it may be contended that the holistic approach prevents practitioners from determining the factual pathology of a particular medical condition, or that it is merely a preliminary façade, with any eventual treatment aimed either primarily or solely at the cure of the disease or condition in question,<sup>15</sup> it nonetheless appears to facilitate the establishment of a high-quality patient-practitioner relationship.<sup>16</sup>

The decision to opt for CAM as a complete or partial alternative to conventional medicine may also represent a shift away from a traditionally patriarchal system, towards one which is matriarchal,<sup>17</sup> particularly as we move away from ‘medicalised’ therapies, such as chiropractic or osteopathy. As there is scant literature addressing this (research overwhelmingly focusses on the gender of those who access and use CAM, rather than on the service providers themselves), it may be a source of further research. The influence of practitioner gender on patient care is an area of increasing interest in conventional medicine, and requires examination in CAM. As it stands, the movement in favour of a sector with greater female influence may be considered rational by reference to the characteristics of such care, identified in studies undertaken in conventional medicine.<sup>18</sup>

CAM is patient-centred and is provided in a manner and in an environment that limits stress and trauma for the patient.<sup>19</sup> By contrast, much of conventional medicine, with its waiting lists,

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<sup>15</sup> Joshua Freeman, ‘Towards a definition of holism’ (2005) 55(511) *British Journal of General Practice* 154, 155.

<sup>16</sup> Stephanie Berger, Elmar Brähler and Jochen Ernst, ‘The health professional-patient-relationship in conventional versus complementary and alternative medicine. A qualitative study comparing the perceived use of medical shared decision-making between two different approaches of medicine’ (2012) 88(1) *Patient Education and Counseling* 129, 135. See also Edzard Ernst and Adriane Fugh-Berman, ‘Complementary and alternative medicine: What is it all about?’ (2002) 59 *Occupational and Environmental Medicine* 140, 141, “It is [in relation to the patient-provider relationship] that conventional medicine should accept culpability; many of us are palpably bored by the management of chronic problems (which, though not medically “serious”, significantly affect the lives of our patients). When we exhaust our therapeutic repertoire in a terminal illness, we may turn our attention elsewhere. Whenever we cannot cure, we tend to fall short in our other duty: to care. It is hardly surprising then that many patients experience the therapeutic relationship with CAM practitioners more rewarding”.

<sup>17</sup> A glance at the gender breakdown for CAM practitioners across five Irish CAM professional bodies (Table 1) shows that 72% are female.

<sup>18</sup> For example, Debra L Roter and Judith A Hall, ‘Physician gender and patient-centered communication: A critical review of empirical research’ (2004) 25 *Annual Review of Public Health* 497. The authors state that their research showed higher levels of questioning on psychosocial issues, higher levels of psychosocial discussion, greater volume of patient information disclosed, higher levels of partnering behaviours (noting a passive, lowered dominance approach), higher levels of emotionally responsive communication, higher levels of positive physician talk, and higher levels of smiling and nodding and awareness of non-verbal communication in female physicians. These characteristics are some of those most important for CAM practitioners, the perceived effectiveness of whose therapies rely heavily on such.

<sup>19</sup> Edzard Ernst and Adriane Fugh-Berman (n 16) 141.

overcrowding, invasive and painful procedures, and rushed, detached interaction,<sup>20</sup> is a source of patient apprehension, rather than a welcoming process with which to engage. It is also unsurprising, given the increasing concern over state intrusion into private affairs,<sup>21</sup> that a sector at liberty to decide how best to treat each patient without substantial fear of censure or interference by regulators, is so popular.

Finally, and of significant relevance to many users,<sup>22</sup> Part II considers the cult of ‘natural’, a boon of postmodern relativism. CAM is perceived and, frequently, promoted, as being the natural alternative to conventional medicine. This must be considered in the context of a culture which increasingly venerates the ‘natural’ and condemns synthetic or so-called chemical products and processes and their consumers. The physical and societally ascribed significance of ‘naturalness’ is discussed in detail, as a key influence in CAM use.

Part III of this chapter further explores the importance of the cultural context for CAM use, encompassing the roles of the internet and the media in the propagation and proliferation of CAM use, and, somewhat ironically, the rejection of technology and commercialism, which can be seen reflected in the way in which CAM is marketed. These elements have contributed significantly, though not always positively, to the popularity of CAM, and any comprehensive and thoughtful regulation of CAM must consider all sources of information, in conjunction with social context in which CAM is accessed.

Notwithstanding the ample *prima facie* rational reasons for CAM use and for the rejection of conventional medicine, this chapter nonetheless concludes that a risk benefit analysis, a fundamental consideration in any medical treatment, favours use of conventional medicine for almost all medical conditions, and that its transgressions, however grave to date (and there is, sadly, no doubt that further transgressions will occur and will continue to come to light into the future), do not outweigh its benefit. Though some CAM therapies have shown efficacy in some specific conditions,<sup>23</sup> the primary and transferrable benefits of CAM, which are documented in detail in Part II, are those which

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<sup>20</sup> Though not always the case, patient-doctor interaction in conventional medicine is often characterised and perceived as such. See Rebecca M Widder and Douglas C Anderson (n 6) 291.

<sup>21</sup> There are many examples of this, from the domestic constitutional restrictions on termination of pregnancy provided for within the remit of the right to life in Art 40.3.3°, or the uneven criminalisation of some private, recreational drug use, and the legalisation of others, to the impetus upon parents to vaccinate their children or to have certain tests performed, as observed in the case of *North Western Health Board v HW & CW* [2001] 3 IR 622 (SC).

<sup>22</sup> Edzard Ernst and Adriane Fugh-Berman (n 16) 143, “CAM is (perceived as) natural, and “natural” implies “no side effects”. As part of the questionnaire disseminated as part of this thesis, participants were asked about the influences on their CAM use. 46% of participants stated that the fact that a therapy was considered natural was influential in their choice. This was the second most influential factor overall, with a personal recommendation from a friend or family member being the most influential.

<sup>23</sup> Klaus Linde and others, ‘Acupuncture for the prevention of episodic migraine’ (2016) Cochrane Database of Systematic Reviews CD001218. The review concluded that “The available evidence suggests that a course of acupuncture consisting of at least six treatment sessions can be a valuable option for people with migraine... Overall the quality of the evidence was moderate”.

improve patient satisfaction, offer feelings of wellbeing, participation and empowerment, align with individual patient ethos and provide for high quality communication between practitioner and patient. This creates a context in which the effect of simultaneous or subsequent conventional medical treatment is supported and enhanced, as well as providing a placebo effect of its own. There can be no doubt that this element of patient care is lacking in conventional medicine, much to its detriment. Such an approach should be integrated into conventional practice and its provenance and value acknowledged. However, conventional medicine, despite its foibles, remains the best proven arena for the treatment of illness or injury.

## PART I

### CHOOSING CAM AND THE REJECTION OF CONVENTIONAL MEDICINE

#### 1. A CAUSE FOR INTROSPECTION

There can be no doubt that conventional medicine is flawed. While much is made of the considerable technological, practical and pharmaceutical advances made by conventional medicine to date, one must not underplay the degrading influence of poor practice, corruption and unethical behaviour, nor the traumatic and high-risk features of modern medicine. Similarly, underfunding, over-crowding and the lack of personal attention characteristic of much of conventional medicine cannot be said to be in the consumer or the patient's best interest.

CAM practitioners, as mentioned above, afford their patients time and personal attention. Much can be said for this alone, as it contributes to the experience of wellbeing,<sup>24</sup> as well as encouraging a spirit of participation and ownership in the treatment process, discouraging both the traditional paternalism and the more contemporary adversarial "us versus them" archetype notable in much of conventional medicine,<sup>25</sup> which may contribute to higher rates of dissatisfaction with higher levels of litigation as a consequence.<sup>26</sup>

Many of the issues endemic in conventional medicine are objectively good reasons for patients and consumers to retreat from the sector. As noted above, these problems extend beyond the practices of physicians themselves to the broader healthcare institutions, the pharmaceutical industry, research institutions, academic publications and statutory bodies, resulting in physical, psychological and financial harm and the loss of public trust. With this in mind, it is apt to begin by considering the negative impact of profit motivation in healthcare.

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<sup>24</sup> Felicity Goodyear-Smith and Stephen Buetow, 'Power issues in the doctor-patient relationship' (2001) 9(4) *Health Care Analysis* 449, 456. The authors discuss the 'doctor as drug' and its significance in the patient experience.

<sup>25</sup> Riyaz A Kaba and Prasanna Sooriakumaran, 'The evolution of the doctor-patient relationship' (2007) 5(1) *International Journal of Surgery* 57. The authors provide a concise summary of the changes in the doctor-patient dynamic over time. See also, Teresa Hellín, 'The physician-patient relationship: Recent developments and changes' (2002) 8(3) *Haemophilia* 450 and Richard Miech, 'The doctor-patient relationship: Friend or adversary?' (1995) 62(2) *The Linacre Quarterly* 13.

<sup>26</sup> Kerry Phelps and Craig Hassed, *General Practice: The Integrative Approach* (Churchill Livingstone/Elsevier 2011) 156.

## 1.1 THE NEGATIVE IMPACT OF PROFIT AS A PRIMARY MOTIVATOR IN HEALTHCARE

The potential for profit is a fundamental stimulus for industry.<sup>27</sup> Profits fund research, provide employment and drive progress, in healthcare and other sectors. However, profit motivation unchecked by concern for human health has given rise to significant human harm and has created an impetus among consumers to seek out alternative sources of healthcare.

### 1.1.1 FAILURE TO DISCLOSE RISKS

Among the highest profile and costliest issues arising in the broad arena of conventional medicine have been those resulting in recall and removal of a pharmaceutical product from the market. Many of these have come about after long periods of widespread product promotion and use, sometimes long after the adverse effects were notified to the producer.<sup>28</sup> Such manifestly unethical behaviour in name of protecting corporate profits mars, not only the reputation of the company in question, but of healthcare as a whole, undermining public confidence in what is nonetheless a vital, lifesaving service.

The events precipitating a pharmaceutical product recall have historically been a source of significant consumer/patient mortality and morbidity.<sup>29</sup> Unfortunately, the current model of conventional medicine relies heavily on pharmaceutical products, and so a patient requesting treatment without their use is unlikely to find satisfaction in the conventional sector. This effectively leaves consumers with the choice of, reluctantly or otherwise, accepting the risks of potentially unsafe pharmaceutical products or opting out of conventional medicine entirely.

Recalls occur following adverse effects suspected or discovered during clinical trials but subsequently downplayed or concealed by researchers or the pharmaceutical company in question,<sup>30</sup> adverse effects observed or reported during post-marketing surveillance,<sup>31</sup> or quality control failures, encompassing adulteration or variation in

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<sup>27</sup> Sidney A Shapiro, 'Divorcing profit motivation from new drug research: A consideration of proposals to provide the FDA with reliable test data' (1978) 1978 Duke Law Journal 155, 162.

<sup>28</sup> Igho J Onakpoya, Carl J Heneghan and Jeffrey K Aronson, 'Delays in the post-marketing withdrawal of drugs to which deaths have been attributed: A systematic investigation and analysis' (2015) 13 BMC Medicine 26, "many withdrawals still occur more than 1 or 2 years after the reports of deaths begin to appear".

<sup>29</sup> Adnan Elfarra, *Advances in Bioactivation Research* (Springer 2009) 27.

<sup>30</sup> Anna Wilde Mathews and Barbara Martinez, 'Warning signs: E-mails suggest Merck knew Vioxx's dangers at Early Stage' *The Wall Street Journal* (1 November 2004) <[www.wsj.com/articles/SB109926864290160719](http://www.wsj.com/articles/SB109926864290160719)> accessed 16 October 2016.

<sup>31</sup> 'Drug maker pleads guilty over lethal side effects' *The New York Times* (14 December 1984), "The SmithKline Beckman Corporation has pleaded guilty and two of its medical officials have pleaded no contest to charges of failing to report to the Food and Drug Administration the lethal side effects of the blood-pressure drug Selacryn" <[www.nytimes.com/1984/12/14/us/drug-maker-pleads-guilty-over-lethal-side-effects.html](http://www.nytimes.com/1984/12/14/us/drug-maker-pleads-guilty-over-lethal-side-effects.html)> accessed 10 February 2016.



dose.<sup>32</sup> These events and, in particular, the failure of the parties at fault to disclose the details and extent of the risk to human health, fundamentally undermine the ability of front line staff to work effectively and to retain the confidence of their patients, contributing to the exodus towards CAM. They have given rise to a number of high profile cases costing billions of euros and further damaging the reputation of medicine as a whole.

Vioxx, an anti-arthritic product produced by Merck, provides an excellent example of this.

### **CASE STUDY - VIOXX**

Rofecoxib, under the proprietary names of Vioxx and Ceoxx, was a COX-2 inhibitor, which was licenced in Ireland by Merck for use in patients with osteoarthritis and rheumatoid arthritis, between 1999 and 2004. Rofecoxib was marketed, very successfully,<sup>33</sup> as having a lower risk of gastrointestinal complications than other similar drugs. This was confirmed during a large clinical trial, named the VIOXX Gastrointestinal Outcomes Research (VIGOR) Trial, which began just before the drug was approved by the US Food and Drug Administration in 1999. In that trial, which involved 8,000 participants, half were given Vioxx and half were given naproxen, an older non-steroidal anti-inflammatory drug.

As the VIGOR trial progressed, in late 1999 the trial Data and Safety Monitoring Board (DSMB) met to discuss the data gleaned from the study. While their first meeting discussed the relative gastroprotective effects of Vioxx becoming apparent, their second and third meetings addressed the larger than expected number of cardiovascular events in the Vioxx group, suggesting either a cause in that product or a protective quality in its comparator. The trial continued and, by December 1999, the number of participants with cardiovascular complications in the Vioxx group was double that of the naproxen group.<sup>34</sup>

A decision was made by Merck to analyse the data on cardiovascular complications a month before the end of the trial, consequently excluding any cardiovascular data obtained during the final month. It was later disclosed that three additional heart attacks

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<sup>32</sup> Food and Drug Administration, 'FDA advises consumers about recalled drugs from Able Laboratories' (27 May 2005) <[www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108438.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108438.htm)> accessed 16 March 2016.

<sup>33</sup> Merck, 'Annual Report 1999' (1999), "Vioxx: Our biggest, fastest and best launch ever" <<http://proquest.umi.com/pqdweb?did=1009549892&sid=1&Fmt=1&clientId=15020&RQT=309&VName=HNP>> accessed 12 February 2016.

<sup>34</sup> Ann Boyd, *Science and Ethics in Dialogue: Ethical Research Conduct and Genetic Information Application* (Biota Publishing 2015) 71.

occurred in the Vioxx group during this period.<sup>35</sup> The FDA were informed of these additional events in October 2000, but the results of the study<sup>36</sup> were published in November 2000, based on the foreshortened cardiovascular monitoring period and incomplete data. It concluded that there was a reduced risk of gastrointestinal complications for Vioxx relative to its comparator, naproxen. It found a slightly elevated risk of cardiovascular events but nothing statistically significant.<sup>37</sup> In February 2001, the FDA published the complete data, provided by Merck, including the three additional cardiac events. Later that year, a meta-analysis was performed<sup>38</sup> including these additional events and the outcome found limited protective effect from naproxen<sup>39</sup> and suggested an elevated risk of cardiovascular events arising from Vioxx.<sup>40</sup> However, notwithstanding this and other similar studies published between 2002 and 2004,<sup>41</sup> Vioxx remained on the market until 2004, when the data from the Adenomatous Polyp Prevention on Vioxx (APPROVe) study<sup>42</sup> once again showed increased risk of cardiovascular events after eighteen months of treatment, but also earlier in some cases.<sup>43</sup> Merck withdrew Vioxx globally in September that year. In a *Lancet* article in 2005, the authors stated that, during the time Vioxx was on the market, “an estimated 88,000–140,000 excess cases of serious coronary heart disease probably occurred in the USA”.<sup>44</sup> It went on to warn that, “in view of the findings of the VIGOR trial and subsequent observational studies, withdrawal or restriction of rofecoxib should have happened much earlier”,<sup>45</sup> concluding that “In the future, when trials such as VIGOR show that a new treatment confers a greater risk of a serious adverse effect than a standard treatment, we must be much more careful about allowing its unrestrained use”.<sup>46</sup>

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<sup>35</sup> Harlan M Krumholz and others, ‘What have we learnt from Vioxx?’ (2007) 334(7585) *British Medical Journal* 120, 121.

<sup>36</sup> Claire Bombardier and others, ‘Comparison of upper gastrointestinal toxicity of Rofecoxib and Naproxen in patients with rheumatoid arthritis’ (2000) 343(21) *New England Journal of Medicine* 1520.

<sup>37</sup> *ibid* 1526.

<sup>38</sup> Debabrata Mukherjee, Steven E Nissen and Eric J Topol, ‘Risk of cardiovascular events associated with selective COX-2 inhibitors’ (2001) 286(8) *Journal of the American Medical Association* 954.

<sup>39</sup> This was reinforced in 2002 in Wayne A Ray and others, ‘Non-steroidal anti-inflammatory drugs and risk of serious coronary heart disease: An observational cohort study’ (2002) 359(9301) *Lancet* 118, 121, and later in David J Graham and others, ‘Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory Drugs: Nested Case-Control Study’ (2005) 365(9458) *Lancet* 475, 480.

<sup>40</sup> Debabrata Mukherjee, Steven E Nissen and Eric J Topol (n 38) 958.

<sup>41</sup> Wayne A Ray and others (n 39) and Daniel H Solomon and others, ‘Relationship between selective cyclooxygenase-2 inhibitors and acute myocardial infarction in older adults’ (2004) 109(17) *Circulation* 2068, 2072.

<sup>42</sup> Robert S Bresalier and others, ‘Cardiovascular events associated with rofecoxib in a colorectal adenoma chemoprevention trial’ (2005) 352(11) *New England Journal of Medicine* 1092.

<sup>43</sup> *ibid* 1100.

<sup>44</sup> David J Graham and others (n 39) 480.

<sup>45</sup> *ibid*.

<sup>46</sup> *ibid*.

In a 2007 article in the British Medical Journal, entitled ‘What Have We Learned From Vioxx?’, the authors, in attempting to apportion blame, point, not solely to the manufacturers of Vioxx, whose conduct was, at a minimum, unethical and misleading, but to the delay in action by the FDA, who had access to earlier clinical trials which were never published,<sup>47</sup> and who ought to have ordered that further studies be performed once the potentially increased cardiovascular risk was disclosed to them in 2001, and to the academic journals who published results in what the authors deemed to be an uncritical manner, with little notice given to the significant involvement of Merck employees and contractors in authoring the papers.

In 2007, Merck settled an estimated 26,600 cases in the US for a total of \$4.85 billion,<sup>48</sup> with other proceedings pending globally at the time of writing.

Merck continues to experience fallout in the wake of the Vioxx withdrawal. In 2016, the company agreed to pay “\$830 million to resolve a class-action lawsuit brought by shareholders, alleging the drug maker and its executives made false and misleading statements about the safety of Vioxx between its introduction in 1999 and its market withdrawal in 2004”.<sup>49</sup>

There are many similar stories. Troglitazone, marketed as Rezulin, was a drug for the treatment of Type 2 diabetes. In a Phase III trial, participants showed signs of hepatotoxicity. When marketing authorisation was applied for in the US, some members of the FDA queried the side effects but ultimately approved Rezulin for the US market in 1997. A letter published in the New England Journal of Medicine in 1998<sup>50</sup> disclosed elevated markers for hepatotoxicity in trial participants but these were inaccurate, with actual detected marker levels being much higher than stated.<sup>51</sup> Warnings of potential hepatotoxicity, together with restrictions on indication and advice on regular testing for

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<sup>47</sup> These studies, known as Study 085 and Study 090, showed, on a much smaller scale, similar cardiovascular effects. Interestingly, the Wall Street Journal reported that an internal memo from Merck in 1996 stated that Vioxx patients on the trial would be at an increased risk of cardiovascular problems unless they also took aspirin. See Anna Wilde Mathews and Barbara Martinez (n 30), “A Merck official ... wanted to conduct a trial to prove Vioxx was gentler on the stomach than older painkillers. But to show the difference most clearly, the Vioxx patients couldn’t take any aspirin. In such a trial, “there is a substantial chance that significantly higher rates” of cardiovascular problems would be seen in the Vioxx group, the memo said. ... A similar view was expressed in a Feb. 25, 1997 e-mail by a Merck official, Briggs Morrison. He argued that unless patients in the Vioxx group also got aspirin, “you will get more thrombotic events” – that is, blood clots, which may lead to stroke or heart attack – “and kill the drug”” <[www.wsj.com/articles/SB109926864290160719](http://www.wsj.com/articles/SB109926864290160719)> accessed 16 October 2016.

<sup>48</sup> Heather Won Tesoriero, Sarah Rubenstein and Jamie Heller, ‘Merck’s tactics largely vindicated as it reaches big Vioxx settlement’ *The Wall Street Journal* (10 November 2007) <[www.wsj.com/articles/SB119461288943387907](http://www.wsj.com/articles/SB119461288943387907)> accessed 8 February 2016.

<sup>49</sup> Peter Loftus, ‘Merck to pay \$830 million to settle Vioxx shareholder suit’ *The Wall Street Journal* (15 January 2016) <[www.wsj.com/articles/merck-to-pay-830-million-to-settle-vioxx-shareholder-suit-1452866882](http://www.wsj.com/articles/merck-to-pay-830-million-to-settle-vioxx-shareholder-suit-1452866882)> accessed 8 February 2016.

<sup>50</sup> Paul B Watkins and Randall W Whitcomb, ‘Hepatic dysfunction associated with Troglitazone’ (1998) 338(13) *New England Journal of Medicine* 916.

<sup>51</sup> Jay S Cohen, ‘Risks of troglitazone apparent before approval in USA’ (2006) 49(6) *Diabetologia* 1454.

liver function, were added the packaging insert in 1999<sup>52</sup> and Rezulin was finally withdrawn in 2000, having been associated with 94 cases of acute liver failure. Affected patients were found to have a low rate of spontaneous recovery with most progressing to reversible liver failure within one month of onset.<sup>53</sup>

Together with the failure of the manufacturer to disclose the full extent of the data on adverse effects, the FDA had fast-tracked the approval of Rezulin as a first-in-class drug and had not required that any warning be given as to potential hepatotoxicity.<sup>54</sup> This, once again, points to failures on both sides of the regulatory divide.

Rezulin was never approved in Ireland and was withdrawn in the UK in 1997 after the hepatotoxicity was established.<sup>55</sup>

The loss of public trust in the wake of these incidents, particularly in circumstances where vital data only comes to light during investigations or legal proceedings, is catastrophic for the reputation of the conventional medical profession as a whole, for individual physicians, who may, through no fault of their own, cause harm to their patients by prescribing a drug which disclosed incomplete data in order to gain approval, and for patients, who may turn instead to treatments with less evidence in support of their safety and efficacy, but, significantly, a better reputation.

The requirement of full data disclosure to regulators *ab initio* would help to prevent or limit unsafe or inefficacious products entering the market, would permit appropriate warnings to be given as to potential risks, and would assist prescribers in choosing the most appropriate drug for their patients, limiting the negative impacts on both the patient and the sector.

In 2013, the British Medical Journal changed its policy on the publication of clinical trials, refusing submissions for which the authors did not “commit to making the relevant anonymised patient level data available on reasonable request”.<sup>56</sup> Similar policy changes have been made by PloS Medicine<sup>57</sup> and by the Annals of Internal Medicine,<sup>58</sup> demonstrating a spreading consensus on the need for transparency and disclosure of trial data. This policy, if properly utilised, would apply to all clinical trials,

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<sup>52</sup> World Health Organisations ‘Troglitazone: Restricted indications: USA’ (1999)

<<http://apps.who.int/medicinedocs/en/d/Js2269e/1.14.html#Js2269e.1.14>> accessed 17 March 2016.

<sup>53</sup> Neil Kaplowitz, Laurie D DeLeve, *Drug-Induced Liver Disease* (Elsevier Science 2013) 530.

<sup>54</sup> Howard Brody, *Hooked: Ethics, the Medical Profession, and the Pharmaceutical Industry* (Rowman & Littlefield 2008) 276.

<sup>55</sup> *ibid.*

<sup>56</sup> Fiona Godlee and Trish Groves, ‘The new BMJ policy on sharing data from drug and device trials’ (2012) 345 British Medical Journal.

<sup>57</sup> PloS Medicine, ‘Data Availability’ <<http://journals.plos.org/plosmedicine/s/data-availability>> accessed 26 September 2016.

<sup>58</sup> Annals of Internal Medicine, ‘Information for Authors - Data Sharing and Reproducible Research’ <<http://annals.org/aim/pages/authors#research-publication-ethics>> accessed 26 September 2016.

including those from the CAM sector, improving the quality of information available to practitioners overall.

### 1.1.2 OFF-LABEL MARKETING

While, as discussed below, physicians are permitted to prescribe a medication for a condition for which it is not officially licenced (known as “off label” prescribing), pharmaceutical companies are prohibited from marketing their product with indications for which the product is not licenced.<sup>59</sup> This is known as off-label marketing.<sup>60</sup> Such practices are illegal and, it is hoped,<sup>61</sup> do not form part of contemporary industry behaviour in Ireland. Relevant codes of practice have been put in place, aiming to ensure that this continues to be the case.<sup>62</sup> However, these illegal practices in other jurisdictions, particularly the US, have resulted in significant patient harm and loss of life, giving rise to substantial settlements on the part of the pharmaceutical companies in question. Despite the fact that this did not take place in Ireland, the practices at issue are representative of past behaviour in the sector as a whole.<sup>63</sup> The ease and speed with which information and outrage can now be disseminated has ensured that consumers are made aware of this corruption and the harm caused by it. Irrespective of where the illegal behaviour took place, trust in the pharmaceutical sector, and, by extension, in those who prescribe their products, has been negatively impacted.<sup>64</sup>

Off-label marketing is of particular interest in a study of regulatory issues in CAM, as, again, similar issues are relevant – lack of evidence for safety or efficacy, marketing claims based on research with questionable methodology, consumer or patient expenditure on products and services unsupported by high-quality evidence and fraudulent or misleading behaviour and subsequent risk to health and life for consumers. The case of paroxetine, an antidepressant, provides an excellent example of all of these issues, but it is by no means alone. Such cases permeate conventional medicine and

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<sup>59</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67, art 87.

<sup>60</sup> European Federation of Pharmaceutical Industries and Associations, ‘Promotion of off-label use of medicines by European healthcare bodies in indications where authorised medicines are available – position paper’ (EFPIA 2011). The authors define “off-label marketing” as “any use of an authorised medicinal product not covered by the terms of the marketing authorisation, including the use of the product for a different indication, different dose or dosage or for a patient group not specified on the summary of the product characteristics (SPC)”.

<sup>61</sup> By their nature, such practices are not always detectable.

<sup>62</sup> Irish Pharmaceutical Healthcare Association (IPHA), ‘Code of Practice for the Pharmaceutical Industry’ (2015) <[http://transparency.efpia.eu/countries/download/13/document/ipha-code-of-practice-for-the-pharmaceutical-industry\\_v-8.1-jan-2015.pdf](http://transparency.efpia.eu/countries/download/13/document/ipha-code-of-practice-for-the-pharmaceutical-industry_v-8.1-jan-2015.pdf)> accessed 6 May 2016.

<sup>63</sup> Transparency International, *Corruption in the pharmaceutical sector: Diagnosing the challenges* (Transparency International UK 2016); John Braithwaite, *Corporate Crime in the Pharmaceutical Industry* (Routledge Revivals) (Taylor & Francis 2013).

<sup>64</sup> Mark Kessel, ‘Restoring the pharmaceutical industry's reputation’ (2014) 32 *Nature Biotechnology* 983.

have led to numerous substantial and heavily publicised settlements since the beginning of the decade.

#### **CASE STUDY – SEROXAT/PAXIL**

Paroxetine, marketed under the name Seroxat in Ireland or Paxil in the US,<sup>65</sup> is a selective serotonin reuptake inhibitor (SSRI), licenced for the treatment of adults with major depression and anxiety disorders.<sup>66</sup> Paroxetine was approved by the US Federal Drug Administration (FDA) for adults from 1992 and in Ireland from 1999, but additional clinical trials were performed in order to determine whether the product might also be approved for use in children and adolescents. Such approval would have broadened the market for Paxil, resulting in substantial profits for the manufacturer, SmithKline Beecham (SB) (post 2000, GlaxoSmithKline (GSK)).

Of the numerous studies carried out by SB/GSK between 1994 and 2001 on the use of Paxil in children and adolescents,<sup>67</sup> only one of these was published. Study 329, carried out between 1994 and 1998, compared the safety and efficacy of Paxil with the safety and efficacy of an existing tricyclic antidepressant, imipramine, and with a placebo, in children and adolescents. The study, published in the Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP), found that Paxil was “generally well tolerated and effective for major depression in adolescents”.<sup>68</sup> GSK representatives used this study to encourage physicians to prescribe Paxil off-label for children and adolescents. However, the data emerging from the studies performed by GSK and others,<sup>69</sup> of which the company was aware at the time of developing these marketing strategies,<sup>70</sup> disclosed the lack of efficacy and elevated risk of suicidality and other psychiatric conditions. According to an expert report<sup>71</sup> submitted in the course of later

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<sup>65</sup> For simplicity, the name Paxil will be used throughout, unless specifically referring to Ireland or the UK.

<sup>66</sup> Since it was first marketed, the indications for the use of paroxetine have been expanded to include, “obsessive compulsive disorder (repetitive, obsessive thoughts with uncontrollable behaviour), panic disorder (panic attacks, including those caused by agoraphobia, which is a fear of open spaces), social anxiety disorder (fear or avoidance of social situations), post-traumatic stress disorder (anxiety caused by a traumatic event) and generalised anxiety disorder (generally feeling very anxious or nervous)”. See Seroxat Package Leaflet: Information for the Patient 1

<[www.hpra.ie/img/uploaded/swedocuments/2171054.PPA0465\\_055\\_001.1ac85f4c-ec15-45a4-b82c-dc97504fea0c.000001Seroxat%20PIL.160126.pdf](http://www.hpra.ie/img/uploaded/swedocuments/2171054.PPA0465_055_001.1ac85f4c-ec15-45a4-b82c-dc97504fea0c.000001Seroxat%20PIL.160126.pdf)> accessed 29 February 2016.

<sup>67</sup> Study 377, carried out from 1995-1998 in multiple international centres, and Study 701, carried out from 2000-2001 in the US and Canada, both failed to demonstrate safety and efficacy of Paxil above that of placebo.

<sup>68</sup> Martin B Keller and others, ‘Efficacy of paroxetine in the treatment of adolescent major depression: A randomized, controlled trial’ (2001) 40(7) Journal of the American Academy of Child & Adolescent Psychiatry 762.

<sup>69</sup> David Healy, ‘Emergence of antidepressant induced suicidality’ (2000) 6 Primary Care Psychiatry 23, 27.

<sup>70</sup> GSK, ‘Seroxat Paxil – Adolescent depression: Position piece on the Phase III clinical studies’ (October 1998) 1. This is reproduced in Appendix I.

<sup>71</sup> Joseph Glenmullen, ‘Expert report on GSK internal documents relating to Paxil and suicidality’ (2007).

legal proceedings,<sup>72</sup> “Analyses of GlaxoSmithKline’s Paxil data demonstrate a causal link between the antidepressant and suicidal behaviour. This has been true since 1989 although the “bad” Paxil numbers obscured the risk for a decade-and-a-half”. The omission and obscuring of this core data was, once again, the source of significant human cost, to the benefit of pharmaceutical corporations, ghostwriters, academics and physicians. A brief overview of the misleading practices alleged in the case of *United States v GlaxoSmithKline*<sup>73</sup> and the reports entered therein is set out below.

### ***United States v GlaxoSmithKline***

It was alleged that, over the process of drug testing, submission for approval for adult use, and subsequent testing and off-label marketing for use in children and adolescents, GSK had:

- (a) Concealed significant data on suicidality in adult patients<sup>74</sup>;
- (b) Added measures of efficacy not defined in the initial research protocol for children and adolescents, which enhanced the outcome for paroxetine, separating it from placebo;<sup>75</sup>
- (c) Declined to apply for FDA authorisation for use in children and adolescents, based on the lack of evidence of efficacy over placebo;<sup>76</sup>
- (d) Nonetheless, hired Scientific Therapeutics Information, a specialist PR company, to draft an article for a prominent journal, misstating the safety and efficacy of Paxil in children and adolescents, based, ostensibly, on the data gleaned from Study 329 – GSK and the named authors commented upon and approved this draft before submission<sup>77</sup>;
- (e) Successfully submitted the article<sup>78</sup> in 2001, in which a respected physician, paid by GSK, stated that Paxil “is generally well tolerated and effective for major depression”, concluding that “the findings of this study

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<sup>72</sup> *United States v GlaxoSmithKline* C.A No. 11-10398-RWZ [12], [14].

<sup>73</sup> *ibid.*

<sup>74</sup> Joseph Glenmullen (n 71) 72, “Analyses of GlaxoSmithKline’s Paxil data demonstrate a causal link between the antidepressant and suicidal behaviour. This has been true since 1989 although the “bad” Paxil numbers obscured the risk for a decade-and-a-half. But in the last year, both GlaxoSmithKline and the FDA have acknowledged the statistically significant increased risk of suicidal behaviour for patients put in Paxil”.

<sup>75</sup> *United States v GlaxoSmithKline* (n 72) [20].

<sup>76</sup> *ibid* [23].

<sup>77</sup> *ibid* [26]. Interestingly, the claim states that the article was first submitted to and rejected by the Journal of the American Medical Association who were “extremely critical of how the article portrayed the study’s results”, stating that the “description of ‘numerically superior’ is not appropriate and results should be described as superior only when significant”.

<sup>78</sup> Martin B Keller and others (n 68).

provide evidence of the efficacy and safety of the SSRI [Paxil], in the treatment of adolescent depression”<sup>79</sup>; the same article was later found to have “distorted the study results and gave the false impression that the study’s findings were primarily positive, when they were, in fact, primarily negative and ... contained a significant safety signal”, which eventually led to the placement of a black box warning on packaging indicating increased risk of suicidality<sup>80</sup>;

- (f) Off-label marketed Paxil for depression in children and adolescents, using the JAACAP article and other off-label information to educate its sales force, despite the failure of its clinical trials to demonstrate safety and efficacy, the elevated risk of suicidality, and the lack of authorisation for that group – this information, though not the documents themselves, was passed on to prescribers<sup>81</sup>;
- (g) Targeted 1,324 child psychiatrists, who exclusively treated patients under the age of 18, for promotion of Paxil, providing them with free samples, which GSK knew would be used in an unapproved patient group<sup>82</sup>;
- (h) Promoted Paxil for children and adolescents during conference events known as Paxil Forum meetings – these were all-expenses-paid events held in scenic locations and attended by prescribers, including child psychiatrists, where talks were given on the use of Paxil in various conditions, including for children – these talks were given by child psychiatrists paid by GSK for this purpose. These meetings were claimed, in a November 2000 GSK memo, to have increased revenues from Paxil prescription by at least \$900,000 that year<sup>83</sup>;
- (i) Paid kickbacks to physicians in the form of speaking and consulting fees, travel, gifts, grants, lunches and entertainment, to induce them to prescribe and recommend Paxil, tracking “return on investment”<sup>84</sup>; and
- (j) Paid physicians to promote their products as “key opinion leaders”, including for off-label uses.<sup>85</sup>

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<sup>79</sup> *ibid* 770-71.

<sup>80</sup> *United States v GlaxoSmithKline* (n 72) [55]-[60].

<sup>81</sup> *ibid* [55]-[62].

<sup>82</sup> *ibid* [63]-[66].

<sup>83</sup> *ibid* [72]-[75].

<sup>84</sup> *ibid* [236]-[237].

<sup>85</sup> *ibid* [238].



Three substantive charges were levelled at GSK in this case:

1. *The Presentment of False Claims under the False Claims Act*,<sup>86</sup> and
2. *False Statements under the False Claims Act*

During the time for which Paxil was off-label marketed, false and fraudulent statements were made and false or fraudulent records were used by GSK in their interactions with physicians and federal healthcare programs which were “material to the physician’s decision to prescribe these drugs and the United States’ decision to pay claims for these drugs and related services”.<sup>87</sup> These schemes state that rebates are only permissible for “medically accepted indications”<sup>88</sup> and the Medicare statute specifically excludes rebate for items and services that are not “reasonable and necessary”.<sup>89</sup> These charges also involved, *inter alia*, the inducement of physicians to prescribe Paxil off-label, claims for which were then made to federal healthcare programs. Such claims are in contravention of the US Federal Anti-Kickback statute.<sup>90</sup>

### 3. *Unjust Enrichment/Engorgement*

As a result of their fraudulent actions, GSK had benefits conferred upon them by the United States and it would be unjust to allow them to retain these benefits in the circumstances.

This case, which involved not only Paxil but also two other products, was settled by GSK in 2012 for \$3 billion.<sup>91</sup>

Paxil in the US now carries a black box warning stating that it has been demonstrated to carry a risk of suicidality in patients under 24 years of age, but it can still be prescribed off-label for these patients. In the UK and Ireland, Seroxat cannot be prescribed for patients under the age of 18.<sup>92</sup> According to their 2014 Annual Report,<sup>93</sup> GSK sales of Seroxat/Paxil decreased by 19%, bringing in £210 million in 2014.<sup>94</sup> This, it claims, is

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<sup>86</sup> 31 USC §§ 3729–3733.

<sup>87</sup> *United States v GlaxoSmithKline* (n 72) [273].

<sup>88</sup> Medicaid Rebate Statute 42 USC § 1396r-89(k)(6) and Medicare Part D 42 USC § 1395w-102(e)(4)(A)(ii).

<sup>89</sup> 42 USC § 1395y(a)(1)(A).

<sup>90</sup> 42 USC § 1320a-7b(b), “This prohibits any person or entity from offering, making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal healthcare program”.

<sup>91</sup> Jeanne Whalen, Devlin Barrett and Peter Loftus, ‘Glaxo in \$3 billion settlement’ *The Wall Street Journal* (3 July 2012) <[www.wsj.com/articles/SB10001424052702304299704577502642401041730](http://www.wsj.com/articles/SB10001424052702304299704577502642401041730)> accessed 21 March 2016.

<sup>92</sup> Seroxat Package Leaflet (n 66) 1

<[www.hpra.ie/img/uploaded/swedocuments/2171054.PPA0465\\_055\\_001.1ac85f4c-ec15-45a4-b82c-dc97504fea0c.000001Seroxat%20PIL.160126.pdf](http://www.hpra.ie/img/uploaded/swedocuments/2171054.PPA0465_055_001.1ac85f4c-ec15-45a4-b82c-dc97504fea0c.000001Seroxat%20PIL.160126.pdf)> accessed 29 February 2016.

<sup>93</sup> GlaxoSmithKline, ‘Annual Report 2014’ (GSK 2014).

<sup>94</sup> *ibid* 56.

due to generic competition.<sup>95</sup> The report acknowledges the existence of pending legal claims regarding the side effects of Seroxat/Paxil.<sup>96</sup>

The sustained off-label marketing of paroxetine for this unapproved market, despite the lack of evidence of efficacy beyond placebo and the elevated risk of suicidality, was the result of corporate greed at the cost of ethics and human health, regulatory failure, and conflict of interest of the medical professionals who both promoted the product on behalf of GSK and whose prescriptions increased with the many and varied incentives provided by GSK. This is not a solitary tale of corruption, but one that has become familiar in the conventional medical sector, providing yet more evidence, if such is needed, that CAM is a more trustworthy, or, perhaps, a worthier source for healthcare.

Off-label marketing is one of many corrupt practices undermining consumer trust, damaging the global reputation of conventional medicine, prevents physicians from fulfilling their ethical obligations to their patients. It also reinforces a practice which, though legal, carries an elevated level of risk for patients: that of off-label prescribing.

### **1.1.3 OFF-LABEL PRESCRIBING**

Pharmaceutical products may be prescribed for ‘off-label’ purposes by physicians, where a licenced product for the particular condition in question is not available. This is provided for by art 5 of Directive 2001/83/EC, which states,

A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorized health care professional and for use by his individual patients on his direct personal responsibility.<sup>97</sup>

Art 5 provides for derogation from the general requirement in art 6(1) that

No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) No 2309/93.<sup>98</sup>

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<sup>95</sup> *ibid* 23.

<sup>96</sup> *ibid* 209.

<sup>97</sup> Directive 2001/83/EC (n 59), art 5.

<sup>98</sup> Directive 2001/83/EC (n 59), art 6(1).

The art 6 general provision is protective in nature<sup>99</sup> and derogations decrease this protection. For this reason, such derogations must be interpreted strictly.<sup>100</sup>

A physician may prescribe a product which is unauthorised for a particular condition “when it satisfies an unmet medical need”.<sup>101</sup>

Off-label prescribing frequently occurs in paediatric medicine, due to the difficulty in gaining approval for paediatric-specific trials for pharmaceuticals.<sup>102</sup> This is clearly not ideal, as doses must be attenuated depending on patient size and paediatric patients may react adversely to some pharmaceutical products in a different way to adult patients.<sup>103</sup> This was one of the fundamental issues observed in the case of Paxil. While there have been expressions of urgency and some activity towards improving the standard and volume of evidence available for products used in paediatrics,<sup>104</sup> progress is slow, though work is ongoing.<sup>105</sup>

Off-label prescribing also occurs throughout general medicine, though, again, not without risk. Bimbo Onanuga died in the Mater Hospital in Dublin, having been administered misoprostol to induce labour after foetal death at 30 weeks. The product was licenced for the treatment of gastric ulcers but not, at the time of the incident, for the induction of labour.<sup>106</sup> The product was known to carry risk of uterine hyperstimulation, haemorrhage, maternal and foetal death, and various other serious complications, which were explicitly notified to medical practitioners by the

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<sup>99</sup> Case C-143/06 *Ludwigs-Apotheke* [2007] ECR I-9623, paras 33, 35.

<sup>100</sup> Case C-83/99 *Commission v Spain* [2001] ECR I-00445, para 19, “It is settled case-law that provisions which are in the nature of exceptions to a principle must be interpreted strictly”.

<sup>101</sup> Irish Patients’ Association, ‘Patient safety, patients’ rights and off-label prescribing’ (IPA 2012) 2 <[http://irishpatients.ie/news/wp-content/uploads/2012/03/IPA\\_Off\\_Label\\_WEBR-1.pdf](http://irishpatients.ie/news/wp-content/uploads/2012/03/IPA_Off_Label_WEBR-1.pdf)> accessed 16 February 2016.

<sup>102</sup> Clinical trials on minors in Ireland are governed by European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, SI 2004/190, implementing Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L121/34.

<sup>103</sup> Craig Stanley and others, ‘The extent of unlicensed and off-label drug use in the paediatric ward of a district general hospital in Northern Ireland’ (2001) 94(8) *Irish Medical Journal* 237. See also Brendan Drumm and others, ‘Legislation and drug trials’ (1997) 76(4) *Archives of Disease in Childhood* 296.

<sup>104</sup> Regulation 1901/2006/EC of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L378/1. This Regulation “establishes a system of obligations, rewards and incentives, together with horizontal measures to ensure that medicines are regularly researched, developed and authorised to meet the therapeutic needs of children”. See Commission, ‘Better medicines for children - from concept to reality’ COM (2013) 443 final 6.

<sup>105</sup> Commission (n 104) 19, “‘Better Medicines for Children — From Concept to Reality’ is the title of this report. Readers may suggest that, based on the evaluation referred to above, it would be more appropriate to add a question mark. It is evident that it is too early still to make a firm statement. Despite more than five years of experience, the true impact of the Regulation on the health of children will only become apparent over time as experience is accumulated in the longer term”.

<sup>106</sup> Since 2013, misoprostol, under the name Mysodelle, has been licenced in this jurisdiction for induction of labour by Ferring Ireland Ltd.

manufacturer, Searle, in August 2000.<sup>107</sup> At the time of the incident, there was an authorised product available for the same purpose. When asked why it was common practice to use misoprostol instead of the authorised product in such circumstances, Dr. Coulter-Smith, then Master of the Rotunda Hospital, “noted that misoprostal is much cheaper than the available licenced medication. Dr. Coulter-Smith said the licenced drug was not “particularly useful in induction of labour” in this situation”.<sup>108</sup> While there was some evidence available that misoprostol was effective in similar situations,<sup>109</sup> the direct warnings from the manufacturer stating that the product should not be used for that particular purpose<sup>110</sup> and the existence of an authorised product which was not used, raised questions of failures in clinical practice, particularly in relation to off-label prescribing.

Fiscal considerations were deemed by the ECJ in the later case of *Commission v Poland*,<sup>111</sup> to be irrelevant for the purposes of justifying an art 5 derogation.

The Court stated that:

The concept of ‘special needs’, referred to in Article 5(1) of that directive, applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient.<sup>112</sup>

Also, the requirement that medicinal products are supplied in response to a ‘bona fide unsolicited order’ means that the medicinal product must have been prescribed by the doctor as a result of an actual examination of his patients and on the basis of purely therapeutic considerations.<sup>113</sup>

It is apparent from the conditions as a whole set out in Article 5(1) of Directive 2001/83, read in the light of the fundamental objectives of that directive, and in particular the objective seeking to safeguard public health, that the derogation provided for in that provision can only concern situations in which the doctor considers that the state of health of his individual patients requires that a medicinal product be administered for which there is no authorised equivalent on the national market or which is unavailable on that market.<sup>114</sup>

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<sup>107</sup> Michael Cullen, ‘Letter to health care practitioners: Important drug warning concerning unapproved use of intravaginal or oral misoprostol in pregnant women for induction of labor or abortion’ (Searle 23 August 2000).

<sup>108</sup> ‘Pregnant woman died after uterus ruptured’ *The Irish Examiner* (6 November 2013) <[www.irishexaminer.com/ireland/pregnant-woman-died-after-uterus-ruptured-248667.html](http://www.irishexaminer.com/ireland/pregnant-woman-died-after-uterus-ruptured-248667.html)> accessed 21 March 2016.

<sup>109</sup> Zarko Alfirovic, Nasreen Aflaifel and Andrew Weeks, ‘Oral misoprostol for induction of labour’ (2014) Cochrane Database of Systematic Reviews CD001338.

<sup>110</sup> Michael Cullen (n 107).

<sup>111</sup> Case C-185/10 *Commission v Poland* ECR I-0000.

<sup>112</sup> *ibid* para 34

<sup>113</sup> *ibid* para 35.

<sup>114</sup> *ibid* para 36.

Financial considerations cannot, in themselves, lead to recognition of the existence of such special needs capable of justifying the application of the derogation provided for in Article 5(1) of that directive.<sup>115</sup>

Off-label prescription requires that the patient trusts that their physician fully understands the potential risks and consequences of the use of the particular drug for their condition and of the implications of its use with any coexisting conditions or other medications they may also be taking. This is not always certain, as the same volume and quality of information may not be available as for the licenced uses. Adverse effects arising from individual off-label prescriptions may not be reported to regulators and, therefore, a repository for such information may not be available for consultation by prospective prescribers. The prescribing of a medication without a substantial body of evidence supporting it therefore creates additional risk for patients. It seems clear, then, that while there are many circumstances in which the off-label prescription of medicinal products must, as a matter of ethics, be provided for,<sup>116</sup> these should be limited to situations of clinical necessity. Off-label prescribing may be based on a lower standard of evidence, with limited information on safety, dosage, efficacy and adverse effects.<sup>117</sup>

However, the perceived protection provided by this very narrow scope for derogation is somewhat undermined by the lower standards for evidence of safety and efficacy demanded of producers of traditional herbal and homeopathic medicinal products. It seems counterintuitive that, rather than raising expectations, regulators instead chose to lower the bar for these producers, broadening the definition for medicinal products, rather than narrowing it.

Misoprostol, despite being unapproved for the purpose for which it was prescribed at the time of the death of Bimbo Onanuga, was approved for other indications, had substantial research behind it, including for the off-label use in that case, and has since been approved for that use.<sup>118</sup> The traditional herbal and homeopathic medicinal

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<sup>115</sup> *ibid* para 38.

<sup>116</sup> Christian Lenk and Gunnar Duttge, 'Ethical and legal framework and regulation for off-label use: European perspective' (2014) 10 *Therapeutics and Clinical Risk Management* 537.

<sup>117</sup> *ibid* 544, "Our overview shows that there are mainly two kinds of solutions which can be implemented as an interim arrangement. Firstly, a consensus list of accepted off-label uses, backed up by scientific evidence, would at least partly relieve the work of physicians in the field. Such a list could also be administered by the EMA with scientific support from the different European member states. The second solution, as practiced in France, is the evaluation and approval of specific off-label uses by an official expert group. Both solutions would have, from our point of view, the effect of helping physicians handle the ethical and legal paradoxes associated with the off-label use of drugs. At the same time, this would probably lead to a more safe and homogeneous medical supply for the concerned patients. For European citizens, a harmonized approach would presumably be of even greater value".

<sup>118</sup> Since 2013, misoprostol is authorised in Ireland for use in the induction of labour under the brand name Mysodelle.

products currently on the market need not demonstrate the same weight or standard of evidence. Narrowing the circumstances in which off-label prescription is appropriate is vital, but it will not remediate the weaknesses in the authorisation process itself.

The presence of complex regulatory mechanisms in conventional healthcare in its many forms may be reassuring, but where they leave the most vulnerable party – the patient or consumer – at risk of harm in order to increase and protect corporate profits, these mechanisms, or their appropriate use by regulators, require re-examination and revision.

## **1.2 SYSTEMIC FAILURES**

Even where corporate profiteering is not a motivational factor, underfunding and demand for expediency, combined with a lack of due care, has resulted in human harm and in reputational damage for the conventional medical sector. In Ireland, two notable controversies have had serious, long-term impacts for patients within the public health system: the infection of haemophiliacs with HIV or Hepatitis C through transfusion of infected blood products prior to 1985; and the unnecessarily widespread use of the symphysiotomy procedure on women during and after childbirth in the mid-twentieth century. While the former resulted from failures along production and delivery lines, from policy makers on, the latter came about as a result of patriarchal traditions, the desire for expedience in medical procedures, poor communication, disregard for the health of female patients, and the interference by non-medical influences in clinical decision-making. Given the focus on the problems originating in the pharmaceutical sector throughout Part I, it is important to emphasise that the issues are, in reality, more variable in nature and have a farther reach than may at first be apparent.

### **1.2.1 THE ADMINISTRATION OF INFECTED BLOOD PRODUCTS IN IRELAND**

Developments from the 1970s facilitated the treatment of patients with haemophilia, a clotting disorder which can lead to prolonged bleeding, in their own homes, where previously they required extensive periods of hospitalisation and bed rest.<sup>119</sup> Home treatment involved the transfusion of blood products imported or produced by the Blood Transfusion Service Board (BTSB), who had specific responsibility as the public service body with expertise in blood products.<sup>120</sup> Due to insufficiencies in domestic supply, some of the blood products were sourced from outside Ireland (commonly in the US), from paid donor populations with high rates of HIV and Hepatitis C infection.

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<sup>119</sup> Judge Alison Lindsay, *Report of the Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters* (“the Lindsay Tribunal”) (Stationery Office 2002) 30-31.

<sup>120</sup> *ibid* 48. This became relevant during the course of the Tribunal as it was found that there was greater reliance on them than there was on commercial providers of blood products.

Prior to 1985, there was no mechanism through which the blood products could be treated to neutralise infections and testing procedures for HIV were only developed at that time. A number of haemophiliacs receiving transfusions contracted one or both of the viruses, leading to serious illness and loss of life.

The Lindsay Tribunal,<sup>121</sup> established in 1999 to investigate the events that lead to the infection of these patients, found a series of failures in record keeping and tracing,<sup>122</sup> in communication with other agencies<sup>123</sup> and patients<sup>124</sup> and in taking decisive and timely action to ensure that infected blood products were recalled and removed from circulation,<sup>125</sup> which contributed to and magnified the physical and psychological harm suffered.<sup>126</sup>

Here, administrative failures, lack of sensitivity and disregard for the rights of patients, all occurring within the domestic public health system and without commercial motivation, contributed to lasting harm to haemophiliacs in Ireland and further loss of trust in the conventional health system.

### 1.2.2 THE PRACTICE OF SYMPHYSIOTOMY IN IRELAND

Symphysiotomy is a rarely-used obstetric procedure, performed in childbirth where there is an obstruction to delivery and a caesarean section is either inappropriate or unsafe.<sup>127</sup> It involves the severing of the pubic symphysis to widen the birth canal, facilitating delivery. The procedure was first described in 1597<sup>128</sup> and was in use in some Irish maternity hospitals from 1944.<sup>129</sup> Symphysiotomy is considered to be a relatively safe procedure where it is necessary,<sup>130</sup> but its use in Irish hospitals between 1944 and 1984 was often without the informed consent of the patients in question,<sup>131</sup>

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<sup>121</sup> *ibid.*

<sup>122</sup> *ibid* 140. The BTSB failed to implement, in a timely manner, a “look back” process, whereby donors newly diagnosed with HIV and who had donated previously would have their donations traced in order to determine the infection status of the donee.

<sup>123</sup> *ibid* 51.

<sup>124</sup> *ibid* 32.

<sup>125</sup> *ibid* 76.

<sup>126</sup> Many patients and their families felt that the Lindsay Tribunal report did not go far enough. See ‘Long-suffering group feels let down by Judge Lindsay's report’ *The Irish Times* (14 September 2002) <[www.irishtimes.com/news/long-suffering-group-feels-let-down-by-judge-lindsay-s-report-1.1095442](http://www.irishtimes.com/news/long-suffering-group-feels-let-down-by-judge-lindsay-s-report-1.1095442)> accessed 10 March 2016.

<sup>127</sup> Charlotte Howell and others, *Managing Obstetric Emergencies and Trauma* (Cambridge University Press 2014) 429.

<sup>128</sup> M Dumont, ‘[The long and difficult birth of symphysiotomy or from Severin Pineau to Jean-Rene Sigault]’ (1989) 18(1) *Journal de Gynecologie, Obstetrique et Biologie de la Reproduction* 11.

<sup>129</sup> Oonagh Walsh, ‘Report on Symphysiotomy in Ireland 1944-1984’ (Department of Health 2013) 4.

<sup>130</sup> Charlotte Howell and others (n 127) 429, 430.

<sup>131</sup> Oonagh Walsh (n 129) 68.

was not always based on clinical necessity,<sup>132</sup> and lead to serious, lifelong disability, psychological harm and family breakdown for many young Irish women.<sup>133</sup>

At the time during which symphysiotomy became popular in Ireland, its use had already declined in Europe.<sup>134</sup> Its popularity was founded, not merely on its relative safety and expedience, but on the fact that it provided a permanent widening of the pelvic girdle, facilitating, not only the delivery in progress, but future deliveries. Caesarean sections, which were also used for some difficult deliveries, gave rise to increased risk of uterine rupture, adhesions and bladder injury<sup>135</sup> in subsequent procedures. This risk, it was considered, could have driven the women in question to seek either artificial contraception or surgical sterilisation, both of which were “contrary to then current natural law teachings”,<sup>136</sup> which held significant influence in clinical care at that time.

Though some of these procedures were undoubtedly necessary, some patients received a symphysiotomy after childbirth. While this may have been performed in order to facilitate future deliveries, it was not always. Olivia Kearney underwent a “symphysiotomy before closure”,<sup>137</sup> after she delivered her child by caesarean section in 1969. The procedure carried risk of

...sepsis, and haematomas at the site of the incision. There may be injuries of the urethra and bladder neck. Stress incontinence was found to be a fairly common sequela, though often regained without specific treatment. There was the risk of diminution in locomotor function through compromise of the sacroiliac.

These risks may be justified by reference to the benefit to the mother or the child or both, “[b]ut here Dr. Connolly opted to carry out this procedure, not to facilitate the birth, but after the baby’s delivery”.<sup>138</sup> The Court in this case found no medical justification for the procedure. Most pertinently, MacMenamin J noted that:

The Constitution identifies rights which are to be protected and vindicated because they belong to each human person because of their very humanity. Among the values which have been recognised by the Courts are human dignity, bodily integrity, and autonomy, that is the capacity to make informed decisions affecting one’s own health. The duty to protect those rights is not confined to the Courts. Each health professional is, and was always, under a similar duty. Although the finding of the Court is founded in negligence, what happened here

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<sup>132</sup> *ibid* 19.

<sup>133</sup> *ibid* 93-94, 98-103. See also *Kearney v McQuillan & NEHB* [2012] IESC 43 [35]-[37].

<sup>134</sup> *ibid* 10.

<sup>135</sup> Hugo McVey, ‘The treatment of disproportion by combined lower segment section with symphysiotomy’ (1955) 355 *Irish Journal of Medical Science* 299.

<sup>136</sup> *Kearney v McQuillan & NEHB* (n 133) [8] (MacMenamin J).

<sup>137</sup> *ibid* [12].

<sup>138</sup> *ibid* [15].



was a betrayal of trust; it was an invasion and violation of the rights just identified; it was the gravest kind of negligence.<sup>139</sup>

Along with the significant, permanent and unjustified physical harm caused to Ms Kearney and to other patients, the loss of trust and dignity is a common theme throughout all of these cases, creating a close association with conventional medicine itself and further damaging trust among consumers and patients.

Conventional medicine and its agents have been responsible for the unethical and inhumane treatment of ethnic minorities,<sup>140</sup> the carrying out of clinical research on underprivileged, vulnerable populations,<sup>141</sup> and the sustained facilitation of archaic, unnecessary and unethical medical procedures,<sup>142</sup> and this is over and above the problems inherent in day to day practice, such as inappropriate prescribing, causing adverse effects<sup>143</sup> and longer term public health issues such as addiction<sup>144</sup> and antibiotic resistance.<sup>145</sup> Patients are exposed to lengthy public medical<sup>146</sup> and surgical<sup>147</sup> waiting times and the well-documented risks of chronic understaffing.<sup>148</sup> It is unsurprising, then, that CAM appears eminently more ethical, safer, gentler and more humane, though almost entirely unregulated. With this in mind, a closer examination of the perceived benefits of CAM is provided in Part II.

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<sup>139</sup> *ibid* [27].

<sup>140</sup> William M Cobb, 'The Tuskegee syphilis study' (1973) 65(4) *Journal of the National Medical Association* 345.

<sup>141</sup> Commission to Inquire into Child Abuse, *Third Interim Report - December 2003* (Stationery Office 2003) 209-228 on vaccine trials carried out on children in residential care homes in Ireland <[www.childabusecommission.ie/publications/documents/abuse.pdf](http://www.childabusecommission.ie/publications/documents/abuse.pdf)> accessed 16 March 2016. See also Patrick I Okonta, 'Ethics of clinical trials in Nigeria' (2014) 55(3) *Nigerian Medical Journal* 188 on the trial of an antibiotic, Trovan, for the treatment of meningitis in children during an outbreak in Kano, Nigeria. This was predominantly a poor and uneducated population, unlikely to benefit from the drug once marketed.

<sup>142</sup> Judge Maureen Harding Clarke *The Lourdes Hospital Inquiry - An Inquiry into Peripartum Hysterectomy at Our Lady of Lourdes Hospital, Drogheda* (Stationery Office 2006).

<sup>143</sup> Rose Galvin and others, 'Prevalence of potentially inappropriate prescribing and prescribing omissions in older Irish adults: Findings from The Irish Longitudinal Study on Ageing study (TILDA)' (2014) 70(5) *European Journal of Clinical Pharmacology* 599, 604.

<sup>144</sup> Kathryn L Hahn, 'Strategies to prevent opioid misuse, abuse, and diversion that may also reduce the associated costs' (2011) 4(2) *American Health & Drug Benefits* 107, 110.

<sup>145</sup> Lee C Ventola, 'The antibiotic resistance crisis: Part 1: Causes and threats' (2015) 40(7) *Pharmacy and Therapeutics* 277, 278.

<sup>146</sup> National Treatment Purchase Fund, 'Outpatient National by Group/Hospital as at 25/02/2016' (2016) <[www.ntpf.ie/home/pdf/2016/02/nationalnumbers/out-patient/National01.pdf](http://www.ntpf.ie/home/pdf/2016/02/nationalnumbers/out-patient/National01.pdf)> accessed 21 March 2016.

<sup>147</sup> National Treatment Purchase Fund, 'Inpatient/Day Case National by Speciality as at 25/02/2016' (2016) <[www.ntpf.ie/home/pdf/2016/02/nationalnumbers/in-patient/National02.pdf](http://www.ntpf.ie/home/pdf/2016/02/nationalnumbers/in-patient/National02.pdf)> accessed 21 March 2016.

<sup>148</sup> Hilary Humphreys, 'Overcrowding, understaffing and infection in hospitals' (2006) 99(4) *Irish Medical Journal* 102, and Ronda G Hughes, *Patient Safety and Quality: An Evidence-based Handbook for Nurses* (Agency for Healthcare Research and Quality 2008) 1-18, "Findings from research have indicated that understaffing is associated with an increase in errors and adverse events, such as medication errors, pressure ulcers, health care associated infections, and increased mortality rates in hospitalized patients".

## PART II

### AN ANALYSIS OF THE POSITIVE CONSUMER SENTIMENT ASSOCIATED WITH CAM

#### 2. EXPANDING THE SCOPE OF CARE

CAM, as set out at various points throughout this thesis, instils in consumers a sense of wellbeing. While this, in itself, may be both subjective and immeasurable, the conditions giving rise to this effect are quite apparent. CAM delivers some important elements of quality healthcare, which enhance the patient experience, decrease recovery time and foster willingness to continue with care.<sup>149</sup> Time spent with individual patients is substantial, with a readiness on the part of its practitioners to listen and to look beyond the injury or illness complained of. As already noted above, this is not the case in conventional care, which is often rushed, delayed and demands the placement of a patient onto a particular treatment pathway,<sup>150</sup> with little room for flexibility or individualisation.

If quality healthcare is the desired endpoint and key patient needs are not being met, reflection and recalibration must be undertaken by conventional healthcare providers, who might consider looking to the CAM sector for a frame of reference. Broadening the scope of relevant considerations for physicians in assessing patients would be an excellent starting point. In this respect, a brief overview of holism, and of its embrace by CAM, is of assistance.

##### 2.1 HOLISM

CAM, in its many forms, often grounds itself in holism, claiming to treat the whole individual and not solely the disease of which they complain.<sup>151</sup> Holism<sup>152</sup> was the norm in the prescientific era, when “physical manifestations of illness were almost always explained in spiritual terms”,<sup>153</sup> and most, if not all, aspects of human life were influenced by theistic or supernatural belief. It has an extensive lineage extending from around 560BC to the current day, though, since the introduction of the Hippocratic paradigm, convention has increasingly

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<sup>149</sup> Richard L Street and Paul Haidet, ‘How well do doctors know their patients? Factors affecting physician understanding of patients’ health beliefs’ (2011) 26 *Journal of General Internal Medicine* 21, 25.

<sup>150</sup> For example, the standard treatment of a patient with atrial fibrillation, a common cardiac arrhythmia, is the use of rate and/or rhythm control together with an anticoagulant. See National Medicines Information Centre, ‘The contemporary management of atrial fibrillation’ (2006) 12(3) *NMIC Bulletin*. This protocol is standard, notwithstanding the serious effects that such medications have on energy levels and clotting, meaning that younger sufferers or those with very active lifestyles may be disproportionately negatively affected.

<sup>151</sup> CAM DOC Alliance, ‘Holistic approach and the contribution of CAM’ (2015)

<[www.camdoc.eu/Complementary\\_Medicine/Holistic\\_approach.html](http://www.camdoc.eu/Complementary_Medicine/Holistic_approach.html)> accessed 21 January 2016.

<sup>152</sup> Jan Smuts, *Holism and evolution* (Macmillan 1926). Smuts devised the word “holism”, which was known previously as “wholism”.

<sup>153</sup> Sneha Mantri, ‘Holistic medicine and the Western medical tradition’ (2008) 10(3) *American Medical Association Journal of Ethics* 177.

favoured pathophysiological<sup>154</sup> and, more recently, evidence-based<sup>155</sup> approaches, and holism has become an alternative (‘other’) construct, of limited and sporadic interest to conventional practitioners. However, far from being confined to the annals of medical history, holism has experienced a resurgence in CAM, as a broad philosophical foundation for comprehensive care of the mind, body and soul. This is unsurprisingly a popular proposition, and one which, it is argued, has been all too easily discarded with the bathwater of other archaic health philosophies during the perpetual evolution of conventional healthcare.

### 2.1.1 THE PHILOSOPHY OF HOLISM AND HOLISTIC MEDICINE

Though holistic practice predates the Hippocratic tradition, the term “holism” is a relatively modern one, coined by Jan Smuts in 1926,<sup>156</sup> to describe the treatment of a system as a whole, rather than as a collection of parts. This was based on the Aristotelian assertion in the same vein and runs through many distinct areas, from psychology<sup>157</sup> to engineering.<sup>158</sup> Providing a definition of holism is not a particularly simple endeavour. As noted by Bowman,

...holism continues to reference disparate sets of ideas and there remains many context sensitive interpretations that include metaphysical, aesthetic, epistemological, organismic, embodied or spiritual components, to name but a few. Holism is a term that is dramatically context-sensitive.<sup>159</sup>

Of course, it is almost certainly not the philosophical underlay of holistic practice that is of most importance to patients, but rather what it broadly represents – namely, the rejection of the disease-focussed, reductionist approach so often associated<sup>160</sup> with conventional medicine.<sup>161</sup> However, this is merely one interpretation of holism in

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<sup>154</sup> The term ‘biomedical’ is also used interchangeably.

<sup>155</sup> Sonja J Lewis and Burton I Orland, ‘The importance and impact of evidence-based medicine’ (2004) 10(5 Supp A) *Journal of Managed Care Pharmacy* S3, S4, “EBS is, in fact, the new paradigm for medical practice. This new model deemphasizes intuition, unsystematic clinical experience, and the use of pathophysiology as the foundation for making clinical decisions. Instead, EBM emphasizes the importance of the results of large clinical trials in formulating individual treatment strategies”.

<sup>156</sup> Jan Smuts (1926) 86.

<sup>157</sup> George Klir, *Facets of Systems Science* (Springer US 2012) 37.

<sup>158</sup> John Reap, Dayna Baumeister and Bert Bras, ‘Holism, biomimicry and sustainable engineering’ (American Society of Mechanical Engineers 2005) 423.

<sup>159</sup> Charles Bowman, ‘Reconsidering holism in Gestalt therapy: A bridge too far?’ in Talia Bar-Joseph Levine (ed), *Gestalt Therapy: Advances in Theory and Practice* (Taylor & Francis 2012) 30.

<sup>160</sup> Mario Bunge, *Medical Philosophy: Conceptual Issues in Medicine* (World Scientific 2013).

Bunge points out that conventional medicine applies systemism rather than reductionism, suggesting that, whereas holism looks at the person as a whole, it fails to look at the parts to any great extent, ignoring anatomy and physiology in the process. The systemism of conventional medicine acknowledges both the parts and the whole.

<sup>161</sup> George Klir (n 157) 37. The author argues that holism is the antithesis of reductionism, though Joshua Freeman (n 15) 155 disagrees, arguing instead that, “Holism does not mean ‘anything outside traditional

healthcare. The CAM DOC Alliance (a European body representing the Council for Homeopathy (ECH), the European Council of Doctors for Plurality in Medicine, the International Council of Medical Acupuncture and Related Techniques, and the International Federation of Anthroposophic Medical Associations), sets out its own parameters for holistic practice, stating

Holism does not reject the biomedical concept of disease, nor does it attempt to replace it with its own. Rather, it seeks to include all that expand this concept to include a wide spectrum of predisposing factors that the average medical doctor typically (although not necessarily) has neither the time, the interest, nor the training to explore.<sup>162</sup>

Freeman takes a similar stance, warning that there is no such thing as a holistic therapy, but that holistic healthcare encompasses the most suitable approaches for a particular patient from all methodologies, including the use of surgery or pharmaceuticals.<sup>163</sup> Whatever its definition, this integrative potential has, in practice, not been embraced to a substantial extent in Ireland. While, as set out below, efforts have been made to broaden the perspective of conventional medicine using models which variously consider environmental, psychological, cultural, social and existential elements among others, there remains a perception of CAM as offering greater potential and willingness to embrace many different approaches to healthcare, rather than dogmatically abiding by one particular approach in all cases.

The segmented and highly specialised structure of conventional medicine is such that, were a patient to see a specialist in every field, their needs might still not be met. It acts to inhibit the development of a holistic approach by each individual practitioner, who has neither the time nor the capacity to get to know their patients and to understand their lives and beliefs, diminishing the potential to use this information to guide treatment. This does not necessarily reflect poorly on the practitioners in question but is reflective of the problems inherent in the ostensibly reductionist approach of conventional medicine and in the systemic lack of resources.<sup>164</sup>

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allopathy'. In themselves, herbal healing or faith healing or exercise therapy or cultural therapies or shamanism are no more holistic than the use of pharmaceuticals or surgery".

<sup>162</sup> CAM DOC Alliance (n 151).

<sup>163</sup> Joshua Freeman (n 15) 155.

<sup>164</sup> Carolyn Tarrant and others, 'Qualitative study of the meaning of personal care in general practice' (2003) 326(7402) *British Medical Journal* 1310, 1312. One specialty in which a holistic approach it is both notable and vital, is in the area of general practice. Tarrant noted that whole person or holistic care was one of the key factors in personal care, stating, "Many patients' accounts centred on dealing with the "whole person" in the context of their life and illness, rather than just treating the presenting illness. Patients often referred to the importance of professionals knowing about them and their family history".

## 2.2 BIOLOGICAL REDUCTIONISM

Despite established links between mind and body,<sup>165</sup> and the limited role played by healthcare alone in determining human health,<sup>166</sup> the reductive approach continues to play a dominant role in conventional care. Basic reductionism and empirical evidence-based practice has its origins in the Hippocratic era, gaining predominance in the sixteenth century,<sup>167</sup> and today Cartesian biological reductionism<sup>168</sup> informs much of conventional medical practice, which is itself, by happy coincidence, divided into areas of ever-narrowing specialty and subspecialty. Biological reductionism has contributed substantially to human health and to our understanding of key physical, chemical and biological processes since its introduction. However, if, as contended by Aristotle and many others since, the whole is formed of more than just the individual parts,<sup>169</sup> the question arises of whether healthcare can be comprehensive when considering only the physical components of the patient. This is at the forefront of the dichotomy between conventional medicine and CAM, and the answer appears to be that it cannot. Schroeder,<sup>170</sup> citing McGinnis et al,<sup>171</sup> stressed the limits of the purely biomedical, reductive approach, noting that genetic, social, environmental, and behavioural factors influence health to a significantly greater degree than medical care alone.

Figure 3 shows the determinative contribution made by healthcare in cases of premature death, which is estimated at 10%. By way of contrast, genetic predisposition combined with the behavioural patterns of the patient bore substantially greater influence on outcome, at 70%. Also notable is the contribution of social circumstances, at 15%.

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<sup>165</sup> A simple example of this is the brain-gut connection, whereby the limbic system, which is the emotional centre of the brain, plays a significant role in the manifestation of gastrointestinal symptoms. See Howard Mertz, 'Role of the brain and sensory pathways in gastrointestinal sensory disorders in humans' (2002) 51 Gut i29, i33.

<sup>166</sup> Figure 3.

<sup>167</sup> George Klir (n 157) 37.

<sup>168</sup> Thomas Bidell, 'Vygotsky, Piaget and the dialectic of development' (1988) 31(6) Human Development 329, "...the traditional Cartesian approach tends to isolate aspects of complex phenomena into static, decontextualized elements".

<sup>169</sup> Jan Smuts (n 152) 86.

<sup>170</sup> Steven A Schroeder, 'We can do better — improving the health of the American people' (2007) 357(12) New England Journal of Medicine 1221.

<sup>171</sup> Michael J McGinnis, Pamela Williams-Russo and James R Knickman, 'The case for more active policy attention to health promotion' (2002) 21(2) Health Affairs 78.

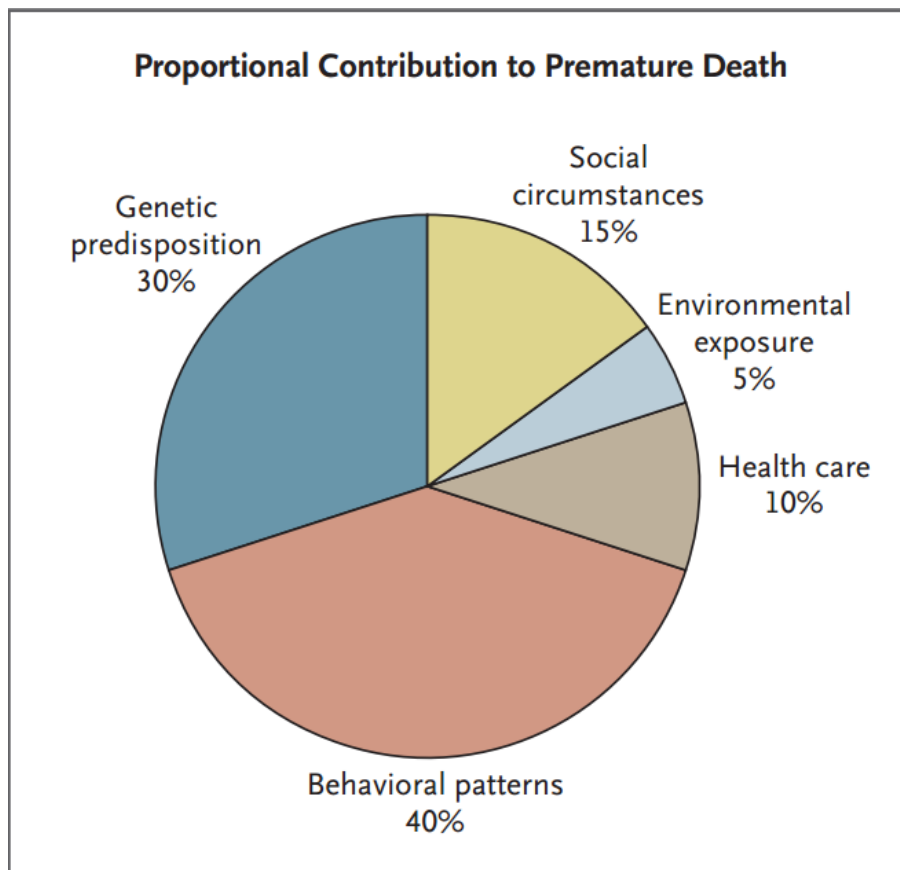


*Figure 3 - Schroeder derives a chart from the data provided by McGinnis, estimating the influence of medical care on premature death at approximately 10%, whereas the influence of genetic and behavioural factors totals approximately 70%.*

This represents a stark reminder for conventional practitioners to ensure that the entire patient background and its centrality in individual and public health be acknowledged, and is something which has been given consideration by various academics, who have then sought to soften the hard-line reductionist approach, without veering too far from the course of convention.

## 2.3 ALTERNATIVE MODELS

Attempts to temper the hard linearity of reductive biomedicine, while also limiting the less palatable vitalist aspects of holism, have manifested, in one form, in the development of the biopsychosocial model. Dr. George Engel introduced the biopsychosocial (BPS) model for healthcare in 1977, in what was, perhaps, a response to the limitations of the biomedical model, which, he said, “can make provision neither for the person as a whole nor for data of a psychological or social nature”.<sup>172</sup>

<sup>172</sup> George Engel, ‘The clinical application of the biopsychosocial model’ (1980) 137(5) American Journal of Psychiatry 535, 536.

Engel's approach sought to broaden the diagnostic and interventional basis to encompass factors such as genetic composition, prior learning history, current psychological status, and sociocultural influences, as well as the biological issues most often considered by conventional medicine.<sup>173</sup> These, as we have seen, contribute far more to patient health than current conventional practices suggest.

Engel's model was not without its critics, with McLaren rejecting it as nothing more than an attempt to buck the trend of biological reductionism.<sup>174</sup> He did, however, concede that:

What [Engel] argued powerfully, however, is that too many modern physicians are not of 'reasonable sensitivity', for which he blamed modern medical training:

'The reductionist scientific culture of the day is largely responsible for the public view of science and humanism as antithetical. ... The triumphs of the biomedical model all have been in the areas for which the model has provided a suitable framework for scientific study'.

That is to say, biomedical science was very successful so long as it did not stray too far from the same theoretical position as veterinary science.<sup>175</sup>

McLaren's dismissal of the BPS model ultimately found him on the wrong side of history as the model or a variation of it can be found throughout conventional medical literature and practice.<sup>176</sup> However, for some, the BPS model does not represent a sufficient departure from reductionism. The EURACT (European Academy of Teachers in General Practice) Model took things a step further, adding cultural and existential factors back into the BSP model.<sup>177</sup> The re-emergence of these considerations in particular facets of healthcare theory reflect a reversion to the more spiritual and esoteric aspects of holism, and this has received support in some quarters,<sup>178</sup> but it may nonetheless represent a bridge too far for acceptance into modern

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<sup>173</sup> Robert J Gatchel and others, 'The biopsychosocial approach to chronic pain: Scientific advances and future directions' (2007) 133(4) *Psychological Bulletin* 581, 582.

<sup>174</sup> Niall A McLaren, 'A critical review of the biopsychosocial model' (1998) 32(1) *Australian and New Zealand Journal of Psychiatry* 86, 89, "Engel simply demonstrated a need for a particular approach, talked about it for a while then announced that he had found it. He had not. All he offered was an emotive case for more humanity and less technology in medicine: little more than a heartfelt plea based in a particular ontological stance. It was not a theory, and it was certainly not a model".

<sup>175</sup> *ibid* 91. Indeed, references to patients being treated like animals are rarely far from the headlines. See 'Patients 'being treated like animals' at Wexford Hospital' *Wexford People* (16 June 2010) <[www.wexfordpeople.ie/news/patients-being-treated-like-animals-at-wexford-hospital-27715381.html](http://www.wexfordpeople.ie/news/patients-being-treated-like-animals-at-wexford-hospital-27715381.html)> accessed 10 March 2016, and 'Glan Clwyd Hospital: Patients kept like 'animals in a zoo'' *BBC News* (28 May 2015) <[www.bbc.com/news/uk-wales-north-east-wales-32904599](http://www.bbc.com/news/uk-wales-north-east-wales-32904599)> accessed 10 March 2016.

<sup>176</sup> Francesc Borrell-Carrió, Anthony L Suchman, Ronald M Epstein, 'The biopsychosocial model 25 years later: Principles, practice, and scientific inquiry' (2004) 2 *Annals of Family Medicine* 576.

<sup>177</sup> Joshua Freeman (n 15).

<sup>178</sup> *ibid* 155 and Andrew R Hatala, 'The status of the "biopsychosocial" model in health psychology: Towards an integrated approach and a critique of cultural conceptions' (2012) 1(4) *Open Journal of Medical Psychology* 51.

conventional medicine,<sup>179</sup> something which may also contribute to the shift towards CAM, as the perception of conventional medicine as being closed-minded or rigid surfaces once more.<sup>180</sup>

### 3. CAM AS A REPRESENTATION OF ‘OTHERNESS’

CAM, as the name suggests, presents an alternative to medical orthodoxy, whether or not it is utilised as such. This is often an appealing prospect where a patient has suffered some insult or suboptimal treatment at the hands of conventional medicine, or, as Beyerstein asserts, where there exists “the belief that society’s shortcomings must be due to active connivance by powerful, secret kabals, rather than merely the cumulative mistakes of well-intentioned planners”.<sup>181</sup> Whether this view is justified, the very fact that CAM exists outside of, and is in many cases opposed to, the principles and practices (and, as we have just seen, the reductionism) of conventional medicine is another motivating factor in the use of CAM.<sup>182</sup>

Three particular observations may also be relevant here: the significantly greater freedom from regulation and oversight in the practice of CAM when compared with conventional medicine, the rejection of commercialisation and technology in medicine, and the shift towards a matriarchal model of care.

#### 3.1 FREEDOM FROM STATE INTERFERENCE IN DELIVERY OF CARE

The lack of effective regulation for CAM in Ireland is at the core of this thesis. While some consider this to cultivate a harmful and fertile environment in which charlatanry may propagate, consumers may instead perceive it as creating a haven from the increasingly Orwellian oversight of the state.<sup>183</sup> In fact, it is unsurprising, given the much-maligned funding and resourcing issues strangling the conventional medical sector,<sup>184</sup> and the questionable State

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<sup>179</sup> Ian D Coulter and Evan M Willis, ‘The rise and rise of complementary and alternative medicine: A sociological perspective’ (2004) 180(11) *Medical Journal of Australia* 587. The authors note that, in Australia, despite the fact that “all the CAM groups subscribe, in one way or another, to the principle of “vitalism” ...many of the therapies of the traditional paradigms have been incorporated into current practice without adopting vitalistic principles”.

<sup>180</sup> Joshua Freeman (n 15) 155. Interestingly, Freeman notes that many CAM providers are more reductionist in their behaviour than they portray, taking patient information from all key areas described by the EURACT model but ultimately only attempting to treat the physical ailment within the fairly narrow remit of biomedicine.

<sup>181</sup> Barry L Beyerstein, ‘Alternative medicine and common errors of reasoning’ (2001) 76(3) *Academic Medicine* 230, 232.

<sup>182</sup> Peter Kennedy and Carole Ann Kennedy, *Using Theory to Explore Health, Medicine and Society* (Policy Press 2010) 57.

<sup>183</sup> Henry A Giroux, ‘Totalitarian paranoia in the post-Orwellian surveillance state’ (2014)

<[www.truth-out.org/opinion/item/21656-totalitarian-paranoia-in-the-post-orwellian-surveillance-state](http://www.truth-out.org/opinion/item/21656-totalitarian-paranoia-in-the-post-orwellian-surveillance-state)> accessed 2 March 2016.

<sup>184</sup> Fiachra Ó Cionnaith, ‘HSE made cuts of €2.7bn during recession’ *Irish Independent* (1 April 2014)



intrusion into clinical decision-making,<sup>185</sup> that the lack of governmental involvement in CAM is considered a positive attribute by many users.

This is not an aspect fully exploited by the CAM sector, as it simultaneously promotes the freedom and potential of their particular branch of healthcare, while also drawing attention to its lack of oversight and regulation, something about which the Irish public, to date, have neither seemed unduly concerned,<sup>186</sup> nor particularly well aware.<sup>187</sup>

Facilitating, by omission to regulate, the continued provision of CAM services outside of any formal system of supervision is sub-optimal for the protection of consumers, who, despite their drive to subvert the strict parameters of conventional care, do not benefit from the lack of minimum standards for education, training, safety or efficacy, ethical practice or grievance procedures.

### 3.2 REVOLT AGAINST TECHNOLOGY AND COMMERCIALISATION

The movement of patients towards the use of CAM may also be considered a rejection of the problems brought about by technology and commercialisation in conventional medicine and in society as a whole. With increasing technological infiltration into areas which were previously ‘analogue’, questions arise as to the implications of permanent connectivity, and the long-term effects on human interaction, cognition and privacy, particularly in a sector not always praised for the communication skills of its practitioners.

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<[www.irishexaminer.com/ireland/hse-made-cuts-of-27bn-during-recession-263841.html](http://www.irishexaminer.com/ireland/hse-made-cuts-of-27bn-during-recession-263841.html)> accessed 10 February 2016. The author notes that the budget cuts resulted in “12,000 less HSE staff than when the recession began; A 21,000 inpatient drop and 30,000 day case drop between 2012 and 2014; A near €100m cut to the cost of the drugs payment reimbursement scheme; A trebling of people waiting over six and 12 months for inpatient and day-case hospital treatment; 941 less beds in the public hospital system; [a]nd the loss of two million home help hours a year, from 11 million in 2006 to nine million at the end of last year”.

<sup>185</sup> The impingement of legal considerations on clinical decision-making in Ireland has had grave consequences for patients and has created a chilling effect on clinical practice. Of relevance is the 2014 case of an expectant mother who, after suffering a catastrophic thrombotic event which lead to brain death, was placed on somatic support in order to ensure that her pregnancy would continue until a determination could be made on whether discontinuation would be legally permissible. This was as a result of the parity of constitutional protection for the lives of the foetus and of the mother. Minister for Health Leo Varadkar addressed the issue that “difficult decisions that should be made by women and their doctors, a couple “or the next-of-kin where there is no capacity”, and on the basis of best clinical practice, are now made on foot of legal advice”, stating, “That isn’t how it should be””. See Shane Phelan, ‘Clinically dead pregnant woman being kept alive by hospital’ *Irish Independent* (17 December 2014)

<[www.independent.ie/irish-news/health/clinically-dead-pregnant-woman-being-kept-alive-by-hospital-30845660.html](http://www.independent.ie/irish-news/health/clinically-dead-pregnant-woman-being-kept-alive-by-hospital-30845660.html)> accessed 16 March 2016. Such a situation flies in the face of the provisions on clinical autonomy set out in the World Medical Association, *Declaration of Madrid on Professionally-led Regulation* (2009) and the World Medical Association, *Council Resolution on Criminalisation of Medical Practice* (2013).

<sup>186</sup> Patricia Fox and others (n 2), on the popularity of CAM generally, despite the lack of regulation.

<sup>187</sup> Overall, 44% of respondents stated that they did not know how CAM was regulated. See Chapter 6.

This can be seen in the unrelenting insinuation of the corporate interests into clinical healthcare decision-making, in the delegation of many aspects of medicine to technology<sup>188</sup> and the loss of the ‘art of medicine’ in favour of the science, a phenomenon which has been termed “high tech, low touch”.<sup>189</sup> As personal attention and interaction is a central element of a positive patient experience, it is unsurprising that the replacement of human skills with technology<sup>190</sup> may encourage patients to seek a more humane treatment modality.

### 3.3 PREFERENCE FOR A MATRIARCHAL MODEL OF HEALTHCARE

With the resurgence of vocal feminism,<sup>191</sup> an argument might also be made for a shift in consumer sentiment towards a female-led system of care.

A brief, non-scientific review of registered members of five prominent professional bodies for CAM disciplines in Ireland showed that 72% of practitioners were female,<sup>192</sup> a phenomenon which is not mirrored, particularly at the consultant level,<sup>193</sup> in conventional medicine.

Table 1 demonstrates that the division is particularly stark for practitioners of homeopathy, with only 11% of those registered being male, and for reiki, with only 6% of registered practitioners being male.

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<sup>188</sup> For example, frequent in-hospital reviews of patients with implantable cardiac devices are slowly becoming obsolete as daily, weekly and monthly monitoring is performed remotely via the internet. This eliminates the need for patients to travel to the hospital regularly and minimises acquired infection risk but also removes the potential for patient-practitioner (it is usually not a physician but a physiologist who performs this procedure) interaction unless in the case of device malfunction or serious arrhythmia. See Haran Burri and David Senouf, ‘Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators’ (2009) 11(6) *Europace* 701, 705.

<sup>189</sup> Edzard Ernst, ‘The role of complementary and alternative medicine’ (2000) 321(7269) *British Medical Journal* 1133, 1134.

<sup>190</sup> William W Parmley, ‘The decline of the doctor-patient relationship’ (1995) 26(1) *Journal of the American College of Cardiology* 287, 288.

<sup>191</sup> Finn Mackay, *Radical Feminism: Feminist Activism in Movement* (Palgrave Macmillan 2015) 7. See also, various recent media campaigns with their basis in gender equality, such as He for She <[www.heforshe.org/en](http://www.heforshe.org/en)> accessed 2 March 2016, Ask Her More <<http://therepresentationproject.org/the-movement/askhermore/>> accessed 2 March 2016, and Waking the Feminists <[www.wakingthefeminists.org/](http://www.wakingthefeminists.org/)> accessed 2 March 2016.

<sup>192</sup> This review, undertaken on 6 March 2016, analysed publicly available member lists for five of the largest Irish representative bodies, (the Reiki Federation of Ireland, the Irish Society of Homeopaths, the Acupuncture Council of Ireland, the Chiropractic Association of Ireland and the Osteopathic Association of Ireland) dividing membership by gender. For detail on the relative popularity of each practice among Irish consumers, see Chapter 6.

<sup>193</sup> Medical Council, ‘Medical Workforce Intelligence Report’ (Medical Council 2014) 51. The report notes that only 28.9% of all hospital consultants are female.

| REPRESENTATIVE BODY                 | FEMALE PRACTITIONERS | MALE PRACTITIONERS | % FEMALE |
|-------------------------------------|----------------------|--------------------|----------|
| Reiki Federation of Ireland         | 105                  | 7                  | 94       |
| Irish Society of Homeopaths         | 236                  | 29                 | 89       |
| Acupuncture Council of Ireland      | 282                  | 122                | 70       |
| Chiropractic Association of Ireland | 52                   | 50                 | 51       |
| Osteopathic Council of Ireland      | 59                   | 79                 | 43       |

Table 1 - Gender of Irish CAM practitioners by discipline.

Interestingly, the gender gap appears to close as the perception of the particular therapy in question becomes more medicalised, and is, perhaps, treated with more gravitas. For example, both osteopathy and chiropractic use the title “doctor” (Doctor of Osteopathy (D.O.) and Doctor of Chiropractic (D.C.)), though, in Ireland, this is most common for chiropractors) and both have proportionately higher numbers of male practitioners than most other therapies, with male membership at 57% and 49% respectively. The results of this simple, ad hoc survey accurately reflect the results of previous international research. The higher percentage of male practitioners in chiropractic and osteopathy relative to other CAM modalities is, according to Nissen,<sup>194</sup> the result of the “full-time training and science-oriented curriculum”, different from the ““talking” therapies like naturopathy, homeopathy and Western herbal medicine which are practiced by more women than men”.<sup>195</sup> This appears to imply that, as a practice is perceived to move closer to the norm of conventional medicine and the role closer to that of conventional physician, the number of male practitioners increases. In line with Nissen’s hypothesis, it may also be argued that the significant plant outlay required to establish, for example, a chiropractic business requires a commitment to full time work in that role, whereas homeopathy or reiki can be practiced on a part time or casual basis with minimal overhead, providing flexibility for practitioners which may be particularly appealing for those with other jobs or caring responsibilities.<sup>196</sup>

<sup>194</sup> Nina Nissen, ‘Challenging perspectives: Women, complementary and alternative medicine, and social change’ (2011) 3(2) Interface 187.

<sup>195</sup> *ibid* 191.

<sup>196</sup> Central Statistics Office, *Women and Men in Ireland 2011* (Stationery Office 2012) 27, “98% of those who were looking after home or family in 2011 were women”.

It is also noteworthy that the results are similar notwithstanding the differences in recognition and regulation of these therapies between Ireland and other jurisdictions.

Despite the fact that CAM has clearly not escaped the gender divide notable in STEM professions the world over, it benefits substantially (some might say, primarily) from the human elements of practice, provided, predominantly, by women. Conversely, much of the discussion on the “feminisation” of conventional medicine<sup>197</sup> betrays a distinctly negative attitude<sup>198</sup> and the call of CAM, with its embrace of what may be considered to be “feminine” qualities,<sup>199</sup> presents a welcome change for patients and consumers. Such qualities as humility, gentleness, kindness, compassion and sensitivity,<sup>200</sup> are often found lacking in conventional medicine and yet may contribute significantly to the success of CAM, not merely in terms of attracting consumers but in cultivating a placebo effect<sup>201</sup> and a positive, beneficial treatment experience,<sup>202</sup> another factor that should perhaps be considered by those seeking to improve both performance and longer-term outcomes in conventional medicine.

### 3.4 A SOURCE OF SATISFACTION ABSENT IN CONVENTIONAL MEDICINE

Much of the conventional healthcare experience is inherently stressful, from waiting lists and staff and bed shortages, to test results, surgery, drug side effects and, particularly in hospitals, a new physician with each visit. CAM avoids almost all of these negative situations, instead offering predominantly non-invasive, one-to-one therapy and providing continuity of care. Not only this, but CAM often provides a source of pleasure for patients.<sup>203</sup> Therapies such as

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<sup>197</sup> Medical Council (n 193) 49. The concerns surrounding the “feminisation” of medicine do not take into account the fact that female doctors continue to be markedly underrepresented at consultant level and in many of the more prestigious specialties, such as neurosurgery, trauma and orthopaedic surgery and oral and maxillo-facial surgery.

<sup>198</sup> Celia Hall, ‘Influx of women doctors ‘will harm medicine’*’ The Telegraph* (3 August 2004) <[www.telegraph.co.uk/news/uknews/1468508/Influx-of-women-doctors-will-harm-medicine.html](http://www.telegraph.co.uk/news/uknews/1468508/Influx-of-women-doctors-will-harm-medicine.html)> accessed 12 February 2016.

<sup>199</sup> Roby Jose Ciju, *The Art of Perfect Living: The 7 Personal Powers for Perfection* (Partridge Publishing India 2014) 18.

<sup>200</sup> *ibid.*

<sup>201</sup> Launa Colloca and Christian Grillon, ‘Understanding placebo and nocebo responses for pain management’ (2014) 18(6) *Current Pain and Headache Reports* 419, 423, “Current knowledge of placebo and nocebo effects provides direct evidence for a pain- inhibiting or facilitating mechanism in the human brain and spinal cord, which can be activated by cognitive manipulations of expectations through verbal suggestions, pharmacologic, and nonpharmacologic conditioning, and social learning”.

<sup>202</sup> Kenneth Howard, David Orlinsky and James A Hill, ‘Patients’ satisfactions in psychotherapy as a function of patient-therapist pairing’ (1970) 7(3) *Psychotherapy: Theory, Research & Practice* 130. On the importance of positive psychology, see Barbara L Fredrickson, ‘The broaden-and-build theory of positive emotions’ (2004) 359(1449) *Philosophical Transactions of the Royal Society B: Biological Sciences* 1367, 1373.

<sup>203</sup> Frauke Musiala, Thomas Weiss, ‘The healing power of touch: The specificity of the ‘unspecific’ effects of massage’ (2014) 21 *Forschende Komplementärmedizin* 282. The authors refer to “the positive hedonic aspects of gentle touch”. See also, Eeva Sointu, *Theorizing Complementary and Alternative Medicines: Wellbeing, Self, Gender, Class* (Palgrave Macmillan 2012) 197; Nayelhi Saavedra and Shoshana Berenzon, ‘Pleasure, transformation and treatment. Use of alternative medicines to treat emotional illnesses in Mexico City’ (2013)

massage, reiki, acupuncture and aromatherapy are inherently relaxing, considered by some to be a “self-indulgent time-out from or reward for a stressful job”,<sup>204</sup> giving it a significant advantage over conventional care.

### 3.5 EMPHASIS ON PREVENTATIVE MEASURES

According to Eisenberg,<sup>205</sup> the lack of focus on health promotion and preventative measures in conventional medicine is a contributory factor in the preference of patients for CAM.<sup>206</sup> Prevention of illness and lifetime “wellness” programs are a cornerstone of CAM marketing, making them an influential factor in choice. Much of the preventative force in CAM lies in its emphasis on improving overall lifestyle,<sup>207</sup> and reducing stress,<sup>208</sup> which draws, once again on the principle of holism underlying CAM.

### 3.6 PROMOTION OF SELF-DETERMINATION

Yates et al<sup>209</sup> observe that two of the determining factors in the choice of CAM by oncology patients are the desire of patients to feel in control of their illness<sup>210</sup> and the increase in patient engagement and responsibility concerning their treatment plan.<sup>211</sup> Particularly in long-term illness, the loss of control experienced by patients arises both from the unpredictability of their condition and their lack of power over it, and also from the expectation that patients should “accede to the authoritative knowledge and practice of their medical providers”.<sup>212</sup> Warren et al note that there is a disconnect between the message of “empowerment” offered by conventional illness management programs (and heavily promoted in international health policy)<sup>213</sup> and the practices of healthcare providers themselves, which “are often accompanied

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22 Saúde e Sociedade 164, 167; Ruth Barcan, *Complementary and Alternative Medicine: Bodies, Therapies, Senses* (Bloomsbury Publishing 2013) 41.

<sup>204</sup> *ibid* 42.

<sup>205</sup> David M Eisenberg and others, ‘Unconventional medicine in the United States - prevalence, costs, and patterns of use’ (1993) 328(4) *New England Journal of Medicine* 246.

<sup>206</sup> *ibid* 251.

<sup>207</sup> Brent A Bauer and Milt Hammerly, ‘CAM in preventive medicine: Promises and challenges for the clinician’ (2004) 1(2) *Evidence-Based Integrative Medicine* 123, “the emphasis on lifestyle that is inherent in most CAM therapies may yield a unique opportunity to enhance preventative health approaches”.

<sup>208</sup> *ibid* 127.

<sup>209</sup> Jennifer S Yates and others, ‘Prevalence of complementary and alternative medicine use in cancer patients during treatment’ (2005) 13(10) *Supportive Care in Cancer* 806.

<sup>210</sup> *ibid* 807. This is reinforced by Bauml J and others, ‘Does perceived control predict complementary and alternative medicine (CAM) use among patients with lung cancer? A cross-sectional survey’ (2014) 22(9) *Supportive Care in Cancer* 2465.

<sup>211</sup> Jennifer S Yates and others (n 209) 807.

<sup>212</sup> Narelle Warren, Rachel Canaway, Nalika Unantenne and others, ‘Taking control: Complementary and alternative medicine in diabetes and cardiovascular disease management’ (2013) 17(4) *Health* 323, 324.

<sup>213</sup> European Patients Forum, ‘EPF background brief: Patient empowerment’ (2015) <[www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing\\_paperpatient-](http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing_paperpatient-)

by subtle but significant messages that contradict the tenets of empowerment: medical practitioners reinforce professional dominance through both covert and overt methods, while failing (or refusing) to acknowledge their patients' bodily experiences and authority".<sup>214</sup> By contrast, "CAM providers enable more egalitarian communication and active participation within the therapeutic relationship, and so facilitate greater autonomy",<sup>215</sup> making it an attractive alternative for patients.

#### 4. THE IMPORTANCE OF PATIENT PERCEPTION

Having reviewed some of the objective benefits of CAM for patients and consumers, it is important to consider some of the subjective factors influencing and perpetuating the use of CAM.

Patient perception of CAM and its attributes plays a substantial role in its popularity, regardless of clinical accuracy or feasibility.<sup>216</sup> CAM is commonly promoted on the basis of its 'naturalness', which is perceived as imbuing it with positive qualities relative to conventional 'chemical' medicine. CAM is broadly considered to be both safe and efficacious by users, despite the dearth of high quality evidence in support of most of the claims made by its proponents. Patients may also perceive an alignment of CAM with their personal healthcare ethos, which is difficult to quantify and is often a fluid construct, as patients are subject to the ebb and flow of public opinion, disseminated by personal acquaintances and media sources.

The perceptions of CAM users play a key role in their healthcare decision-making and optimised consumer protection requires both an improved understanding of the influences involved and a commitment to better public education, both formally and in the context of higher quality, open and non-judgmental physician-patient relationships. An examination of the influences in question is provided below.

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mpowerment\_final\_external.pdf> accessed 22 March 2016, and World Health Organisation, 'Empowering patients' (2012)

<[www.euro.who.int/en/health-topics/noncommunicable-diseases/pages/news/news/2012/4/empowering-patients](http://www.euro.who.int/en/health-topics/noncommunicable-diseases/pages/news/news/2012/4/empowering-patients)> accessed 22 March 2016.

<sup>214</sup> Narelle Warren, Rachel Canaway, Nalika Unantenne and others (n 212) 324.

<sup>215</sup> *ibid* 326.

<sup>216</sup> Mandreker Bahall and Mark Edwards, 'Perceptions of complementary and alternative medicine among cardiac patients in South Trinidad: A qualitative study' (2015) 15 *BMC Complementary and Alternative Medicine* 99, 102-104, "The use of CAM is based largely on patient perception regardless of the clinical reality. The perceived characteristics, rationale, mode of action, and therapeutic outcomes of CAM influence its use. With scientific advancements and an improved understanding of the pathophysiology of many diseases, one would expect patients to welcome, accept, and rely on evidence-based guidelines to manage cardiac disease. On the contrary, perception, despite its unscientific nature, continues to influence the use of CAM alone or in combination".

## 4.1 PERCEIVED EFFECTIVENESS

There are many reasons why some patients perceive or experience greater effect from CAM than from conventional medicine. For example, their condition may be one unrecognised by conventional medicine,<sup>217</sup> limiting the potential for an efficacious (or perceived efficacious) treatment. This, combined with what may be a long and difficult battle for recognition and diagnosis,<sup>218</sup> may contribute significantly to the relief felt by patients upon meeting with a sympathetic and credent CAM practitioner, however poorly-regulated and whatever the evidence for the treatment proffered.

In more worrying cases, however, patients diagnosed with a serious or life-threatening illness, such as cancer, who do not want or cannot tolerate what is often a punishing conventional therapeutic regime, are attracted to CAM as a less harsh, but ostensibly as effective, alternative.<sup>219</sup> This was described by Shumay et al,<sup>220</sup> who found:

In many cases, the CAM choice was perceived to be considerably less aversive than the conventional treatment option or was perceived to make more “intuitive” sense. A common viewpoint expressed by participants was that conventional treatment and CAM have different methods and purposes. Participants pointed out that CAM works with the body’s own resources in a natural way to promote healing, while conventional treatment is short-sighted and merely attacks the symptom without addressing underlying imbalances.

In choosing CAM as an alternative to conventional treatment, the participants stated that they were satisfied with CAM’s effectiveness and described sources of evidence for this, including personal evidence (most frequently cited), medical and anecdotal evidence, and belief. Participants’ personal experience of continuing to be alive, feeling well, or having subjective improvement in symptoms was proof for them that a particular CAM treatment worked. Participants also used medical evidence (e.g., PSA tests or mammography) to demonstrate that their condition was improved and attributed this to the CAM. Anecdotal evidence based on others’ reported benefits from CAM was

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<sup>217</sup> Michele L Pearson and others, ‘Clinical, epidemiologic, histopathologic and molecular features of an unexplained dermatopathy’ (2012) 7 PLoS ONE e29908

<<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0029908>> accessed 3 March 2016. This article describes a study to establish the presence in a group of patients of a skin pathology known by sufferers as “Morgellon’s disease”, characterised by skin lesions with the presence of organic fibres. The study found no common cause for the skin lesions, but noted that (a) the fibres were most likely cotton material, (b) that the lesions appeared to be caused, in many cases, by neurotic skin excoriation, dermatitis, pruritis or insect bites, and (c) that “the prevalence of co-existing neuropsychiatric morbidity appeared to be high” among participants. Interestingly, and quite relevantly, the subjects of this study were predominantly middle-aged Caucasian women, the very category identified as being the predominant users of CAM in the SLAN data. See Patricia Fox and others (n 2), and Paul Posadzki and others (n 1).

<sup>218</sup> Haig Donabedian, ‘Delusions of parasitosis’ (2007) 45(11) *Clinical Infectious Diseases* e131. The author refers throughout to the conflict in the physician-patient interaction, which is characteristic in the treatment of, or failure to treat, patients suffering from delusional parasitosis.

<sup>219</sup> Mandreker Bahall and Mark Edwards (n 216) 105, “The attractiveness of CAM arises from its perceived ability to prevent and treat illness with minimal adverse effects while decreasing complications caused by conventional medications”.

<sup>220</sup> Diane M Shumay and others, ‘Why some cancer patients choose complementary and alternative medicine instead of conventional treatment’ (2001) 50(12) *Journal of Family Practice* 1067.

sufficient for at least one participant to state that she felt CAM was effective. A number of participants stated that they did not have any demonstrable evidence of the effectiveness of CAM, such as improved symptoms or medical evidence, but that they nonetheless continued to believe that CAM was working for them. Participants' reasoning included statements about how the particular CAM made logical sense to them and therefore "must work," or that they had a long history of belief in the benefits of CAM. Only one participant admitted that she was not sure if CAM had helped her.<sup>221</sup>

At the time of writing, there is no high quality evidence that any CAM therapy is effective in the treatment of cancer.<sup>222</sup> While this is discussed in greater depth in Chapter 3, it is important to emphasise that the perceived benefits of CAM for cancer and other conditions provide significant motivation in healthcare decision-making<sup>223</sup> and that education is needed to ensure that patients receive high quality, factual information, particularly in light of the substantial weight carried by personal testimony, which is addressed briefly in Part III.

CAM therapies, which are often costly, but particularly so in the ostensible treatment of life threatening illness, would not find a market were providers to disclose, during the consent process, that there was no evidence that the therapy offered was efficacious for the condition from which the consumer was suffering. As noted by Stephen Barrett and William Jarvis, "...no one wants to be cheated, especially in matters of life and health. Victims of disease do not demand quack treatments because they want to exercise their "rights", but because they have been deceived into thinking that they offer hope".<sup>224</sup> In addition, where there is deception or failure to disclose material information during the consent process, consent is invalid and the autonomy of the patient is not vindicated.

## **4.2 THE SAFETY OF CAM, RELATIVE TO CONVENTIONAL MEDICINE**

Consumers and patients are bombarded with warnings on diet and nutrition, environment, physical movement, sleep, parenting style and product safety - medicine is no different. Daily

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<sup>221</sup> *ibid.*

<sup>222</sup> American Cancer Society, 'Complementary and alternative therapies for advanced cancer', "Alternative treatments may be offered as cancer cures. These treatments have not been proven safe and effective in clinical trials. Some of these methods may pose danger, or have life-threatening side effects. But the biggest danger in most cases is that you may lose the chance to be helped by standard medical treatment. Delays or interruptions in your medical treatments may give the cancer time to grow and make it less likely that treatment will help" <[www.cancer.org/treatment/understandingyourdiagnosis/advancedcancer/advanced-cancer-cam](http://www.cancer.org/treatment/understandingyourdiagnosis/advancedcancer/advanced-cancer-cam)> accessed 10 March 2016.

<sup>223</sup> See Chapter 6. 40% of respondents stated that perceived effectiveness was a motivation in choosing to use or procure a CAM therapy.

<sup>224</sup> William Jarvis and Stephen Barrett, "Health freedom"

<[www.quackwatch.com/01QuackeryRelatedTopics/hfreedom.html](http://www.quackwatch.com/01QuackeryRelatedTopics/hfreedom.html)> accessed 2 September 2016.



reports of drug recalls,<sup>225</sup> vaccination scares,<sup>226</sup> side effects,<sup>227</sup> medical misadventure,<sup>228</sup> and antibiotic resistance<sup>229</sup> contribute much to the argument that CAM is safer than conventional medicine. This is not entirely incorrect. Homeopathy, for example, developed at a time when conventional medicine was extremely dangerous and the death rate for those treated with homeopathy was comparatively much lower.<sup>230</sup> Still today, relatively low rates of morbidity and mortality arise directly as a result of CAM, suggesting that it is safer than conventional medicine, though this fails to account for the consumer risk, for the indirect risk arising from the delay in obtaining conventional care as a result of using CAM, and for underreporting.

Mainstream and alternative media frequently reference the risks and dangers in conventional medicine, in ways which range from moderate and roughly accurate,<sup>231</sup> to outlandish and paranoid.<sup>232</sup> Reports are often accompanied by information on an ostensibly safer alternative. The most negative and best publicised of this information tends to relate to issues of public health or serious or chronic illness, both situations in which the use of CAM is most hazardous. For example:

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<sup>225</sup> 'Precautionary recall of chemotherapy drugs' RTÉ (16 October 2015) <[www.rte.ie/news/2015/1016/735288-chemotherapy-drugs/](http://www.rte.ie/news/2015/1016/735288-chemotherapy-drugs/)> accessed 3 March 2016.

<sup>226</sup> Carolyn Brown, 'H1N1 vaccine and narcolepsy link discovered' (2015) 187(12) Canadian Medical Association Journal E371. For the original study, see Syed Sohail Ahmed and others, 'Antibodies to Influenza Nucleoprotein Cross-React with Human Hypocretin Receptor 2' (2015) 7(294) Science Translational Medicine 1, "differences in vaccine nucleoprotein content and respective immune response may explain the narcolepsy association with Pandemrix".

<sup>227</sup> Eric Wooltorton, 'Paroxetine (Paxil, Seroxat): Increased risk of suicide in pediatric patients' (2003) 169(5) Canadian Medical Association Journal 446.

<sup>228</sup> Paul Cullen, 'Savita Halappanavar jury returns unanimous medical misadventure verdict' Irish Times (9 April 2013) <[www.irishtimes.com/news/health/savita-halappanavar-jury-returns-unanimous-medical-misadventure-verdict-1.1365716](http://www.irishtimes.com/news/health/savita-halappanavar-jury-returns-unanimous-medical-misadventure-verdict-1.1365716)> accessed 10 March 2016.

<sup>229</sup> SARI Infection Control Subcommittee, 'The Control and Prevention of MRSA in Hospitals and in the Community' (Health Service Executive) 5, "The impact of MRSA is considerable; in Ireland approximately 40-50% of isolates of *Staphylococcus aureus* recovered from bloodstream infections are methicillin resistant, and this is significantly higher than in some European countries such as the Netherlands and the Scandinavian countries ... Patients with MRSA bloodstream infection are twice as likely to die from their infection, compared to patients with bloodstream infection caused by methicillin-sensitive *S. aureus*. Furthermore, isolates with reduced susceptibility or isolates that are completely resistant to glycopeptide antibiotics have been described in other countries such as the USA and France, and will probably appear in Ireland eventually".

<sup>230</sup> Ben Goldacre, 'A kind of magic?' *The Guardian* (16 November 2007), "During the 19th-century cholera epidemic, death rates at the London Homeopathic Hospital were three times lower than at the Middlesex Hospital. Homeopathic sugar pills won't do anything against cholera, of course, but the reason for homeopathy's success in this epidemic is even more interesting than the placebo effect: at the time, nobody could treat cholera. So, while hideous medical treatments such as blood-letting were actively harmful, the homeopaths' treatments at least did nothing either way" <[www.theguardian.com/science/2007/nov/16/sciencenews.g2](http://www.theguardian.com/science/2007/nov/16/sciencenews.g2)> accessed 4 January 2016.

<sup>231</sup> Jenny Hope, 'Painkillers taken by millions could increase heart risk: Prolonged use 'leads to significant danger'' *Daily Mail* (29 May 2013) <[www.dailymail.co.uk/health/article-2333067/Painkillers-taken-millions-increase-heart-risk-Prolonged-use-leads-significant-danger.html](http://www.dailymail.co.uk/health/article-2333067/Painkillers-taken-millions-increase-heart-risk-Prolonged-use-leads-significant-danger.html)> 3 January 2016. The report, while not inaccurate, fails to mention that aspirin, also a non-steroidal anti-inflammatory drug (NSAID), has cardioprotective effects and is recommended in the prevention and treatment of cardiovascular disease. The entirely negative portrayal of NSAIDs in this article and others may create unnecessary distress for patients, encouraging them to seek a less safe, less efficacious alternative.

<sup>232</sup> Dane Wigington, 'Western mainstream medicine, a mechanism of death' (2014) <[www.geoengineeringwatch.org/western-mainstream-medicine-a-mechanism-of-death/](http://www.geoengineeringwatch.org/western-mainstream-medicine-a-mechanism-of-death/)> accessed 10 March 2016.

- (a) Homeopathic remedies have been recommended as an alternative to conventional antimalarial treatment, which can cause side effects such as nausea and vomiting<sup>233</sup>;
- (b) Amygdalin, incorrectly sold as ‘Vitamin B17’, is recommended as an alternative cancer therapy, which attacks only cancer cells, leaving healthy cells unharmed<sup>234</sup>;
- (c) Chlorine dioxide has been recommended for the treatment of HIV<sup>235</sup>;
- (d) Black salve, a corrosive paste formed from bloodroot, among other ingredients, is sold for the self-treatment of skin cancer among other issues.<sup>236</sup>

Safety cannot be assessed in a vacuum. For these conditions and many others, the lack of efficacy and the consequent potential for adverse effects and outcomes from delayed conventional treatment (indirect risks) together with the fact that some of these substances are not, in fact, inert but potentially extremely dangerous (direct risks), suggests that CAM is not definitively safer than conventional medicine. In addition, as efficacy has not been demonstrated for the vast majority of CAM therapies for any condition, CAM fails to satisfy the risk-benefit balance demanded as part of ethical healthcare practice and decision-making.

CAM, at its safest and most ethically sound, is used by patients with minor, self-limiting illnesses.<sup>237</sup> As the gravity of the condition increases, the use of CAM becomes increasingly

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<sup>233</sup> Kate Birch and Cilla Whatcott, *The Solution: Homeoprophylaxis: The Vaccine Alternative* (AuthorHouse 2012) 93, 98.

<sup>234</sup> Issels Immuno-Oncology, ‘Laetrile and its use in cancer treatment’ <[www.issels.com/newissels/treatment-summary/laetrile/](http://www.issels.com/newissels/treatment-summary/laetrile/)> accessed 10 March 2016.

<sup>235</sup> MMS Healthy for Life, ‘MMS & HIV’ <[www.mmshealthyforlife.com/category/testimonials-mms-hiv/](http://www.mmshealthyforlife.com/category/testimonials-mms-hiv/)> accessed 10 March 2016. Chlorine dioxide is an industrial bleach used, among other things, in the treatment of medical waste to limit risk of infection. It was found to decrease the infectivity of HIV in treated medical waste. This does not imply safety or efficacy as a medical treatment for HIV in humans. See R Wesley Farr and Cheryl Walton, ‘Inactivation of human immunodeficiency virus by a medical waste disposal process using chlorine dioxide’ (1993) 14(9) *Infection Control and Hospital Epidemiology* 527.

<sup>236</sup> Amazon.co.uk, ‘Drawing Balm/Cream 15g (Bloodroot) Organic, Natural Authentic’, “Contains ingredients to draw out certain types of *unhealthy cells* [emphasis added], infections, spots, toxins from stings & bites”. This product is an escharotic, which kills cells with which it comes into contact, irrespective of whether they are cancer cells <[www.amazon.co.uk/Drawing-Bloodroot-Organic-Natural-Authentic/dp/B015AAVP40](http://www.amazon.co.uk/Drawing-Bloodroot-Organic-Natural-Authentic/dp/B015AAVP40)> accessed 22 September 2016. See Felicia Saltzberg, Gregory Barron and Neil Fenske, ‘Deforming self-treatment with herbal “black salve”’ (2009) 35 *Dermatologic Surgery* 1152; Sandra S Osswald and others, ‘Self-treatment of a basal cell carcinoma with “black and yellow salve”’ (2005) 53(3) *Journal of the American Academy of Dermatology* 508; Caroline Payne, ‘“Black Salve” and melanomas’ (2010) 64(3) *Journal of Plastic, Reconstructive & Aesthetic Surgery* 422.

<sup>237</sup> It might be argued that this is not ethically sound, as treatment for self-limiting illnesses is, by its nature, unnecessary, and for a treatment to gain attribution in such circumstances perpetuates a perception of efficacy where no such efficacy exists.

riskier, either by virtue of the effects it may cause, its unproven efficacy or in the delay it may cause in seeking conventional medical care.

### 4.3 PERCEIVED 'NATURALNESS'

The idea that natural is better than synthetic permeates modern society, but nowhere is it the source of more impassioned rhetoric than in the field of healthcare.

CAM is frequently sold under the premise of it being natural, with representative marketing, imagery<sup>238</sup> and language, appealing to the human desire to be healthy, energetic and youthful.<sup>239</sup> The 'natural' characteristic of a therapy may refer to its composition or its mechanism of action. Homeopathic remedies provide a good example of the complexity of claiming that a product or therapy is natural. Remedies may be made from substances that are considered synthetic, chemical or non-natural.<sup>240</sup> However, they may nonetheless be promoted as a natural remedy by claiming that they trigger a natural healing response in the body. This disregards the fact that pharmaceutical products might also be said to use this same mechanism but are nonetheless rejected as 'chemical' and therefore 'bad'. Of course, everything is chemical,<sup>241</sup> and 'natural' is neither a determinant of 'good' nor of 'healthy'.<sup>242</sup> That these terms are used to encourage the making of value judgments on the part of consumers creates risk of physical and financial harm.

The assertion that something natural is automatically healthier or more beneficial than a synthetic analogue is a logical fallacy. De Souza differentiates between several positions, including Aristotle's positive naturalism,<sup>243</sup> (natural, therefore good), negative naturalism,

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<sup>238</sup> Sites promoting CAM consistently use imagery of leaves, forests, or flowers to reinforce the connection with nature. By way of example, see Dublin Holistic Centre <[www.dublinholisticcentre.com/](http://www.dublinholisticcentre.com/)> accessed 1 October 2016; Bawn Holistic Centre <[www.bawnholistic.com/](http://www.bawnholistic.com/)> accessed 1 October 2016; Bodywise Clinic <[www.thebodywiseclinic.ie/specialists-in-natural-health-care/](http://www.thebodywiseclinic.ie/specialists-in-natural-health-care/)> 1 October 2016.

<sup>239</sup> BHIA, 'The many faces of homeopathy'

<[www.bhia.org/articles/alternative-health/homeopathy.html](http://www.bhia.org/articles/alternative-health/homeopathy.html)> accessed 19 February 2016. See also, 'Natural Medicine and Homeopathy'

<[www.transformativehealth.co.uk/natural-medicine-and-homeopathy-forest-row/](http://www.transformativehealth.co.uk/natural-medicine-and-homeopathy-forest-row/)> accessed 21 March 2016.

<sup>240</sup> Ainsworths Remedy Store <[www.ainsworths.com/index.php?node=\\_RemedyStore2](http://www.ainsworths.com/index.php?node=_RemedyStore2)> accessed 10 March 2016.

<sup>241</sup> John R Wyman, *Safety and the Security Professional: A Guide to Occupational Safety and Health Strategies* (Butterworth-Heinemann 2000) 207, "A chemical is anything created in a chemical process. What this means is that everything is a chemical. Air is composed of chemicals, the sandwich from the vending machine is composed of chemicals – everything is composed of chemicals".

<sup>242</sup> Chung-Hsin Chen and others, 'Aristolochic acid-induced upper tract urothelial carcinoma in Taiwan: Clinical characteristics and outcomes' (2013) 133(1) *International Journal of Cancer* 14, "Aristolochic acid (AA), a component of all Aristolochia-based herbal medicines, is a potent nephrotoxin and human carcinogen associated with upper urinary tract urothelial carcinomas (UUC)".

<sup>243</sup> Aristotle, *Nicomachean Ethics* (Martin Ostwald (ed), Prentice Hall 1999) 1178a 5-7, "What is by nature proper to each thing will be at once the best and the most pleasant for it".

seen in the teachings of the Catholic church<sup>244</sup> (unnatural, therefore bad), and neutralism (natural, therefore neither good nor bad). Though arguments in favour of the use of CAM tend towards the first and second of these, the third is also fallacious – naturalness does not negate positive or negative characteristics.

The scope and range of what is natural and therefore good is predictably anthropocentric, and subject to a broad range of interpretations. Sharks whose cartilage is harvested for unproven natural alternative cancer remedies,<sup>245</sup> may justifiably feel that the premature termination of their lives is, in fact, unnatural and therefore bad.<sup>246</sup> Any intervention in the natural course of a disease process might be considered unnatural, as noted above,<sup>247</sup> but use of a homeopathic remedy consisting of a synthetic substance (Figure 4) may be considered natural due to the healing response it is said to trigger in the body.<sup>248</sup> This also conflicts with the idea that synthetic is not natural and is therefore not good.

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<sup>244</sup>The Holy See, 'Catechism of the Catholic church: Chastity and homosexuality', "Basing itself on Sacred Scripture, which presents homosexual acts as acts of grave depravity, tradition has always declared that "homosexual acts are intrinsically disordered." They are contrary to the natural law" <[www.vatican.va/archive/ccc\\_css/archive/catechism/p3s2c2a6.htm#2357](http://www.vatican.va/archive/ccc_css/archive/catechism/p3s2c2a6.htm#2357)> accessed 9 March 2016.

<sup>245</sup> Cancer Research UK, 'Shark cartilage' [www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/complementary-alternative/therapies/shark-cartilage](http://www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/complementary-alternative/therapies/shark-cartilage)> accessed 4 February 2016.

<sup>246</sup> Hector G Ortega and others, 'Fatal asthma from powdering shark cartilage and review of fatal occupational asthma literature' (2002) 42(1) American Journal of Industrial Medicine 50. Workers who produce shark cartilage may feel that natural does not necessarily mean good.

<sup>247</sup> Viera Scheibner, 'Measles vaccines Part II; Benefits of contracting measles' (2013) <[www.vaccinationcouncil.org/2013/01/29/measles-vaccines-part-ii-benefits-of-contracting-measles-by-dr-viera-scheibner-phd](http://www.vaccinationcouncil.org/2013/01/29/measles-vaccines-part-ii-benefits-of-contracting-measles-by-dr-viera-scheibner-phd)> accessed 1 January 2016.

<sup>248</sup> School of Homeopathy, 'What is homeopathy?', "The ... medicine acts as a stimulus to the natural vital response, giving it the information it needs to complete its healing work" <[www.homeopathyschool.com/why-study-with-us/what-is-homeopathy/](http://www.homeopathyschool.com/why-study-with-us/what-is-homeopathy/)> accessed 3 January 2016.

The screenshot shows the Ainsworths website interface. At the top, there is a navigation bar with links: Home, About Us, Products, Homoeopathic Remedies, and Bach Flower Remedies. Below this is a search bar and a 'My Account' section. The main content area is titled 'Find a remedy' and features a grid of letters (A-Z) for selection. A message states: 'You have reached the maximum number of remedies for one combination.' To the right, a box titled 'Remedies in your combination' lists five items: Aviation Fuel 30C (Centesimal), Washing Powder - Persil Automatic 30C (Centesimal), Brushwood Weed Killer 30C (Centesimal), Cigarette - Silk Cut Light 30C (Centesimal), and Dental Anaesthetic 30C (Centesimal). Below this list are dropdown menus for 'Select the potency scale' (set to Centesimal), 'Select the potency' (set to 30C), 'Form and Size' (set to Tablets (Lactose)), and 'Select the size' (set to 1g Vial).

Figure 4 - A sample remedy available from Ainsworths Homeopathic Dispensary, containing aviation fuel, washing powder, weed killer, cigarette and dental anaesthetic, all unnatural (synthetic) substances utilised to create a 'natural' remedy.

Despite a lack of consensus on the meaning of 'natural', the perception that natural is good permeates healthcare. Early parenting and maternity care provide further examples of this. Breastfeeding and natural childbirth are no longer seen as optimal outcomes, to be achieved where possible, but are, instead, treated as the only truly acceptable outcomes,<sup>249</sup> moral imperatives used to discern good parents from bad.<sup>250</sup> This is reinforced by domestic and international health policy,<sup>251</sup> to the extent that the advertisement of formula for babies under the age of six months is prohibited within the EU,<sup>252</sup> as is the use of images of babies on

<sup>249</sup> Judith A Lothian, 'Why natural childbirth?' (2000) 9(4) Journal of Perinatal Education 44, 46. The author compares "natural birth" with "births that become complicated with the cascade of interventions", omitting the potential for an uncomplicated medically assisted birth. She notes that "Confident women who are supported and encouraged and who enjoy the freedom to tap into their own wisdom find deep satisfaction in giving birth naturally", that "Some women choose to give birth naturally because they love the challenge", and "others find great satisfaction in working hard and "getting the job done"". She does not appear to apply these qualities, at any point, to those who do not opt for natural childbirth, or are not afforded the chance to do so.

<sup>250</sup> Michele L Crossley, 'Breastfeeding as a moral imperative: An autoethnographic study' (2009) 19(1) Feminism & Psychology 71, 73.

<sup>251</sup> World Health Organisation, *Code on the Marketing of Breastmilk Substitutes* (WHO 1981).

<sup>252</sup> Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC [2006] OJ L401/1, art 14(1), as implemented in Ireland by the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007, SI 852/2007, reg 8(1).

formula packaging for children under one year of age,<sup>253</sup> lest a parent receive the impression that feeding an infant other than by breast is an acceptable option. This undermines the intelligence and the choices of parents and indirectly contributes to the demonisation of those who cannot and those who do not wish to breastfeed their child. Such is the pressure (or, as euphemised by Lee and Furedi, “strong cultural affirmation”)<sup>254</sup> on women to do the natural thing and breastfeed their child, that some women partaking in research have exaggerated the extent to which they breastfeed, skewing the outcome,<sup>255</sup> and many more have experienced negative psychological effects arising either from the perception of failure having been unable to begin or sustain breastfeeding or having decided initially not to breastfeed.<sup>256</sup> This despite the fact that, according to one study, although breastfeeding provides definite beneficial effects for babies and in early childhood, many of the claims made by breastfeeding advocates are overstated,<sup>257</sup> particularly when examined longitudinally.

The pursuit of naturalness at any cost has had other troubling consequences. The 2015 *Report of the Morecambe Bay Investigation*<sup>258</sup> found that the dogmatic and “over-zealous” adherence by some members of staff to the pursuit of the natural childbirth approach led, at times, to inappropriate and unsafe care.<sup>259</sup> A similar underlying objective was also noted in the report on the practice of symphysiotomy in Ireland, discussed in detail above.<sup>260</sup>

Martucci et al found that “Promoting breastfeeding as “natural” may be ethically problematic, and, even more troublingly, it may bolster this belief that “natural” approaches are presumptively healthier. This may ultimately challenge public health’s aims in other contexts”.<sup>261</sup> The authors give the example of changes in vaccination behaviour, but this applies equally to the embrace of CAM. Where patients and consumers are told by everyone from their politicians to their healthcare providers that natural is best, there can be no surprise when they comply with that edict.

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<sup>253</sup> Commission Directive 2006/141/EC (n 252), art 13(5), as implemented in Ireland by SI 852/2007 (n 252), reg 6(6).

<sup>254</sup> Ellie Lee and Frank Furedi, ‘Mothers’ experience of, and attitudes to, using infant formula in the early months’ (2005).

<sup>255</sup> Cynthia G Colen and David M Ramey, ‘Is breast truly best? Estimating the effects of breastfeeding on long-term child health and wellbeing in the United States using sibling comparisons’ (2014) 109 *Social Science & Medicine* 55.

<sup>256</sup> Anna Byrom, ‘Feeding guilt’ (2013) 16(3) *The Practising Midwife* 18.

<sup>257</sup> Cynthia G Colen and David M Ramey (n 255) 62-63. See also, Sophie von Stumm and Robert Plomin, ‘Breastfeeding and IQ growth from toddlerhood through adolescence’ (2015) 10 *PLoS One* e0138676, and Asnat Walfisch and others, ‘Breast milk and cognitive development—the role of confounders: A systematic review’ (2013) 3 *British Medical Journal Open*. These studies found no statistically significant longitudinal benefit to IQ or cognitive development directly attributable to breastfeeding and found that uncontrolled-for confounding factors often contributed detrimentally to similar study outcomes.

<sup>258</sup> Bill Kirkup, *Report of the Morecambe Bay Investigation* (Stationery Office 2015).

<sup>259</sup> *ibid* para 1.3.

<sup>260</sup> Oonagh Walsh (n 129) 92.

<sup>261</sup> Jessica Martucci and Anne Barnhill, ‘Unintended consequences of invoking the “natural” in breastfeeding promotion’ (2016) 137(4) *Pediatrics* e20154154.

#### 4.4 COALESCENCE WITH PERSONAL HEALTHCARE ETHOS

The ‘personal healthcare ethos’ is the patient’s personal beliefs about their disease process, the most appropriate course of care for their particular condition and the most beneficial lifestyle changes for their optimal wellbeing. It may encompass social, vitalist, spiritual or cultural elements. Where healthcare aligns with the patient’s ethos, they are more likely to comply with the regimen and are more likely to play an active role in their wellbeing.<sup>262</sup>

The personal health care ethos of a patient may be inadequately understood by the conventional physician,<sup>263</sup> poorly articulated by the patient and, as noted above, subject to influence from family and friends, resulting in frequent augmentation or alteration. The fluid nature of the individual healthcare ethos may provide patients with a tool with which to reject the services of a physician who is, perhaps, not as attentive as the patient might wish, or with whom they have an idiosyncratic relationship.

As noted in Part I, much of conventional care is not individualised and matters of ethos are not frequently acknowledged in patient care, let alone made a guiding principle. CAM might not coalesce with every facet of each individual patient ethos, but might instead provide flexibility and openness in therapeutic options, emphasising the importance of patient input. Respect for patient ethos is a key aspect in empowering the patient to partake actively in their own healthcare, something sorely lacking in conventional medicine, where decisions are made almost exclusively by physicians. The approach taken by CAM in this respect provides significant benefits for patients, who may feel empowered to make positive lifestyle changes and who are more likely to deal positively with adverse effects. Whatever the patient’s particular healthcare ethos, the broad remit of CAM is undoubtedly more accepting, welcoming personal involvement to a far greater extent than conventional care.

Use of CAM is not without logic or rationality. Despite clear issues in respect of clinical evidence of efficacy and safety, many of the interpersonal aspects of CAM are beneficial for patients, whether in terms of empowerment, control, or positive therapeutic experience gleaned through the communication skills of the provider, all of which contribute to an enhanced placebo effect, a greater feeling of involvement and a perception of increased wellbeing. This is particularly important for patients with chronic conditions, for whom constant pain or disability can affect, not only physical, but psychological and emotional wellbeing, leaving them feeling as if they have no control over their condition. Thus, it is clear

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<sup>262</sup> Richard L Street and Paul Haidet (n 149), “...a key, empirically supported tenet of health behavior theories is that a patient’s beliefs about health (e.g., cause of disease, controllability of a condition, value of different remedies) predict health behaviors such as medication adherence, utilization of health care services, and lifestyle decisions...”.

<sup>263</sup> *ibid.*

that CAM can contribute significantly to general wellbeing, though its designation as “medicine” remains questionable.

However, healthcare is not provided in a vacuum and prospective patients are influenced by a number of additional societal factors which may be determinative of healthcare choice and of future wellbeing. These are discussed in Part III.



## PART III

### OTHER FACTORS

#### 5. SOCIAL CONTEXT AND OTHER MISCELLANEOUS INFLUENCES ON CONSUMER CHOICE

The argument that ‘good CAM and bad conventional medicine drive consumers towards CAM’<sup>264</sup> perhaps oversimplifies the issue, which is, in reality, multifaceted and nuanced. The external, societal factors influencing healthcare decision-making are those which affect public interest, information propagation and peer or social pressure. Although these are numerous, the three upon which Part III will primarily focus are:

1. Internet propagation of healthcare information;
2. Excessive reliance on anecdotal evidence; and
3. False equivalence.

Each is discussed below.

##### 5.1 INTERNET PROPAGATION OF HEALTHCARE INFORMATION

While there exists a long and fascinating history of conspiracy theorists<sup>265</sup> and pseudoscientists,<sup>266</sup> the niche outlets willing to accept and publish their hypotheses have, by their nature, been limited, as was their audience, providing a natural filter from the mainstream media. However, as in so many other areas of modern life, the internet has contributed significantly to the capacity of academics, true-believing crusaders and self-interested

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<sup>264</sup> Mandreker Bahall and Mark Edwards (n 216). The authors describe these as “push and pull factors”.

<sup>265</sup> Jaron Harambam and Stef Aupers, ‘Contesting epistemic authority: Conspiracy theories on the boundaries of science’ (2015) 24(4) *Public Understanding of Science* 466, 467, “Conspiracy theories are ... not new. Narratives about the malevolent acts of Jews or the secret societies of Templars, Rosicrucians, Illuminati, and Freemasons have been circulating in Western societies at least since the crusades in the early Middle Ages ... Although such theories about an “exotic Other” still exist, some scholars argue that conspiracy theories are nowadays increasingly about our “own” modern societies, its institutions, and agents ... Contemporary conspiracy theories address the “enemy within” ... — the secret and malicious forces that lurk beyond the surface of modern society and operate within the institutions of politics, the medical industry, multinationals, and the laboratories of scientists. By formulating such alternative accounts about the “real truth”—about “what is the case” and “what lies behind it” - conspiracy theorists contest the epistemic authority of science. They openly resist the “regime of truth” ... through which science has “the legitimate power to define, describe and explain bounded domains of reality””.

<sup>266</sup> Marjaana Lindeman, ‘Motivation, cognition and pseudoscience’ (1998) 39 *Scandinavian Journal of Psychology* 257. The author attempts to “offer a prospect of understanding the durability and strength of pseudoscience’s popularity and the reasons why scientific evidence may perhaps never be able to abolish pseudoscientific beliefs”. See also, Robert McDougall, ‘Strange enthusiasms: A brief history of American pseudoscience’ <[www.columbia.edu/cu/21stC/issue-3.4/macdougall.html](http://www.columbia.edu/cu/21stC/issue-3.4/macdougall.html)> accessed 10 January 2016.

charlatans alike for instant, prolific,<sup>267</sup> and unfiltered<sup>268</sup> global information propagation. This has impacted modern healthcare in a multitude of ways, from facilitating information sharing between physicians,<sup>269</sup> to allowing sufferers of particular medical conditions to seek support in like-minded online communities<sup>270</sup> or spreading fear about everything from eggs<sup>271</sup> to chemotherapy.<sup>272</sup>

The internet has also had a profound effect on the physician-patient dynamic, the quality of which, as discussed above, plays a key role in patient decision-making. Among the positive contributions made in this respect have been:

- i. The overall increase in patient knowledge<sup>273</sup> - this may allow the physician, in some cases, to provide more detailed or relevant information to the individual patient in their short consultation period than if they were required to explain a particular condition or treatment from general first principles;
- ii. The shift in the established knowledge and power balance,<sup>274</sup> ensuring that physicians, while still necessarily and appropriately respected, do not attract the blind and unquestioning deference which has not always contributed positively to patient care<sup>275</sup>;
- iii. Increased control for the patient in respect of their healthcare, where they have some knowledge and input. This may lead to better compliance with a medical protocol or greater acceptance of the limitations of their treatment.<sup>276</sup>
- iv. Patients may, in some cases, present new or helpful ideas not previously considered by their physician. This may include the integration of CAM practices into their personal treatment regime.

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<sup>267</sup> Kenneth Cukier, 'Data, data everywhere' *The Economist* (25 February 2010), "Information has gone from scarce to superabundant" <[www.economist.com/node/15557443](http://www.economist.com/node/15557443)> accessed 8 March 2016.

<sup>268</sup> Joseph A Diaz and others, 'Patients' use of the internet for medical information' (2002) 17(3) *Journal of General Internal Medicine* 180, 183.

<sup>269</sup> Lee C Ventola, 'Social media and health care professionals: Benefits, risks, and best practices' (2014) 39(7) *Pharmacy and Therapeutics* 491.

<sup>270</sup> *ibid* 495.

<sup>271</sup> J David Spence and others, 'Egg yolk consumption and carotid plaque' (2012) 224(2) *Atherosclerosis* 469. This study compared the danger arising from the cholesterol content of eggs with the dangers of smoking on atherosclerotic changes. The contents of the paper have unsurprisingly been publicised by several mainstream media outlets, but its credibility has been roundly questioned in subsequent issues of the same academic journal, with pithy titles such as Dylan Oliver and others, 'Putting eggs and cigarettes in the same basket; are you yolking?' (2013) 227(1) *Atherosclerosis* 184, and Lucan SC, 'Egg on their faces (probably not in their necks); the yolk of the tenuous cholesterol-to-plaque conclusion' (2013) 227(1) *Atherosclerosis* 182.

<sup>272</sup> Dani Veracity, 'Killer cancer treatment: How toxic chemotherapy kills both cancer cells and cancer patients' (2005) <[www.naturalnews.com/012727\\_chemotherapy\\_cancer\\_treatments.html](http://www.naturalnews.com/012727_chemotherapy_cancer_treatments.html)> accessed 10 January 2016.

<sup>273</sup> Joseph A Diaz and others (n 268) 184.

<sup>274</sup> Felicity Goodyear-Smith and Stephen Buetow (n 24) 451.

<sup>275</sup> *ibid* 450-51. See, for example, Judge Maureen Harding Clarke (n 142).

<sup>276</sup> Felicity Goodyear-Smith and Stephen Buetow (n 24) 451-52.

- v. Patients may obtain public health information through the internet more expeditiously than they otherwise would and may themselves contribute to the dissemination of that information through various forms of social media. If the initial integrity of the information is maintained,<sup>277</sup> this is a powerful tool in public health education.

However, the efficiency and openness of the internet also contributes to the spread of misinformation, which critically undermines the necessary and appropriate authority of physicians, the objectives of public health measures and the reputation of conventional medicine as a whole, while promoting ‘safe’, ‘natural’ or ‘traditional’ alternatives, which are often not as claimed.<sup>278</sup>

#### **5.1.1 THE IMPACT OF MISINFORMATION ON HEALTHCARE AND THE DECISION TO USE CAM**

The influence of the internet on the embrace of CAM and the rejection of conventional medicine should not be underestimated. While the widespread availability of CAM raises questions of consumer protection, as noted throughout this thesis, one of its most worrying areas of impact is in public health and, in particular, in the fields of prophylaxis and vaccination. Parents seeking online information on vaccines may encounter ample content for and against their administration. While pro-vaccination websites may argue for the protection they provide from, for example, measles (which may be considered by some to be a trivial childhood illness, despite the fact that it caused 114,900 deaths globally in 2014, even with a vaccination rate of 85%),<sup>279</sup> anti-vaccination websites, often with deceptively authoritative names such as the ‘International Medical Council on Vaccination’,<sup>280</sup> promote the benefits of contracting measles and warn against the toxic ingredients and effects of the vaccines and the

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<sup>277</sup> Unfortunately, this is not a given. See Karl Vance, William Howe and Robert P Dellavalle, ‘Social internet sites as a source of public health information’ (2009) 27(2) *Dermatologic Clinics* 133. The authors, while recognising the role of social media in public education, cite the potential for blind authorship, lack of source citation, and presentation of opinion as fact as potential problems for those seeking information.

<sup>278</sup> Chor Kwan Ching and others, ‘Adulteration of herbal antidiabetic products with undeclared pharmaceuticals: A case series in Hong Kong’ (2012) 73(5) *British Journal of Clinical Pharmacology* 795. See also, Junhua Zhang and others, ‘The safety of herbal medicine: From prejudice to evidence’ (2015) 2015 *Evidence-based Complementary and Alternative Medicine eCAM* 316706, “Advocates will advertise that herbal medicine originated from nature and belongs to green therapy and has no toxin or adverse effect and people can take it in the long term and so forth. These sayings are slogans of the advocates which have misled people with less medical knowledge”.

<sup>279</sup> World Health Organisation, ‘Measles’ (2016) <[www.who.int/mediacentre/factsheets/fs286/en/](http://www.who.int/mediacentre/factsheets/fs286/en/)> accessed 5 January 2016.

<sup>280</sup> International Medical Council on Vaccination <[www.vaccinationcouncil.org](http://www.vaccinationcouncil.org)> accessed 1 January 2016.

medical interference in the ‘natural’ course of the disease.<sup>281</sup> While the sites visited by concerned parents often have a specific focus on health issues, similar content is also highly visible on non-targeted social media sites, such as Facebook<sup>282</sup> and Pinterest,<sup>283</sup> further aiding dissemination.

Where a parent is convinced, either of the dangers of vaccination or by the appealing tableau of ‘nature taking its course’, they may then seek a medical system which concurs. This is unlikely to be conventional medicine, practitioners of which are frequently labelled as “pushers” of vaccination,<sup>284</sup> but rather CAM, which often proclaims the benefits of natural medicine,<sup>285</sup> has been found to exhibit an anti-vaccination bias<sup>286</sup> and may even offer alternative vaccination products or protocols.<sup>287</sup> This, as noted in Chapter 3, endangers, not only the child left unvaccinated by parental choice, but other children who may be unvaccinated by necessity. It also decreases herd immunity, impacting community and wider levels of disease protection.

This bias is unfortunately not short-lived. Once the misinformation has been disseminated and anti-vaccination views have been formed, even correcting the inaccuracies to show that there is no link between vaccine and injury does not reinstate the intention to vaccinate.<sup>288</sup> This may affect, not only subsequent children in a family but future generations, given the significant influence of personal testimony on healthcare decision-making, discussed below.<sup>289</sup>

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<sup>281</sup> Viera Scheibner (n 247).

<sup>282</sup> Rachel Buchanan and Robert D Beckett, ‘Assessment of vaccination-related information for consumers available on Facebook’ (2014) 31(3) Health Information and Libraries Journal 227.

<sup>283</sup> Jeanine Guidry and others, ‘On pins and needles: How vaccines are portrayed on Pinterest’ (2015) 33(39) Vaccine 5051.

<sup>284</sup> Ethan Huff, ‘Pharma-connected vaccine pushers chemically abuse children in push for medical tyranny’ (2015) <[www.naturalnews.com/048701\\_mandatory\\_vaccination\\_medical\\_tyranney\\_pharmaceutical\\_propaganda.htm](http://www.naturalnews.com/048701_mandatory_vaccination_medical_tyranney_pharmaceutical_propaganda.html)l> accessed 4 January 2016.

<sup>285</sup> ‘Alliance for Natural Health International – About Us’ <[http://anhinternational.org/about-us\\_2/](http://anhinternational.org/about-us_2/)> accessed 16 February 2016.

<sup>286</sup> Edzard Ernst, ‘Rise in popularity of complementary and alternative medicine: Reasons and consequences for vaccination’ (2001) 20 (Suppl 1) Vaccine S90, S92. See also, World Health Organisation, ‘Bulletin of the World Health Organization’ (2008) 86(6) 425, “[t]he Internet has ... become a forum for alternative medicine practitioners to present their anti-vaccination ideas and promote alternative products”.

<sup>287</sup> Kate Birch, ‘Vaccine free – homeopathic education for the immune system’. The author provides a homeopathic preventative protocol for measles using disease tissue called ‘nosodes’. There is currently no high-quality evidence to support the efficacy of this protocol <<https://vaccinefree.wordpress.com/infectious-disease-prevention-homeopathy/measles-alternative-prevention-mn/>> accessed 4 January 2016. See also ‘Nosodes: Homeopathic alternative to vaccines’ <[www.thehealthyhomeeconomist.com/nosodes-homeopathic-alternative-to-vaccines/](http://www.thehealthyhomeeconomist.com/nosodes-homeopathic-alternative-to-vaccines/)> accessed 4 January 2016.

<sup>288</sup> Brendan Nyhana and Jason Reifler, ‘Does correcting myths about the flu vaccine work? An experimental evaluation of the effects of corrective information’ (2015) 33(3) Vaccine 459

<sup>289</sup> Elihu Katz and Paul Lazarsfeld, *Personal Influence, the Part Played by People in the Flow of Mass Communications* (Free Press 1966) 175f.

### 5.1.2 THE IMPACT OF INCOMPLETE OR DECONTEXTUALISED INFORMATION

Another area of risk for the dissemination of misinformation is in disease prophylaxis and treatment. Some CAM sites provide information on alternative prophylactic treatments for malaria, a highly dangerous tropical disease responsible for an estimated 438,000 deaths in 2015.<sup>290</sup> Where travellers seek alternatives to the often-unpleasant and well-documented side effects of anti-malarial drugs,<sup>291</sup> they may encounter CAM websites, containing very convincing information on how unsafe, inefficacious and profit-driven conventional medicine is and how natural, alternative treatments or no treatment at all are the healthier choices.<sup>292</sup> Some sites recommend the use of artemisinin, a product which is used as part of traditional herbal medicine, to treat malaria.<sup>293</sup> Diligent lay researchers may seek confirmation of this from trusted sites belonging to credible sources such as the World Health Organisation or US Centre for Disease Control. However, they may not realise that artemisinin should only be used as part of an artemisinin combination therapy (ACT) (a combination antimalarial drug in which artemisinin is one component) and never as a monotherapy (on its own).<sup>294</sup> This and similar decontextualised and selective fact publication by some CAM sites worsens already-serious public health risks (in this particular case, by increasing the potential for drug resistance and decreasing the likelihood of a full and expeditious cure for the individual consumers in question), while also convincing the general public of the veracity of their claims and the validity and power of their practices. Sadly, it is an approach which is not limited to malaria,<sup>295</sup> and is one which worsens the risk to public

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<sup>290</sup> World Health Organisation, *World Malaria Report 2015* (World Health Organization 2015) 40.

<sup>291</sup> NHS, 'Anti-Malarial Medication' (2015) <[www.nhs.uk/Conditions/Malaria/Pages/Treatment.aspx](http://www.nhs.uk/Conditions/Malaria/Pages/Treatment.aspx)> accessed 2 March 2016.

<sup>292</sup> Didi A Ruchera, 'The use of homeopathic prophylaxis and treatment for malaria in endemic areas of Kenya' (2010), "The scientific allopathic community entirely misses the boat on the treatment of infectious diseases. The approach itself is defective. One of the major defects in the conventional approach is the futile search for the so-called "active ingredient" in any natural substance in order to isolate it, analyze it, and then chemically synthesize it in order to mass produce it. Of course this approach maximizes profit for the lucky pharmaceutical company that can produce such a product. But unfortunately, Mother Nature doesn't work that way, and hence man-made drug-resistant bugs that are more dangerous and virulent are polluting our home (Earth), and endangering the lives of millions of people. We humans are building our own tombs with this misguided, greed-inspired approach to medicine" <<http://hpathy.com/homeopathy-papers/the-use-of-homeopathic-prophylaxis-and-treatment-for-malaria-in-endemic-areas-of-kenya/>> accessed 14 March 2016.

<sup>293</sup> 'Artemisinin: Herbal treatment that really works for malaria' (2006) <<http://articles.mercola.com/sites/articles/archive/2006/12/30/herbal-treatment-that-really-works-for-malaria.aspx>> accessed 4 January 2016.

<sup>294</sup> World Health Organisation, 'WHO calls for an immediate halt to provision of single-drug artemisinin malaria pills' (2006), "The use of single-drug artemisinin treatment – or monotherapy – hastens development of resistance by weakening but not killing the parasite" <[www.who.int/mediacentre/news/releases/2006/pr02/en/](http://www.who.int/mediacentre/news/releases/2006/pr02/en/)> accessed 16 March 2016.

<sup>295</sup> Debby Bruck, 'Strains of drug resistant tuberculosis in India' (2012), "A groundbreaking new study showing that vitamin C can kill drug resistant tuberculosis could pave the way for the nutrient to go into widespread use as an effective defence against many diseases, says a top holistic physician ... Researchers reported in the journal *Nature Communications* that the vitamin killed off TB bacteria by itself without the drug" <[www.homeopathyworldcommunity.com/forum/topics/strains-of-drug-resistant-tuberculosis-in-india](http://www.homeopathyworldcommunity.com/forum/topics/strains-of-drug-resistant-tuberculosis-in-india)> accessed 5 January 2016. The study in question, Catherine Vilchèze and others, 'Mycobacterium tuberculosis

health, particularly in developing countries without an infrastructure sufficient to cope with an increase in infection rates.

### 5.1.3 THE ROLE OF HEALTH LITERACY

Along with the potential benefits arising from utilisation of the internet as a source of healthcare information, broad deficiencies in critical thinking and health literacy have become more apparent,<sup>296</sup> increasing risk of physical and financial harm to patients and consumers. Health literacy has been defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions”.<sup>297</sup> Poor health literacy has been linked, not only with higher levels of hospitalisation,<sup>298</sup> but also with decreased understanding of preventative lifestyle choices. Adolescents, for example, have been found to have difficulty in detecting advertising, government misinformation and propaganda.<sup>299</sup> Allied to this may also be a lack of understanding of the standards of evidence supporting the safety and efficacy of medical therapies. However, although lower levels of education are indicative of lower levels of health literacy, this may not be decisive of CAM use.

In Ireland and elsewhere, the predominant users of CAM are well-educated,<sup>300</sup> suggesting that educational level may not be determinative of health literacy, given the lack of evidence in favour of safety and efficacy.

Healthcare information sourced on the internet, though potentially accurate, may also be misunderstood by patients.<sup>301</sup> This had led to requests for inappropriate diagnostic procedures or treatments,<sup>302</sup> with which physicians then felt compelled to comply, for

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is extraordinarily sensitive to killing by a vitamin C-induced Fenton reaction’ (2013) 4 Nature Communications 1881, did not, in fact, recommend the use of vitamin C as a monotherapy for tuberculosis, but suggested, based on *in vitro* testing, that the addition of an oxidative component such as vitamin C to a drug complex may improve the efficacy of the treatment.

<sup>296</sup> Eszter Hargittai and others, ‘Trust online: Young adults’ evaluation of web content’ (2010) 4 International Journal of Communication 468, 470, “Generally speaking, research has found, across a wide range of ages in both online and offline contexts, that people have difficulty with these skills. While children are exposed to online media at an increasingly early age, studies have shown that many adolescents do not possess the expertise required to search the Web efficiently or critically assess the credibility of what they find”.

<sup>297</sup> US Department of Health and Human Services, *Healthy People 2010* (Government Printing Office 2000) 11-20.

<sup>298</sup> David W Baker and others, ‘Health literacy and the risk of hospital admission’ (1998) 13(12) Journal of General Internal Medicine 791, 794.

<sup>299</sup> Leah Graham and Pangiotis Metaxas, “Of course it’s true; I saw it on the internet!”: Critical thinking in the internet era’ (2003) 46(5) Communications of the ACM 70, 73.

<sup>300</sup> Patricia Fox and others (n 2), and Rebecca M Widder and Douglas C Anderson (n 6).

<sup>301</sup> Monica Mureroa and Ronald E Rice, *The Internet and Health Care: Theory, Research, and Practice* (Taylor & Francis 2013) xix.

<sup>302</sup> Gunther Eysenbach and Christian Kohler, ‘Does the internet harm health? Database of adverse events related to the internet has been set up’ (2002) 324(7331) British Medical Journal 239.

fear of undermining the patient-physician relationship.<sup>303</sup> This is costly, inefficient and ethically questionable but those unwilling to accede to such unreasonable requests risk their patients seeking care elsewhere.

## 5.2 ANECDOTAL EVIDENCE AND PERSONAL TESTIMONY

Personal influence is considered to be highly effective in directing decision-making<sup>304</sup> and the testimony of friends and family as to the benefits of CAM is a similarly well-documented and powerful factor in healthcare decision-making. Not only do those speaking in favour of a CAM treatment or, particularly, of its efficacy for a serious illness, provide significant weight and power to the argument for its use by others in similarly dire situations, but it also lends credence to its efficacy for less serious conditions. After all, if it works for something as serious as cancer, it must be powerful enough to treat a minor infection/stomach pain/headache. This is, of course, another example of fallacious reasoning, with most available CAM therapies unsupported by high quality evidence of safety and efficacy.

Mountfield et al<sup>305</sup> place the responsibility for patient reliance on the opinions of friends and family squarely at the feet of physicians, whose underwhelming communication skills have precipitated the desire for patients to seek their information elsewhere.<sup>306</sup>

Whereas pre-internet healthcare decisions were subject to a greater element of self-selection bias (information would be gleaned from special-interest publications, alternative healthcare providers specifically visited by the individual seeking information, or through peer recommendation, which is also subject to selection and confirmation biases), CAM internet sources are instantly accessible to all and are not, by design, always distinguishable from conventional health sites.

The gravitation towards CAM may not simply be a result of positive CAM marketing, negative publicity in relation to wrongs in the conventional sector or any of the other individual factors mentioned above but a combination of many of these. Conventional medicine has itself contributed to its downturn in popularity and to the position in which consumers now find

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<sup>303</sup> Robert A Bell, Michael S Wilkes and Richard L Kravitz, 'Advertisement-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses' (1999) 48(6) *Journal of Family Practice* 446.

<sup>304</sup> Elihu Katz and Paul Lazarsfeld (n 289) 175f. The authors repeatedly reinforce the significance of personal influence in purchasing decisions and the comparably limited efficacy of other forms of marketing. The impact of anecdotal evidence on consumer decision-making is significant based on the responses from the short questionnaire disseminated as part of the research for this thesis. See Chapter 6.

<sup>305</sup> Réme Mountifield and others, 'Doctor communication quality and friends' attitudes influence complementary medicine use in inflammatory bowel disease' (2015) 21(12) *World Journal of Gastroenterology* 3663.

<sup>306</sup> *ibid* 3668, "The quality of patient doctor communication is a key determinant, and failure to actively address CAM use in consultation may promote patient "default" to other advice sources such as family, friends and other social contacts, which ultimately undermines the patient doctor relationship".

themselves. With the significant benefits of medicine come risks and those risks have been magnified by profit motivations and human failures, all of which have been widely publicised and condemned, but nowhere more visibly or accessibly than online, making global indignation part of the normal conversation rather than a focused reaction to what are disturbing and inexcusable but, nonetheless, relatively rare occurrences in conventional medicine overall.

### 5.3 THE RISE OF FALSE EQUIVALENCE

Finally, modern journalism, in an effort to ensure balance in reporting, has instead resorted to false equivalence, which may be neatly described as “the practice of giving equal media time and space to demonstrably invalid positions for the sake of supposed reportorial balance”.<sup>307</sup> This may manifest as having a respirologist and a homeopath discussing the most effective treatment for asthma, or an immunologist and a celebrity debating the individual and public health implications of vaccination.<sup>308</sup> One viewpoint is supported by clinical evidence, the other is not, but is treated as being equally valid, creating that impression in the minds of audience members and affecting healthcare choice. This increases risk, as “Ultimately, negative health outcomes could occur if media sources are influencing patients to take unproven products, quit effective medications or undergo unsanctioned procedures”.<sup>309</sup> To suggest, in the course of an interview or debate, that patients should stop conventional therapy for an established medical condition or that they should try an unproven alternative, would be an unethical and professionally dangerous stance for a conventional medical practitioner to take, but it is one that is more likely to be taken by a CAM practitioner, who is, during that interview, treated and, consequently, viewed as, a contributor of equal validity and stature. This is a worrying situation, and one which is exacerbated by the aforementioned lack of health literacy. Journalists should perhaps consider, not only the importance of fact and evidence in accurate reporting, or the vital role it plays in public health education, but also that reporting on an issue with evidence heavily favouring one side is not *per se* biased. Appropriate balance is not obtained by unfairly weighting the argument with less evidence behind it.

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<sup>307</sup> Bob Garfield, ‘False equivalence: How ‘balance’ makes the media dangerously dumb’ *The Guardian* (11 October 2013) <[www.theguardian.com/commentisfree/2013/oct/11/false-equivalence-balance-media](http://www.theguardian.com/commentisfree/2013/oct/11/false-equivalence-balance-media)> accessed 16 September 2016.

<sup>308</sup> Nicole Bootsman, David F Blackburn and Jeff Taylor, ‘The Oz craze: The effect of pop culture media on health care’ (2014) 147(2) *Canadian Pharmacists Journal* 80.

<sup>309</sup> *ibid.*



## CONCLUSION

Medicine, as observed by Ben Goldacre, is broken.<sup>310</sup> The fundamentals of conventional medicine, encompassing its strong ethical framework, Hippocratic goals, and established, statutory standards of accountability are undoubtedly an admirable starting point on paper, but implementation of these elements has frequently been found wanting. Breaches of ethics, good practice and legality have undoubtedly sullied the image and the reputation of conventional medicine and its allied professions, and have cost countless lives. Meanwhile, the CAM system, with what are perhaps equally benevolent and meritorious objectives, has its therapies derided or dismissed outright by conventional practitioners and supporters and the sector as a whole goes largely ignored by the legislature. This is an unfair situation. However, the difference in treatment is not unmerited. Out of conventional medicine, despite its follies, have come refined therapeutic methods and products, which have eased suffering, have saved substantially more lives than they have taken, and have increased human longevity in their modern form.<sup>311</sup> Its problems are not unrecognised by the profession itself, even if resolution has not come quickly in many cases, and many of these failures, such as the use of questionable trial methodology, giving inaccurate but predictably favourable results,<sup>312</sup> non-or-incomplete disclosure of key study data,<sup>313</sup> misleading statistical analysis used for marketing,<sup>314</sup> and the failure of regulators to intervene in a timely manner, are notable in both conventional medicine and CAM.

The case studies set out in Part I demonstrate failures of systems, ethics, reason or decency. Conventional medicine itself is not at fault, but rather those who practice it. Where the pure data is analysed and the human ‘noise’ removed, the data speaks for the safety and efficacy, for better or worse. For CAM, with its limited, if expanding, data volumes, and little by way of convincing evidence supporting the safety and efficacy of a great majority of its therapies, the interpersonal skills of its practitioners contribute significantly to the value and substance of the therapies.

The ills of conventional medicine do not change the lack of evidence underpinning much of CAM. They should not distract from the misleading CAM practices in respect of the description, marketing, risks and limitations of CAM therapies, nor do they prevent the CAM sector from rising to the challenges of demonstrating safety and efficacy to the same standard as conventional medicine. Reliance on specially-tailored licencing regimes and augmented research methodologies keeps CAM separate, instead of facilitating its acceptance alongside the mainstream, in whatever capacity. There are often many potential treatment regimens for individual conditions in conventional medicine and

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<sup>310</sup> Ben Goldacre, *Bad Pharma: How Medicine is Broken, And How We Can Fix It* (Harper Collins Publishers 2012) ix.

<sup>311</sup> Charles McConnel and Leigh Turner, ‘Medicine, ageing and human longevity’ (2005) 6(Suppl 1) EMBO Reports S59, S60.

<sup>312</sup> Joseph Glenmullen (n 71) 2-3.

<sup>313</sup> Kirby Lee, Peter Bacchetti and Ida Sim, ‘Publication of clinical trials supporting successful new drug applications: A literature analysis’ (2008) 5(9) PLoS Medicine e191 1348, 1349.

<sup>314</sup> *United States v GlaxoSmithKline* (n 72) [56]-[57].

there is no reason why CAM could not add one, two, or ten more, provided that they can meet the same standards as the others.

It is imperative, as we proceed to Chapter 3 to examine some of the failures in consumer protection which can be associated with CAM, that we do not ignore or forget the very grave failures of the better funded, tighter regulated, longer established and highly esteemed conventional medical sector. Aside from the perspective and humility that such reflection affords, it may also serve as a reminder of actions, structures and processes best avoided in any novel regulatory mechanism.

## **SECTION B**



## CHAPTER 3

### CAM AND THE CONSUMER

#### INTRODUCTION

While the principle '*caveat emptor*' is unlikely to disappear from the realm of consumer affairs in the foreseeable future, we nonetheless progress towards the development a well-delineated and thoughtfully-composed system of protection for consumers whose reasonable diligence and care is not sufficient to prevent their eventuating loss or harm, whether physical, psychological or financial, direct or indirect. In view of the risks inherent in the use of untested, unproven, or merely unregulated medical products or services by members of the public, consumer protection is significantly compromised by their unfettered and widespread advertisement and availability.

Very many of the claims made by those providing CAM products and services lack substantiation by high-quality research. Consumers relying on these claims are at risk of harm, arising either from the CAM therapy itself or as a result of using such a therapy and consequently either delaying or declining to seek conventional medical care. The consequences for some of these consumers have been tragic. Untreated cancers,<sup>1</sup> tissue necrosis and permanent disfigurement from attempts to remove cancerous growths using corrosive 'natural' pastes,<sup>2</sup> cerebrovascular accident caused by cervical spinal manipulation,<sup>3</sup> and septicaemia and death from inappropriate CAM treatment of childhood eczema,<sup>4</sup> a common and relatively minor dermatological condition, are just a few of many serious sequelae and indirect harms arising from the use of CAM therapies. Others are described in detail at various points throughout this thesis.<sup>5</sup>

The sale and supply of CAM products and services in this jurisdiction poses a problem for regulators in their role as consumer guardian. However, engagement with the issue has been underwhelming, as evidenced, not only by the clear and abundant availability of CAM therapies on the Irish market, but also in the lack of acknowledgement of CAM or any associated consumer protection issues by

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<sup>1</sup> Barrie Cassileth and Ian Yarett, 'Cancer quackery: The persistent popularity of useless, irrational 'alternative' treatments' (2012) 26 *Oncology* 754.

<sup>2</sup> Felicia Saltzberg and others, 'Deforming self-treatment with herbal "black salve"' (2009) 35 *Dermatologic Surgery* 1152. The modern fixation with 'naturalness' is discussed in Chapter 2 and was evident in the results of the questionnaire in Chapter 6. Here, 46% of respondents said that 'naturalness' was a motivation for their use or procurement of a particular CAM therapy.

<sup>3</sup> Edzard Ernst, 'Adverse effects of spinal manipulation: A systematic review' (2007) 100 *Journal of the Royal Society of Medicine* 330.

<sup>4</sup> *R v Thomas Sam; R v Manju Sam (No. 18)* [2009] NSWSC 1003.

<sup>5</sup> For example, the use of chelation therapy in the 'treatment' of autism spectrum disorder, discussed in Chapters 4 and 5, or the use of homeopathic remedies as an alternative to prophylaxis or vaccination, discussed in Chapter 2.

the Competition and Consumer Protection Commission, formerly the National Consumer Agency, in their annual reports.<sup>6</sup> This is clearly suboptimal.

While the broad suite of consumer protection legislation *inter alia* prohibits the use of unfair or misleading claims in the formation of a consumer contract<sup>7</sup> or provides for redress where a product fails to meet the requisite level of merchantability,<sup>8</sup> its utility is largely undermined by its lack of enforcement in respect of the sale of CAM products, by an ill-equipped mechanism for oversight and enforcement in the area of CAM services, and by the substantive legislation governing medicinal products for human use.<sup>9</sup> It is to these shortcomings that this chapter is addressed.

The chapter is divided into two parts. Part I provides a substantive discussion of the Irish consumer landscape for the sale of CAM products, with emphasis on three core pieces of consumer legislation: the Consumer Protection Act 2007 (hereafter “the 2007 Act”); the Liability for Defective Products Act 1991 (hereafter “the 1991 Act”); and the Sale of Goods and Supply of Services Act 1980 (hereafter “the 1980 Act”). As noted previously,<sup>10</sup> a number of concerns arise in relation to the relative risk-benefit ratio of CAM treatments, the extent to which consumers understand the nature of what they are procuring, and whether there is any onus of disclosure on CAM providers, particularly given the lack of mandated ethical parameters similar to those applicable within the parallel realm of conventional medicine. However, disclosure is also central to consumer protection, and unfair or misleading claims or omissions in relation to the existence of the product or any of its key characteristics may be actionable under the 2007 Act.

The protection of CAM consumers has been further complicated by the apparent conflict between consumer protection legislation and the existing legislative framework governing medicinal products for human use. Whereas the former demands, among many other things, clear and accurate labelling, prohibiting the use of false or misleading claims, the latter permits the use of archaic units of measurement which are not easily legible by the public, accepts extremely low standards of evidence for efficacy, such as homeopathic provings or evidence of use of a particular herbal substance in the state for a specified condition over a prolonged period of time (where evidence is required at all) and facilitates the marketing of some products (most notably, homeopathic medicinal products) through significantly less rigorous licencing schemes than others. This is consolidated by the sale of CAM

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<sup>6</sup> CCPC Annual Reports <[www.ccpc.ie/consumers/about/annual-reports/](http://www.ccpc.ie/consumers/about/annual-reports/)> accessed 19 September 2017. If reports exist but are not accessible by the public, the problem remains the same.

<sup>7</sup> Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council [2005] OJ L179/22, as implemented in Ireland by the Consumer Protection Act 2007.

<sup>8</sup> Sale of Goods and Supply of Services Act 1980.

<sup>9</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 as implemented in Ireland by Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540.

<sup>10</sup> See Chapter 1.

medicinal and other products by pharmacists, which is in contravention of the Code of Conduct of the Pharmaceutical Society of Ireland<sup>11</sup> and which may contribute further to consumer confusion and loss of trust in the sector.

The cognitive dissonance between legislators demanding, on the one hand, transparency and clarity in the information provided to consumers, while simultaneously facilitating the establishment and perpetuation of a Byzantine, multi-tiered regulatory mechanism for medicinal products for human use on the other, is disquieting and requires urgent reconsideration. In order to determine how best to limit potential deleterious effects on the consumer, the prospect of governmental intervention and oversight must be broached, although this carries with it a perceived validation that is, as yet, unearned by the sector. Nonetheless, such difficulties cannot comprise a sufficient excuse to simply accept the status quo. Part I thus concludes that, while consumer law in Ireland is reasonably protective in nature and that normal rules governing the sale of goods should apply to and be appropriately enforced in the CAM sector, the Irish consumer remains vulnerable to confusion and manipulation when confronted with a CAM product directly or indirectly offering a cure.

Part II provides a discussion of the available protections for consumers of CAM services, with particular emphasis on the provisions of the 1980 Act requiring that the service provider possess the necessary skills to provide such a service, and that the service be provided with due skill, care and diligence. The standards for CAM practices vary between factions in each discipline, and obtaining or producing a definitive statement on capacity to provide a particular service, and on what level of care, skill or diligence is required for that service, is not as simple as it seems. The questions of who sets the standards and on what basis, are key. The *laissez faire* approach taken by Irish regulators allows innovative practitioners to establish their own therapy, or branch of an existing therapy, with its own unique standards, and to provide services freely within those manufactured and ultimately fluid parameters, which is a worrying situation for consumers, for whom certainty and standardisation is vital.

However, these entrepreneurial anomalies aside, existing therapies provide plenty of food for thought. Chiropractic, an established CAM service which, alongside osteopathy, is statutorily self-regulated in the UK<sup>12</sup> and elsewhere, provides a CAM framework within which the application and applicability of the 1980 Act and the European Communities (Unfair Terms in Consumer Contracts) Regulations 1995<sup>13</sup> may be considered. While discussion of the esoteric, philosophical and theoretical aspects of CAM and its regulation lends depth and texture to the analysis in this thesis, such analysis ultimately addresses real world issues and must remain rooted in pragmatism.

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<sup>11</sup> Pharmaceutical Society of Ireland, 'Code of Conduct for Pharmacists' (PSI 2009).

<sup>12</sup> By the UK Chiropractors Act 1994 and the UK Osteopaths Act 1993, respectively.

<sup>13</sup> Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts [1993] OJ L95/29, as implemented by European Communities (Unfair Terms in Consumer Contracts) Regulations 1995, SI 1995/27.

Of particular relevance in the 1995 Regulations are the prohibitions in sch 3 of terms inappropriately excluding or limiting the legal rights of the consumer vis-à-vis the seller or supplier or another party in the event of total or partial non-performance or inadequate performance by the seller or supplier of any of the contractual obligations, including the option of offsetting a debt owed to the seller or supplier against any claim which the consumer may have against him,<sup>14</sup> and terms giving the seller or supplier the right to determine whether the goods or services supplied are in conformity with the contract, or giving him the exclusive right to interpret any term of the contract.<sup>15</sup> The 1995 Regulations represent an attempt to limit the imbalance in power between businesses and consumers, and form a particularly important piece of the framework for future CAM service regulation.

The chapter concludes that the continued sale of CAM goods demands increased scrutiny from consumer advocates, particularly given the unsubstantiated nature of many of the claims,<sup>16</sup> direct or indirect, made by their producers, in contravention of the ‘claim to cure’ provisions of the 2007 Act<sup>17</sup> (s 55(1)(5) of the Act states, “A trader shall not engage in ... a representation that a product is able to cure an illness, dysfunction or malformation, if it cannot”), among other issues relating to the merchantability of such products.

It is argued that the clear conflict between consumer protection and medicinal product legislation presents a significant obstacle in the road to consumer enlightenment and that an overhaul is required to standardise and simplify the process of registration, leaving only a single, high-quality mechanism for medicinal product authorisation and increasing consumer clarity overall.<sup>18</sup>

Finally, it is asserted that the provision of a CAM service is a positive act and that there ought to be a greater onus placed on service providers to provide therapies that are safe, effective, standardised and ethical, delivered with due skill, care and diligence,<sup>19</sup> and in compliance with statutory obligations,<sup>20</sup> while ensuring that any condition not treatable by them be referred to a conventional

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<sup>14</sup> European Communities (Unfair Terms in Consumer Contracts) Regulations 1995, SI 1995/27, sch 3, 1(b).

<sup>15</sup> *ibid* sch 3, 1(m).

<sup>16</sup> Noted at various points throughout the chapter are the sale of anti-snoring jewellery, anti-arthritis jewellery, detoxifying foot patches, medicinal products with no active ingredient present in them, a lethal toxin masquerading as a neglected cancer panacea, and numerous herbal remedies, which are not only potentially dangerous in themselves but can also cause serious complications due to their propensity for dangerous interactions with other medicinal products, both CAM and conventional.

<sup>17</sup> Consumer Protection Act 2007, s 55(1)(5) states, “A trader shall not engage in ... a representation that a product is able to cure an illness, dysfunction or malformation, if it cannot”.

<sup>18</sup> It is acknowledged, however, that this may adversely affect those therapies with scientific viability and evidence of efficacy, which, by reason of complexity and lack of resources, may be unable to fulfil the requirements of the Product Authorisation mechanism. Some herbal products fall within this category.

<sup>19</sup> Sale of Goods and Supply of Services Act 1980, s 39(b).

<sup>20</sup> For example, the requirement of obtaining vetting as appropriate under the National Vetting Bureau (Children and Vulnerable Persons) Act 2012.



medical practitioner without delay.<sup>21</sup> The importance of fair terms in contracts for CAM services is also highlighted.

The widespread and prolific availability of CAM products and services, the safety and efficacy of which are often untested or unproven, appears to point to an insufficiency of consumer protection in this jurisdiction, a situation underlined by the lack of enforcement proceedings issued by the Competition and Consumer Protection Commission for the sector.<sup>22</sup> Full utilisation of existing consumer protection legislation would provide an excellent interim (or, in lieu of more comprehensive changes, permanent), relatively inexpensive, and broadly applicable method of regulating CAM and other sectors, and would require little by way of additional law. Even were this not the case, issues of expense, unpopularity or complexity must not become justifications for a lack of action in this particular area of consumer risk.

With all this in mind, we first turn to consider the issues arising in respect of the sale of CAM goods.

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<sup>21</sup> This is a subjective determination on the part of the practitioner, which may give rise to uneven application of such a standard.

<sup>22</sup> A site search of [www.ccpc.ie](http://www.ccpc.ie) showed no relevant enforcement proceedings for CAM practitioners <[www.google.ie/search?rlz=1C1CAFA\\_enIE654IE654&biw=1536&bih=710&q=site%3Awww.ccpc.ie&oq=site%3Awww.ccpc.ie&gs\\_l=psy-ab.3...798919.799333.0.799733.2.2.0.0.0.69.130.2.2.0....0...1.1.64.psy-ab..0.0.0.D6w27xW7PQM](http://www.google.ie/search?rlz=1C1CAFA_enIE654IE654&biw=1536&bih=710&q=site%3Awww.ccpc.ie&oq=site%3Awww.ccpc.ie&gs_l=psy-ab.3...798919.799333.0.799733.2.2.0.0.0.69.130.2.2.0....0...1.1.64.psy-ab..0.0.0.D6w27xW7PQM)> accessed 24 August 2017.

## **PART I**

### **THE SALE OF CAM GOODS**

*It is the natural tendency of the ignorant to believe what is not true. In order to overcome that tendency, it is not sufficient to exhibit the true; it is also necessary to expose and announce the false.*<sup>23</sup>

#### **1. KEY AREAS OF FOCUS**

In assessing whether CAM products have a case to answer under consumer law, three questions from the suite of available consumer protection legislation are of particular importance:

- (a) Are the claims made in relation to the product unfair or misleading for the purposes of the Consumer Protection Act 2007?
- (b) Is the product of merchantable quality for the purposes of the Sale of Goods and Supply of Services Act 1980?
- (c) Is the product defective under the provisions of the Liability for Defective Products Act 1991?

Each is examined in turn.

#### **2. ARE THE CLAIMS MADE IN RELATION TO THE PRODUCT UNFAIR OR MISLEADING FOR THE PURPOSES OF THE CONSUMER PROTECTION ACT 2007?**

Advertisement and the making of claims in respect of products, whether or not they induce the formation of a contract, affect the economic welfare of consumers and traders.<sup>24</sup> Without necessarily realising what they are,<sup>25</sup> consumers may have encountered, or even purchased, products from brands such as Helios, Weleda, Nelsons or Bach Original Flower Remedies (part of the Nelsons brand and

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<sup>23</sup> Henry Louis Mencken and Marion Elizabeth Rodgers, *H.L. Mencken: Prejudices, Fourth, Fifth, and Sixth Series* (Library of America 2010) 251.

<sup>24</sup> Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising [2006] OJ L376/21, Fourth recital, Preamble.

<sup>25</sup> Andrew Gilbey and Shaun Holt, 'Beliefs about homeopathy among patients presenting at GP surgeries' (2009) 122 *New Zealand Medical Journal* 94, 95, "Contrary to expectation, our survey suggests that among patients consulting orthodox medical practitioners, the majority of respondents believe that they understand how homeopathy works, that it is supported by scientific evidence, is concentrated, and helps the condition for which it was being taken ... as most homeopathy users believed that it works despite the complete lack of scientific plausibility or evidence, there must be other explanations for its apparent success including placebo responses and confusion between clinical improvements due to homeopathy and the natural history of the illness".

one of the most well-known of which is ‘Rescue Remedy’). These are widely available from reputable pharmacies,<sup>26</sup> supermarkets,<sup>27</sup> health stores<sup>28</sup> and online,<sup>29</sup> found alongside copper bracelets sold for arthritis<sup>30</sup> and rings which claim to prevent snoring.<sup>31</sup> Yet, there is insufficient substantial evidence<sup>32</sup> that these CAM products treat the conditions represented by them,<sup>33</sup> a significant cause for concern in respect of the misleading nature of the claims and their influence on consumer decision-making.

Establishing whether a claim has been made, in order to determine whether that claim is unfair or misleading, is not quite the simple, binary process it seems. Even for those CAM medicinal products prohibited by law from providing a therapeutic indication for use (that is, the condition they ostensibly treat),<sup>34</sup> there are many other clever ways of wording and illustrating an advertisement so as to create an impression within the mind of the consumer of the curative capacity of a particular

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<sup>26</sup> A search on Mccabespharmacy.com for ‘Nelsons’ produced 7 relevant results  
<[www.mccabespharmacy.com/catalogsearch/result/?q=nelsons](http://www.mccabespharmacy.com/catalogsearch/result/?q=nelsons)> accessed 28 November 2013. The sale of CAM products by pharmacists in Ireland is of particular concern and is discussed in detail below.

<sup>27</sup> A search on Tesco.ie for ‘Nelsons’ produced 3 relevant results  
<[www.tesco.ie/groceries/product/search/default.aspx?searchBox=nelsons](http://www.tesco.ie/groceries/product/search/default.aspx?searchBox=nelsons)> accessed 28 November 2013.

<sup>28</sup> A search on Hollandandbarrett.ie for ‘Nelsons’ produced 12 relevant results  
<[www.hollandandbarrett.ie/pages/categories.asp?cid=105&searchterm=nelsons&rdcnt=1&page=2](http://www.hollandandbarrett.ie/pages/categories.asp?cid=105&searchterm=nelsons&rdcnt=1&page=2)> accessed 28 November 2013.

<sup>29</sup> A search on Amazon.co.uk for ‘Nelsons’ produced 1,048 relevant results  
<[www.amazon.co.uk/s/ref=sr\\_pg\\_2?fst=as%3Aoff&rh=n%3A65801031%2Ck%3Anelsons%2Cp\\_89%3ANelson%7CNelsons%7CNelsons+Baby%7CNelson+Bach%7CNelsons+Bach%7CNelsons+GmbH%7CNelson+Homeopathics&page=2&bbn=65801031&keywords=nelsons&ie=UTF8&qid=1450197297](http://www.amazon.co.uk/s/ref=sr_pg_2?fst=as%3Aoff&rh=n%3A65801031%2Ck%3Anelsons%2Cp_89%3ANelson%7CNelsons%7CNelsons+Baby%7CNelson+Bach%7CNelsons+Bach%7CNelsons+GmbH%7CNelson+Homeopathics&page=2&bbn=65801031&keywords=nelsons&ie=UTF8&qid=1450197297)> accessed 15 December 2015.

<sup>30</sup> Boots.ie offers ‘Boots Pharmaceuticals Silver Plated Copper Bracelet (Small/Medium)’  
<[www.boots.ie/en/Boots-Pharmaceuticals-Silver-Plated-Copper-Bracelet-Small-Medium-\\_1162472/](http://www.boots.ie/en/Boots-Pharmaceuticals-Silver-Plated-Copper-Bracelet-Small-Medium-_1162472/)> accessed 28 November 2013.

<sup>31</sup> Mccabespharmacy.com offers the ‘Good Night Anti Snoring Ring’  
<[www.mccabespharmacy.com/good-night-anti-snoring-ring-medium.html](http://www.mccabespharmacy.com/good-night-anti-snoring-ring-medium.html)> accessed 15 December 2015.

<sup>32</sup> Federal Food, Drug, and Cosmetic Act 1962, s 505(d), defined “substantial evidence of effectiveness” as, “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof”.

<sup>33</sup> Edzard Ernst, ‘Homeopathy: What does the “best” evidence tell us?’ (2010) 192 Medical Journal of Australia 458, 459, “the most reliable evidence – that produced by Cochrane Reviews – failed to demonstrate that homeopathic medicines have effects beyond placebo”. See also Stewart J Richmond and others, ‘Copper bracelets and magnetic wrist straps for rheumatoid arthritis – analgesic and anti-inflammatory effects: A randomised double-blind placebo controlled crossover trial’ (2013) 8 PLoS ONE e71529, which found, “Wearing a magnetic wrist strap or a copper bracelet did not appear to have any meaningful therapeutic effect, beyond that of a placebo, for alleviating symptoms and combating disease activity in rheumatoid arthritis”. The author was unable to find any published studies, positive or negative, relating to anti-snoring rings. However, in 2010 the Australian Competition and Consumer Commission took an action against a company selling similar rings under ss 52 and 53(c) of the Australian Trade Practices Act 1974, which respectively prohibit misleading or deceptive statements in a commercial transaction and prohibit false representations in respect of, *inter alia*, the characteristics, uses or benefits of a product. See Trade Practices Act 1974, Undertaking to the Australian Competition and Consumer Commission given for the purposes of section 87B by ATQOL Pty Ltd, ACN 086 436 615, 22 March 2010.

<sup>34</sup> Directive 2001/83/EC (n 9), art 14(1). Homeopathic medicinal products for human use registered under the Simplified Registration Scheme (SRS), are not permitted to carry a therapeutic indication.

therapy for a given condition. Inviting the consumer to extrapolate from the name of the product<sup>35</sup> or service<sup>36</sup> or through the use of broad, factual statements such as, “people commonly seek homeopathic treatment for...”,<sup>37</sup> or “allergies are often treated with chiropractic care”,<sup>38</sup> which are accurate but do not provide any information as to the effect of using these therapies on the conditions concerned, are two such practices.

Claims as to efficacy made by producers of medicinal products<sup>39</sup> for human use and of medical devices<sup>40</sup> fall under the remit of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (hereafter, “the Control of Placing on the Market Regulations”)<sup>41</sup> and under the European Communities (Medical Devices) Regulations 1994 (hereafter, “the 1994 Regulations”)<sup>42</sup> respectively. Article 2 of Directive 2001/83/EC defines ‘medicinal product’ as

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.<sup>43</sup>

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<sup>35</sup> CAM products with names such as ‘Pollenna’, ‘Noctura’, ‘Coldenza’, ‘Vertigoheel’ or ‘Tonsilotren’ give rise to inferences as to the condition for which the treatment is being sold, without stating it outright.

<sup>36</sup> CAM therapies such as applied kinesiology benefit from association with similarly-named practices such as kinesiology, the scientific study of human movement.

<sup>37</sup> Irish Society of Homeopaths (ISH), ‘What can Homeopathy treat?’, “Everything from trauma and acute or short term illness to many types of chronic conditions can be effectively treated by Homeopathy. It is impossible to list them all, however many people commonly seek homeopathic treatment for stress, anxiety, insomnia, depression, fatigue and headaches, period and fertility problems, pregnancy related conditions, menopause and children's illnesses. Other common conditions people seek homeopathic treatment for include ear, nose, throat and eye disorders, respiratory illnesses, digestive and urinary tract problems, bone, joint and skin conditions. Homeopathy may also be effective where there is no specific diagnosis” <[www.irishhomeopathy.ie/homeopaths/index.php?option=com\\_content&view=article&id=52&Itemid=70](http://www.irishhomeopathy.ie/homeopaths/index.php?option=com_content&view=article&id=52&Itemid=70)> accessed 27 November 2013. The ISH is a representative body and not a commercial provider of CAM, and so it falls outside the remit of the 2007 Act. However, as is often the case, the exact wording provided by the ISH is reproduced on the website Dervishdublinholistics.com, for example, which is a commercial enterprise and which is thus subject to the provisions of the 2007 Act. See Appendix II, Non-Commercial versus Commercial Claims.

<sup>38</sup> Blum.ie, ‘We May Help You With > Asthma’ <[www.blum.ie/wellness\\_topics/c\\_7\\_asthma.html](http://www.blum.ie/wellness_topics/c_7_asthma.html)> accessed 28 November 2013. The webpage is reproduced in Appendix III, Commercial Claims.

<sup>39</sup> Directive 2001/83/EC (n 9), art 2.

<sup>40</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L169/01, as implemented in Ireland by European Communities (Medical Devices) Regulations 1994, SI 1994/252. “Device” is defined in reg 2(1) of the Regulations as “a medical device, that is to say an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which must achieve one of the performances intended by the manufacturer so that they are suitable for either (i) diagnosis, prevention, monitoring, treatment or alleviation of disease, (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, (iii) investigation, replacement or modification of the anatomy or of a physiological process, or (iv) control of conception”.

<sup>41</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540.

<sup>42</sup> European Communities (Medical Devices) Regulations 1994, SI 1994/252.

<sup>43</sup> Directive 2001/83/EC (n 9).

Art 2(a) is of particular interest, as, for example, most of the homeopathic medicinal products available in Ireland do not carry indications but may nonetheless be positioned in a particular section of the retail outlet housing, for example, medication for the treatment of stomach complaints. The positioning of homeopathic medicinal products in specific sections, though not directly claiming an indication, presents them as being efficacious for that condition, despite the lack of high quality evidence in support of this and despite its labelling notifying the consumer that it is “A homeopathic medicinal product for the symptomatic relief of (or treatment of).....based on homeopathic tradition and not on the outcome of clinical trials”.<sup>44</sup> Art 2(b) casts a wide net which may also take in food products making medical claims, an example of which (bitter apricot kernels) is discussed later in the chapter.

The term “misleading advertising” is defined in the Medicinal Products (Control of Advertising) Regulations 2007 (hereafter “the Control of Advertising Regulations”)<sup>45</sup> as

...any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor.<sup>46</sup>

A misleading claim on a medicinal product in one retail establishment may encourage a consumer to purchase that product, leaving the same product offered elsewhere without the misleading claim at a disadvantage, and leaving the consumer with a product which may not be fit for the purpose for which it was purchased. A difficulty arises in relation to reg 5(a) of the Control of Advertising Regulations, which states:

The provisions of these Regulations shall not apply to:- (a) the labelling of medicinal products and the accompanying package leaflets, where such labelling and package leaflets are in compliance with Regulation 16 of the Medicinal Products (Control of Placing on the Market) Regulations 2007.

Regulation 16 refers to Title V of the 2001 Directive on medicinal products for human use,<sup>47</sup> which provides a list of particulars to be carried on the outer or immediate packaging of medicinal products. Of particular interest is art 69, which provides that homeopathic medicinal products<sup>48</sup> must carry a

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<sup>44</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540, reg 11(5).

<sup>45</sup> Medicinal Products (Control of Advertising) Regulations 2007, SI 2007/541.

<sup>46</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540, reg 4(1).

<sup>47</sup> Directive 2001/83/EC (n 9), as implemented in Ireland by Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540.

<sup>48</sup> Directive 2001/83/EC (n 9), as amended, art 1.5 defines a homeopathic medicinal product as “[a]ny medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the

number of points of information, the most pertinent of which are the name of the stock or stocks used and the degree of dilution,<sup>49</sup> together with a statement of the product's designation as a "homeopathic medicinal product without approved therapeutic indications",<sup>50</sup> or "A homeopathic medicinal product for the symptomatic relief of (or treatment of).....based on homeopathic tradition and not on the outcome of clinical trials".<sup>51</sup> Once listed, the products are excluded from the remit of the Control of Advertising Regulations, notwithstanding the fact that, past a certain degree of dilution,<sup>52</sup> they are unlikely to contain any trace of the active ingredients displayed on the label. This conflict, discussed later in this chapter, undermines the ability of the consumer to make a fully informed decision, weakening their position overall.

## 2.1 LICENCING OF MEDICINAL PRODUCTS FOR HUMAN USE

Medicinal products for human use must be licenced by the Health Products Regulatory Authority (HPRA)<sup>53</sup> in order to be advertised for sale in Ireland.<sup>54</sup> There are, at present, no less than four discrete licencing mechanisms for such products (Table 2), selected based on the nature of product in question (incorporating the relevant evidence available for submission by the producer) and on the potential physical risk it represents to the user.<sup>55</sup>

Legislation governing the placing on the market of medicinal products<sup>56</sup> and medical devices<sup>57</sup> demands evidence<sup>58</sup> as to the safety, quality and efficacy of products, but the standards of each vary depending on the classification of the product in question. Comprehensive documentation establishing the safety, quality and efficacy of a medicinal product authorised under either the centralised<sup>59</sup> or decentralised<sup>60</sup> Product Authorisation (PA) procedures must be submitted

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pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles".

<sup>49</sup> *ibid* art 69.1.

<sup>50</sup> *ibid*. This applies to homeopathic medicinal products registered under the Simplified Registration Scheme, as provided for by art 13.2 and set out in detail in art 14.1 of the 2001 Directive. Homeopathic medicinal products bearing therapeutic indications must either be authorised under the National Rules Scheme or the full Product Authorisation mechanism.

<sup>51</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007 (n 44) reg 11(5).

<sup>52</sup> Past a potency of 12C or 23X, there is unlikely to be even one mole of the active ingredient contained in the homeopathic medicinal product.

<sup>53</sup> Established by Irish Medicines Board Act 1995, s 3, as amended by Health (Pricing and Supply of Medical Goods) Act 2013, s 36.

<sup>54</sup> Medicinal Products (Control of Advertising) Regulations 2007, SI 2007/541, reg 6(1).

<sup>55</sup> Directive 2001/83/EC (n 9), Twenty-First recital, Preamble.

<sup>56</sup> *ibid*, as implemented in Ireland by Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540.

<sup>57</sup> European Communities (Medical Devices) Regulations 1994, SI 1994/252.

<sup>58</sup> Directive 2001/83/EC (n 9), art 8.

<sup>59</sup> HPRA, 'Licencing Procedures - Centralised' (2016)

<[www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/licensing-procedures](http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/licensing-procedures)> accessed 14 September 2016.

<sup>60</sup> HPRA, 'Licencing Procedures – Decentralised and Mutual Recognition' (2016)

before an authorisation is granted. Pharmacovigilance and surveillance in respect of the product must be maintained<sup>61</sup> and authorisation may be withdrawn if it is later found that, *inter alia*, the product is harmful under normal conditions of use,<sup>62</sup> that it lacks therapeutic efficacy or that the risk-benefit balance is not favourable,<sup>63</sup> or that its qualitative and quantitative composition is not as declared.<sup>64</sup> However, a number of categories of medicinal products, such as many homeopathic and traditional herbal preparations, are specifically excluded from stipulations demanding standard scientific evidence of efficacy, and are instead addressed separately in the National Rules Scheme (NRS) and the Simplified Registration Scheme (SRS) for homeopathic medicinal products, and in the Traditional Herbal Medicinal Products Registration Scheme (THMPRS) for traditional herbal medicinal products. Whereas all medicinal products authorised through the PA mechanism must submit evidence of safety and efficacy gleaned through pharmacological tests, pre-clinical tests and clinical trials<sup>65</sup> within a substantial dossier of other clinical, expert, cohort and surveillance information, as set out in art 8 of the 2001 Directive on Medicinal Products for Human Use,<sup>66</sup> traditional herbal and homeopathic medicinal products may instead rely on antiquity and tradition of use for their licencing, a significantly lower standard. It is difficult to surmise the rationale behind such a distinction (beyond its clear benefit for providers of such products), although it is suggested, once again, that the safety of the products in question is the primary consideration for regulators, trumping all other principles of consumer protection. The coexistence of full product authorisation and less comprehensive licencing schemes seems an unnecessary complication in an already convoluted, confusing and inaccessible infrastructure.

Where resources, rather than viability, prevent the requirements of the PA mechanism from being met, financial support should be provided, facilitating advancement in medicine without lowering the bar and putting consumer at risk.

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<[www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/licensing-procedures](http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/licensing-procedures)> accessed 14 September 2016.

<sup>61</sup> Directive 2001/83/EC (n 9), art 8(n).

<sup>62</sup> *ibid* art 117(a).

<sup>63</sup> *ibid* art 117(b) and (c).

<sup>64</sup> *ibid* art 117(d).

<sup>65</sup> Directive 2001/83/EC (n 9), art 8(3)(i), as amended.

<sup>66</sup> Directive 2001/83/EC (n 9).

| LICENCING     | APPLICATION                                                                                                                                      | EVIDENCE OF SAFETY                                                                                                                                                                                                                                                                                                                                                                                                             | EVIDENCE OF EFFICACY                                                                                                                                                                                                                                                                                                                                                                            |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PA</b>     | All medicinal products for human use that are ineligible for the NRS, THMPRS and the SRS. These products carry therapeutic indications.          | The safety of the medicinal product is established based on comprehensive documentation detailing the results of pharmaceutical tests, pre-clinical trials and clinical trials, with provisions for pharmacovigilance and risk management - Directive 2001/83/EC, art 8.3(i).                                                                                                                                                  | The efficacy of the medicinal products is established based on comprehensive documentation detailing the results of pharmaceutical tests, pre-clinical trials, clinical trials and surveillance, with provisions for pharmacovigilance - Directive 2001/83/EC, art 8.3(i).                                                                                                                      |
| <b>THMPRS</b> | Traditional herbal medicinal products with a sufficiently long medicinal use in the Community. These products may carry therapeutic indications. | The safety of the medicinal product is established based on bibliographic review of safety data, together with the submission of an expert report - Directive 2004/24/EC, art 16c 1(d).                                                                                                                                                                                                                                        | The efficacy of the medicinal product is considered to be plausible on the basis of long-standing use and experience - Directive 2004/24/EC, art 16a 1(e).                                                                                                                                                                                                                                      |
| <b>NRS</b>    | Homeopathic medicinal products <u>with</u> therapeutic indications.                                                                              | The safety of the medicinal product is established based on relevant published literature or original data on the route of administration and the on the level of dilution involved - SI 2007/540, reg 11.3.                                                                                                                                                                                                                   | The efficacy of the medicinal product is considered to be plausible on the basis of established use in the State for the indication sought – SI 2007/540, reg 11.2(d). Those seeking authorisation may submit providing <i>either</i> the results of studies in relation to the product, <i>or</i> published scientific literature <i>or</i> the results of homeopathic provings. <sup>67</sup> |
| <b>SRS</b>    | Homeopathic medicinal products <u>without</u> therapeutic indications.                                                                           | There is a sufficient degree of dilution to guarantee the safety of the medicinal product ... [which] may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription - Directive 2001/83/EC, art 14.1. | None required. No therapeutic indications permitted.                                                                                                                                                                                                                                                                                                                                            |

Table 2 - A summary of the variation in standards of evidence required for safety and efficacy under the current licencing regimes for medicinal products for human use. Key: PA (Product Authorisation Procedure), THMPRS (Traditional Herbal Medicinal Product Registration Scheme), NRS (National Rules Scheme), SRS (Simplified Registration Scheme).

<sup>67</sup> On the validity of homeopathic provings, particularly pertinent for the development of a state-sanctioned authorisation scheme, see Sarah Brien and others, 'Ultramolecular homeopathy has no observable clinical effects: A randomized, double-blind, placebo-controlled proving trial of Belladonna 30C' (2003) 56 British Journal of Clinical Pharmacology 562, 566, Flávio Dantas and others, 'A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995' (2007) 96 Homeopathy 4, and Sarah Brien and others, 'How do homeopaths make decisions? An exploratory study of inter-rater reliability and intuition in the decision-making process' (2004) 93 Homeopathy 125, 130.



An average consumer attempting to negotiate this labyrinth is likely to give up before finding the information he or she requires and so this opaque and inaccessible system does little to support the objectives of improving consumer health literacy or promoting patient empowerment.

## **2.2 SALE OF CAM MEDICINAL PRODUCTS FOR HUMAN USE**

The mire of divergent regulatory mechanisms set out above results in less clarity and an ever-decreasing opportunity for the consumer to obtain the clear, concise, accurate information they require to make either an informed healthcare choice or a well-rounded consumer decision. This is particularly problematic when many products, regardless of their regulatory provenance, end up on the same shelf, in the same section of the pharmacy, and unsuspecting consumers understandably fail to tell them apart, one sore throat cure appearing much the same as another. Those who do notice that a product is labelled, for example, as a ‘homeopathic medicinal product without approved therapeutic indications’<sup>68</sup> may still be no closer to understanding its meaning.<sup>69</sup> Those who understand its meaning and wish to know how much of the active ingredient they are to ingest have quite a task ahead, as the potency is measured in degrees of dilution rather than in any internationally recognised metric or imperial unit. If transparency and clear concise information are the starting point in the journey towards excellence in consumer protection and freedom of choice in healthcare, the overall framework, European in origin, has missed the mark in this sector to a significant extent.

### **2.2.1 A BRIEF SOJOURN INTO THE SALE OF CAM PRODUCTS BY PHARMACISTS IN IRELAND**

Although there is some evidence of efficacy for particular therapeutic modalities in specific conditions,<sup>70</sup> given the existing uncertainty in respect of many CAM therapies, any positive claim of curative properties ought to be viewed with suspicion by consumers and, most importantly, by regulators, who should be seen to apply the same standard scientific rigour for such claims across the therapeutic spectrum.<sup>71</sup> It is also vital that those working in settings such as retail pharmacies avoid the promotion or sale of unproven therapies as, not only may it lead consumers to forgo tried and tested

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<sup>68</sup> Medicinal Products (Control of Advertising) Regulations 2007, SI 2007/541.

<sup>69</sup> Andrew Gilbey and Shaun Holt (n 25) 94-95.

<sup>70</sup> Klaus Linde and others, ‘Acupuncture for migraine prophylaxis’ (2009) Cochrane Database of Systematic Reviews CD001218.

<sup>71</sup> In this respect, the variance in standards for the licencing of medicinal products for human use is troublesome and idiosyncratic.

conventional therapy and promote the “encroachment of quackery in medicine”,<sup>72</sup> but because it is in contravention of a number of the principles established by the Code of Conduct<sup>73</sup> of the Pharmaceutical Society of Ireland under s 7(2)(a)(iii) of the Pharmacy Act 2007.<sup>74</sup> The Code of Conduct contains six principles, four of which are of direct relevance here:

#### *Principle One*

*The practice by a pharmacist of his/her profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient. This is the primary principle and the following principles must be read in light of this principle*

In order to fulfil his/her obligations under this principle a pharmacist should:

- Ensure the health of the patient is their primary focus ...
- Use their professional skills, competence and specialised knowledge about medicines, health-related products, medicinal and non-medicinal therapies for the benefit of patients ...
- Not purchase or supply any product, including a medicinal product, where there is reason to doubt its safety, efficacy or quality or where a product may impose a hazard to a patient’s health or wellbeing ...
- Encourage the rational and proper use of medicines ...
- Promote compliance with effective medicine and treatment regimes, and seek to address issues that may impinge on a patient obtaining the best result from his treatment ...<sup>75</sup>

#### *Principle Two*

*A pharmacist must employ his/her professional competence, skills and standing in a manner that brings health gain and value to the community and the society in which he/she lives and works*

In order to fulfil his/her obligations under this principle a pharmacist should:

- Support cost-effective therapies and prudent use of healthcare resources ...
- Ensure all information provided to the public is legal, truthful and rational ...<sup>76</sup>

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<sup>72</sup> W Steven Pray, ‘Why pharmacists should not sell homeopathic products’ (2010) 15 Focus on Alternative and Complementary Therapies 280.

<sup>73</sup> Pharmaceutical Society of Ireland (n 11).

<sup>74</sup> Pharmacy Act 2007, s 7(2)(a)(iii), “Without prejudice to the generality of subsection (1), but subject to the other provisions of this Act – (a) it is the duty of the Society to ... (iii) draw up codes of conduct for pharmacists”.

<sup>75</sup> Pharmaceutical Society of Ireland (n 11) 6.

<sup>76</sup> *ibid* 7.

### *Principle Three*

*A pharmacist must never abuse the position of trust which they hold in relation to a patient and in particular, they must respect a patient's rights, including their dignity, autonomy, and entitlements to confidentiality and information*

In order to fulfil his/her obligations under this principle a pharmacist should:

- Ensure the position of trust they hold in respect of a patient is never abused...
- Ensure the patient is treated with courtesy, dignity, integrity and honesty ...
- Ensure that their professional judgement is not impaired by personal or commercial interests including incentives, targets or similar measures ...
- Provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of medicines, health-related products and services provided by them ...
- Recognise the entitlement of the patient to appropriate information and disclose material risks associated with medication therapy ...<sup>77</sup>

### *Principle Four*

*A pharmacist must conduct himself/herself in a manner which enhances the service which their profession as a whole provides to society and should not act in a way which might damage the good name of their profession*

In order to fulfil his/her obligations under this principle a pharmacist should:

- Not practise under conditions which compromise their ability to exercise their professional judgement and integrity or the quality of their practice ...<sup>78</sup>

The sale through retail pharmacies of, for example, homeopathic medicinal products, which lack high quality evidence of efficacy, prevents the pharmacist from meeting his or her primary objective of ensuring that the health of the patient is their primary focus. The academic and professional education of pharmacists demands a minimum standard of scientific literacy and rigour and so their endorsement of homeopathic products by way of their sale and supply, according to Pray, must instead come about through “wilful ignorance, blatant dishonesty or overwhelming greed”.<sup>79</sup>

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<sup>77</sup> *ibid* 8.

<sup>78</sup> *ibid* 9.

<sup>79</sup> W Steven Pray (n 72) 282, “To know the scientific method, but to ignore its power and utility is perhaps even worse than to be scientifically illiterate. Selling quack products lowers respect for the pharmacy in the eyes of physicians and others who adhere to the principles of legitimate medicine”.

The sale of homeopathic medicinal products does not promote compliance with effective treatment regimens and, in fact, may discourage consumers from seeking conventional diagnosis and care, making a potentially serious condition all the more difficult to treat when it is eventually diagnosed.

Homeopathic medicinal products are not cost effective. While such products may appear cheaper than many conventional medicinal products, as there is often no active ingredient present and there is currently no significant evidence of efficacy, the homeopathic medicinal product is, in fact, of significantly less value for its cost. Any pharmacist failing to make the consumer aware of this and continuing to provide such products is failing in their duty to ensure that the information provided is truthful and rational.

The sale of homeopathic medicinal products, together with other unproven therapies, is a blatant abuse of the trust placed in pharmacists by consumers. The positioning of homeopathic medicinal products, which, in order to receive a certificate of registration under reg 11 of the Medicinal Products (Control of Placing on the Market) Regulations, 2007, must only provide guarantees of quality<sup>80</sup> and safety,<sup>81</sup> adjacent to conventional medicinal products, which have demonstrated efficacy, in addition to meeting the safety and quality standards required by the Product Authorisation regime, is confusing and dangerous for the consumer, who may not understand the difference between the two.

The sale of homeopathic and other inefficacious products in retail pharmacies is in direct contravention of these obligations. Notwithstanding this, these products are widely available in such establishments, suggesting a need for closer scrutiny to ensure compliance.

### **2.3 ASSESSING THE POTENTIAL IMPACT OF THE DYSSYNCHRONY BETWEEN CONSUMER PROTECTION AND OTHER LEGISLATION**

Despite the conflict between medicinal products and consumer protection legislation, CAM medicinal products remain on the market, suggesting the triumph of the former over the latter. While both are applicable, consumer law prohibits the making of false or misleading claims, whereas the medicinal products legislation, specifically in respect of traditional herbal and homeopathic products,<sup>82</sup> permits the sale of products with clinical indications supported by

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<sup>80</sup> Medicinal Products (Control of Placing on the Market) Regulations, SI 540/2007, reg 11(3).

<sup>81</sup> *ibid* reg 11(4).

<sup>82</sup> Specifically, those homeopathic medicinal products licenced under the National Rules Scheme, though there are none licenced at the time of writing.

questionable evidence of efficacy. As noted, the existing legislation governing medicinal products for human use<sup>83</sup> (and medical devices)<sup>84</sup> favours safety over efficacy, it being a consistent requirement across all licencing mechanisms, to the detriment of other consumer rights. While there can be no doubt that safety should remain a priority, it is asserted that the right of consumers to know what they are purchasing and not to be actively misled as to the nature of the product through clever or deceptive marketing, requires greater emphasis. Each of the three potential areas of consumer impact is discussed in turn.

### **2.3.1 CAM AND THE CONSUMER PROTECTION ACT 2007**

The labelling and advertising of any product, encompassing the claims made by marketing material and at the point of sale, may exploit consumer vulnerability, undermining their rights under consumer protection legislation. It may also detrimentally affect other traders and skew the market overall. This was succinctly described by Nathan Reilly,<sup>85</sup> who stated:

The presence of dishonest traders in the market drives both honest traders and the market out of existence. Providing higher quality products costs suppliers more than providing products of lower quality, but if consumers cannot tell the difference between those products, there is no immediate commercial incentive on traders to provide better quality. Bad quality drives out good.<sup>86</sup>

Claims of puffery are unlikely to be successful. For example, stating that “Everything from trauma and acute or short-term illness to many types of chronic conditions can be effectively treated by homeopathy”<sup>87</sup> is not hyperbole but a claim of therapeutic

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<sup>83</sup> Directive 2001/83/EC (n 9), as implemented by Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540.

<sup>84</sup> Council Directive 93/42/EEC (n 40), as implemented by European Communities (Medical Devices) Regulations 1994, SI 1994/252.

<sup>85</sup> Nathan Reilly, ‘The Consumer Protection Act 2007: Rationalising the regulation of misleading commercial practices in Ireland—Part I’ (2008) 6 Commercial Law Practitioner 127.

<sup>86</sup> *ibid* 128.

<sup>87</sup> Appendix II, Irish Society of Homeopaths (ISH), ‘What can Homeopathy treat?’ <[www.irishhomeopathy.ie/homeopaths/index.php?option=com\\_content&view=article&id=52&Itemid=70](http://www.irishhomeopathy.ie/homeopaths/index.php?option=com_content&view=article&id=52&Itemid=70)> accessed 27 November 2013. This is not a direct provider of CAM service, but a representative body, providing information to the public, along with a register of practitioners. These claims are misleading but do not fall under the remit of the 2007 Act, as they are not in a commercial context. However, these claims are reproduced on commercial sites, where they then fall within the scope of the Act. See Dervish Dublin Holistics, ‘What can Homeopathy treat?’ <[www.dervishdublinholistics.com/dublin-homeopathy-co-op.html](http://www.dervishdublinholistics.com/dublin-homeopathy-co-op.html)> accessed 6 September 2016.

efficacy. This is misleading on the best available evidence, as “There is no good-quality evidence that homeopathy is effective as a treatment for any health condition”.<sup>88</sup>

The mechanism for determining whether a claim misleads<sup>89</sup> the consumer for the purposes of ss 42, 43 or 55(1)(g) of the 2007 Act<sup>90</sup> represents a key step towards the goal of improving consumer welfare in this area.

The 2007 Act empowers consumers by providing them with a mechanism through which they may obtain the information they require in order to make an informed decision in respect of products or services.<sup>91</sup> Such empowerment is scarcely more important than in the field of healthcare, where decisions taken may have life-altering implications. The 2007 Act implements the Unfair Commercial Practices Directive,<sup>92</sup> (hereafter “the UCPD”), which introduces a “mandatory general principle of good faith to govern the practices of traders engaged in selling products and services to consumers across all market sectors”.<sup>93</sup> The objective of the UCPD is to optimise consumer access to accurate product or service information, thus providing protection from inequitable or unfair trading practices and boosting consumer confidence overall.<sup>94</sup> However, as a maximum harmonisation mechanism,<sup>95</sup> it is arguable that the extent to which its objectives can be met in a domestic setting is limited. It is clear from the many unverifiable representations made by ostensibly reputable commercial CAM

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<sup>88</sup> NHS Choices, ‘Homeopathy’ (2015) <[www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx](http://www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx)> accessed 10 September 2016.

<sup>89</sup> Directive 2006/114/EC (n 24), art 2(b) describes “misleading advertising” as “any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed ... and which, by reason of its deceptive nature, is likely to affect their economic behaviour”.

<sup>90</sup> Consumer Protection Act 2007, s 55(1)(5) states, “A trader shall not engage in... a representation that a product is able to cure an illness, dysfunction or malformation, if it cannot”.

<sup>91</sup> Commission, ‘Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee - EU Consumer Policy strategy 2007-2013 - Empowering consumers, enhancing their welfare, effectively protecting them’ COM (2007) 99 final 2, “Confident, informed and empowered consumers are the motor of economic change as their choices drive innovation and efficiency”.

<sup>92</sup> Directive 2005/29/EC (n 7).

<sup>93</sup> Hugh Collins, ‘The Unfair Commercial Practices Directive’ (2005) 1(4) *European Review of Contract Law* 417, 418.

<sup>94</sup> Commission, ‘Green Paper on European Union Consumer Protection’ COM (2001) 531 final, s 3.1 states “For consumers, the lack of clarity and security over their rights is an important brake on their confidence and trust. The internal market, like all markets, depends on consumer confidence”.

<sup>95</sup> Joined Cases C-261/07 and C-299/07 *VTB-VAB NV v Total Belgium*, and *Galatea BVBA v Sanoma Magazines Belgium NV* [2009] ECR-I 2949, para 52, “the Directive fully harmonises those rules at the Community level. Accordingly, [...] Member States may not adopt stricter rules than those provided for in the Directive, even in order to achieve a higher level of consumer protection”. See Bethan Evans, ‘Regulation of financial markets in the EU: Mutual recognition vs. harmonisation? The role of regulatory competition in light of the recent financial crisis’ (2001) *Bristol Law Journal* 95, “[M]aximum harmonisation leaves no room for regulatory competition because it imposes uniform regulations across the entire internal market from which states cannot depart, not even to impose stricter standards or regulations with higher levels of protection for consumers. This means that the regulation in that area is exactly the same throughout the Union”. See also, Stephen Weatherill, *EU Consumer Law and Policy* (Edward Elgar Publishing Inc. 2013) 25, “[A] system of maximum harmonisation involves complete transfer of regulatory responsibility from Member States to the EU in the field covered by the measure in question”.

enterprises, examples of which are provided in Appendices II, III and V, that either the UCPD, its implementation in the form of the 2007 Act, or the enforcement of the regulatory mechanism established therein, are not fit for purpose and that, on this basis, the representations made by EU in respect of the protections offered by the UCPD are themselves unfair and misleading.

The 2007 Act does not specifically address medicinal products, medical devices or CAM services. Rather, it prohibits unfair,<sup>96</sup> misleading<sup>97</sup> or aggressive<sup>98</sup> practices deployed by a trader in his dealings with a consumer. The s 41 “unfairness” provisions take a broad brush approach, requiring that traders act in good faith<sup>99</sup> and with a reasonable standard of skill and care.<sup>100</sup> If traders fail to meet the standards set out for either of these provisions, it must not be in such a manner as to be likely to impair the capacity for informed choice<sup>101</sup> or otherwise affect the transactional decision-making<sup>102</sup> of the consumer. This provision, implementing art 5 of the UCPD, “can be applied as a stand-alone provision, as a ‘safety net’, to make sure that any unfair practice which is not caught by the remainder of the Directive can be penalised”.<sup>103</sup>

Section 42 of the 2007 Act provides a general prohibition on “misleading commercial practices”, while s 43 defines the term itself as...

the provision of false information in relation to any matter set out in *subsection* (3) ... [where]... that information would be likely to cause the average consumer to make a transactional decision that the average consumer would not otherwise make.<sup>104</sup>

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<sup>96</sup> Consumer Protection Act 2007, s 41.

<sup>97</sup> *ibid* s 42.

<sup>98</sup> *ibid* s 52.

<sup>99</sup> *ibid* s 41(a)(i).

<sup>100</sup> *ibid* s 41(a)(ii).

<sup>101</sup> *ibid* s 41(b)(i).

<sup>102</sup> *ibid* s 41(b)(ii). ‘Transactional decision’ is defined in s 1 of the 2007 Act and was described in the Case C-281/12 *Trento Sviluppo srl, Centrale Adriatica Soc. Coop. Arl v Autorità Garante della Concorrenza e del Mercato*, 19 December 2013, paras 35, 36 and 38, “[a]ny decision taken by a consumer concerning whether, how and on what terms to purchase’ is a transactional decision. That concept therefore covers not only the decision whether or not to purchase a product, but also the decision directly related to that decision, in particular the decision to enter the shop. ... Article 2(k) of the directive must be interpreted as meaning that any decision directly related to the decision whether or not to purchase a product is covered by the concept of ‘transactional decision’.

<sup>103</sup> Commission, ‘Report From the Commission to the European Parliament, the Council and the European Economic and Social Committee: First Report on the application of Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (‘Unfair Commercial Practices Directive’)’ COM (2013) 139 final.

<sup>104</sup> Consumer Protection Act 2007, s 43(1).

Such a practice is also considered to be misleading if

... it would be likely to cause the average consumer<sup>105</sup> to be deceived or misled in relation to any matter set out in *subsection (3)* and to make a transactional decision that the average consumer would not otherwise make.<sup>106</sup>

Section 43(3) sets out, in detail, the matters for which the provision of false information is considered misleading and which may cause the consumer to be deceived and would be likely to cause the average consumer to make a transactional decision that they would not otherwise make, and so it is appropriate to examine those most relevant to CAM:

- (a) Misleading commercial practice in relation to the existence or nature of the product<sup>107</sup>
- (b)(iv) Misleading commercial practice in relation to a product's benefits or fitness for purpose<sup>108</sup>
- (b)(v) Misleading commercial practice in relation to the results to be expected from it,<sup>109</sup>
- (b)(vi) Misleading commercial practice in relation to the risks a product presents to consumers,<sup>110</sup> and
- (b)(viii) Misleading commercial practice in relation to a product's composition, ingredients, components or accessories.<sup>111</sup>

The importance of each and its relevance is examined in turn.

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<sup>105</sup> Case C-210/96 *Gut Springenheide* [1998] ECR I-04657, para 31.

<sup>106</sup> Consumer Protection Act 2007, s 43(2).

<sup>107</sup> *ibid* s 43(3)(a).

<sup>108</sup> *ibid* s 43(3)(b)(iv).

<sup>109</sup> *ibid* s 43(3)(b)(v).

<sup>110</sup> *ibid* s 43(3)(b)(vi).

<sup>111</sup> *ibid* s 43(3)(b)(viii).



**(a) MISLEADING COMMERCIAL PRACTICE IN RELATION TO THE EXISTENCE OR NATURE OF THE PRODUCT<sup>112</sup>**

The existence and availability of CAM products are not in doubt, but the presence of the active ingredient claimed to be in the product or the healing or curative nature of the products themselves are, however, two potential problems under the 2007 Act.

***Homeopathic Medicinal Products***

Homeopathic medicinal products are produced by the serial dilution of the active ingredient or ingredients in order to ‘potentise’<sup>113</sup> or strengthen their ostensible effects. Homeopathic products come in a number of standard potencies, the most common of which are decimal (denoted D or X and referring to a 1:10 solution), centesimal (denoted C and referring to a 1:100 solution) and millesimal (denoted M, referring to a 1:1000 solution). Here, the “1” refers to the number of parts of the active ingredient per parts solvent. In other words, one drop of the original active ingredient in ninety-nine drops of water creates a 1C solution - not so dilute as to cause a stir amongst sceptics or pharmacists. One drop of that 1C solution in a further ninety-nine drops of water creates a 2C<sup>114</sup> solution and so forth. As the potentisation progresses, the quantity of the original active ingredient remaining in the solution decreases. A 6X solution amounts to one part active ingredient per million parts solvent. 6C amounts to one part active ingredient per ten trillion parts solvent. Past the potency of 23X or 12C,<sup>115</sup> according to Avogadro’s constant,<sup>116</sup> it is unlikely that even one mole<sup>117</sup> of the active ingredient noted on the label remains in the solution. If present, that mole is unlikely to create any effect, therapeutic or otherwise, in the human body. However, one of the more common homeopathic potencies is 30C and this is not the most dilute by far.<sup>118</sup>

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<sup>112</sup> *ibid* s 43(3)(a).

<sup>113</sup> ‘Potentize’ To render the latent power of (anything) available

<[www.thefreedictionary.com/potentised](http://www.thefreedictionary.com/potentised)> accessed 2 December 2013. This term is used almost exclusively in the practice of homeopathy.

<sup>114</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540, reg 3(d), “For the purpose of this Regulation and subject to subparagraph (4), the safety of the homeopathic medicinal product shall be demonstrated ... by establishing that the medicinal product contains not more than one part per 10,000 of the mother tincture”. This corresponds with a potency of 4X or 2C, considered a weak homeopathic remedy.

<sup>115</sup> This means that there is one part original active ingredient in 100,000,000,000,000,000,000 parts water.

<sup>116</sup> Wolfgang Demtröder, *Atoms, Molecules and Photons: An Introduction to Atomic, Molecular and Quantum Physics* (Springer 2010) 12. Avogadro’s constant ( $6.02214129 \times 10^{23} \text{ mol}^{-1}$ ) describes the number of particles per one mole of any particular substance.

<sup>117</sup> Michael Clugston and Rosalind Flemming, *Advanced Chemistry* (OUP Oxford 2000) 33. A mole is the amount of any substance that contains the exact same number of particles as there are atoms in exactly 12g of carbon-12. This number of particles is Avogadro’s constant.

<sup>118</sup> Simon Singh and Edzard Ernst in *Trick Or Treatment? Alternative Medicine on Trial* (Transworld 2009) 125, describe the use of 100,000C remedies by some homeopathic pharmacies.

Given such minute probability of there being any of the active ingredient labelled in many of the homeopathic remedies readily available to consumers, any representation of its presence in the form of labelling, verbal representation on the part of the trader, or written representation provided with or near the product, could certainly be considered to be misleading for the purposes of the 2007 Act,<sup>119</sup> whether such a product is licenced under the NRS or the SRS.

**(b)(iv) MISLEADING COMMERCIAL PRACTICE IN RELATION TO A PRODUCT'S BENEFITS OR FITNESS FOR PURPOSE**

As noted previously, there are numerous examples of CAM products<sup>120</sup> carrying therapeutic indications without the substantive scientific evidence of efficacy demanded of conventional medical devices and medicinal products. As noted above, any such claims are made in an indirect manner through implication or not on the product labelling itself but through a search for a particular ailment.<sup>121</sup> They nonetheless fall within the definition of 'misleading' for the purposes of the 2007 Act.

CAM products are sold, as their title suggests, as medical products of a complementary or alternative nature, with the implied or stated objective of treating illness. If such a CAM medicinal product is represented as being sold for this purpose in lieu of high quality scientific evidence<sup>122</sup> as to its efficacy, this ought to be considered misleading for the purposes of the 2007 Act, notwithstanding the fact that such products are

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<sup>119</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L36/34, as amended, together with Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540, reg 11, addresses the labelling and registration requirements for homeopathic /medicinal products, requiring a minimum dilution of 1: 10,000 (4X or 2C) but providing no lower limit for the quantity of the active ingredient that must be present in the final product.

<sup>120</sup> Boots.ie offers 'Boots Pharmaceuticals Silver Plated Copper Bracelet (Small/Medium)' <[www.boots.ie/en/Boots-Pharmaceuticals-Silver-Plated-Copper-Bracelet-Small-Medium-\\_1162472/](http://www.boots.ie/en/Boots-Pharmaceuticals-Silver-Plated-Copper-Bracelet-Small-Medium-_1162472/)> accessed 28 November 2013 and Mccabespharmacy.com offers the 'Good Night Anti Snoring Ring' <[www.mccabespharmacy.com/good-night-anti-snoring-ring-medium.html](http://www.mccabespharmacy.com/good-night-anti-snoring-ring-medium.html)> accessed 15 December 2015. See also 'Boots Pharmaceuticals Health Bracelet', the packaging for which states "Boots Pharmaceuticals Health Bracelet believed by many people to help with a stressful lifestyle, pain relief and circulatory problems". This is a diffuse non-claim, which is highly misleading, notwithstanding that it is factual. Section 43(4) of the 2007 Act provides that it is not a defence in any proceeding to show that the information is factually correct <[www.boots.ie/en/Boots-Pharmaceuticals-Health-Bracelet-medium-large-\\_1155409/](http://www.boots.ie/en/Boots-Pharmaceuticals-Health-Bracelet-medium-large-_1155409/)> accessed 2 December 2013. Finally, see 'Chi Detox Foot Patches 30s', the packaging for which claims that the product "detoxifies the body while you sleep, improves energy [and] eases joint and muscle pain". These claims are non-specific and so are difficult to disprove but are misleading nonetheless. The author found no studies affirming or negating the efficacy of such products for the indication claimed <[www.mccabespharmacy.com/detox-foot-patches-chi.html](http://www.mccabespharmacy.com/detox-foot-patches-chi.html)> accessed 2 December 2013.

<sup>121</sup> CAM products with names such as 'Pollenna', 'Noctura', 'Coldenza', 'Vertigoheel' or 'Tonsilotren' give rise to inferences as to the condition for which the treatment is being sold, without stating it outright.

<sup>122</sup> Directive 2001/83/EC (n 9), art 8(3).

permitted under the 2001 Directive and the Control of Placing on the Market Regulations.

This is also relevant to the results to be expected from the product.

**(b)(v) MISLEADING COMMERCIAL PRACTICE IN RELATION TO THE RESULTS TO BE EXPECTED FROM THE PRODUCT**

***Homeopathic Medicinal Products***

The two augmented licencing procedures for homeopathic medicinal products in Ireland diverge on the issue of therapeutic indication, with products authorised under the NRS permitted to carry a therapeutic indication stating that it is “intended for the symptomatic relief” of a condition for which evidence of efficacy was submitted. Regulation 11(2)(d) of the Control of Placing on the Market Regulations requires demonstration only that the class of homeopathic medicinal product to which the proposed product belongs, “has been in use in the State as a homeopathic treatment for the indication sought”. Under the guidelines issued by the HPRA, evidence must be submitted in one of the following forms:

- i. Study reports in relation to the product which is the subject of the application
- ii. Published scientific literature or the results of investigations commonly known as homeopathic provings; which consist of the administration of a substance to a human subject in order to ascertain the symptoms produced by that substance.<sup>123</sup>

There is no onus on producers to prove through standard research or clinical trials that the product is effective and the homeopathic provings permitted as evidence, as noted previously,<sup>124</sup> have been found to be unreliable and inconsistent.

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<sup>123</sup> Health Products Regulatory Authority, ‘Guide to National Rules Scheme for Homeopathic Medicinal Products for Human Use’ (IMB 2010) 9. This is a key aspect of homeopathy. Caffeine administered to a patient causes insomnia. Therefore, when significantly diluted and shaken (succussed) appropriately, it will then cure insomnia.

<sup>124</sup> Sarah Brien and others, ‘Ultramolecular homeopathy has no observable clinical effects. A randomized, double-blind, placebo-controlled proving trial of Belladonna 30C’ (2003) 56 British Journal of Clinical Pharmacology 562, 566, Flávio Dantas and others, ‘A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995’ (2007) 96 Homeopathy 4, and Sarah Brien and others, ‘How do homeopaths make decisions? An exploratory study of inter-rater reliability and intuition in the decision making process’ (2004) 93 Homeopathy 125, 130.

Regulation 11(5)(a)-(d) provides four additional labelling and packaging requirements for homeopathic medicinal products to those required for medicinal products generally under reg 16. The homeopathic medicinal product must state that:

- (a) the product is homeopathic and has been registered as such;
- (b) any evidence of efficacy has not been based on clinical trials;
- (c) use of the product is for symptomatic relief of the condition to which the indication relates; and,
- (d) the user should consult a doctor if symptoms persist.

These additional requirements, it is argued, are insufficient to ensure that the right to information on the part of the consumer is vindicated, particularly in relation to reg 11(5)(c), referring to symptomatic relief of a medical condition, which is the primary purpose for which the products are sold. Permitting the sale of products carrying indications based on homeopathic provings, even with the additional warnings set out above, misleads consumers as to the results to be expected from their product, particularly based on the level of dilution and lack of other evidence of efficacy.

Although no homeopathic medicinal products are authorised under the NRS at this time, according to the HPRA,<sup>125</sup> the scheme remains available.

Products registered under the SRS may not carry therapeutic indications, leaving retailers to determine how best to market the product. This does not appear to contribute to consumer protection overall.

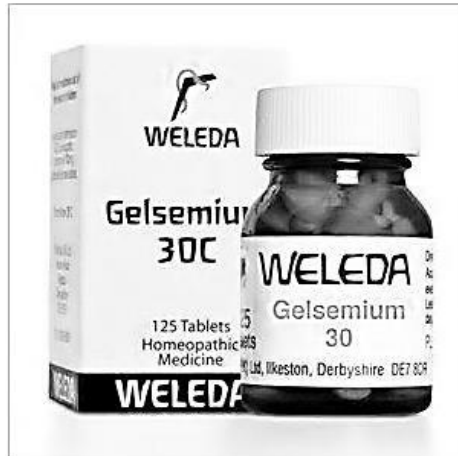
Figures 5 and 6 provide examples of the same homeopathic remedy with the same potency, sold by different online retailers (one of which is Irish), with different therapeutic indications accompanying, but not physically on the labelling of, the product.

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<sup>125</sup> Health Products Regulatory Authority, 'Find a Homeopathic Medicine' (2016) <[www.hpra.ie/homepage/medicines/medicines-information/homeopathic-medicines?query=HOR&field=>](http://www.hpra.ie/homepage/medicines/medicines-information/homeopathic-medicines?query=HOR&field=>)> accessed 10 September 2016.

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## Weleda Gelsemium 30C

€ 7.95

Qty:

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### Quick Overview

For Colds; influenza; sore throat; runny nose; tight headaches; nervous anxiety. For sufferers of conjunctivitis; inflamed burning eyes; hay fever; catarrh; heavy aching muscles; flushing aching and trembling.

Figure 5 - 30C potency homeopathic remedy (Gelsemium) with therapeutic indication of Colds; influenza; sore throat; runny nose; tight headaches; nervous anxiety ... conjunctivitis; inflamed burning eyes; hay fever; catarrh; heavy aching muscles; flushing aching and trembling.<sup>126</sup>

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## Weleda Gelsemium 30C - Pack of 125 Tablets

by Weleda

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Price: **£6.74** (£0.67 / 100 g) & **FREE Delivery** in the UK on orders You Save: £0.01

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**Want it Friday, 4 April?** Order it within **7 hrs 56 mins** and choose **Two-Day**

- Homeopathic medicine
- It can be used in nature such as occasional sleeplessness
- It should be taken as a short 7 day course
- A traditional remedy designed for the homeopathic treatment of eye complaints
- Suitable for vegetarians

**6 new** from £6.74

Figure 6 - 30C potency homeopathic remedy (Gelsemium, as per Figure 5) with the therapeutic indications of occasional sleeplessness and eye complaints.<sup>127</sup>

<sup>126</sup> Healthstore.ie, 'Weleda Gelsemium 30C' <[www.thehealthstore.ie/index.php/weleda-gelsemium.html](http://www.thehealthstore.ie/index.php/weleda-gelsemium.html)> accessed 12 March 2014.

<sup>127</sup> Amazon.co.uk, 'Weleda Gelsemium 30C' <[www.amazon.co.uk/Weleda-Gelsemium-30C-Pack-Tablets/dp/B004FJIYCI/ref=sr\\_1\\_1?ie=UTF8&qid=1395685155&sr=8-1&keywords=gelsemium+30c+weleda](http://www.amazon.co.uk/Weleda-Gelsemium-30C-Pack-Tablets/dp/B004FJIYCI/ref=sr_1_1?ie=UTF8&qid=1395685155&sr=8-1&keywords=gelsemium+30c+weleda)> accessed 12 March 2014.

This product is registered in Ireland under the SRS (Registration No. HOR0407/024/00), which means that it is not permitted to carry a therapeutic indication, nor should such an indication appear in related advertising.<sup>128</sup> This is clearly misleading as to the expected effects of the product, in contravention of s 43(3)(iv) of the 2007 Act.

### ***Traditional Herbal Medicinal (THM) Products***

As is the case with homeopathic medicinal products, traditional herbal medicinal products authorised under the Control of Marketing Regulations<sup>129</sup> are not required to provide the same standard of evidence for efficacy as those products authorised under the full PA mechanism, but instead, may obtain licencing under the THMPRS. Such products may carry therapeutic indications, and the efficacy of the traditional herbal medicinal product must be “plausible on the basis of long-standing use and experience”.<sup>130</sup> This is *prima facie* logical. After all, why would people continue to use something for over 30 years<sup>131</sup> if it did not work? In fact, there are many reasons, ranging from confirmation bias,<sup>132</sup> the conflation of correlation with causation,<sup>133</sup> regression to the mean,<sup>134</sup> the placebo effect associated with undergoing any sort of therapy<sup>135</sup> or simply the misattribution of efficacy to the herbal product, rather than to another

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<sup>128</sup> Medicinal Products (Control of Advertising) Regulations 2007, SI 2007/541, sch.

<sup>129</sup> Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L136/85, as implemented by Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540.

<sup>130</sup> *ibid* art 16a 1(e).

<sup>131</sup> *ibid* art 16c 1(c), “The application shall be accompanied by: ... bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community”.

<sup>132</sup> Robert Carroll, *The Skeptic's Dictionary: A Collection of Strange Beliefs, Amusing Deceptions, and Dangerous Delusions* (Wiley 2011) 81, “‘Confirmation Bias’ is defined as “a type of selective thinking whereby one tends to notice and to look for what confirms one’s beliefs, and to ignore, not look for, or undervalue the relevance of what contradicts one’s beliefs”.

<sup>133</sup> Also known as the ‘*post hoc ergo propter hoc*’ fallacy, the patient assumes that because they recovered after they took the remedy, that they recovered *because* they took the remedy.

<sup>134</sup> Simon D Shorvon and others, *The Treatment of Epilepsy* (Wiley 2009) 320, “Regression to the mean” is defined as “the tendency of patients to seek medical attention during periods of [seizure] exacerbation, which tend to be naturally followed by a spontaneous decline of [seizure] frequency towards its average value”.

<sup>135</sup> Howard Brody, *Placebos and the Philosophy of Medicine. Clinical, Conceptual, and Ethical Issues* (University of Chicago Press 1980) 1, “Placebo”: a biomedically inert substance given in such a manner to produce relief ... and the resulting effect upon the patient is known as the placebo effect”.

product.<sup>136</sup> Prolonged use may loosely imply efficacy, but it does not provide proof of it, in spite of legislative assertions to the contrary, making direct or indirect claims as to therapeutic results misleading under the 2007 Act. Consumers of THM products are consequently at a disadvantage when compared with consumers of medicinal products authorised under the full PA mechanism.

In respect of THM products, however, it is necessary to acknowledge the genuine potential and demonstrated benefits of some substances for patients.<sup>137</sup> Many existing pharmaceutical products have been developed from plants with medicinal properties.<sup>138</sup> It is argued that the complexity of herbal substances renders the rigorous requirements of the PA mechanism and the time, costs and facilities required to fulfil them, unworkable, and so the “long standing use and experience” requirements are the best available alternative at present. Ideally, of course, this would not be the case and support would be provided for sufficient research and testing to meet the PA requirements.

#### **(b)(vi) MISLEADING COMMERCIAL PRACTICE IN RELATION TO THE RISKS A PRODUCT PRESENTS TO CONSUMERS**

##### ***Miscellaneous Medicinal Products***

Despite the perception that CAM therapies are a safer option than conventional medicine,<sup>139</sup> products are available to Irish consumers which fail to disclose their inherent risks.

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<sup>136</sup> It should be noted that the manner and stringency of regulation is in question, rather than herbal medicinal products generally, many of which have contributed significantly to conventional medicine and have demonstrated pharmacological effects in their own right.

<sup>137</sup> For example, Yong-Hua Cui and Yi Zheng, ‘A meta-analysis on the efficacy and safety of St John’s wort extract in depression therapy in comparison with selective serotonin reuptake inhibitors in adults’ (2016) 12 Journal Neuropsychiatric Disease and Treatment 1715. The authors found similar efficacy in mild and moderate depressive disorders and fewer side effects than SSRIs. See also Eric A Apaydin and others, ‘A systematic review of St. John’s wort for major depressive disorder’ (2016) 5 Systematic Reviews 1. St John’s Wort is currently only available by prescription in Ireland, due to concerns of drug interaction.

<sup>138</sup> For example, digitalis (foxglove) has anti-arrhythmic properties. Digoxin, used in the treatment of atrial fibrillation, is extracted from digitalis plants.

<sup>139</sup> Diane M Shumay and others, ‘Why some cancer patients choose complementary and alternative medicine instead of conventional treatment’ (2001) 50(12) Journal of Family Practice 1067.

## *Amygdalin*

Amygdalin, a cyanogenetic glycoside,<sup>140</sup> also known as Laetrile,<sup>141</sup> or (misleadingly) as “vitamin B17”,<sup>142</sup> is found in apricot kernels and is touted as an alternative cancer therapy.<sup>143</sup> Apricot kernels are easily accessible, with the website of one established Irish health retailer writing of them, “Bitter Apricot Kernels ... have long been used in traditional Chinese medicine to relieve coughs, asthma and lubricate the bowel. The kernels are rich in amygdalin”.<sup>144</sup> The site advises that users consume no more than three kernels a day, but gives no indication of the reason or the serious implications of excessive consumption, nor does it inform consumers of the dangers of crushing and eating the apricot kernels,<sup>145</sup> which allows the amygdalin contained in them to mix with  $\beta$ -glucosidase, an enzyme found in the small intestine, releasing free cyanide.<sup>146</sup> This could also be considered a misleading omission for the purposes of s 46.

### *Food or Medicinal Product?*

Interestingly, the apricot kernels, as part of the apricot, may be considered to be a food, defined as “...any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans...”.<sup>147</sup> However, due to the claims that the product is used for the relief of coughs and asthma, the fact that it may not occur to the average consumer to buy it as a food product (in normal circumstances the flesh of the apricot is eaten and the stone is discarded) without the claim, and the fact that the product

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<sup>140</sup> V Herbert, ‘Laetrile: The cult of cyanide - poisoning for profit’ (1979) 32 American Journal of Clinical Nutrition 1121, “Cyanogenetic glycosides are chemical substances made up of cyanide, aldehyde or ketone and sugar”.

<sup>141</sup> “Laetrile” is short for “laevo-mandelonitrile-beta-glucuronoside” and is the tradename for the synthetic form of amygdalin.

<sup>142</sup> Irving J Lerner, ‘Laetrile: A lesson in cancer quackery’ (1981) 31 CA 91, 92.

<sup>143</sup> William Serfontein, *Cancer Diagnosed: What Now?* (Xlibris Corporation 2011) 273. See also, Robert Laplante, *Cancer No Chemo* (iUniverse 2013) 140.

<sup>144</sup> ‘Apricot Kernals’ <[www.nuanaturals.com/#!online-store/cjt5!/Apricot-Kernals/p/47110102](http://www.nuanaturals.com/#!online-store/cjt5!/Apricot-Kernals/p/47110102)> accessed 16 January 2016. This product is a raw food product, suggesting that it has not been processed and, therefore, that the levels of amygdalin have not been diminished. In Günnur Tunçel and others, ‘The effects of grinding, soaking and cooking on the degradation of amygdalin of bitter apricot seeds’ (1995) 53 Food Chemistry 447-449, the authors found that “both grinding and soaking cause a considerable reduction in the cyanogenic potential”. However, they concluded that “none of the products obtained were considered safe for human consumption. i.e. a further microbiological detoxification must be added”. Consumers purchasing raw apricot kernels are unlikely to possess the knowledge or the means to process the kernels in this way so as to make them safe for consumption.

<sup>145</sup> In fact, the website recommends blending the kernels into soups and smoothies.

<sup>146</sup> V Herbert (n 140) 1126.

<sup>147</sup> Regulation 178/2002/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, art 2.



contains toxins that may have a substantial detrimental effect on human health, it is asserted that it should be considered a medicinal product.<sup>148</sup>

**(b)(viii) MISLEADING COMMERCIAL PRACTICE IN RELATION TO A PRODUCT'S COMPOSITION, INGREDIENTS, COMPONENTS OR ACCESSORIES**

***Homeopathic Medicinal Products***

As with the s 43(2)(a) provision relating to the existence and nature of the product, the sale of homeopathic medicinal products provides an excellent example of misleading practice in relation to a product's composition or ingredients, given the uncertainty in respect of the quantity and, indeed, the very presence of an active ingredient as the level of dilution increases.

Section 46 addresses the issue of misleading omissions, stating that a commercial practice is misleading if the trader omits or conceals material information that the customer would need to make an informed transactional decision, where such a practice would be likely to cause such a consumer to make a transactional decision that they would not otherwise make.<sup>149</sup> The information provided by the trader, if any, must not be unclear, unintelligible, ambiguous or untimely.<sup>150</sup> The materiality of the information provided by the trader encompasses, *inter alia*, the main characteristics of the product, to an extent appropriate to the medium and product.<sup>151</sup>

The omission of information on a CAM product regarding its status as such or failing to provide, in concise, plain language, a statement of demonstrated clinical efficacy, may be considered misleading under the Act, as this information is material and would affect the transactional decision of the average consumer, notwithstanding its validity under legislation governing medicinal products for human use. This applies, for example, to homeopathic medicinal products registered under the SRS and to those authorised under the NRS.

A product registered under the SRS must currently carry a statement that it is a "homeopathic medicinal product without therapeutic indications".<sup>152</sup> The phrasing and

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<sup>148</sup> Directive 2001/83/EC (n 9), as amended, art 1(2), 'Medicinal product' is defined as "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings" or, "(b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

<sup>149</sup> Consumer Protection Act 2007, s 46(1).

<sup>150</sup> *ibid* s 46(2)(a).

<sup>151</sup> *ibid* s 46(3)(a).

<sup>152</sup> Directive 2001/83/EC (n 9), as amended, art 69.1.

words do not form part of the vernacular and could be made significantly clearer for the average consumer, stating instead, “this product has/has not been tested using standard clinical trials and has not been scientifically proven to relieve the symptoms of, or cure any condition”.<sup>153</sup>

Those products authorised under the NRS and carrying a therapeutic indication must currently bear a label stating that “any evidence of efficacy on the part of the product has not been based on the outcome of clinical trials”.<sup>154</sup> Again, this could be clarified for consumers, stating instead that the product is “a homeopathic medicinal product, which has not been demonstrated to be efficacious through the use of standard clinical trials but which some people have traditionally used for the symptomatic relief of...”. Indeed, even this revised statement of efficacy such products may not go far enough to enlighten the consumer as to the true nature of the available evidence. A standard system of clinical trials, whereby a consumer could directly compare two medicinal products of whatever kind, making a purchasing decision on that basis, would be a simpler, clearer and more equitable approach to take, and would remove the existing requirement for labelling that obscures, rather than clarifies, the true nature of product. Any medicinal product made available for human use should be proven safe, of a standard quality and efficacious.

The manner in which remedies are labelled, including a statement of the quantity of active ingredient per dose, given in a standard, internationally recognisable unit of measurement for the medium in question, is crucial for informed consumer choice. In Ireland, the quantity of active ingredients is commonly provided in either grams, milligrams or micrograms, or in millilitres or percentage of total.<sup>155</sup> Application, by manufacturers of homeopathic medicinal products, of a metric which inverts the convention through the use of increasing numerical values to represent decreasing concentration of the active ingredient, together with the use of unfamiliar, homeopathy-specific units (“X”, “C”, “M”) is contrary to the requirements of s 46(2)(a) that information not be provided in a manner that is unclear, unintelligible or ambiguous. Failing to provide clear information on dose or presence of an active ingredient obscures consumer understanding of the product and its compositional characteristics and should be considered misleading for the purpose of s 46.

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<sup>153</sup> It is asserted that, for those products where clinical trials have taken place, any garnered evidence as to efficacy for any condition would have been provided to the IMB so as to obtain a higher standard of authorisation under the NRS, in order to carry a therapeutic indication and a more compelling rationale for purchase by consumers.

<sup>154</sup> Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540, reg 11(5)(b).

<sup>155</sup> Medicinal Products (Prescription and Control of Supply) Regulations 2003, SI 2003/540, sch 1(b).

In addition, s 55(1) provides a list of prohibited commercial practices, the most relevant of which is a prohibition on the making of a representation that a product is able to cure an illness, dysfunction or malformation, if it cannot.<sup>156</sup> For the purposes of the Act, “representation” includes

...any oral, written, visual, descriptive or other representation by a trader, including any commercial communication, marketing or advertising and any term or form of a contract, notice or other document used or relied on by a trader in connection with a consumer transaction.<sup>157</sup>

This includes information provided by the trader in-store and any documentation provided by them that is likely to influence the transactional decision. Interestingly, under s 68, where the truth of a representation made by the trader is at issue, the trader must show on the balance of probabilities that it is true, otherwise it will be presumed untrue. This shift in the burden of proof from the consumer to the trader goes some small way towards balancing the inequality of power between the parties.

## **2.4 ENFORCEMENT UNDER THE 2007 ACT AND THE COMPETITION AND CONSUMER PROTECTION ACT 2014**

*[L]egislators must not only seek to prevent the perpetuation of false information in the market place, they must ensure that there is a regulatory regime in operation which acts as a deterrent to unscrupulous traders, overcoming any perverse incentives which would otherwise arise if misleading practices were punished purely by the market and private law.<sup>158</sup>*

Part V of the 2007 Act sets out the penalties for those using unfair and misleading commercial practices. It also provides for the possibility of both statutory and civil remedies, which are available to those suffering damage caused by such practices. Finally, and perhaps most significantly, the Act establishes the National Consumer Agency,<sup>159</sup> since replaced by the Competition and Consumer Protection Commission (CCPC),<sup>160</sup> an amalgamated independent

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<sup>156</sup> Consumer Protection Act 2007, s 55(1)(g). See also *Lietuvos Respublikos konkurencijos taryba nutarimas dėl reklaminių teiginių apie prekes, kurioms priskiriamas įvairaus pobūdžio poveikis sveikatai, atitiktis Lietuvos Respublikos reklamos įstatymo* [2011] No. 2S-17 (“Kristalė”), where the Lithuanian Competition Council found [31] that, “In order to be able to say that the product referred to in the advertisement has the properties of these features, [it] should be confirmed by the existence of objective data related specifically to the same products, assessing their relative impacts”. The Council went on to state that, “Such an effect referred to in the advertisement should be based on independent clinical research”.

<sup>157</sup> Consumer Protection Act 2007, s 2(1).

<sup>158</sup> Nathan Reilly (n 85) 129.

<sup>159</sup> Consumer Protection Act 2007, s 7(1).

<sup>160</sup> Competition and Consumer Protection Act 2014, s 9.

statutory body charged with, *inter alia*, promoting and protecting the interests and welfare of consumers,<sup>161</sup> investigating suspected offences,<sup>162</sup> enforcing consumer protection legislation,<sup>163</sup> and encouraging compliance.<sup>164</sup>

It is asserted that the CCPC must play a key role in the overhaul of the regulatory framework for CAM therapies and therapists.

### **3. IS THE PRODUCT OF MERCHANTABLE QUALITY FOR THE PURPOSES OF THE SALE OF GOODS AND SUPPLY OF SERVICES ACT 1980?**

Having provided numerous examples of unfair, misleading or misrepresentative commercial practices in the realm of CAM, it is necessary to examine the substantive matter of the sale or provision of the CAM products or services themselves. Again, several issues arise in this regard.

First, and as mentioned repeatedly throughout this chapter, there is a notable lack of high quality scientific evidence as to the efficacy of such therapies.<sup>165</sup> Section 14(2) of the 1980 Act states that goods must be of merchantable quality, defined in s 14(3) as “fit for the purpose or purposes for which goods of that kind are commonly bought and as durable as it is reasonable to expect having regard to any description applied to them, the price (if relevant) and all the other relevant circumstances”.<sup>166</sup> As CAM products, such as homeopathic medicinal products, are commonly purchased and used to treat injury or illness or to maintain health, the question arises of whether they can be considered to be of merchantable quality, where the best available evidence suggests that they are no better than placebo.<sup>167</sup> Such a lack of proven efficacy is all the more worrying in respect of

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<sup>161</sup> *ibid* s 10(1)(b).

<sup>162</sup> *ibid* s 10(1)(c).

<sup>163</sup> *ibid* s 10(1)(d).

<sup>164</sup> *ibid* s 10(1)(e).

<sup>165</sup> Edzard Ernst, ‘A systematic review of systematic reviews of homeopathy’ (2002) 54 *British Journal of Clinical Pharmacology* 577, and Edzard Ernst and Peter H Canter, ‘A systematic review of systematic reviews of spinal manipulation’ (2006) 99 *Journal of the Royal Society of Medicine* 192.

<sup>166</sup> Sale by description is provided for in s 13 of the 1980 Act, which states: (1) that “Where there is a contract for the sale of goods by description, there is an implied condition that the goods shall correspond with the description (2) A sale of goods shall not be prevented from being a sale by description by reason only that, being exposed for sale, they are selected by the buyer (3) A reference to goods on a label or other descriptive matter accompanying goods exposed for sale may constitute or form part of a description”. The packaging of good may comprise an element of the description, as set out in *Re Moore & Co and Landauer & Co* [1921] 2 KB 519, 523 (Bankes LJ). In addition, that the goods in question may be sold by description even if they are made available for inspection, provided that the article sold is sold as a thing corresponding to a description (ss 2 of the 1980 Act), was set out in the case of *O’Connor v Donnelly* [1944] Ir Jur Rep 1, where Gavan Duffy J followed the case of *Grant v Australian Knitting Mills Ltd* [1936] AC 85, 99-100. However, the buyer must rely on the description, as addressed in detail in *Harlingdon and Leinster Enterprises Ltd v Christopher Hull Fine Art Ltd* [1991] 1 QB 564.

<sup>167</sup> Aijing Shang and others, ‘Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy’ (2005) 366 *Lancet* 726.

other products sold for the treatment of serious illness such as cancer<sup>168</sup> or HIV,<sup>169</sup> even before the side-effects<sup>170</sup> caused by the substances themselves are considered.

Sections 14(2) and 14(3) of the 1980 Act apply to any product sold in the course of business. Section 14(2) states that there is implied into such contracts for sale a condition that the goods supplied are of merchantable quality, meaning that they are as fit for the purpose or purposes for which goods of that kind are commonly bought.<sup>171</sup> Although goods containing latent defects are not considered to be merchantable in most circumstances,<sup>172</sup> it may be significantly more difficult to argue that a qualitatively normal CAM product is not of merchantable quality for the purposes of the Act.

As CAM products are primarily purchased for their curative properties and, to a lesser extent, for their minimal deleterious effects,<sup>173</sup> if the product is not suitable to fulfil that purpose or fails to do so in the expected manner, is an action under s 14(2) and (3) open to the consumer? Additionally, if a trader is asked for a product to treat a particular condition and the product he supplies fails to fulfil this specific purpose, is this actionable under s 14(4) of the Act?<sup>174</sup>

The situation in respect of the s 14(2) and (3) provisions is not straightforward. A trader might, for example, argue that the product is commonly bought as part of an overall holistic theme, its objectives being ‘wellness’, ‘healthfulness’ or ‘balance’, along with other such diffuse goals, without making any specific reference to healing. Traders may be reluctant to make direct claims in respect of the effects of CAM products, and so a consumer challenging the merchantability of a product on this

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<sup>168</sup> Stefania Milazzo, Edzard Ernst, Stephane Lejeune and others, ‘Laetrile treatment for cancer’ (2011) 11 Cochrane Database of Systematic Reviews CD005476.

<sup>169</sup> Jianping Liu, Eric Manheim and Mingxing Yang, ‘Herbal medicines for treating HIV infection and AIDS’ (2005) 3 Cochrane Database of Systematic Reviews CD003937.

<sup>170</sup> V Herbert (n 140) lists a number of serious side-effects associated with the ingestion or injection of Laetrile, such as hypotension, tachycardia, collapse, dyspnoea, nausea, vomiting, diarrhoea, headache, palpitations, muscular twitching, hypothyroidism, restlessness, sweating, bilateral optic atrophy, nerve deafness, mental slowing, myelopathy, convulsion, coma and death. See also, US Food and Drug Administration, ‘FDA warns consumers of serious harm from drinking Miracle Mineral Solution (MMS)’ (2010). The FDA found that “The product, when used as directed, produces an industrial bleach that can cause serious harm to health” and “received several reports of health injuries from consumers using this product, including severe nausea, vomiting, and life-threatening low blood pressure from dehydration. ... MMS claims to treat multiple unrelated diseases, including HIV, hepatitis, the H1N1 flu virus, common colds, acne, cancer, and other conditions. The FDA is not aware of any research that MMS is effective in treating any of these conditions”

<[www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220747.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220747.htm)> accessed 8 December 2015.

<sup>171</sup> Sale of Goods and Supply of Services Act 1980, s 14(3).

<sup>172</sup> *ibid* s 14(2). This states that there is no implied condition as to merchantability where the defect is drawn to the attention of the buyer before the contract was entered into or where the buyer has examined the goods prior to entering into the contract and such examination ought to have revealed the defect.

<sup>173</sup> Diane M Shumay and others (n 137). The author does not agree with the opinion that CAM is harmless or without side-effects but concurs that the perception of harmlessness represents a significant consumer motivation for the widespread use of such treatments. See Chapter 6.

<sup>174</sup> Sale of Goods and Supply of Services Act 1980, s 14(4), the contract for the sale of goods to a buyer who requested them for a particular specified purpose contains an implied condition as to the fitness of those goods for that purpose, unless the buyer did not rely or should not reasonably have relied upon the skill or judgement of the seller.

ground may have difficulty establishing a case. Indirect claims may, however, be taken into account as being part of the description applied to the goods under s 14(3).

It is particularly notable that, as with the 2007 Act, a homeopathic product sold to a consumer, which is so dilute as to contain none of the active ingredient listed on the label, may not be considered to be of merchantable quality under the 1980 Act but may still be registered for placing on the market under the NRS and the SRS, which provide for a minimum but not a maximum degree of dilution.

In relation to s 14(4), if a trader or his agent represents to a consumer that a particular product is suitable to treat the specific condition about which the consumer has inquired and the consumer relies reasonably on the skill and judgement of the trader, there is an implied condition that it will do so and detrimental reliance is foreseeable.<sup>175</sup> If the consumer states or implies that they are relying on the expertise of the trader as to whether the item being purchased is fit for a particular purpose, or if the goods are merely purchased from a trader whose ordinary business it is to sell such items, it is implied into the contract that the goods are fit for such a purpose.<sup>176</sup> If the product does not (or cannot) perform as represented,<sup>177</sup> or where the misrepresentation forms part of the contract,<sup>178</sup> the consumer may seek to rescind the completed contract under s 44 of the 1980 Act, and seek damages where the misrepresentation causes loss under s 45. Again, the provisions of the NRS and SRS contradict this.

Similarly to s 68 of the 2007 Act, under s 45(1) of the 1980 Act, where the consumer is induced to enter a contract on foot of a misrepresentation, the burden of proof shifts and the trader will be liable for damages if they cannot prove their belief in the truth of the representation at the time it was made. This is not particularly burdensome for the trader and provides only a modicum of support for a misled consumer with an inequality of arms. Finally, s 45(2) provides that the court may award damages in lieu of rescission, having considered the effects of both on both parties.

#### **4. IS THE PRODUCT DEFECTIVE UNDER THE PROVISIONS OF THE LIABILITY FOR DEFECTIVE PRODUCTS ACT 1991?**

A further problem arises in respect of product safety and the provisions of the Liability for Defective Products Act 1991, (hereafter “the 1991 Act”), relating to defectiveness. Section 5(1) of the Act states

...For the purposes of this Act a product is defective if it fails to provide the safety which a person is entitled to expect, taking all circumstances into account, including—

- (a) the presentation of the product,

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<sup>175</sup> *Hedley Byrne v Heller & Partners* [1963] AC 465, 466.

<sup>176</sup> *Wallis v Russell* [1902] 2 IR 585 (CA), 627.

<sup>177</sup> Sale of Goods and Supply of Services Act 1980, s 44(b).

<sup>178</sup> *ibid* s 44(a).

- (b) the use to which it could reasonably be expected that the product would be put, and
- (c) the time when the product was put into circulation.

Though, clearly, CAM products containing defects such as contaminants do not provide the safety which a person is entitled to expect for the purposes of the 1991 Act,<sup>179</sup> some difficulty lies in determining whether a qualitatively normal CAM product is 'safe'. Liability under the 1991 Act is strict,<sup>180</sup> meaning that the plaintiff need only show a defect causing damage in the absence of a defence.<sup>181</sup> Proof of negligence on the part of the respondent is not required. However, the defect of some CAM products such as Ayurvedic remedies,<sup>182</sup> traditional Chinese medicinal preparations,<sup>183</sup> or products sold to treat serious illnesses, such as Laetrile, lies not only in the product *per se*, but in its presentation and the use to which it could reasonably be expected to be put. Such products may give rise to dangerous interactions when used alongside other CAM or conventional pharmaceutical products,<sup>184</sup> may cause serious problems for consumers with particular existing medical conditions, or may be unsafe by virtue of their active ingredients.<sup>185</sup> Damage caused by such a product, in circumstances where it is sold without a comprehensive listing of contraindications, precautions and potential side-effects, may bring it and the class of CAM medicinal products or devices within the remit of the 1991 Act.

In addition, homeopathic preparations rely on the presence of a miniscule quantity of a particular active ingredient or a combination of ingredients, to have the effect claimed in treating specified conditions. If, due to the very high degree of dilution, that ingredient is determined to be absent in

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<sup>179</sup> For example, the presence of inconsistent levels of a toxic substance. See US Food and Drug Administration (FDA), 'Hyland's Teething Tablets: recall - risk of harm to children' (2010) <[www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm230764.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm230764.htm)> accessed 12 December 2015. See also, US Food and Drug Administration, 'FDA warns against the use of homeopathic teething tablets and gels' (2016) <[www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm523468.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm523468.htm)> accessed 3 October 2016.

<sup>180</sup> Liability for Defective Products Act 1991, s 2(1).

<sup>181</sup> *ibid* s 6.

<sup>182</sup> Vishesh Agarwal, Akhil Abhijnhan and Prakash Raviraj, 'Ayurvedic medicine for schizophrenia' (2007) Cochrane Database of Systematic Reviews CD006867.

<sup>183</sup> Chung-Hsin Chen and others, 'Aristolochic acid-associated urothelial cancer in Taiwan' (2012) Proceedings of the National Academy of Sciences <[www.pnas.org/content/early/2012/04/03/1119920109.full.pdf+html](http://www.pnas.org/content/early/2012/04/03/1119920109.full.pdf+html)> accessed 12 December 2013.

<sup>184</sup> Thomas YK Chan, 'Interaction between warfarin and danshen (*Salvia miltiorrhiza*)' (2001) 35 *Annals of Pharmacotherapy* 501, 503.

<sup>185</sup> Jeffrey Brent, *Critical Care Toxicology: Diagnosis and Management of the Critically Poisoned Patient* (Mosby 2005) 1308. Yohimbine, the active ingredient in yohimbe, a herbal product used as a treatment for erectile dysfunction, causes hypertension and should be avoided in anyone with pre-existing hypertension.

its entirety,<sup>186</sup> such a product could conceivably be considered defective under the 1991 Act, as well as being actionable under ss 14(3), 44 and 45 of the 1980 Act.

Considering the significant number of CAM goods and services available and the impression created by some providers of such in the minds of the average consumer,<sup>187</sup> the average member of a particular group of consumers,<sup>188</sup> and the average member of a particularly vulnerable group of consumers<sup>189</sup> that such goods and services are not only at least as effective as conventional medical treatment,<sup>190</sup> but are also safer<sup>191</sup> and more holistic<sup>192</sup> (particularly convincing when such treatments are endorsed by family and friends),<sup>193</sup> the disparity between such marketing and proven effect, combined with dearth of meaningful oversight, is distinctly disquieting.

Upon review of the legislation as a collective, it appears that the emphasis remains on safety rather than efficacy, which is simultaneously reassuring and frustrating for consumers. For CAM products such as some herbal or homeopathic preparations, magnetic bracelets or detoxifying foot patches, as long as the consumer is not at risk of harm, the element of efficacy is left virtually unexplored. Clearly, this is an unacceptable situation and one which requires urgent revision to ensure full vindication of consumer rights in respect of CAM.

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<sup>186</sup> Edzard Ernst, 'Is homeopathy a clinically valuable approach?' (2005) 26 Trends in Pharmacological Sciences 547, "many homeopathic remedies are diluted beyond Avogadro's number ( $6.0225 \times 10^{23}$ ) where the likelihood approaches zero that a single molecule of the original substance is contained in the remedy". Clearly, the presence of a single molecule of active ingredient is also unlikely to have any curative effect.

<sup>187</sup> Case C-210/96 *Gut Springenheide* (n 105), para 31, and, later, Directive 2005/29/EC (n 6) in the eighteenth recital to the Preamble, state that the "average consumer" is one who "is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors".

<sup>188</sup> Directive 2005/29/EC (n 6), eighteenth recital to the Preamble, and the Consumer Protection Act 2007, s 2(2)(a).

<sup>189</sup> *ibid*, nineteenth recital to the Preamble, and the Consumer Protection Act 2007, s 2(2)(b).

<sup>190</sup> Dennis L Citrin and others, 'Beliefs and perceptions of women with newly diagnosed breast cancer who refused conventional treatment in favor of alternative therapies' (2012) 17 The Oncologist 607, 609.

<sup>191</sup> *ibid*.

<sup>192</sup> André Busato and Beat Künzi, 'Differences in the quality of interpersonal care in complementary and conventional medicine' (2010) 10 BMC Complementary and Alternative Medicine 63, 69.

<sup>193</sup> Opher Caspi and others, 'Alternative medicine or "alternative" patients: A qualitative study of patient-oriented decision-making processes with respect to complementary and alternative medicine' (2004) 24 Medical Decision Making 64, 70.



## PART II

### THE SUPPLY OF CAM SERVICES

#### 5. CONTRACTS FOR THE SUPPLY OF SERVICES

The supply of services<sup>194</sup> in Ireland falls under the auspices of numerous general and specific pieces of regulatory infrastructure, depending on the particular service in question. For the purpose of this thesis, it is instructive to acknowledge, in particular, two relevant general pieces of legislation and one specific piece, namely: the 1980 Act; the 2007 Act; and the European Communities (Unfair Terms in Consumer Contracts) Regulations 1995.

A discussion of service provision under the 1980 Act gives rise to a number of questions, including who determines whether a provider has the necessary skills to provide a CAM service for the purposes of the Act, what those skills are, on what criteria the determination is based and what the definition of “due skill, care and diligence” means in the context of CAM. To understand the protection provided by it for users of CAM services, it is necessary to determine the extent of the application of s 39.

The 1980 Act applies to contracts for the supply of services where the supplier acts in the course of business. Section 39 of the 1980 Act provides a list of implied terms for contracts for the provision of services under the Act, stating that:

- a) the service provider must have the necessary skill to render the service<sup>195</sup>;
- b) he will supply the service with due skill, care and diligence<sup>196</sup>;
- c) where materials are used, they will be sound and reasonably fit for the purpose for which they are required<sup>197</sup>; and
- d) where goods are supplied under the contract, they will be of merchantable quality.<sup>198</sup>

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<sup>194</sup> Treaty on the Functioning of the European Union (TFEU) OJ C202/1, Art 57 provides a negative definition of services, stating, “Services shall be considered to be ‘services’ within the meaning of the Treaties where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons. ‘Services’ shall in particular include: (a) activities of an industrial character; (b) activities of a commercial character; (c) activities of craftsmen; (d) activities of the professions”. Services might be considered as intangible, whereas goods are tangible. For example, a homeopath may take a history, build a profile of the patient and recommend a homeopathic medicinal product to treat the patient or consumer (service) and a homeopathic dispensary may then sell the product (good) to the consumer.

<sup>195</sup> Sale of Goods and Supply of Services Act 1980, s 39(a).

<sup>196</sup> *ibid* s 39(b).

<sup>197</sup> *ibid* s 39(c).

<sup>198</sup> *ibid* s 39(d).

These are neither conditions nor warranties, as provided for in relation to the sale of goods, and so exclusion clauses are permitted where both parties had notice of the exclusion,<sup>199</sup> where normally excluded in the course of dealing or where both parties are aware of the common practice of exclusion in such trade. Service providers must also ensure that they stay within the bounds of the European Communities (Unfair Terms in Consumer Contracts) Regulations 1995,<sup>200</sup> which applies to any term in a consumer contract which has not been individually negotiated<sup>201</sup> and which could be deemed unfair, resulting in a “significant imbalance in the parties’ rights and obligations under the contract to the detriment of the consumer”.<sup>202</sup> Determination of the unfairness of a term and whether the service provider acted in good faith,<sup>203</sup> is based, *inter alia*, on the strength of the bargaining positions of the parties and the extent to which the seller or supplier has dealt fairly and equitably with the consumer whose legitimate interests he has to take into account.<sup>204</sup> Schedule 3 sets out a list of terms deemed to be unfair, the most relevant of which, for the purposes of CAM services, are those:

- (a) excluding or limiting the legal liability of a seller or supplier in the event of the death of a consumer or personal injury to the latter resulting from an act or omission of that seller or supplier;
- (b) inappropriately excluding or limiting the legal rights of the consumer vis-a-vis the seller or supplier or another party in the event of total or partial non-performance or inadequate performance by the seller or supplier of any of the contractual obligations, including the option of offsetting a debt owed to the seller or supplier against any claim which the consumer may have against him;
- (k) enabling the seller or supplier to alter unilaterally without a valid reason any characteristics of the product or service to be provided; and,
- (m) giving the seller or supplier the right to determine whether the goods or services supplied are in conformity with the contract, or giving him the exclusive right to interpret any term of the contract.

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<sup>199</sup> *Parker v The South Eastern Railway Company* [1877] 2 CPD 416, 428 (Bramwell LJ). See also, *Early v Great Southern Railway Company* [1938] 1 IR 409 (SC). In *Spurling Ltd v Bradshaw* [1956] EWCA Civ 3, Denning LJ stated, “[T]he more unreasonable a clause is, the greater the notice which must be given of it. Some clauses which I have seen would need to be printed in red ink on the face of the document with a red hand pointing to it before the notice could be held to be sufficient”.

<sup>200</sup> Council Directive 93/13/EEC (n 13), as implemented by European Communities (Unfair Terms in Consumer Contracts) Regulations 1995, SI 1995/27.

<sup>201</sup> European Communities (Unfair Terms in Consumer Contracts) Regulations 1995, SI 1995/27, reg 3(1).

<sup>202</sup> *ibid* reg 3(2).

<sup>203</sup> *ibid*.

<sup>204</sup> *ibid* sch 2.

Additionally, the *contra proferentem* rule applies,<sup>205</sup> whereby any term deemed to be ambiguous or unclear will be determined in favour of the consumer as the weaker party in the bargain. Where a contract term is deemed unfair, it will not be binding on the parties.<sup>206</sup>

The rules established by the 1980 Act and the 1995 Regulations ought to influence the behaviour of traders in the provision of CAM services. In attempting to undertake a pragmatic analysis of these rules, mentioned briefly in the introduction to this chapter, it is helpful to provide a framework within which their application may be considered. Chiropractic provides such a framework.

Chiropractic is a popular CAM service based on the belief that the nervous system, skeletal system and muscular system interact and that if that interaction is blocked (known as a “subluxation”),<sup>207</sup> disease and/or pain will occur.<sup>208</sup> It is categorised as a manipulative therapy, whereby the joints (predominantly in the vertebral column) are moved in such a way as to correctly align the bones, muscles and nerves in order to prevent or treat such disease or pain. It is an established CAM therapy, which is statutorily regulated in a number of jurisdictions including the UK,<sup>209</sup> although not in Ireland at the present time. It is apt to provide a brief overview of chiropractic, before returning to consider the law on supply of services in this light.

## 5.1 A BRIEF OVERVIEW OF CHIROPRACTIC

Chiropractic was founded in 1895 by Daniel David Palmer, who hypothesised that vertebral manipulation could cure disease.<sup>210</sup> As with homeopathy and acupuncture, his claimed to be a vitalist philosophy linking illness with disruption in the flow of nervous energy or “universal intelligence”,<sup>211</sup> a concept not dissimilar to that of intelligent design.<sup>212</sup>

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<sup>205</sup> *ibid* reg 5(2).

<sup>206</sup> *ibid* reg 6(1).

<sup>207</sup> International Chiropractors Association, “What are vertebral subluxations? - A vertebral subluxation is the result of spinal bones with improper motion or position affecting nerve communications between your brain and your body ... Only a chiropractic examination can detect vertebral subluxations. And only chiropractic adjustments can reduce their effect to your nervous system, naturally” <[www.chiropractic.org/content.asp?contentid=171](http://www.chiropractic.org/content.asp?contentid=171)> accessed 15 December 2015.

<sup>208</sup> *ibid*.

<sup>209</sup> UK Chiropractors Act 1994, s 32(1), “A person who (whether expressly or by implication) describes himself as a chiropractor, chiropractic practitioner, chiropractitioner, chiropractic physician, or any other kind of chiropractor, is guilty of an offence unless he is a registered chiropractor”.

<sup>210</sup> Robert A Leach, *The Chiropractic Theories: A Textbook of Scientific Research* (Lippincott Williams & Wilkins 2004) 15.

<sup>211</sup> DD Palmer, *The Chiropractor's Adjuster: A Textbook of the Science, Art and Philosophy of Chiropractic for Students and Practitioners* (Portland Printing House 1910).

<sup>212</sup> Ronald L Numbers, *The Creationists: From Scientific Creationism to Intelligent Design* (Harvard University Press 2006) 373, 379–380. See also Alana K Callender, ‘The mechanistic/vitalistic dualism of chiropractic and general systems theory: Daniel D. Palmer and Ludwig von Bertalanffy’ (2007) 14 *Journal of Chiropractic Humanities* 1. However, Callender astutely points towards the dualism that incorporates both the vitalist and the mechanical aspects of chiropractic treatment, the latter of which is emphasised in modern chiropractic practice.

As noted above, chiropractic is based upon the assertion that all disease is caused by vertebral subluxations, which are misalignments of the spine. B.J. Palmer, the son of Daniel Palmer, stated that:

Chiropractors have found in every disease that is supposed to be contagious, *a cause in the spine* ... If we had one hundred cases of small-pox, I can prove to you where, in one, you *will* find a subluxation and you will find the *same conditions* in the other ninety-nine.<sup>213</sup>

Chiropractors aim to correct these subluxations, removing the symptoms and the cause of the disease.

It is important, however, to differentiate between medical and chiropractic subluxation.

### 5.1.1 MEDICAL VERSUS CHIROPRACTIC SUBLUXATION

Medical or orthopaedic subluxation is defined as

... a painful partial dislocation. Simple misalignment of a vertebra, also referred to as a 'subluxation', is commonly caused by disc degeneration, curvatures, spondylolysis and structural abnormalities. Such a subluxation may or may not be mechanically symptomatic and can be seen on a plain X-ray image. In the absence of pathology, such as disc herniation or osteophyte formation, these common vertebral subluxations or misalignments rarely affect spinal nerves and have never been associated with organic disease. Spinal nerves supply musculoskeletal structures. The body's organs are supplied primarily by autonomic nerve ganglia and plexuses located outside the spinal column, and by cranial and sacral nerves that pass through solid bony openings, providing overlapping nerve supply independent of spinal nerves that pass through moveable vertebrae.<sup>214</sup>

Chiropractic subluxation, however, is described as

... [a] lesion or dysfunction in a joint or motion segment in which alignment, movement integrity and/or physiological function are altered, although contact between joint surfaces remains intact. It is essentially a functional entity, which may influence biomechanical and neural integrity.<sup>215</sup>

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<sup>213</sup> Bartlett J Palmer, *The Philosophy of Chiropractic* (Palmer School of Chiropractic 1909).

<sup>214</sup> Samuel Homola, 'Real orthopaedic subluxations versus imaginary chiropractic subluxations' (2010) 15 *Focus on Alternative and Complementary Therapies* 284.

<sup>215</sup> World Health Organisation, *WHO Guidelines on Basic Training and Safety in Chiropractic* (WHO 2005) 4.

Chiropractic subluxations are not visible upon x-ray examination,<sup>216</sup> nor has the reliability of other detection methods been established.<sup>217</sup> Further, medical or orthopaedic subluxations are not associated with any organic disease state,<sup>218</sup> while chiropractic subluxations are claimed to give rise to systemic disease as a result of impaired nerve function. The combination of chiropractic subluxation and associated disease is known as a “subluxation complex”.<sup>219</sup>

### 5.1.2 THE SHIFTING SANDS OF CHIROPRACTIC TREATMENT

With the general incremental shift towards evidence-based medicine, the existence of chiropractic subluxations has been the subject of debate in recent years. Though the stance taken by the World Federation of Chiropractic in 2001 was an affirmation of their belief in the existence of such subluxations,<sup>220</sup> in 2010 the General Chiropractic Council, (hereafter “GCC”), the regulatory body for the chiropractic industry in the UK, stated that the theory of chiropractic subluxation as the cause of disease was not supported by any clinical evidence.<sup>221</sup> However, at the time of writing, many practitioners in Ireland refer to chiropractic subluxation as the basis for the therapy they offer, claiming to treat conditions such as asthma,<sup>222</sup> colic,<sup>223</sup> ulcers, or

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<sup>216</sup> Anthony L Rosner and others, *The Role of Subluxation in Chiropractic* (Foundation for Chiropractic Education and Research 1997), “slight misalignments may not be detectable by any of the current technological methods”.

<sup>217</sup> Simon D French, Sally Green and Andrew Forbes, ‘Reliability of chiropractic methods commonly used to detect manipulable lesions in patients with chronic low-back pain’ (2000) 23 *Journal of Manipulative and Physiological Therapeutics* 231, 237, “The assessment of commonly used chiropractic diagnostic methods to detect manipulable lesions in the lower thoracic and lumbar spine and the sacroiliac joints in patients with chronic mechanical low-back pain has revealed that the measures are not reproducible. The decision to manipulate was not reproducible either by the same examiners on different occasions or by different examiners on the same occasion. On the basis of the results of this study, the use of these examination techniques to detect manipulable lesions in patients with chronic mechanical low-back pain should not be seen by practitioners to provide reliable information concerning where to direct a manipulative procedure”.

<sup>218</sup> Samuel Homola (n 210).

<sup>219</sup> World Health Organisation (n 211) 4, “Subluxation complex - A theoretical model and description of the motion segment dysfunction, which incorporates the interaction of pathological changes in nerve, muscle, ligamentous, vascular and connective tissue”.

<sup>220</sup> WFC Policy Statement, ‘Adoption of the ACC Paradigm Approved by the Assembly of the World Federation of Chiropractic’ (2001).

<sup>221</sup> UK General Chiropractic Council, ‘Guidance on Claims made for the Chiropractic Vertebral Subluxation Complex’ (2010).

<sup>222</sup> Appendix III. See also Maria Hondras, Klaus Linde and Arthur P Jones, ‘Manual Therapy for asthma’ (2005) 2 *Cochrane Database of Systematic Reviews* CD001002.

<sup>223</sup> Clontarfchiropractic.ie, ‘More about Chiropractic’ <[www.clontarfchiropractic.ie/what-we-do/more-about-chiropractic](http://www.clontarfchiropractic.ie/what-we-do/more-about-chiropractic)> accessed 16 October 2016. See also Dawn Dobson and others, ‘Manipulative therapies for infantile colic’ (2012) *Cochrane Database of Systematic Reviews* CD004796, “The studies involved too few participants and were of insufficient quality to draw confident conclusions about the usefulness and safety of manipulative therapies. Although five of the six trials suggested crying is reduced by treatment with manipulative therapies, there was no evidence of manipulative therapies improving infant colic when we only included studies where the parents did not know if their child had received the treatment or not”.

dysmenorrhoea,<sup>224</sup> through the use of vertebral manipulation. There is some evidence of beneficial effect for chiropractic therapy in lower back pain, though the studies in the relevant systematic review were of variable quality and the review concluded that

...while combined chiropractic interventions slightly improved pain and disability in the short term and pain in the medium term for acute and subacute low-back pain, there is currently no evidence to support or refute that combined chiropractic interventions provide a clinically meaningful advantage over other treatments for pain or disability in people with low-back pain. Any demonstrated differences were small and were only seen in studies with a high risk of bias.<sup>225</sup>

Though numerous other studies have been carried out on the efficacy of chiropractic treatment in various conditions, as with homeopathy and acupuncture, studies were of varying quality and so meta-analysis was the most appropriate method of review. Such a meta-analysis, including studies published over five years, concluded that, “[g]iven the possibility of adverse effects, the review does not suggest that spinal manipulation is a recommendable treatment”, though it did acknowledge the existence of some (“minimal”) evidence of efficacy in the treatment of acute or chronic back pain.<sup>226</sup> It is difficult to justify the commercial availability of unproven treatments, and as is the case with many other therapies mentioned throughout this thesis, the situation is not improved by the risks of chiropractic treatment.

### 5.1.3 RISK-BENEFIT IN CHIROPRACTIC

Not only does the efficacy of the chiropractic treatment for virtually all conditions remain unproven, but it also carries with it inherent risks, the most serious of which is vascular dissection (most commonly vertebral artery dissection, known as VAD), causing stroke and death. VAD can be caused by the use of a chiropractic procedure known as the High Velocity Thrust (HVT) technique, a short, sharp motion<sup>227</sup> applied

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<sup>224</sup> Drstevegp.ie, ‘Rathmines Chiropractic’ (2016), “What you may not be aware of is chiropractic’s success in treating a number of non-soft tissue conditions like dysmenorrhea (painful menses), ulcers, migraine headaches and ear infections in children” <[www.drstevegp.ie/rathmines-chiropractic/](http://www.drstevegp.ie/rathmines-chiropractic/)> accessed 16 October 2016. See also Michelle Proctor and others, ‘Spinal manipulation for dysmenorrhoea’ (2006) 3 Cochrane Database of Systematic Reviews CD002119.

<sup>225</sup> Bruce F Walker and others, ‘Combined chiropractic interventions for low-back pain’ (2010) Cochrane Database of Systematic Reviews CD005427.

<sup>226</sup> Edzard Ernst and Peter H Canter (n 163). The authors also noted at 195 that “The evidence from the other systematic reviews of SM for non-spinal pain, dysmenorrhoea, infantile colic, asthma, cervicogenic dizziness and any condition is uniformly negative ... Overall, the demonstrable benefit of SM seems to be minimal in the case of acute or chronic back pain; controversial in the case of headache; or absent for all other indications”.

<sup>227</sup> Andrew Vickers and Catherine Zollman, ‘The manipulative therapies: Osteopathy and chiropractic’ (1999) 31 British Medical Journal 1176.

to the cervical spine by twisting the head. This sudden force can tear the vertebral artery, forming a clot which blocks or reduces blood flow to the brain, a condition known as cerebrovascular accident or stroke.

Proponents of chiropractic point to a lack of evidence of direct causation between chiropractic treatment and vascular dissection.<sup>228</sup> However, a number of studies and systematic reviews have shown that, though rare,<sup>229</sup> a likely causal link between chiropractic treatment and VAD exists.<sup>230</sup> Ernst concurs with Leon-Sanchez et al<sup>231</sup> on the issue of under-reporting of adverse events (suggesting that they are less rare than claimed),<sup>232</sup> with Ernst concluding that, “the risks of chiropractic neck manipulations by far outweigh the benefits”.<sup>233</sup> Not only is this risk-benefit analysis significant for the purpose of determining whether the system of oversight currently in place for chiropractic and for other CAM services Ireland is sufficient to protect consumers, but it must be a factor in determining the position and status of such services under consumer protection legislation.

With all this in mind, we return to the provisions of s 39 to consider whether a chiropractor has the necessary skill to render their service.

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<sup>228</sup> Donald R Murphy, ‘Current understanding of the relationship between cervical manipulation and stroke: What does it mean for the chiropractic profession?’ (2010) 18 *Chiropractic & Osteopathy* 22.

<sup>229</sup> Andres Leon-Sanchez, Albert Cuetter and Gustavo Ferrer, ‘Cervical spine manipulation: An alternative medical procedure with potentially fatal complications’ (2007) 100 (2) *Southern Medical Journal* 201. Leon-Sanchez et al consider that incidents of complications from cervical manipulation are more common than reported. They also find, at 203, that “Despite the fact that some studies report slight benefit of CSMT for pain management, composite data from high quality prospective studies and randomized controlled trials is needed before definitive practice recommendations are outlined and public advice is given regarding the risk, benefits and incidence of serious complications after CSMT. For the time being, this article reinforces the need for extreme caution when recommending CSMT for patients suffering neck pain and headache”.

<sup>230</sup> Edzard Ernst, ‘Deaths after chiropractic: A review of published cases’ (2010) 64 *International Journal of Clinical Practice* 1162, 1163, “This systematic review demonstrates that numerous deaths have been associated with chiropractic. Usually high-velocity, short-lever thrusts of the upper spine with rotation are implicated. They are believed to cause vertebral arterial dissection in predisposed individuals which, in turn, can lead to a chain of events including stroke and death. Many chiropractors claim that, because arterial dissection can also occur spontaneously, causality between the chiropractic intervention and arterial dissection is not proven. However, when carefully evaluating the known facts, one does arrive at the conclusion that causality is at least likely. Even if it were merely a remote possibility, the precautionary principle in healthcare would mean that neck manipulations should be considered unsafe until proven otherwise. Moreover, there is no good evidence for assuming that neck manipulation is an effective therapy for any medical condition. Thus, the risk-benefit balance for chiropractic neck manipulation fails to be positive”. Incidentally, Leon-Sanchez et al argue that part of the problem in minimising the risks inherent in cervical spinal manipulation lies in the current inability to delineate and understand the risk factors.

<sup>231</sup> Andres Leon-Sanchez, Albert Cuetter and Gustavo Ferrer (n 225) 202.

<sup>232</sup> Edzard Ernst (n 226) 1164.

<sup>233</sup> *ibid.*

## **5.2 DOES THE PRACTITIONER HAVE THE NECESSARY SKILL TO RENDER THE SERVICE?**

This very much depends on what the service is deemed to be. Without appropriate delineation by the service provider and the consumer, the service in question may be considered to be that of treating or curing a specific condition, of alleviating symptoms, either by the physical manipulation of the joints or by the skilled exploitation of a placebo effect, or merely of promoting or contributing to a state of “wellness” or “healthfulness”, diffuse claims that are general in nature and are therefore extremely difficult to refute. A consumer availing of chiropractic services ought to be made aware of the limitations of the service they are to receive in clear, unambiguous terms. However, this is less likely where the contract for services is created orally.

As chiropractic in Ireland is not statutorily regulated and the title of “chiropractor” is not protected, advertisement and provision of chiropractic services requires no particular qualification or standard of education on the part of the provider.<sup>234</sup> As part of the voluntary self-regulation scheme, chiropractors who have attended European Council of Chiropractic Education (ECCE) or Council on Chiropractic Education International (CCEI) recognised colleges, who carry personal indemnity insurance and who can provide references, may apply for membership of the Chiropractic Association of Ireland (hereafter “the CAI”),<sup>235</sup> permitting them to advertise as a member. While a minimum standard of education for membership is somewhat reassuring, it remains the case that such education does not ensure the provision of an efficacious therapy or the ability to treat many of the conditions claimed, and lack of membership or even lack of any educational qualification whatsoever does not preclude practice as a chiropractor in this jurisdiction. The consumer cannot, in such circumstances, be sure that the practitioner has the skills to render the service.

## **5.3 DID THE PRACTITIONER SUPPLY THE SERVICE WITH DUE SKILL, CARE AND DILIGENCE?**

A similar term to that relating the negligence principle of standard of care, the determination of whether a service provider acted with due skill, care and diligence must take into account what the service is determined to be. A relaxing massage to improve an overall feeling of wellbeing requires a different set of skills and care to spinal manipulation specifically sought out for the treatment of lower back pain or other medical conditions. The question also arises of what level of skill should be attributed to a chiropractor as a matter of course. Unless they are registered under s 37 of the Medical Practitioners Act 2007, chiropractors are not registered

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<sup>234</sup> This was set out in Chapter 1.

<sup>235</sup> Chiropractic Association of Ireland, ‘Joining the CAI’ <[www.chiropractic.ie/cai-membership/info/joining-the-cai](http://www.chiropractic.ie/cai-membership/info/joining-the-cai)> accessed 10 November 2014.



medical practitioners and cannot practice or claim to practice as such. However, chiropractic is recognised as a “health service” under s 2 of the Health Insurance (Amendment) Act 2001, suggesting that chiropractors are, in fact, health service providers and, as such, they should be subject to the same or similar standards as other health service providers.

#### **5.4 WHERE MATERIALS WERE USED, WERE THEY SOUND AND REASONABLY FIT FOR THE PURPOSE FOR WHICH THEY WERE REQUIRED?<sup>236</sup>**

In the case of chiropractic, this may refer to traction machines, straps, x-ray equipment and numerous other devices. Chiropractors may possess x-ray equipment<sup>237</sup> for use by appropriately qualified practitioners, provided that the equipment and its environment be maintained.<sup>238</sup> However, use of x-rays is subject to justification under reg 7.1 of the European Communities (Medical Ionising Radiation Protection) Regulations 2002<sup>239</sup> and, given the questionable existence of chiropractic subluxations and the questionable efficacy of chiropractic for most conditions, the fitness of any x-ray equipment for chiropractic diagnosis informing treatment is questionable. Demonstrating fitness for purpose requires careful wording in order to avoid falling outside both fitness for purpose provisions and the justification provisions. For example, x-ray equipment is fit for the purpose of diagnosing fractures and dislocations, but these are not what many Irish chiropractors claim to treat. Claiming instead that x-rays are used to outrule such injuries before treating any chiropractic subluxations may provide the required justification and may establish that the equipment is fit for that particular purpose under the 1980 Act. However, the use of x-rays, with their associated risks, to diagnose a questionable injury<sup>240</sup> in order to inform a course of therapy with unproven efficacy should not, in reality, be justifiable. According to a report by the HSE,<sup>241</sup>

The most common type of examination is lumbar spines ... the Chiropractic Association of Ireland has stated that the effective dose from a lumbar spine series is about 1.5

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<sup>236</sup> Sale of Goods and Supply of Services Act 1980, s 39(c).

<sup>237</sup> Radiologic Protection Act 1991 (Ionising Radiation) Order 2000, SI 2000/125, art 4(1).

<sup>238</sup> *ibid*, art 21.

<sup>239</sup> European Communities (Medical Ionising Radiation Protection) Regulations 2002, SI 2002/478, reg 7.1, “Medical exposure referred to in regulation 4.1 shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefit it produces including the direct health benefits to an individual and the benefits to society against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation”.

<sup>240</sup> UK General Chiropractic Council (n 217).

<sup>241</sup> Health Service Executive, ‘Report on the Chiropractic Review of Compliance with Statutory Instrument 478(2002), S.I. No.303(2007) and S.I. No.495(2010)’ (HSE 2013).

milliSieverts. This equates to approximately 75 chest x-rays when taking the average dose for a chest x-ray as 0.02 milliSieverts.<sup>242</sup>

This flies in the face of the European Commission statement that “[t]he aim of quality assurance programmes is to optimize the imaging process in order to avoid unnecessary exposures or overexposures to the patients”,<sup>243</sup> considering the systematic review finding only weak evidence of efficacy for chiropractic treatment of lower back pain.

## **5.5 WHERE GOODS WERE SUPPLIED UNDER THE CONTRACT, WERE THEY OF MERCHANTABLE QUALITY?**

The standard provisions on merchantability apply in cases where goods are provided under a contract for the provision of services. In general, chiropractors do not provide goods as part of their service but those who do must conform to the standards of merchantability.

## **5.6 POTENTIALLY UNFAIR TERMS IN CONSUMER CONTRACTS**

In any potential contract between a service provider, such as a chiropractor, and a consumer, exclusionary terms may arise, affecting the rights of the consumer under the contract, in contravention of the European Communities (Unfair Terms in Consumer Contracts) Regulations 1995, sch 3(a), (b), (k) and (m) respectively.

Short of prohibiting the provision of CAM services in their entirety, which is as undesirable as it is drastic, it is difficult to provide a satisfactory solution to the existing lack of oversight. To establish a statutory body for all CAM service providers would be expensive and administratively difficult, given the variance between disciplines. It would also lend as-yet-unearned validity to such practices. Nonetheless, statutory registration would provide a level of consumer confidence, allowing for surveillance and ensuring that an appropriately rigorous and transparent grievance procedure be made available. Statutory self-regulation, as noted in Chapter 1, is a privilege not yet earned by CAM practitioners as a cohort. A voluntary scheme provides ostensible validity but little protection for consumers. In Ireland, many service providers are members of societies associated with their chosen discipline, although this is made less significant by the fact that there are multiple societies and associations open to such providers and that lack of membership does not preclude practice.

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<sup>242</sup>ibid 6.

<sup>243</sup> Commission, ‘Radiation Protection, Implementation of the “Medical Exposure Directive” (97/43/Euratom) - Proceedings of the International Workshop’ (Directorate-General Environment, Nuclear Safety and Civil Protection, Madrid, April 1998) 107.

As CAM service providers in Ireland are not regulated the same way as conventional medical practitioners, it is difficult to state with any certainty that they are under any ethical obligation to, for example, fully explain the potentially unproven nature of the treatment they are providing, to ensure that the consumer understands the risks associated with the service provided, particularly relative to the uncertain benefits, or not to dissuade the consumer from seeking conventional medical treatment. However, this does not negate their obligations under consumer protection law, which, if appropriately enforced, could provide greater certainty and protection for consumers of CAM products and services into the future.

## CONCLUSION

Consumers of CAM in Ireland are significantly disadvantaged by the protective regime currently in place. Ineffective and dangerous products sold and services rendered by variably qualified practitioners represent serious risk to consumers, many of whom are already in a vulnerable position, by virtue of age, infirmity or ignorance, as to what they are purchasing. While the lack of enforcement of the relevant provisions on unfair or misleading claims in the 2007 Act, a narrow interpretation of the term “defective products” in the 1991 Act, and a similarly narrow interpretation of “merchantable quality” in the 1980 Act, permit many ineffective CAM products to remain on the market, a significant obstacle to the vindication of consumer rights in Ireland is the conflict between the priorities of the general consumer protection legislation and those of the legislation governing human medicinal products and medical devices. Currently, the safety of the products takes priority, as it does in other jurisdiction, leaving other core consumer rights behind.

Whereas protecting the safety of consumers is necessarily of primary concern to regulators and, in this way, the existing legislation is prioritised appropriately, more focus is required on protecting the financial wellbeing of the consumer, as well as taking into account the indirect risks to consumers arising from the lack of demonstrated efficacy of many CAM products. While implementing an increase in the domestic level of consumer protection in respect of unfair or misleading claims is complicated by establishment of the European regime as a maximum harmonisation measure, increased scrutiny of traders and full use of the sanctions set out in Part 5 of the 2007 Act, where appropriate, is undoubtedly within the bounds of what is permitted by the UCPD.

CAM service provision also requires significant oversight to ensure that therapies provided are safe, effective, standardised and ethical, practiced with due care, skill and diligence,<sup>244</sup> and that any condition not treatable by the service provider be immediately referred to a conventional medical practitioner. This mechanism is lacking in the existing consumer framework and, realistically, there is no way of ensuring that the therapist chosen by the consumer has the requisite diagnostic skills to make an appropriate referral. This is left to chance.

Additionally, any intervention involving the use of dangerous substances or procedures, such as the use of diagnostic or other ionising radiation by particular CAM service providers requires immediate review to ensure that such use is justified under the provisions of the European Communities (Medical Ionising Radiation Protection) Regulations 2002.

Finally, it is argued that the conflict between consumer protection and medicinal product legislation presents quite a significant obstacle in the road to consumer enlightenment and that change is required to standardise and simplify the process of registration, leaving only a single mechanism for medicinal product authorisation and greater consumer clarity overall.

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<sup>244</sup> Sale of Goods and Supply of Services Act 1980, s 39(b).

## CHAPTER 4

### CHILDREN AND CAM

*The right to choose CAM for children raises fundamental questions about individual rights and freedoms versus collective rights and freedoms, and who should be designated as the ultimate decision-maker.<sup>1</sup>*

#### INTRODUCTION

Having set out the nuanced issues in respect of ethics, consumer protection and substantive risk of harm associated with the use of CAM in Ireland as a result of the lack of effective regulation of the sector, it is instructive to consider the potential for additional or disproportionate effects in a particular population. Children, who are considered to be less competent than adults and are therefore subject and vulnerable to their choices, form such a population.<sup>2</sup> The expansion of CAM use into the realm of children's healthcare gives rise to questions of consent, of the tension between parental rights and responsibilities<sup>3</sup> and of the onus on the State to ensure that a minimum level of protection be established to safeguard the best interests and the welfare of the child.

The use of CAM by children is common<sup>4</sup> and increasing in popularity,<sup>5</sup> with children of parents who use CAM being up to five times more likely to be treated with it than others.<sup>6</sup> As in the case of adult users, CAM use for children is not without benefits. It might be said, for example, that the use of a homeopathic treatment for influenza may prevent the inappropriate use of an antibiotic, the overuse of which is both topical and of significant concern in the global health and scientific communities at present.<sup>7</sup> However, despite these potential or perceived benefits, the scant evidence of efficacy for

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<sup>1</sup> Julie Stone, *An Ethical Framework for Complementary and Alternative Therapists* (Routledge 2002) 131.

<sup>2</sup> Noirin Hayes, *Children's Rights - Whose right? A review of child policy development in Ireland* (TCD Policy Institute 2002) 11; Department of Children and Youth Affairs, *State of the Nation's Children* (Government Publications, 2012) 10, "In 2011, there were 1,148,687 children living in Ireland. This accounted for one-quarter (25%) of the total population of Ireland". This is a substantial population subset.

<sup>3</sup> Deirdre Madden, *Medical Ethics and the Law* (Butterworths 2002) 464-465. Madden is of the opinion that it might be "preferable to move towards replacing the language of parental rights with 'parental responsibility' which places parents, in consultation with their children, in the position of educating and maintaining them, not because of an authority conferred on parents, but in the interests of the child. This would recognise children as persons to whom duties are owed, as opposed to possessions over which power is wielded". The concept of patient duty (or decision-maker duty, in the case of parents) is expanded upon in Rachel O'Sullivan, 'The Patient's Duties to Others: Limitations to the Principle of Autonomy in Healthcare Decision Making' (2015) 14 (7) *Cork Online Law Review* <[www.corkonlinelawreview.com/editions/2015/ROSullivan.pdf](http://www.corkonlinelawreview.com/editions/2015/ROSullivan.pdf)> accessed 8 December 2015.

<sup>4</sup> See Chapter 6.

<sup>5</sup> Evonne Low and others, 'Complementary and alternative medicine use in Irish paediatric patients' (2008) 177 *Irish Journal of Medical Science* 147. See also, Salvatore Italia and others, 'Patterns of complementary and alternative medicine (CAM) use in children: A systematic review' (2014) 173 *European Journal of Pediatrics* 1413, 1424.

<sup>6</sup> Katherine Hunt and Edzard Ernst, 'The evidence-base for complementary medicine in children: A critical overview of systematic reviews' (2011) 96 *Archives of Disease in Childhood* 769.

<sup>7</sup> Steven L Barriere, 'Clinical, economic and societal impact of antibiotic resistance' (2015) 16 *Expert Opinion on Pharmacotherapy* 151, 152, "The increasing prevalence of antibiotic-resistant bacterial infections seen in clinical practice stems from antibiotic use both within human medicine and veterinary medicine. In human

many CAM therapies for children<sup>8</sup> and the risk of adverse effects,<sup>9</sup> together with the potential for the child to be treated exclusively with CAM, depriving him or her of conventional medical care,<sup>10</sup> demand closer scrutiny by lawmakers, in an attempt to offset the most serious dangers for users. Given the inherent vulnerability of children, considerations of relative benefit and risk arising from CAM therapies ought to weigh heavily on the minds of law and policy-makers, who are in the position of determining whether such therapies should be available on the Irish market, and of parents, who ultimately choose and give consent by proxy for the treatment of their non-autonomous children using such therapies.

This chapter examines some of the risks for, and the protections available to, children treated with CAM. Although one might expect that the same basic protections would be available to all children irrespective of the healthcare choices of their parents, this is not the case. Measures in place for the protection of child safety and welfare heavily favour children treated within the conventional sphere. Even where the choices of parents are objectively not in the best interests of the child, such that his or her safety or welfare is likely to be prejudicially affected,<sup>11</sup> courts are unlikely to intervene where there is no grave and immediate threat to the life or health of the child.<sup>12</sup> This model of assessment does not appropriately account for the risks of CAM, which tend to be longer-term and to include indirect risks, arising from, for example, the replacement of a conventional vaccination with an inefficacious or unproven alternative regime.

Children receiving CAM through the choice of their parents are subject to the same risk and lack of benefit as adult patients, treatment which is objectively not in their best interests. The creation of further disadvantage by the unequal applicability of child protection measures in the sector and minimal scope for timely intervention is unacceptable.

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medicine, the major problem contributing to the emergence of resistant bacteria is the misuse and overuse of antibiotics". However, see Robert T Mathie and others, 'Homeopathic Oscillocochinum® for preventing and treating influenza and influenza-like illness' (2015) Cochrane Database of Systematic Reviews CD001957, "There is insufficient good evidence to enable robust conclusions to be made about Oscillocochinum® in the prevention or treatment of influenza and influenza-like illness. Our findings do not rule out the possibility that Oscillocochinum® could have a clinically useful treatment effect but, given the low quality of the eligible studies, the evidence is not compelling".

<sup>8</sup> Katherine Hunt and Edzard Ernst (n 6) 773.

<sup>9</sup> Lim Alissa, 'Adverse events associated with the use of complementary and alternative medicine in children' (2011) 96 Archives of Disease in Childhood 297, 298. Adverse effects of complementary medicine use (without cessation of conventional medical care) included, among others, thyrotoxicosis, hypercalcaemia, acidosis, seizures and apnoea, liver failure requiring transplant and allergic reaction. Adverse effects of alternative medicine use (with the cessation of conventional medical care) ranged from the child receiving unnecessary treatment, failure to thrive and sepsis, to death in four recorded cases. See also, Edzard Ernst, 'Serious adverse effects of unconventional therapies for children and adolescents: A systematic review of recent evidence' (2003) 162 European Journal of Pediatrics 72. Adverse effects vary with the particular therapy and may be direct or indirect.

<sup>10</sup> *R v Thomas Sam; R v Manju Sam (No. 18)* [2009] NSWSC 1003.

<sup>11</sup> The Irish Constitution, Art 42A.2.1°.

<sup>12</sup> *North Western Health Board v HW & CW* [2001] 3 IR 622 (SC), 755.

This chapter does not attempt to provide a definitive statement on child law in Ireland, with neither the space nor the scope to do so. Rather, the existing law provides the general context within which the analysis of the implications for children treated using CAM takes place.

Part I begins by examining the role and effect of parental decision-making in child healthcare. The problems for children arising from their parents' choice to use CAM are not limited to issues of risk and benefit or to consumer protection. They also include the implications associated with the isolated nature of CAM treatment, which, if used as an alternative to conventional care, effectively closes several avenues for mandatory reporting,<sup>13</sup> undermining the child's right to be heard,<sup>14</sup> and, of particular importance in a paediatric population, facilitates the subversion or substitution of established public health measures, such as vaccination or prophylaxis. Part I considers the implications of the extremely broad scope for parental choice in CAM, contrasting it with the relatively limited and specific scope afforded to parents within conventional care. It is argued that, where education and training are neither standardised nor mandatory, where information provided by practitioners may be inaccurate or incomplete, where the best available evidence does not support efficacy sufficient to ethically outweigh the risk involved, the virtual parental carte blanche provided by CAM is neither protective of the child nor justifiable in his or her best interests.<sup>15</sup>

With this said, Part II considers the interaction between the use of CAM for children and the protections available to them in the justice system. It begins by setting out the relative positions and rights of the parent and child under the Constitution. As the ultimate arbiter of the rights of both parties, the judicial interpretation of these rights has a significant effect on the approach to be taken by prospective legislators, on the confidence of parents in their own autonomy and authority and on the ongoing viability for CAM and other practitioners treating children. It is argued that the threshold for intervention to vindicate or protect the rights of the child as distinct from the family in matters of welfare has traditionally been set so high as to cast doubt on its likely usefulness where an ineffective or unethical but not immediately life-threatening CAM product or service is used to treat a child. The changes in this respect, in light of the passing of the Thirty-First Amendment and the explicit acknowledgement of the rights of the child, seem unlikely to significantly enhance protection for children in this area without a reconsideration of the intervention threshold. While courts will properly avoid harsh and intrusive intervention except where there is a serious risk to the health or life of the child, greater emphasis must now be placed on actively protecting his or her best interests, an onus which will also pass down to legislators in formulating novel regulation in this area.

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<sup>13</sup> Children First Act 2015, s 14.

<sup>14</sup> The Irish Constitution, Art 42A.4.2°; United Nations Convention on the Rights of the Child (UNCRC), Art 12.

<sup>15</sup> Maebh Harding and Donal Coffey, 'Commentary on *North Western Health Board v HW and CW* (the PKU case)' in Mairéad Enright, Julie McCandless and Aoife O'Donoghue (eds) *Northern/Irish Feminist Judgments: Judges' Troubles and the Gendered Politics of Identity* (Hart Publishing 2017). Harding argues that the assumption made by the members of the court in *NWHB*, that the rights of the child were inevitably best protected by upholding the integrity (including the autonomy) of the marital family unit, was "rather lazy".

The questionable protection afforded to children in this sector not only raises questions of unprotected constitutional rights, but also of compliance with international obligations, including the right of a child to be treated with respect for his or her inherent dignity,<sup>16</sup> the right to survival,<sup>17</sup> the right to be heard,<sup>18</sup> the right to have decisions made in his or her best interests<sup>19</sup> and the right to health and health service.<sup>20</sup> Ireland's reputation in effectively promoting these rights has been less than impressive<sup>21</sup> and it is hoped that, within this small, discrete area, the opportunity to act positively and definitively to improve the status quo under any or all of these headings will be seized upon.

Part III of this chapter examines the broader legislative protections available to children generally, with particular focus on child welfare and safety. Recent additions to the suite of child protection legislation have enhanced reporting and vetting obligations, which may superficially provide reassurance for parents choosing a CAM practitioner to work with their child. However, a review of the legislation reveals its inconsistent applicability to all CAM providers and the consequent absence of protection afforded to those treated by them. Failure to utilise or appropriately tailor existing protections has been a consistent theme of this thesis and this is yet another example.

The recognition and active protection of the rights of children, while gaining ground in Ireland, suffer from a lack of certainty, within which, further lack of certainty in respect of CAM treatment is nested. It is argued that the provision of healthcare within a vulnerable population demands, at a minimum, that existing protections be fully utilised and, where found lacking, that novel provisions be developed to address inequalities brought about by virtue of that vulnerability. It is to these vulnerabilities that we first turn.

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<sup>16</sup> Charter of Fundamental Rights of the European Union (2010) OJ C83/02, Art 1.

<sup>17</sup> UNCRC, Art 6.

<sup>18</sup> *ibid* Art 12.

<sup>19</sup> *ibid* Art 3.

<sup>20</sup> *ibid* Art 24.

<sup>21</sup> Committee on the Rights of the Child, 'Forty-third session - Consideration of Reports Submitted by States Parties under Article 44 of the Convention of the Rights of the Child: Concluding observations: Ireland' (UNCRC 2006), para 6, "While welcoming various measures taken to follow-up and implement the Committee's previous concluding observations, the Committee regrets that some of the concerns expressed and recommendations made have not yet been fully addressed, in particular those related the status of the child as a rights-holder and the adoption of a child rights-based approach in policies and practices".



## PART I

### PARENTAL DECISION-MAKING IN HEALTHCARE

*...those who torment us for our own good will torment us without end for they do so with the approval of their own conscience.*<sup>22</sup>

#### 1. BALANCING PARENTAL FREEDOM AND DUTY IN HEALTHCARE DECISION-MAKING

While it is often necessary to speak in the abstract of risks and benefits, it is appropriate to exemplify and draw attention to issues of particular concern. For children treated with CAM, these are issues which extend beyond those of the competent adult sphere, revolving, primarily, around consent by proxy and the power and responsibility afforded to parents based on the presumption that they act in the best interests of the child, while, in reality, their judgment may be detrimentally affected by numerous internal and external factors. It is argued that parental decision-making in healthcare requires support and guidance not sufficiently provided for in respect of CAM, either through the advice of conventional healthcare providers, in legislation or in jurisprudence. Without it, children the subject of such decisions are placed at increased risk of harm. We begin by examining the paradox of parental choice in conventional medicine and in CAM, with focus on the scope of the decisions to be made in each.

Parental choice in matters of healthcare should not be unlimited. A situation whereby a parent determines *ab initio* which medicinal product or procedure will work best for their child negates the expertise and value of medicine generally and puts the health and the life of the child at risk.

Parental choice in conventional medicine is, if not limited, then more refined in its scope than in CAM.<sup>23</sup> Medications prescribed and provided have been approved as being safe for use, as being so beneficial as to outweigh risks or side effects and as being of a standard quality (in Ireland, this role is performed by the Health Products Regulatory Agency, established under s 3(4) of the Irish Medicines Board Act 1995, as amended by s 36 of the Health (Pricing and Supply of Medical Goods) Act 2013).<sup>24</sup> Medical procedures have normally been ethically approved, tested, peer-reviewed, and

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<sup>22</sup> CS Lewis, *God in the Dock* (WB Eerdmans 2002) 292.

<sup>23</sup> Chris Macdonald and Scott Gavura, 'Alternative Medicine and the Ethics of Commerce' (2016) 30 *Bioethics* 77, "... when physicians and pharmacists advise patients on the merits of a mainstream pharmaceutical product, they are effectively explaining the odds that the product will work for that particular patient. Such advice is (or should be) based on a combination of clinical judgment, a thorough understanding of human physiology (and, where relevant, pharmacokinetics) and a sound understanding of the relevant clinical data. In particular, health professionals rely on assumptions based on an understanding of biology and physiology and an understanding that the intervention being offered doesn't generally violate our basic understandings about the way the body (or for that matter, the universe) works. While they might not always know the precise mechanisms by which a specific drug works, they do ground their judgment in evidence, and also don't need to invent an explanation for their function out of whole cloth. They also, in general, rely on scientific standards to test medicines and treatments, methods that attempt to eliminate biases and to establish cause and effect".

<sup>24</sup> Health (Pricing and Supply of Medical Goods) Act 2013, s 36, "Section 3 of the Irish Medicines Board Act 1995 is amended by inserting the following after subsection (3): "(4) The body that, immediately before the

then refined based on outcome. Physicians must be registered with the Medical Council in order to practice in Ireland.<sup>25</sup> The choice ultimately made by a parent in this situation is to accept one or more of the physician-recommended, ethically approved therapies available for a particular condition, or to refuse therapy entirely.

However, the parent opting for CAM, as an alternative or as a complementary therapy, cannot, in all cases, know what he or she is procuring for the child.<sup>26</sup> Parents must choose an appropriate modality from the vast selection available; they must rely on their chosen CAM provider within that modality to correctly diagnose the medical condition from which their child is suffering, to understand and acknowledge the limits of their own skills and to know and to inform them if the product or therapy is likely to interact with a conventional treatment simultaneously taken by their child or whether it is contraindicated for another condition from which the child also suffers. They must trust, on behalf of their child, that a product offered or recommended is qualitatively and quantitatively safe and will treat the condition in question. As there is no minimum requirement for training or education to practice in any CAM discipline in Ireland and very limited evidence of efficacy for many of the therapies on offer, however, it is difficult so see how this trust can be justified. The parental *carte blanche*, though ostensibly democratic and undoubtedly appealing, facilitates the funnelling of risk accepted by a competent but perhaps inadequately informed parent to a more vulnerable person who lacks the capacity to investigate the evidence for the treatment they are to undergo, to effectively object to treatment and, due to the inherently private nature of CAM therapy, to make their voice heard by someone who will act to protect their best interests where their parent cannot or will not.<sup>27</sup>

## **1.1 INFORMATION AND CONSENT BY PROXY**

As discussed in Chapter 1, for consent to medical treatment to be valid, the patient or consumer must be provided with all information material to the decision being made. This includes

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commencement of section 36 of the Health (Pricing and Supply of Medical Goods) Act 2013, was known as the Irish Medicines Board shall, from such commencement, cease to be known by that name and instead be known as the Health Products Regulatory Authority”.

<sup>25</sup> Medical Practitioners Act 2007, s 37, “Subject to section 38, an unregistered medical practitioner shall not— (a) practise medicine, or (b) subject to section 50, advertise the practitioner’s services as a medical practitioner”.

<sup>26</sup> US Food and Drug Administration, ‘FDA Issues Consumer Safety Alert: Hyland’s Teething Tablets may pose a risk to children’ (2010)

<[www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm230761.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm230761.htm)> accessed 6 December 2015. In addition, some traditional Chinese herbal remedies, widely available, have been demonstrated to contain prescription medication. See Food and Drug Administration, ‘Import Alert 66-10’

<[www.accessdata.fda.gov/cms\\_ia/importalert\\_173.html](http://www.accessdata.fda.gov/cms_ia/importalert_173.html)> accessed 6 December 2015. This was also noted in Edzard Ernst (n 9).

<sup>27</sup> For example, the Children First Act 2015, sch 2, provides a list of designated mandatory reporters, containing numerous conventional healthcare professionals but no CAM providers.

information on adverse effects that are particularly common or particularly grave, and might, therefore, influence the decision made by the patient.<sup>28</sup>

Inadequate information provided to parents calls into question the validity of their consent for the treatment of their child. Consent to CAM treatment may be called into question where an adverse effect is not notified to the parent, or, for example, a benefit is claimed without the existence of high quality substantiation.<sup>29</sup> As this is the case for many CAM therapies for many conditions, there is a general cause for concern in respect of the sector, which is magnified where consent by proxy is at issue. This is consent given to treatment of the child where he or she is not deemed competent to consent by virtue of age and maturity.<sup>30</sup> Per Denham J in *McK v Information Commissioner*:<sup>31</sup>

A parent's rights and duties include the care of a child who is ill. As a consequence a parent is entitled to information about the medical care a child is receiving so that he or she may make appropriate decisions for the child, as his or her guardian. The presumption is that a parent is entitled to access such information. That position is not absolute. The circumstances may be such that the presumption may be rebutted. But the primary position is that the presumption exists.<sup>32</sup>

Where consent is rendered invalid by a deficit in the information provided, an actionable battery may be committed on the child by the CAM provider, even before the physical or psychological risks associated with the treatment are considered. The information deficit acting to invalidate consent could, in theory, be attenuated with the provision of relevant information by a conventional practitioner, where accessed. However, CAM users have

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<sup>28</sup> *Geoghegan v Harris* [2000] 3 IR 536 (HC) (Kearns J), citing *Canterbury v Spence* (1972) 464 F. 2d 772, 788, on materiality, “A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summons discussion with the patient. There is no bright line separating the significant from the insignificant; the answer in each case must abide a rule of reason”. The reasonable patient test is now applicable in Irish law.

<sup>29</sup> See Appendix V, Complaint to the Advertising Standards Authority of Ireland in respect of ReikiinIreland.com.

<sup>30</sup> Non-Fatal Offences Against the Person Act 1997, s 23(1), “The consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his or her person, shall be as effective as it would be if he or she were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his or her parent or guardian”. Section (2) states that, “In this section “*surgical, medical or dental treatment*” includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment”. It is unsettled whether a person aged 16 or 17 can refuse treatment consented to by his or her parents. The treatment of children under the age of 16, in general, requires parental consent. The assent of the child should also be sought, by providing information similar to that provided to the parent, in language appropriate to the age and maturity of the child. This reflects the right of the child to have his voice heard in matters concerning him, under Art 12 of the UNCRC. See Ursula Kilkelly and Mary Donnelly, *The Child's Right to be heard in the Healthcare Setting: Perspectives of children, parents and health professionals* (Stationery Office 2006).

<sup>31</sup> *McK v Information Commissioner* [2006] IESC 2.

<sup>32</sup> *ibid* [23].

historically been reluctant to disclose their CAM use to their conventional physician or healthcare provider,<sup>33</sup> and this is no different for parents using CAM for their children.<sup>34</sup> According to Sidora-Arcoleo et al, “[t]he most frequently reported barriers to CAM disclosure, among the general population as well as families with children, were a feeling that the HCP [healthcare provider] did not need to know about CAM use, fear of a negative response from the HCP, and the HCP did not ask”.<sup>35</sup> While efforts to understand the motivations for patient use of CAM, efforts to provide high quality advice on the risk-benefit profile associated with the various therapies available to patients for their particular condition and efforts to refrain from being judgmental or condescending in addressing CAM use generally might encourage greater levels of disclosure, the clear separation between the conventional and CAM sectors and the rhetoric permeating discussion or debate comparing the two create a perception of rivalry that is difficult to dispel. Effecting change in consumer perception in order to elicit a better standard of disclosure of CAM use cannot begin and end in the consulting room but must be reflected in the public discussion of CAM in the media. This does not require and should not involve the creation of false equivalence between the two sectors, but rather a simple attempt by both sides to avoid inflammatory value judgments,<sup>36</sup> focussing instead on the established facts.

In addition to its effects on consent in lieu of access to necessary information, the reluctance or refusal on the part of some parents to disclose their child’s CAM use increases the risk of interactions arising from parallel treatments across the two domains<sup>37</sup> and it is undoubtedly in the best interest of the child to avoid this situation. The adoption of a more measured tone by all seems a small price to pay.

The risk of harm associated with inadequately informed consent reflects the significant burden placed on parents who choose to treat their child using CAM therapies when compared with those exclusively following the conventional path. However, the risk is not limited to the child

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<sup>33</sup> Maria Chao, Christine Wade, and Fredi Kronenberg, ‘Disclosure of complementary and alternative medicine to conventional medical providers: variation by race/ethnicity and type of CAM (2008) 100 *Journal of the National Medical Association* 1341.

<sup>34</sup> Kimberly Sidora-Arcoleo and others, ‘Don’t ask, don’t tell: Parental nondisclosure of complementary and alternative medicine and over-the-counter medication use in children’s asthma management’ (2008) 22 *Journal of Pediatric Health Care* 221, 222, “In the general pediatric population, studies show that the majority of parents do not disclose CAM use to their child’s HCP”. The study found that, of the parents using CAM for the treatment of their child’s asthma, “54% of those parents did not disclose usage”.

<sup>35</sup> *ibid.*

<sup>36</sup> Nick Collins, ‘Homeopathy is nonsense, says new chief scientist’ *The Telegraph* (18 April 2013) <[www.telegraph.co.uk/news/health/news/10003680/Homeopathy-is-nonsense-says-new-chief-scientist.html](http://www.telegraph.co.uk/news/health/news/10003680/Homeopathy-is-nonsense-says-new-chief-scientist.html)> accessed 10 October 2016; Rosa Silverman, ‘Homeopathy is ‘rubbish’, says chief medical officer’ *The Telegraph* (24 January 2013) <[www.telegraph.co.uk/news/health/news/9822744/Homeopathy-is-rubbish-says-chief-medical-officer.html](http://www.telegraph.co.uk/news/health/news/9822744/Homeopathy-is-rubbish-says-chief-medical-officer.html)> accessed 10 October 2016.

<sup>37</sup> Leonard Bielory, ‘Complementary and alternative interventions in asthma, allergy, and immunology’ (2004) 93 *Annals of Allergy, Asthma, & Immunology* S45.

receiving treatment and the parent giving consent, but may affect the broader community, as in the case of vaccination.

## **1.2 THE PUBLIC HEALTH IMPLICATIONS OF PARENTAL CHOICE - CAM AND VACCINATION**

Not only is CAM use for children a potential source of battery and of physical and psychological harm, but CAM use generally has been linked with various public health risks,<sup>38</sup> including decreased vaccination uptake, which has caused a resurgence in vaccine-preventable infectious disease and which disproportionately affects the health and the lives of children, none of whom have the capacity to give their consent.

According to the World Health Organisation, in its bulletin of June 2008,<sup>39</sup>

...the Internet has become a significant channel for anti-vaccination views. The popular video-sharing web site YouTube offers a plethora of anti-vaccination clips. The Internet has also become a forum for alternative medicine practitioners to present their anti-vaccination ideas and promote alternative products.<sup>40</sup>

The dissemination of anti-vaccination literature and advice and the active discouragement of engagement and compliance with established vaccination protocols by CAM practitioners<sup>41</sup> and proponents,<sup>42</sup> which is frequently accompanied by the offer of an alternative vaccination protocol, is highly unethical, displaying as it does a distinct conflict of interest on the part of the practitioner and a worrying disregard for the human health they claim to protect and promote. Direct users of CAM services and those accessing sources of CAM information are statistically less likely to be in favour of vaccination and are less likely to ensure the

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<sup>38</sup> This includes, among other issues, dissuading CAM users from undertaking conventional treatment for cancer or HIV.

<sup>39</sup> World Health Organisation, 'Bulletin of the World Health Organization' (June 2008) 86(6) 425.

<sup>40</sup> *ibid.*

<sup>41</sup> Karunaflame.com, 'Vaccine Dilemma' <[www.karunaflame.com/karunaflame/articles/health-dangers-medical-misconceptions/vaccination-dilemma/](http://www.karunaflame.com/karunaflame/articles/health-dangers-medical-misconceptions/vaccination-dilemma/)> accessed 10 October 2016

<sup>42</sup> John Rappoport, 'Vaccines cause brain damage: The mothers know' (2014) <<http://news-beacon-ireland.info/?p=20169>> accessed 10 October 2016. See also, John Rappoport, 'Natural health is a silver bullet to medical vampires' (2016) <<https://jonrappoport.wordpress.com/category/freedom/>> accessed 10 October 2016.

vaccination of their children than those who favour conventional medicine.<sup>43</sup> Per Downey et al.,<sup>44</sup>

Children were significantly less likely to receive each of the four recommended vaccinations if they saw a naturopathic physician. Children who saw chiropractors were significantly less likely to receive each of three of the recommended vaccinations. Children aged 1–17 years were significantly more likely to be diagnosed with a vaccine preventable disease if they received naturopathic care... Pediatric use of complementary/alternative medicine in Washington State was significantly associated with reduced adherence to recommended pediatric vaccination schedules and with acquisition of vaccine-preventable disease.<sup>45</sup>

The undermining of established and highly effective<sup>46</sup> vaccination protocols has already led to a significant decrease in compliance and a resurgence in the incidence of numerous infectious diseases.<sup>47</sup> Loss of herd immunity can have and has had serious consequences for vulnerable groups. Following the now-discredited claims made by Dr Andrew Wakefield that the combination measles, mumps and rubella (MMR) vaccine gave rise to an increased risk of autism,<sup>48</sup> there was a steep decline in the uptake of that vaccination regime by parents, resulting in the resurgence in infection with the measles virus.<sup>49</sup> While most children cope well with a

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<sup>43</sup> LJ Jessop and others, 'Socio-demographic and health-related predictors of uptake of first MMR immunisation in the Lifeways Cohort Study' (2010) 28 *Vaccine* 6338 at 6341. See also, Thomas Waldhoe and others, 'The impact of sociodemographic variables on immunization coverage of children' (1997) 13 *European Journal of Epidemiology* 145, 148 and JA Cassell and others, 'Is the cultural context of MMR rejection a key to an effective public health discourse?' (2006) 120 *Public Health* 783, 789.

<sup>44</sup> Lois Downey and others, 'Pediatric vaccination and vaccine-preventable disease acquisition: Associations with care by complementary and alternative medicine providers' (2010) 14 *Maternal and Child Health Journal* 922.

<sup>45</sup> *ibid.*

<sup>46</sup> Jenifer Ehreth, 'The global value of vaccination' (2003) 21 *Vaccine* 596.

<sup>47</sup> On pertussis, see Eugene Gangarosa and others, 'Impact of anti-vaccine movements on pertussis control: The untold story' (1998) 351 *Lancet* 356, 360, "[O]nce high vaccine uptake and herd immunity are attained, perceived vaccine risks tend to deter individuals from being vaccinated. The result is a lowering of vaccine uptake, contrary to the community's common interest in maintaining high numbers of immunised individuals. What follows is a "tragedy of the commons"—a loss of confidence in vaccine and a resurgence of disease". On polio, see Christopher Clements and others, 'How vaccine safety can become political--the example of polio in Nigeria' (2006) 1 *Current Drug Safety* 117, "Subsequent to this boycott, which the Kano governor had endorsed for a year and then ended in July 2004, cases of polio occurred in a dozen formerly polio-free neighbours of Nigeria. Ethiopia had been polio-free for a year when cases reoccurred. Genetic tests showed that the virus was the same one that originated in northern Nigeria".

<sup>48</sup> Andrew Wakefield and others 'RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children' (1998) 351 *Lancet* 637, 641, "We have identified a chronic enterocolitis in children that may be related to neuropsychiatric dysfunction. In most cases, onset of symptoms was after measles, mumps, and rubella immunisation".

<sup>49</sup> JF Murphy, 'Fallout of the enterocolitis, autism, MMR vaccine paper' (2011) 104 *Irish Medical Journal* 36, "Public confidence in the MMR vaccine was undermined and immunisation rates fell sharply below the critical 92% required for herd immunity. There was a rapid resurgence in the numbers of children affected with measles. Dublin was particularly badly affected ... [a] total of 355 children attended Temple Street A&E with Measles and 111 were admitted with either pneumonitis or dehydration. Seven children required ventilation and 3 children died".

rogue measles infection, some do not<sup>50</sup> and those CAM practitioners claiming to protect the lives or wellbeing of children who would otherwise have received standard vaccinations fail to consider, not only those children,<sup>51</sup> but others exposed to them. Not by their own choice, some of this vulnerable group may be immunocompromised and therefore ineligible to receive the vaccine, some may not have produced antibodies in response to the vaccine, rendering it ineffective and some of the group may be expectant mothers who could not receive the vaccine and, along with their child, may be detrimentally affected to a greater extent than they otherwise would by an infectious disease. The actions of the anti-vaccination movement, which, as noted by the WHO, includes some CAM practitioners, have contributed in no small way to the risk borne by this blameless group. This, despite the fact that no relationship has been found between MMR vaccination,<sup>52</sup> its former mercury-containing preservative<sup>53</sup> and autism spectrum disorder.

Those encouraging parents not to vaccinate behave in an ethically questionable manner based on the available evidence. The role of CAM in the anti-vaccination movement, as noted by Kata<sup>54</sup> and the WHO,<sup>55</sup> is significant and has perpetuated a public health issue which has cost many lives. The dissemination of anti-vaccination rhetoric has contributed further to the body of misinformation to be navigated by parents in making healthcare decisions for their children.

### 1.2.1 ALTERNATIVE VACCINATION AND PROPHYLAXIS

Not only do some members of the CAM community seek to decrease the uptake of vaccination, but, as noted above, some also offer to replace it with an alternative

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<sup>50</sup> Gregory A Poland, 'MMR vaccine and autism: Vaccine nihilism and postmodern science' (2008) 86(9) *Mayo Clinic Proceedings* 869, "Measles is the most transmissible human disease known. Even with modern medical care, approximately 1 of every 3000 infected persons die, and many more are hospitalized or otherwise harmed as a result".

<sup>51</sup> DA Salmon and others, 'Health consequences of religious and philosophical exemptions from immunization laws: Individual and societal risk of measles' (1999) 282 *Journal of the American Medical Association* 47, 49, "...exemptors were at a statistically significant increased risk of contracting measles vs vaccinated individuals for each age group and in every year ... On average, from 1985 through 1992, for persons aged 5 to 19 years, exemptors were 35 times more likely to contract measles than were vaccinated persons".

<sup>52</sup> Luke Taylor and others, 'Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies' (2014) 32 *Vaccine* 3623.

<sup>53</sup> Health Protection Surveillance Centre, 'Thiomersal – Frequently asked questions: What Irish vaccines contain trace amounts of thiomersal?' (2009), "All the vaccines used in the routine infant immunisation programme are thiomersal free. Some vaccines used in older children or adults may contain trace amounts of thiomersal. The trace amounts were equivalent to values below the limit of detection corresponding to less than 18 nanograms per vaccine dose. These trace amounts of mercury have no biologic effect and such products should be considered equivalent to thiomersal-free products"

<[www.hpsc.ie/A-Z/VaccinePreventable/Vaccination/Thiomersal/Factsheet/File,3948,en.pdf](http://www.hpsc.ie/A-Z/VaccinePreventable/Vaccination/Thiomersal/Factsheet/File,3948,en.pdf)> accessed 11 October 2016.

<sup>54</sup> Anna Kata, 'A postmodern Pandora's box: Anti-vaccination misinformation on the Internet' (2010) 28 *Vaccine* 1709, 1710 (Table 1).

<sup>55</sup> World Health Organisation (n 39).

regimen.<sup>56</sup> Homeopathic vaccines containing disease nosodes<sup>57</sup> for anything from pertussis<sup>58</sup> to diphtheria<sup>59</sup> are available to parents unhappy with the existing conventional vaccination programme. However, the risks are significant, given the likely absence of an active ingredient past the 12C potency and the seriousness of the diseases for which people are normally vaccinated.

Similar issues exist in respect of prophylaxis. Delaunay et al<sup>60</sup> provide an example of the use of homeopathic prophylaxis by a female traveller for malaria. The product was entirely ineffective and the patient was infected, resulting in multiple organ failure. The authors concluded that, “[t]his case confirms the inefficacy of homoeopathic drugs for malaria prevention and treatment. Travellers to tropical countries should use recognised prophylactic drugs”.

The offering of unproven vaccine and prophylaxis substitutes is ethically questionable from an individual adult perspective, but is of far greater concern for children, whose immune systems are immature and for whom the implications of contracting an infectious disease may be life threatening. A child given an alternative vaccination may be treated, by his or her parents, as a vaccinated child and may not be kept away from public places, such as school, in the event of an outbreak, as an unvaccinated child would be advised to do.<sup>61</sup> This places both the health of the alternatively vaccinated child and other children at risk.

Vaccination, while contributing significantly to the health of the Irish and global population, is not mandatory in Ireland. However, it is argued that the provision of unproven alternative vaccination protocols creates further risk by giving parents the impression of a protection that does not exist – a real life example of the emperor’s new clothes, with potentially tragic consequences.

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<sup>56</sup> For example, see Balaram Jana, *Preventive and Social Medicine* (B. Jain Publishers Limited 2002) and SK Sharma, *A Complete Guide to Biochemic Remedies* (Diamond Pocket Books Limited 2000).

<sup>57</sup> Steven Pray, ‘The challenge to professionalism presented by homeopathy’ (1996) 60 *American Journal of Pharmaceutical Education* 198, 199, “Nosodes may be prepared from pus, diseased tissue such as a cancerous growth, the stool (these are termed bowel nosodes), or the pathogenic organism itself, such as bacilli from sputum”.

<sup>58</sup> Balaram Jana (n 56) 425, “In whooping cough, *Carbo veg.* has been a reliable protection in hundreds of cases of young children and infants”.

<sup>59</sup> *ibid*, “In diphtheria protection, the remedy *Diphtherinum* is the leading prophylactic but in some severe epidemics of the past, *Merc cyanide* has proved to be very effective as well as curative in this disease”.

<sup>60</sup> Pascal Delaunay and others, ‘Homoeopathy may not be effective in preventing malaria’ (2000) 321 *British Medical Journal* 1288.

<sup>61</sup> World Health Organisation, ‘If you choose not to vaccinate your child, understand the risks and responsibilities’ (WHO 2012) <[www.euro.who.int/\\_\\_data/assets/pdf\\_file/0004/160753/If-You-Choose-Not-to-Vaccinate.pdf](http://www.euro.who.int/__data/assets/pdf_file/0004/160753/If-You-Choose-Not-to-Vaccinate.pdf)> accessed 10 October 2016.



### 1.3 THE IMPACT OF EMOTIONAL DURESS ON PARENTAL DECISION-MAKING

*When the pathologist has read the runes; when the oracles of X-ray, CT scan and biopsy have spoken and hope is guttering low; when the surgeon enters the room accompanied by 'a tallish man ... looking embarrassed ... in hood and gown with a scythe over his shoulder', it is then that the 'alternative' or 'complementary' vultures start circling. This is their moment. This is where they come into their own, for there's money in hope: the more desperate the hope, the richer the pickings.*<sup>62</sup>

Desperation is a powerful motivator and rarely more than when a child is diagnosed with a chronic, debilitating or life-threatening condition. The search for a cause and a cure within conventional parameters may prove fruitless, leaving parents, under a cloud of inevitable self-recrimination and grief, seeking answers elsewhere.<sup>63</sup> However, parental judgment may be significantly compromised by emotional duress,<sup>64</sup> which creates serious risk for the child in question.

By virtue of the inaccuracies in information disseminated on the risks of vaccination, both by CAM proponents and others,<sup>65</sup> children developing autism spectrum disorder (ASD) have been and may be subjected, by their well-meaning but desperate parents, to CAM therapies claiming to 'cure' ASD through heavy metal detoxification, among many other unproven and harmful therapies.<sup>66</sup> In a modality known as chelation therapy,<sup>67</sup> the child is administered intravenous or other chelating agents, such as dimercaptosuccinic acid (DMSA) and disodium ethylenediaminetetraacetic acid (Na<sub>2</sub> EDTA), an agent most frequently used in the water treatment process and in the treatment of lead and digoxin toxicity, which holds no curative

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<sup>62</sup> John Diamond, *Snake Oil and Other Preoccupations* (Random House 2009) xiii-xiv.

<sup>63</sup> Edzard Ernst, 'CAM for cancer?' (2005) 13(9) Support Care Cancer 669, 670, "Desperation must be a prime motivator for choosing CAM; cancer patients simply don't want to leave a single stone unturned in their struggle for survival".

<sup>64</sup> Anne Griswold Peirce and others (eds), *Ethical and Legal Issues for Doctoral Nursing Students: A Textbook for Students and Reference for Nurse Leaders* (DEStech Publications 2013) 58.

<sup>65</sup> Cara Health, 'Naturopathic causes and treatment of autism' <<http://carahealth.ie/health-conditions-a-to-z/nervous-system/autism/326-naturopathic-causes-and-treatment-of-autism-.html#!/c/0/offset=0&sort=normal>> accessed 11 October 2016.

<sup>66</sup> Tao Xiong and others, 'Hyperbaric oxygen therapy for people with autism spectrum disorder (ASD)' (2016) Cochrane Database of Systematic Reviews CD010922, "To date, there is no evidence that hyperbaric oxygen therapy improves core symptoms and associated symptoms of ASD. It is important to note that adverse effects (minor-grade ear barotrauma events) can occur. Given the absence of evidence of effectiveness and the limited biological plausibility and possible adverse effects, the need for future RCTs of hyperbaric oxygen therapy must be carefully considered"; Katrina Williams and others, 'Intravenous secretin for autism spectrum disorders (ASD)' (2012) Cochrane Database of Systematic Reviews CD003495, "There is no evidence that single or multiple dose intravenous secretin is effective and as such currently it should not be recommended or administered as a treatment for ASD".

<sup>67</sup> US National Poison Control Centre, 'Chelation: Therapy or "therapy"?' (2011), "Chelation therapy is a treatment for heavy metal poisoning: iron, mercury, arsenic, and lead. Some people give chelation "therapy" for other conditions such as cardiovascular disease, autism, and Alzheimer's. This exposes patients to risks without benefit" <[www.poisson.org/articles/2011-mar/chelation-therapy](http://www.poisson.org/articles/2011-mar/chelation-therapy)> 10 September 2016.

potential for ASD<sup>68</sup> and carries serious risks to health.<sup>69</sup> Not only this, but some practitioners assert that androgens, such as testosterone, bind with heavy metals in the body, preventing them from being removed during chelation therapy.<sup>70</sup> To remedy this, an anti-androgenic drug such as Lupron (leuprolide acetate) may be administered, which prevents testosterone production, chemically castrating the male child, stopping the production of oestrogen (an end-product for the synthesis of which testosterone is vital) in the female child, and inhibiting reproductive development. There is no high-quality evidence of medical benefit to outweigh the significant risks of the treatment<sup>71</sup> or to justify the significant negative impacts on the dignity and bodily integrity of the child.

A 28% sodium chlorite solution called MMS (Miracle Mineral Supplement/ Solution)<sup>72</sup> has also been marketed for use for a vast array of medical and developmental conditions<sup>73</sup> and its use is encouraged for children.<sup>74</sup> According to Health Canada, sodium chlorite is used as “germicide by veterinarians and as a hard surface disinfectant. Sodium chlorite is commonly used for bleaching textiles, pulp and paper, as well as in the generation of disinfectant for drinking water treatment”.<sup>75</sup> The solution is administered, *inter alia*, as eye-drops, as an oral solution, rectally as an enema, and transdermally, by rubbing on the skin or using in the bath.

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<sup>68</sup>Yashwant Sinha and others, ‘Chelation therapy and autism’ (2006) 333 British Medical Journal 756. See also, AJ Baxter and others, ‘Pediatric fatality secondary to EDTA chelation’ (2008) 46 Clinical Toxicology 1083, 1084.

<sup>69</sup>Centers for Disease Control and Prevention, ‘Deaths Associated with Hypocalcemia from Chelation Therapy - Texas, Pennsylvania, and Oregon, 2003-2005’ (2006) 55(8) Morbidity and Mortality Weekly Report 204, 204-206.

<sup>70</sup>Mark Geier and David Geier, ‘The potential importance of steroids in the treatment of autistic spectrum disorders and other disorders involving mercury toxicity’ (2005) 64 Medical Hypotheses 946, “We put forward the medical hypothesis that autistic disorders, in fact, represents a form of testosterone mercury toxicity, and based upon this observation, one can design novel treatments for autistics directed towards higher testosterone levels in autistic children. We suggest a series of experiments that need to be conducted in order to evaluate the exact mechanisms for mercury-testosterone toxicity and various types of clinical manipulations that may be employed to control testosterone levels”.

<sup>71</sup>Both the Health Service Executive and the UK National Institute for Clinical Excellence advise against the use of chelation for the direct treatment of autism spectrum disorder and the latter specifically advises against the use of testosterone regulation for the same purpose. See, respectively, Health Service Executive, ‘Asperger syndrome – Treating autistic spectrum disorder’ <[www.hse.ie/eng/health/az/A/Asperger-syndrome/](http://www.hse.ie/eng/health/az/A/Asperger-syndrome/)> accessed 16 October 2016; National Institute for Clinical Excellence, ‘Autism spectrum disorder in adults: Diagnosis and management’ (2012), paras 14.14 and 14.19 <[www.nice.org.uk/guidance/CG142/chapter/1-Guidance#interventions-for-autism](http://www.nice.org.uk/guidance/CG142/chapter/1-Guidance#interventions-for-autism)> accessed 16 October 2016.

<sup>72</sup>Paul Lantos and others, ‘Unorthodox alternative therapies marketed to treat Lyme disease’ (2015) 60(12) Clinical Infectious Diseases 1776, 1778.

<sup>73</sup>MMSDrops.com, ‘List of Uses’ (2015) <[www.mmsdrops.com/list-of-uses/](http://www.mmsdrops.com/list-of-uses/)> accessed 16 October 2016. These include, among many, many others, autism, cancer, HIV, Alzheimer’s disease, congestive heart failure, Down Syndrome, fractures, “mad cow disease”, mesothelioma and multiple sclerosis.

<sup>74</sup>CDAutism.org, ‘MMS’, “Isn’t MMS Snake Oil? Not True. Snake oil does not play a critical role in the recovery of 235 children (as of October 2016) with Autism. Our children are getting better, and no amount of rhetoric can take that away. How do I get started? You can start off on Day 1 making an 8oz Baby Bottle with one activated drop, apply one ounce 8 times a day, this way you will get into the habit of the minimum of 8 doses right from the first day”.

<sup>75</sup>Health Canada, ‘Recalls & alerts - Health Risks Associated with Use of Miracle Mineral Solution’ (12 May 2010).

This product is not authorised for sale by the HPRA<sup>76</sup> and its use may cause “health problems such as abdominal pain, nausea, vomiting, and diarrhoea or more serious problems such as, poisoning, kidney failure and harm to red blood cells that reduces the ability of the blood to carry oxygen, among others”.<sup>77</sup> According to the HPRA, it also “has no recognised therapeutic benefits”.<sup>78</sup> Use of MMS is contrary to the best interests of any child but, although its sale or supply is illegal in Ireland due to its lack of HPRA authorisation, its use by parents for their children is not – it too falls within the protective sphere of parental autonomy, leaving children, once again, at significant risk.<sup>79</sup>

Without the creation and enforcement of any minimum standard for education and training, safety and efficacy, true parental choice within a pluralistic medical system is undermined and child and public health are put at risk. The harm caused by provision of ineffective or dangerous therapies to desperate consumers does not discriminate by age but the effect is undoubtedly more unpalatable where the patient is not in a position to effectively object. This powerlessness is made all the more prominent by the way in which CAM in Ireland is provided: in private, often without the knowledge of conventional healthcare providers, and in the absence of an advocate for the child who is not emotionally or financially invested in the effectiveness of the therapy.

While children in Ireland have made progress in respect of rights recognition, this has not been matched by action. Their lack of autonomy in respect of healthcare is a stark reminder of their vulnerability. Irish constitutional law has reinforced the role of the parent as ultimate decision-maker for the child and, in many situations, this is to the benefit of both the child and their family, the presumption being that the parent will act in the child’s best interest. This is discussed in Part II, below. However, where there are complex matters of individual and public health to be decided, parents should not, in all cases, be considered best placed or best qualified to do so.

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<sup>76</sup> HPRA v Patrick Merlehan: Defendant found guilty of placing Miracle Mineral Solution (MMS) on market (28 October 2016).

<sup>77</sup> Health Canada (n 75).

<sup>78</sup> HPRA v Patrick Merlehan (n 76).

<sup>79</sup> This is addressed in Chapter 7, where it is suggested that any therapy found to be inherently unsafe and without benefits that outweigh their risks ought to be prohibited from sale or for use by minors.

## PART II

### CONSTITUTIONAL PROTECTION AND INTERVENTION

#### 2. THE CHILD, THE CONSTITUTION AND CAM

Children, considered to be those under the age of 18 by Art 1 of the United Nations Convention on the Rights of the Child (UNCRC) and throughout domestic legislation on the protection of children,<sup>80</sup> have different capacities to consent or dissent to treatment than adults do, and their words and deeds are often afforded less weight and significance.<sup>81</sup> Indeed, children may be viewed as passive extensions of their parents, “to be raised, whether they like it or not”.<sup>82</sup> This paternalistic approach is apparent in the Constitution and in its interpretation, as reflected in the repeated assertion that the rights and welfare of the child are best vindicated through its family.<sup>83</sup> Contemporary policy, influenced, no doubt, by an avalanche of revelations regarding domestic and institutional child abuse,<sup>84</sup> (facilitated by the historically adult-centric approach to children’s rights in Ireland), and by international human rights law, has begun to take a more enlightened approach to children’s rights, acknowledging the dynamic and progressive nature of competence and espousing a subjective, age-and-maturity-guided approach to child input.<sup>85</sup> This shift is apparent in domestic child protection legislation<sup>86</sup> and, recently, in the Thirty First Amendment to the Constitution, amending the Art 42.5 provisions on education and upbringing and placing children’s rights “within explicit constitutional parameters”.<sup>87</sup> However, it is argued that the judicial recognition of rights and interpretation of the best interests of the child *vis á vis* the family are at odds with the final action taken, particularly

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<sup>80</sup> See, for example, National Vetting Bureau (Children and Vulnerable Persons) Act 2012, Criminal Justice (Withholding of Information on Offences Against Children and Vulnerable Persons) Act 2012, Children First Act 2015, in accordance with s 2 of the Child Care Act 1991.

<sup>81</sup> As noted by Tamar Schapiro, ‘What is a Child?’ (1999) 109 (4) *Ethics* 715, 716.

<sup>82</sup> *ibid* 718. This is also made clear in *Rerum Novarum*, Encyclical of Pope Leo XIII, 15 May 1891, para 14, where it states, “‘The child belongs to the father,’ and is, as it were, the continuation of the father’s personality; and speaking strictly, the child takes its place in civil society, not of its own right, but in its quality as member of the family in which it is born”.

<sup>83</sup> *Re JH (An Infant)* [1985] IR 375, 395 (Finlay CJ) and *North Western Health Board v HW & CW* (n 12) 722 (Denham J).

<sup>84</sup> See *Report of the Commission to Inquire into Child Abuse (“The Ryan Report”)* (Office of Children and Youth Affairs 2009); *Report by Commission of Investigation into Catholic Archdiocese of Dublin (“The Murphy Report”)* (Stationery Office 2009); *Report by Commission of Investigation into the handling by Church and State authorities of allegations and suspicions of child sexual abuse against clerics of the Catholic Diocese of Cloyne (“The Cloyne Report”)* (Stationery Office 2010); *The Ferns Report* (Stationery Office 2005);, *Report of the Kilkenny Incest Investigation* (Stationery Office 1993); *The Roscommon Child Care Case* (Stationery Office 2010); and *Report of the Independent Child Death Review Group* (Department of Children and Youth Affairs 2012).

<sup>85</sup> The Irish Constitution, Art 42A.4.2°, “Provision shall be made by law for securing, as far as practicable, that in all proceedings referred to in subsection 1 of this section in respect of any child who is capable of forming his or her own views, the views of the child shall be ascertained and given due weight having regard to the age and maturity of the child”.

<sup>86</sup> Most recently, the Children First Act 2015.

<sup>87</sup> Geoffrey Shannon, *Children and Family Relationships Law in Ireland: Practice and Procedure* (Clarus Press 2016), para 1.01.

where no legislative guidance has been provided,<sup>88</sup> failing to adequately protect those at longer term of serious risk of harm, which is often the situation in which children treated with CAM find themselves.<sup>89</sup> Where the courts cannot or will not intervene without there being an immediate threat to the child,<sup>90</sup> and the legislature has neglected to provide for a mechanism of regulation, parents are not so much made as left the sole decision-makers in respect of their child's health. This, despite the constitutional presumption, cannot in all cases be considered optimal.

This Part addresses, not whether the rights of the child treated with CAM have been infringed, but whether, in what circumstances and to what extent these children can expect the courts to intervene to vindicate their rights and to protect their best interests.

It is apt to begin by briefly examining the history of child and family in the Constitution, in order to establish the context in which available protections may be accessed and the best interest of the child assessed.

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<sup>88</sup> *North Western Health Board v HW & CW* (n 12) 721 (Denham J), "The screening test in issue is not a scheme established by statute. The Oireachtas has not decided that every child in the country should have this test. Thus this case does not require a decision as to the constitutionality of any legislation or the balancing of the common good against individual or group rights in relation to that legislation. The fact that there is no legislation seeking to make the P.K.U. test compulsory is a relevant factor. If there was such legislation it would be presumed to be constitutional yet open to review. Any such review would involve consideration of the common good while analysing the rights of the family and the child. The fact that there is no legislation requiring that children be given the P.K.U. test is a factor of importance in that, as a consequence, the analysis leading to a decision commences not from such legislation but from the Constitution. Any comment as to what the situation would be if there was legislation governing the P.K.U. test could only be speculative. Legislation is not an issue in this case. Nor is it appropriate to indicate whether or not the Oireachtas should legislate".

<sup>89</sup> Alan D Woolf, 'Herbal remedies and children: Do they work? Are they harmful?' (2003) 112 *Pediatrics* 240, 242-243, "Children differ from adults in their absorption, distribution, metabolism, and excretion of some substances.... they also have developing central nervous and immune systems that may make them more sensitive to the adverse effects of herbs. Infants and young children are physiologically more vulnerable to certain adverse effects of herbs than are adults... The duration of use is another consideration, with longer courses of herbal therapy exposing the patient to a higher risk of acute and subacute, cumulative, or chronic adverse effects. For some herbs, such as those that contain pyrrolizidine alkaloids, there may be no safe dose or duration of use for children... Significant uncertainty surrounds the long-term consequences of exposure to some herbal remedies for which the toxicity profiles are incompletely characterized. Classic concerns include carcinogenicity, mutagenicity, toxicity to the fetus, and the effects of herbs on the lactating woman and breastfeeding infant. Although the chemicals in herbs may have carcinogenic effects, this concern has not been adequately investigated. Some chemicals found in plants are known carcinogens or tumor promoters in animals (eg, pyrrolizidines [comfrey, coltsfoot, senecio], safrole [sassafras], aristolochic acids [wild ginger], catechin tannins [betel nuts]). Whether such chemicals pose a threat for humans remains unknown; children, by virtue of their longer lives, may be particularly vulnerable to herbs that contain chemicals whose carcinogenic effects may not become manifest until a long latency period has passed".

<sup>90</sup> *North Western Health Board v HW & CW* (n 12) 741-742, (Murray J), "It seems however, to me, that there must be some immediate and fundamental threat to the capacity of the child to continue to function as a human person, physically, morally or socially, deriving from an exceptional dereliction of duty on the part of parents to justify such an intervention".

## 2.1 THE HISTORY OF THE CHILD IN THE CONSTITUTION

The Irish Constitution, published in 1937, predictably reflects the mores of its day. The influence of the Roman Catholic Church in Ireland is apparent throughout the text. The Preamble states,

In the Name of the Most Holy Trinity, from Whom is all authority and to Whom, as our final end, all actions both of men and States must be referred, We, the people of Éire, Humbly acknowledging all our obligations to our Divine Lord, Jesus Christ, Who sustained our fathers through centuries of trial ...

There are repeated references to “Almighty God” and “Divine Lord Jesus Christ” peppered throughout the text, demonstrating that, although the reference to the special position of the Roman Catholic Church in Ireland was removed in 1972, significant influences from the Roman Catholic faith remain. Until very recently,<sup>91</sup> it could be seen in the Article 42.5 description of the relative positions of the family<sup>92</sup> and the State. While the wording, since amended, was strikingly similar to the 1929 papal encyclical *Divini Illius Magistri*,<sup>93</sup> the general hands-off approach taken by the authors of the Constitution to the family was one endorsed by Pope Pius XI in *Quadragesimo Anno* in 1931,<sup>94</sup> which espoused subsidiarity of State power to the family unit under the guise of preserving State resources for more important concerns.

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<sup>91</sup> The Thirty-First Amendment of the Constitution (Children) Act 2012 substitutes the former Article 42.5 wording citing parental failure for “physical or moral reasons” as justification for State intervention, with new wording stating that such parental failure must occur “to such extent that the safety or welfare of any of their children is likely to be prejudicially affected”, demonstrating a shift from antiquated, morality-based decision-making to a more pragmatic welfare paradigm.

<sup>92</sup> The family referred to in the Constitution is the marital family under Art 41, as set out in *State (Nicolaou) v An Bord Uchtála* [1966] IR 567, 622, where Henchy J stated, “Article 41 deals with only one kind of family, namely, a family founded on the institution of marriage. Article 41, 1, 1, accords the recognition of the State to such family as “the natural primary and fundamental unit group of Society, and as a moral institution possessing inalienable and imprescriptible rights, antecedent and superior to all positive law”; and Article 41, 1, 2, gives the guarantee of the State to protect it in its constitutional authority, as the necessary basis of social order and as indispensable to the welfare of the nation and of the State. For the State to award equal constitutional protection to the family founded on marriage and the “family” founded on an extra-marital union would in effect be a disregard of the pledge which the State gives in Article 41, 3, 1, to guard with special care the institution of marriage”. This has been affirmed in subsequent cases.

<sup>93</sup> *Divini Illius Magistri*, Encyclical of Pope Pius XI, 31 December 1929, para 45, “It also belongs to the State to protect the rights of the child itself when the parents are found wanting either physically or morally in this respect, whether by default, incapacity or misconduct, since, as has been shown, their right to educate is not an absolute and despotic one, but dependent on the natural and divine law, and therefore subject alike to the authority and jurisdiction of the Church, and to the vigilance and administrative care of the State in view of the common good. Besides, the family is not a perfect society, that is, it has not in itself all the means necessary for its full development. In such cases, exceptional no doubt, the State does not put itself in the place of the family, but merely supplies deficiencies, and provides suitable means, always in conformity with the natural rights of the child and the supernatural rights of the Church”.

<sup>94</sup> *Quadragesimo Anno*, Encyclical of Pope Pius XI, 15 May 1931.

At para 80, it stated:

The supreme authority of the State ought, therefore, to let subordinate groups handle matters and concerns of lesser importance, which would otherwise dissipate its efforts greatly. Thereby the State will more freely, powerfully, and effectively do all those things that belong to it alone because it alone can do them: directing, watching, urging, restraining, as occasion requires and necessity demands. Therefore, those in power should be sure that the more perfectly a graduated order is kept among the various associations, in observance of the principle of "subsidiary function," the stronger social authority and effectiveness will be the happier and more prosperous the condition of the State.

The pre-emptor of this encyclical was *Rerum Novarum*, which stated:

The contention, then, that the civil government should at its option intrude into and exercise intimate control over the family and the household is a great and pernicious error. True, if a family finds itself in exceeding distress, utterly deprived of the counsel of friends, and without any prospect of extricating itself, it is right that extreme necessity be met by public aid, since each family is a part of the commonwealth. In like manner, if within the precincts of the household there occur grave disturbance of mutual rights, public authority should intervene to force each party to yield to the other its proper due; for this is not to deprive citizens of their rights, but justly and properly to safeguard and strengthen them. But the rulers of the commonwealth must go no further; here, nature bids them stop. Paternal authority can be neither abolished nor absorbed by the State; for it has the same source as human life itself. "The child belongs to the father," and is, as it were, the continuation of the father's personality; and speaking strictly, the child takes its place in civil society, not of its own right, but in its quality as member of the family in which it is born. And for the very reason that "the child belongs to the father" it is, as St. Thomas Aquinas says, "before it attains the use of free will, under the power and the charge of its parents" ... The socialists, therefore, in setting aside the parent and setting up a State supervision, act against natural justice, and destroy the structure of the home.<sup>95</sup>

Since 1937, the Irish courts have adhered, overall, to the non-interventionist approach, despite significant societal progress and greater recognition of the value of children and their welfare in the intervening time to date,<sup>96</sup> which is apparent in domestic policy and in international law. The threshold for intervention remains extremely high and this may give rise to difficulties for children being treated with CAM, as, thus far, few situations in general have been deemed

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<sup>95</sup> *Rerum Novarum*, Encyclical of Pope Leo XIII, 15 May 1891, para 14.

<sup>96</sup> National Economic and Social Council, *Strategy into the 21<sup>st</sup> Century* (NESC 1996) 44, "A less tangible but none the less important sign of increased commitment to children both inside and outside of families is the greater concern for the personal rights and needs of children which has emerged since the 1960s"; Tony Fahey, 'State, family and compulsory schooling in Ireland' (1992) 23(4) *Economic and Social Review* 369.

sufficiently exceptional to warrant intervention by the courts.<sup>97</sup> Risk of harm to health has not been deemed sufficient.<sup>98</sup> Risk of harm to psychological wellbeing has not been deemed sufficient.<sup>99</sup> The risk arising from the use of CAM is often a longer-term one, generally arising within a setting of parental care and conscientiousness, and, as such, is extremely unlikely to reach the threshold for intervention (such as an imminent threat to the life of a child or to his or her capacity to continue to function as a human person),<sup>100</sup> until damage is done, a most worrying prospect for the many Irish children being treated at this time. With this said, it is necessary to consider this threshold, in order to determine what protection, if any, might be gleaned from the Art 42 provisions and in what circumstances.

## 2.2 THE GAP BETWEEN RIGHTS RECOGNITION AND RIGHTS PROTECTION

The use of CAM by parents for their children clearly has implications for the child's unenumerated right to bodily integrity under Art 40.3.1°, recognised in *Ryan v Attorney General*,<sup>101</sup> and for the right "to be fed and to live, to be reared and educated, to have the opportunity of working and of realising his or her full personality and dignity as a human being", recognised by O'Higgins CJ in *G v An Bord Uchtála*.<sup>102</sup> These are presumed to be best vindicated within the constitutional family, whose autonomy lies with the parents. Despite the statement by Walsh J, later in that same judgment, that "[T]here is nothing in the Constitution to indicate that in cases of conflict the rights of the parent are always to be given primacy",<sup>103</sup> this has not been reflected in later judgments, including, but not limited to, *N v Health Service Executive*,<sup>104</sup> *Re JH*<sup>105</sup> and *North Western Health Board (NWHB) v HW & CW*<sup>106</sup> and, most

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<sup>97</sup> *North Western Health Board v HW & CW* (n 12) 755 (Hardiman J), "The presumption [that the decisions of parents should not be overridden by the State] is not of course conclusive and might be open to displacement by countervailing constitutional considerations, as perhaps in the case of an immediate threat to life". The terms "might" and "perhaps" do not offer great certainty here either.

<sup>98</sup> *North Western Health Board v HW & CW* (n 12).

<sup>99</sup> *N v Health Service Executive* [2006] IEHC 278, [2006] 4 IR 374 (HC), 418, an expert witness opined that "the second and third respondents had built a strong emotional bond with Ann. The disruption of a well established sense of security and emotional belonging could have a serious effect on Ann's well being and could lead to emotional and behavioural problems. She considered that it was not in Ann's best interest to destroy this well established security and emotional stability in order to meet what she termed as "the sudden needs of her natural parents and their families". The witness described the needs of Ann as being essential in the circumstances of the case by contrast to the needs of her natural parents who to her are strangers. She considered that Ann had reached a stage and age in her development where a change of care givers, environment and established child rearing pattern could have a devastating effect upon her. Though she had no doubt that her natural parents and their families would have tried to do their best, she considered it would be a risky move and a potentially dangerous one on which to embark". The Supreme Court, on appeal, found that this was nonetheless not a situation exceptional enough to override the inalienable rights of the marital family under the Constitution. See also the earlier case of *Re JH an Infant* (n 83).

<sup>100</sup> *North Western Health Board v HW & CW* (n 12) 755 (Hardiman J) and 741-742 (Denham J).

<sup>101</sup> *Ryan v Attorney General* [1965] IR 294 (SC), 313 (Kenny J).

<sup>102</sup> *G v An Bord Uchtála* [1980] 1 IR 32 (SC), 56.

<sup>103</sup> *ibid* 78.

<sup>104</sup> *N v Health Service Executive* (n 99).

<sup>105</sup> *Re JH (An Infant)* (n 83).

<sup>106</sup> *North Western Health Board v HW & CW* (n 12).



recently, in *HSE v B*.<sup>107</sup> In each of these cases, the objective risks of following the wishes of the parents were made clear and yet these wishes were acceded to by the courts, who failed, not with their words but with their actions, to recognise that “[i]t is the child more than anyone else who will have to live with what the court decides”.<sup>108</sup> The best interests of the child in these cases were subjugated to those of their parents.

The *North Western Health Board* case is of particular relevance. Here, the parents sought to prevent the performance of a standard diagnostic test (the heel prick test) used to diagnose phenylketonuria (PKU), galactosaemia, homocystinuria, maple syrup urine disease and hypothyroidism, all metabolic disorders which, if left undiagnosed and therefore untreated, may have serious or life-threatening implications. The parents of the child rejected the test due to its invasive nature and their “strong religious belief, that nobody is allowed to injure anybody else”.<sup>109</sup> The North Western Health Board sought *inter alia* a declaration that it was in the best interests of the child to undergo the test and an injunction against the defendants to facilitate them performing the test. Despite ample evidence that the decision of the parents not to test was objectively not in the best interests of the child, the Court nonetheless found in their favour (Keane CJ dissenting), stating that intervention in the family unit could only be justified in exceptional circumstances, including “an immediate threat to the health or life of the child”<sup>110</sup>; “a degree of parental neglect constituting an abandonment of the child and all rights in respect of him”<sup>111</sup>; and “an immediate and fundamental threat to the capacity of the child to continue to function as a human person, physically, morally or socially, deriving from an exceptional dereliction of parental duty”.<sup>112</sup> This a high threshold, unlikely to be met by most cases involving children treated with CAM contrary to their best interests. The significance of the failure to appropriately account for cumulative, longer-term threat should not be overlooked.

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<sup>107</sup> *HSE v B* (HC, 2 November 2016) (Twomey J). This case was exceptional due to the extremely invasive and traumatic nature of the intervention required to protect the best interests of the child (a forced caesarean section). In addition, there was some conflicting evidence from the UK that the risk to the mother and child from acceding to the wishes of the mother to attempt a natural delivery having had three previous caesarean sections was not as significant as it was considered to be in Irish medical practice. By contrast, this was not the case in, for example, the *NWHB* case, where the medical community was *ad idem* on the relative risks and benefits of PKU testing. Interestingly, in *HSE v B*, the court found that the costs of a child suffering injury by virtue of the mother’s chosen birth method contrary to medical advice would be borne by the mother and not, as in cases of medical negligence, by the State. However, it is argued that the cost would not have been borne by the mother alone. There is a greater, if justifiable, financial obligation placed on the State to make reasonable accommodations for its citizens to fulfil their rights where additional support is needed, in the form of health care, social care and education. This also fails to account for the effect on the other family members involved, including three other children, and on the medical staff of the potential unnecessary loss of two patients.

<sup>108</sup> *Re D* [2006] UKHL 51 [57] (Baroness Hale).

<sup>109</sup> *North Western Health Board v HW & CW* (n 12) 752. This was not pleaded in the Supreme Court.

<sup>110</sup> *ibid* 724 (Denham J).

<sup>111</sup> *ibid* 732-733 (Murphy J).

<sup>112</sup> *ibid* 740-741 (Murray J).

Throughout the judgment, the importance of familial context is apparent; where the parents are generally caring and conscientious, an objectively bad decision, falling short of absolute failure in the absence of an immediate threat to the life of the child, will likely go undisturbed. Children treated with CAM are often in just such a situation and there has been little by way of relevant jurisprudence to provide hope since.

Coffey and Harding present an excellent analysis of this case, with an alternative judgment written by Harding, ostensibly from a feminist perspective. Of the many thought-provoking points made throughout her judgment, three are of particular relevance here and are described briefly below:

- (a) There is a clear problem in considering the rights and best interests of the child as being inevitably best protected by upholding the integrity of the family unit<sup>113</sup>;
- (b) It is inappropriate to apply the test of justification (the ‘exceptional circumstances’ test) for the most draconian possible forms of intervention to cases involving or requiring minimally invasive action<sup>114</sup>; and
- (c) The courts have been too reluctant to appropriately use their inherent jurisdiction to ensure that the best interests of the child are protected.<sup>115</sup>

### **2.2.1 BEST INTERESTS OF THE CHILD AS INEVITABLY BEST PROTECTED BY THE FAMILY**

This has been made clear in the facts of the case itself; while the child’s best interests required the performance of the test, the Court determined that the parents’ constitutional autonomy prevented it. One of the concerns on which the ruling in favour of the parents was based, despite overwhelming and uncontested medical evidence favouring performance of the test, was in relation to the separation of powers, whereby the test would effectively be made mandatory by the judgment. However, Keane CJ dismissed this concern, stating that

...if the court orders this test to be carried out on Paul, the overwhelming likelihood is that it will be carried out in the handful of cases where the parents are adopting the same attitude as that adopted by the defendants in the present case. The fact remains, however, that the central issue in this case is as to whether the constitutional rights of Paul fall to be upheld by the High Court and this court. The duty of the superior courts to uphold the rights of the child arises, to the

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<sup>113</sup> Maebh Harding and Donal Coffey in Mairéad Enright, Julie McCandless and Aoife O'Donoghue (eds) (n 15).

<sup>114</sup> *ibid.* This was also referred to by Keane CJ in *North Western Health Board v HW & CW* (n 12) 707.

<sup>115</sup> Maebh Harding and Donal Coffey in Mairéad Enright, Julie McCandless and Aoife O'Donoghue (eds) (n 15).

extent that it arises at all, because they are not being upheld by the parents and have not been or, cannot be, upheld by the other two organs of the State. For a court in those circumstances to take such steps as are necessary to uphold the constitutional rights of Paul is to do no more than to carry out its duty under the Constitution and in no sense violates the doctrine of the separation of powers.<sup>116</sup>

Children in this same situation have their rights subjugated in the same way and so are entitled to the same protection. Where the circumstances are different, the outcome may also be different. The test would not, therefore, have been made mandatory by ruling that it be performed in this case. In a hypothetical case, a child prevented by the State from receiving CAM treatments may not establish a rule for all children, but only those in the same specific circumstances as that child.

Harding argues that the assumption of inevitable best protection within the bounds of the family is “rather lazy”, replacing, as it does, the “overarching duty of the court to uphold the individual rights of the child with the duty to uphold parental rights and maintain the family unit”, which is, for some unfortunate children, “the most dangerous place of all”.<sup>117</sup>

### **2.2.2 THE ‘EXCEPTIONAL CIRCUMSTANCES’ TEST IS INAPPROPRIATELY RESTRICTIVE FOR MOST SITUATIONS**

Harding argues that the threshold to be met for all manner of intervention is calibrated for intervention at its most invasive, leaving children requiring only a minimal intervention to guard their best interests and vindicate their constitutional rights, without protection, until their life or health is at imminent risk. Parental behaviour that amounts to “a virtual abdication of their responsibility”<sup>118</sup> or will lead to “disastrous consequences ... so immediate and inevitable as to demand intervention and perhaps call into question either the basic competence or devotion of the parents”<sup>119</sup> may enable the State to remove the child permanently from the care and custody of their parents. However, this is thankfully a rare situation and not one which is very likely to be seen in the case of most children receiving CAM, which is time, effort and resource intensive – elements which do not normally suggest an abdication of parental responsibilities.

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<sup>116</sup> *North Western Health Board v HW & CW* (n 12) 704.

<sup>117</sup> Maebh Harding and Donal Coffey in Mairéad Enright, Julie McCandless and Aoife O'Donoghue (eds) (n 15).

<sup>118</sup> *North Western Health Board v HW & CW* (n 12) 733.

<sup>119</sup> *ibid.*

Nonetheless, this fails to protect those children from the harm incurred, directly or indirectly, by virtue of this parental behaviour.

According to the Law Society's Law Reform Committee in their report entitled *Rights-based Child Law: The case for reform*, "in order for the State to intervene to protect the best medical interests of a child, there needs to be a threat to the life, as opposed to the health, of the child".<sup>120</sup> It recommended that

... the State should have the capacity to intervene to protect the best medical interests of the child in the event of a long-term threat of a deteriorating nature, which could be prevented by early intervention. Proportionate intervention should be permitted where the effects of not intervening are severe, and best medical practice suggests that intervention is necessary for the future health of the child.<sup>121</sup>

Ten years and one referendum later, there is little evidence that this has been considered, let alone taken on board.

### **2.2.3 JUDICIAL RELUCTANCE TO RELY ON INHERENT JURISDICTION**

Intervention in the marital family may come about through a number of statutory mechanisms, which provide for applications to be made for this purpose to the court by disagreeing parents or guardians of the child,<sup>122</sup> by the Health Service Executive<sup>123</sup> or by concerned third parties.<sup>124</sup>

Under s 11 of the Guardianship of Infants Act 1964, the court is invited to intervene by the parents or guardians and is required by s 3 of the Act to place the welfare of the child at the forefront on any action taken. Where the parents or guardians are in agreement as to the decision to be made, this procedure is not applicable.

Under s 16 of the Child Care Act 1991:

Where it appears to a health board with respect to a child who resides or is found in its area that he requires care or protection which he is unlikely to receive unless a court makes a care order or a supervision order in respect of him, it shall be the duty of the health board to make application for a care order or a supervision order, as it thinks fit.

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<sup>120</sup> Law Society, 'Rights-based Child Law: The case for reform' (Law Society 2006) 198.

<sup>121</sup> *ibid* 199.

<sup>122</sup> Guardianship of Infants Act, s 11.

<sup>123</sup> Child Care Act 1991, s 15.

<sup>124</sup> Courts (Supplemental Provisions) Act 1961, s 9.

Under s 18(1)(c) of the Act, the court may make a care order where “... the child's health, development or welfare is likely to be avoidably impaired or neglected, and ... the child requires care or protection which he is unlikely to receive unless the court makes an order under this section”. This, while appearing potentially useful for children treated with CAM, remains subject to the ‘exceptional circumstances’ provision in Art 42,<sup>125</sup> diminishing its protective potential for those children, among others. However, the use of the care orders, which effectively shift the parental rights and responsibilities for the care of the child to the State, far exceeds what is required or desirable for the protection of these particular children. This also applies to wardship, the powers for which are vested in the High Court under s 9 of the Courts (Supplemental Provisions) Act 1961. Here, the court must determine that the child in question is at unacceptable risk and that they should be taken into wardship, giving the courts control over the person and property of the child and superceding the control of the parents.<sup>126</sup> What remains, instead, is the pure inherent jurisdiction of the High Court.

According to Donnelly, ““Inherent jurisdiction” is generally understood as referring to the panoply of implied powers which are exercisable by judges for the purpose of regulating curial processes”.<sup>127</sup> It may be considered to originate in Article 34.3.1°, which invests the High Court with “full original jurisdiction in and power to determine all matters and questions whether of law or fact, civil or criminal”. It is argued by Coffey and Harding that the flexibility of the jurisdiction may appropriately be applied to address individual parental decisions,<sup>128</sup> even where parents are in agreement, unlike the s 11 process. This, they state, is necessary, as:

Children cannot easily bring actions to court to protect their own interests, they are not an active part of the legislature and they cannot advocate their own rights. A legal mechanism is required to protect their rights where they are threatened by the decisions of others. The need for such a jurisdiction was recognised at a point in history where individual rights were accorded less value than they are now. In the absence of an express statutory mechanism by which to review parental decisions made by an intact family unit the existence of such a

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<sup>125</sup> *North Western Health Board v HW & CW* (n 12) 712-713 (Denham J), “There are of course cases in which the State may interfere with parental rights, and many of these are detailed in the Child Care Act, 1991. They are the exceptional cases. In my view the decision in the present case by the defendants, who are acknowledged to be caring and conscientious parents, could not be said to constitute an exceptional case, even though the general medical opinion would be quite clear that such decision was wrong. If the State were entitled to intervene in every case where professional opinion differed from that of parents, or where the State considered the parents were wrong in a decision, we would be rapidly stepping towards the ‘Brave New World’ in which the State always knows best”.

<sup>126</sup> Maebh Harding and Donal Coffey in Mairéad Enright, Julie McCandless and Aoife O'Donoghue (eds) (n 15).

<sup>127</sup> Joan Donnelly, ‘Inherent Jurisdiction and Inherent Powers of Irish Courts’ (2009) 2 Judicial Studies Institute Journal 122.

<sup>128</sup> Maebh Harding and Donal Coffey in Mairéad Enright, Julie McCandless and Aoife O'Donoghue (eds) (n 15).

jurisdiction to protect vulnerable children from harm caused by decisions which may adversely impact the child's constitutional rights is surely constitutionally mandated.<sup>129</sup>

Certainly, both children treated with CAM and their families could potentially derive protection from willingness on the part of the High Court to use its inherent jurisdiction in this way. However, the lack of certainty greatly undermines its usefulness at present. As noted by Coffey and Harding, an express statutory review mechanism would be preferable. In the absence of this, a measure of certainty might be created by the introduction of legislation specific to CAM, developing standards and thresholds below which the treatments provided to children should not fall.<sup>130</sup> Failing this, the courts might consider one further piece of guidance in determining whether a notional child treated with CAM against his or her best interests might avail of assistance or intervention.

Strong and comprehensive domestic and European consumer protection legislation exists to protect consumers, including children, from misleading commercial practices in relation to products or services. Unlike in *NWHB*, where the legislature had not legislated to make the PKU test mandatory, the courts have strong legislative guidance for protecting children from the use of unproven and potentially unsafe treatments through consumer protection law, such as the Consumer Protection Act 2007. Where no other statutory guidance exists, this may provide a last-gasp reinforcement for the protection of the best interests of the child.

### 2.3 TOO HIGH A THRESHOLD FOR INTERVENTION?

While it would be very convenient to recommend a process whereby a child could be, relatively easily, taken temporarily into the care of the State in order to provide what is objectively in the best interests of a given child, this is neither realistic nor desirable. The constitutional protections for the integrity of the family unit are not without merit. For example, the at-arms-length supervision of the marital family, while conservative at its heart, has contributed to the availability of contraceptives in Ireland, alleviating the financial and physical hardship of raising a large family.<sup>131</sup>

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<sup>129</sup> *ibid.*

<sup>130</sup> See Chapter 7.

<sup>131</sup> *McGee v Attorney General* [1974] 1 IR 284 (SC). Clearly the Roman Catholic Church did not have this in mind when promoting the autonomy of the family.

However, it is argued that the freedom afforded to parents by the Constitution gives rise to risks in the context of child health. As public and parental opinion is subject to fads, social norms of the time<sup>132</sup> and scare tactics,<sup>133</sup> and, as is made clear in Chapter 6, many reasonable parents have a limited or inaccurate understanding of CAM despite their use of it to treat their children, the care and conscientiousness with which they perform their parental duties and how well they know their own child should not in all circumstances be placed on equal terms with the opinions of an expert medical profession supported by a plethora of evidence, bearing the trust and confidence of the State and acting under a fiduciary duty in the best interests of that child, by virtue of a general constitutional principle.

The new constitutional ‘best interests’ provisions in Art 42A do not stand alone but require that laws be enacted with the aim of protecting them. The thresholds for intervention remain almost unattainably high. For this reason, and as set out in Chapter 7, it is suggested that the question of medical treatment of children using CAM be removed from the purview of the Irish courts, through the introduction of legislation seeking to ensure use in the paediatric population of CAM therapies which can show high quality scientific evidence of safety and efficacy for each medical condition claimed, delivered by professionals trained to a standard established by law and subject to oversight.

Where the legislature has failed to legislate to limit access to CAM, Irish courts are unlikely to see fit to intervene, as was made clear by McCracken J in *NWHB*, where he rejected the plaintiff’s claim, in part, on the basis that;

... the State has not chosen to use its laws to protect Paul in the manner envisaged by Article 40.3.2. The State, through the plaintiff as an organ or body set up by the State, appears to be asking the court to undertake the obligation imposed by the Article. If the State believes that it has an obligation to make it unlawful for parents to refuse to allow their children to undergo tests such as this, the State, through the Oireachtas, could so provide in legislation. That legislation could then be tested in the courts for its constitutionality.<sup>134</sup>

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<sup>132</sup> Unsecured children in the back of a car or smoking in the presence of children were both considered reasonable a number of years ago. They are now both considered unacceptable and the former constitutes an offence under the European Communities (Compulsory use of Safety Belts and Child Restraint Systems in Motor Vehicles) Regulations 2006, SI 2006/240, part 2.

<sup>133</sup> F Godlee and others, ‘Wakefield’s article linking MMR vaccine and autism was fraudulent’ (2011) 342 *British Medical Journal*, Editorial, “Meanwhile the damage to public health continues, fuelled by unbalanced media reporting and an ineffective response from government, researchers, journals, and the medical profession. Although vaccination rates in the United Kingdom have recovered slightly from their 80% low in 2003-4, they are still below the 95% level recommended by the World Health Organization to ensure herd immunity. In 2008, for the first time in 14 years, measles was declared endemic in England and Wales. Hundreds of thousands of children in the UK are currently unprotected as a result of the scare, and the battle to restore parents’ trust in the vaccine is ongoing”.

<sup>134</sup> *North Western Health Board v HW & CW* (n 12) 635.

Intervention in the best interests of the child, while difficult to attain, is possible in principle where there is knowledge of the treatment or risk on the part of a person or persons who can gauge the risk to the child and act accordingly. Where the child is removed from the conventional system and treated in private, and is not in a position to disclose, whether because they lack the capacity or opportunity to do so, the risk to the child is increased. Although legislative measures have been put in place to protect children in a wide range of situations carrying elevated personal risk, it has become clear that these do not sufficiently protect children treated outside the conventional health sphere.



## PART III

### POTENTIAL LEGISLATIVE PROTECTIONS FOR CHILDREN TREATED WITH CAM

#### 3. FOCUSING PROTECTIONS

The decrease in judicial activism since its nadir in the 1960s has seen a corresponding increase in jurisprudence deferring to the constitutional role of the legislature as law-makers. This approach required a proactive stance by the legislature to fill the consequent gap and this process was given support, in respect of the rights of the child, by the ratification of the UNCRC by Ireland in 1992. Of relevance to CAM are:

- (a) Provisions which aim to ensure standardisation of education, training, conduct and competence for health and social professionals;<sup>135</sup> and
- (b) Provisions which require compliance with child protection protocols, including disclosure or discovery of criminal history which may present a risk to a vulnerable party,<sup>136</sup>

both of which may enhance the informed consent by proxy provided by parents. In addition, and of fundamental importance to child protection and welfare in healthcare, it is necessary to consider

- (c) Provisions which aim to ensure that the right of the child to be heard be vindicated.<sup>137</sup>

Children undergoing any form of medical treatment are often rendered more vulnerable than they normally would be, either through their illness, the environment in which treatment is delivered or how it is delivered. Depending on the therapy, this may require physical contact, involve physical pain or discomfort arising from treatment or the removal of items of the child's clothing, leaving both the child and the healthcare provider in a sub-optimal position. There is no clear reason why reporting provisions, among others falling under section (c), should not also apply to CAM practitioners.

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<sup>135</sup> Health and Social Care Professionals Act 2005.

<sup>136</sup> National Vetting Bureau (Children and Vulnerable Persons) Act 2012.

<sup>137</sup> Child Care Act 1991; Protection for Persons Reporting Child Abuse Act 1998; Criminal Justice (Withholding Information on Offences against Children and Vulnerable Persons) 2012; Children First Act 2015.

### 3.1 RELEVANT LEGISLATION

There is now a suite of legislation which is of particular importance in determining the extent of protection afforded to children (and adults) treated with CAM and which provides some insight into the potential for future regulation. These are the Health and Social Care Professional Act 2005, as amended by the Health and Social Care Professionals (Amendment) Act 2012, the National Vetting Bureau (Children and Vulnerable Persons) Act 2012, the Criminal Justice (Withholding Information on Offences against Children and Vulnerable Persons) 2012 and the Children First Act 2015. Together these place on a statutory footing a number of child safeguarding mechanisms which were, in the past, undertaken on a voluntary basis, such as reporting, vetting and publishing child safeguarding statements. These statutory puzzle pieces do not yet sit together harmoniously, with some anomalies and lacunae visible even prior to their passing. Each is discussed in turn below.

#### 3.1.1 THE HEALTH AND SOCIAL CARE PROFESSIONALS ACT 2005

The first and most important piece of legislation for future regulation of the CAM sector in this instance is the Health and Social Care Professionals Act 2005, which, according to its Preamble, was introduced to provide for the establishment of the Health and Social Care Professionals Council and Registration Boards for professions designated in the Act. This body was established in 2007 under the name CORU,<sup>138</sup> “To protect the public by promoting high standards of professional conduct and professional education, training and competence among registrants of the designated professions”.<sup>139</sup>

In its *Statement of Strategy 2010 – 2012*, CORU sets out its aims as:

- Establishing standards in education and codes of conduct, performance and ethics;
- Ensuring that all registrants are “Fit and Proper” as described in the Act;
- Allowing further Health and Social Care professions to be added on approval by the Minister for Health and Children; and
- Enforcing powers through fitness to practise processes.<sup>140</sup>

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<sup>138</sup> Health and Social Care Professionals Council (CORU), *Statement of Strategy 2010 – 2012* (Dublin 2010). <[www.coru.ie/uploads/188163%20A4%20Statement%20of%20Strategy-web.pdf](http://www.coru.ie/uploads/188163%20A4%20Statement%20of%20Strategy-web.pdf)> accessed 19 November 2015.

<sup>139</sup> Health and Social Care Professionals Act 2005, s 7.

<sup>140</sup> Health and Social Care Professionals Council (CORU) (n 138) 8.

The list of professions designated in s 4(1) of the 2005 Act, as amended<sup>141</sup> may be supplemented by regulation, where

- (a) the fitness of the members to practise their profession is not regulated by or under another Act of the Oireachtas,
- (b) the Minister has given interested persons, organisations and other bodies an opportunity to make representations to him or her concerning the proposed designation,
- (c) the Minister considers that it is appropriate and in the public interest that the profession be designated under this Act, and
- (d) the steps in subsection (8) have been taken.<sup>142</sup>

In theory, s 4(2) avails individual CAM specialisations to make representations to the Minister for Health and Children for their inclusion in the list of designated professions. This would benefit the practitioners, as noted on CORU's website, by creating a legally protected title to be used only by registered individuals, by increasing public confidence in the profession, by providing a support network with a unified code of professional conduct and ethics, and by protecting the reputation of the profession, establishing a formal disciplinary procedure for those professionals failing to meet the standards expected of them. This would also, in fact, address some of the most prominent consumer issues arising from CAM practice in Ireland, by providing a public register of professionals for consumers to check, ensuring that the education and qualifications awarded by educational institutions meet established minimum standards and providing the grievance mechanism that, as noted previously, is often opaque or entirely absent. Registration, should it be made available to CAM practitioners, also requires *inter alia* Garda vetting under the National Vetting Bureau (Children and Vulnerable Persons) Act 2012, Police Clearance from all countries of residence for over one year since the applicant turned 18 and a statutory declaration<sup>143</sup> of agreement with the other requirements for registration. While there has in the past been some vague espousal of the potential benefits of, for example, acupuncture and reflexology<sup>144</sup> in the course of

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<sup>141</sup> Health and Social Care Professionals Act 2005, s 4(1), as amended by Health (Amendment) Act 2014, s 6.

<sup>142</sup> *ibid* s 4(2). Section 8 sets out that "Regulations may be made under this section only if - (a) a draft of the proposed regulation has been laid before the Houses of the Oireachtas, and (b) a resolution approving the draft has been passed by each House".

<sup>143</sup> *ibid* s 37(3)(c). See also Health and Social Care Professionals Council (CORU), *Statutory Declaration* <[http://coru.ie/uploads/documents/RevisedStatutory\\_Declaration.pdf](http://coru.ie/uploads/documents/RevisedStatutory_Declaration.pdf)> accessed 18 November 2015.

<sup>144</sup> Seanad Deb 11 December 2012, Health and Social Care Professionals (Amendment) Bill 2012, Second Stage. Senator Marie Moloney asked then Minister for Health Dr James Reilly "Has the Minister proposals to regulate acupuncturists and reflexologists who also operate freely?", to which he replied, "Acupuncture is a safe alternative, particularly in older people, but we do not have any university here that has a prescribed course, therefore, one is at the mercy of the person delivering the service. It is an area I would like examined. I would like to see some of the colleges provide a course on which we could rely to produce suitably qualified

parliamentary debate, there has been little by way of action taken on this basis. At this time, CORU has received no notification from the Minister for Health and Children under s 3(2) of the 2005 Act for the registration of any CAM group,<sup>145</sup> though the Osteopathic Council of Ireland<sup>146</sup> and the Chiropractic Association of Ireland<sup>147</sup> both cite ongoing efforts to obtain designated status under the Act.

The Health and Social Care Professionals (Amendment) Act 2012 clarified and extended the provisions of the 2005 Act, particularly in relation to the recognition of qualifications for the designated professions from other EU Member States.<sup>148</sup>

### **3.1.2 NATIONAL VETTING BUREAU (CHILDREN AND VULNERABLE PERSONS) ACT 2012**

Among the consumer and child protection benefits of CORU registration for CAM professionals is mandatory Garda vetting for each Registrant. Garda vetting is provided for by the National Vetting Bureau (Children and Vulnerable People) Act 2012 (hereafter “the Vetting Bureau Act”), which established the National Vetting Bureau (Children and Vulnerable Persons) Database System.<sup>149</sup> This database is composed of the register of relevant organisations, the register of specified information and the register of vetted persons, under s 6(1) and (2).

The Vetting Bureau Act provides for the protection of children and vulnerable people and introduces procedures that are to apply in respect of persons who wish to undertake certain work or activities relating to children or vulnerable persons or to provide certain services to children or vulnerable persons.<sup>150</sup> The Act makes vetting mandatory, whereas it was previously undertaken on a voluntary basis by relevant organisations.<sup>151</sup>

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individuals to provide these services. The same applies to reflexology, not to the same extent, but it can certainly have a role in respect of relaxation”.

<sup>145</sup> See Appendix VI, Correspondence from CORU Re Upcoming Designations.

<sup>146</sup> Osteopathic Council of Ireland, ‘Regulation and Governance’, “The OCI is in the process of applying for full Irish State regulation under the Health and Social Care Professionals Act (2005), and we are working towards achieving full state regulation by 2014” <[www.osteopathy.ie/node/7](http://www.osteopathy.ie/node/7)> accessed 18 November 2015.

<sup>147</sup> Chiropractic Association of Ireland, ‘Joining the CAI’, “The CAI is active in campaigning for chiropractors in Ireland to be regulated under the Health and Social Care Professionals Act 2005” <[www.chiropractic.ie/cai-membership/info/joining-the-cai](http://www.chiropractic.ie/cai-membership/info/joining-the-cai)> accessed 18 November 2015.

<sup>148</sup> Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22.

<sup>149</sup> National Vetting Bureau (Children and Vulnerable Persons) Act 2012, s 6.

<sup>150</sup> *ibid* Preamble.

<sup>151</sup> National Vetting Bureau (Children and Vulnerable Persons) Bill 2012, Explanatory Memorandum: Purpose of the Bill, “The purpose of this Bill is to provide a legislative basis for the vetting of persons who seek positions of employment relating to children or vulnerable persons. Currently persons applying for such positions are vetted on a non-statutory basis. This Bill will make this vetting mandatory”.

The Vetting Bureau Act addresses organisations employing,<sup>152</sup> contracting for services with,<sup>153</sup> authorising,<sup>154</sup> placing for work experience,<sup>155</sup> offering for employment,<sup>156</sup> regulating<sup>157</sup> or representing<sup>158</sup> persons performing “relevant work activities” relating to children<sup>159</sup> or vulnerable persons.<sup>160</sup>

It does not provide a mechanism for individual vetting applications. Many practitioners are sole traders and do not affiliate with a regulatory or representative body and so have no mechanism through which to obtain vetting by the National Vetting Bureau. It is, of course, the case that Garda vetting does not prevent untoward or harmful behaviour by a therapist, but it may provide a level of assistance and safeguarding for parents choosing an appropriate therapist for their child.

In addition, the Act exempts “private arrangements”, a decidedly grey and mysterious term lurking in s 2, which is defined as

...an arrangement made by an individual for the provision by any person of relevant work or activities -

- (a) for, or for the benefit of, the individual, or
- (b) for, or for the benefit of, a child or vulnerable person who is a member of the individual’s family.<sup>161</sup>

This term is one which applies to a large but undetermined number of CAM practitioners around the country. Both the inability of individual practitioners to apply for vetting and the exemption of those making or partaking in “private arrangements” leave a huge gap through which practitioners may easily avoid vetting, depriving consumers of yet another line of defence against practitioners with a history of relevant offences. The difficulties of this provision did not go unnoticed during parliamentary discussions on the Bill.<sup>162</sup>

Introduced by Minister Kathleen Lynch, the “private arrangement” exclusion was found to be both a contradictory provision and one which, while administratively expedient,

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<sup>152</sup> National Vetting Bureau (Children and Vulnerable Persons) Act 2012, s 2, “relevant organisation” (a)(i).

<sup>153</sup> *ibid* s 2, “relevant organisation” (a)(ii).

<sup>154</sup> *ibid* s 2, “relevant organisation” (a)(iii).

<sup>155</sup> *ibid* s 2, “relevant organisation” (a)(iv).

<sup>156</sup> *ibid* s 2, “relevant organisation” (b).

<sup>157</sup> *ibid* s 2, “relevant organisation” (c).

<sup>158</sup> *ibid* s 2, “relevant organisation” (d).

<sup>159</sup> *ibid* sch 1, Part 1.

<sup>160</sup> *ibid* sch 1, Part 2.

<sup>161</sup> *ibid* s 2, “private arrangement”.

<sup>162</sup> Seanad Deb 27 November 2012, National Vetting Bureau (Children and Vulnerable Persons) Bill 2012: Second Stage.

was anomalous to the general aim of protecting children. This, it was stated, would apply to private babysitting, private tuition and other similarly private arrangements.<sup>163</sup> Later in the same speech, the Minister noted that the exemption for those doing occasional *ad hoc* voluntary work, for example, at a school sports day, was, in part, because they typically do so within public view. There is no justification on this ground for private arrangements, as the child may well be alone with the childminder, tutor or, in this case, CAM practitioner, on a regular and a prolonged basis. Minister Lynch emphasised the importance of ensuring that employers can make informed decisions when employing individuals to work with children or vulnerable persons, but does not appear to relate this urgency to parents, who are significantly less well-resourced than commercial employers. Senator Averil Power pointed out one of the insufficiencies in the private arrangement exclusion, noting the difference between, for example, a grandmother or an aunt caring for a child in their home and a nanny or an *au pair* performing the same role as part of a commercial arrangement. The latter, she says, should be regulated and vetted, as they are performing a service in an unsupervised setting with children in the home.

There is also an apparent contradiction in the exemption provisions within the Act itself. Whereas the “private arrangement” provision in s 2 excludes work done in a private capacity by a service provider hired by a person for the benefit of them or their family member, the explicit exclusions in s 3 include:

- (a) any relevant work or activities undertaken in the course of a family relationship;
- (b) any relevant work or activities undertaken—
  - (i) in the course of a personal relationship, and
  - (ii) for no commercial consideration;
- (c) the giving of assistance by an individual—
  - (i) on an occasional basis, and
  - (ii) for no commercial consideration,

at a school, sports or community event or activity, other than where such assistance includes the coaching, mentoring, counselling, teaching or training of children or vulnerable persons.

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<sup>163</sup> *ibid*, Minister Kathleen Lynch.

The focus of the exclusions here is clearly on non-commercial relationships, where the people involved are known to the child or will have strictly limited contact, a significantly more restrictive category than the one foreseen by the “private arrangement” exclusion. In short, whereas a commercial arrangement under s 3 is not excluded from the requirement to obtain vetting, the s 2 provision broadens the exclusion to anyone providing a service to children in a private capacity. This seriously undermines the protections afforded by the limited s 3 exclusions<sup>164</sup> and the benefits of the Act itself. Senator Power noted that:

It is important ... not to create a system where those who pose a risk to children opt to work in the least regulated part of the sector and can get employment in private homes instead of with child care providers.<sup>165</sup>

This is as relevant to CAM practitioners, who need have no qualifications and may offer a service with unproven safety and efficacy. Arguments made against review of the “private arrangement” exemption for service providers have centred primarily on administrative complexity<sup>166</sup> and on the reluctance to stray into the sacred realm of family decision-making,<sup>167</sup> particularly in respect of inappropriate criminalisation of family members for hiring an unvetted individual.<sup>168</sup> This is a valid concern and the importance of finding a balance in the proposed legislation between aspirational child protection and avoiding trespass on the constitutional rights of both the family and the individual providing a service as part of a “private arrangement” was noted throughout the legislative process. However, the balance does not appear to have been struck in this case. Suggestions for amendments to the Bill ranged from limiting the “private arrangements” exemption to those not acting in their professional capacity<sup>169</sup> to requiring those working in an individual capacity to register with a childcare body (in the case of the specific situation in question – this would also apply to CAM professional bodies) so as to seek vetting through them. Another possible solution, not mentioned at the time of the legislative process, may be to shift the onus of acquiring vetting in private arrangements involving relevant work in a professional capacity, to the service provider. This could be funded by a nominal fee payable by the individual, who has chosen not

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<sup>164</sup> *ibid.* Senator Professor Ivana Bacik notes that such private arrangements may extend over a long period and may involve work with numerous different children or vulnerable people at various locations.

<sup>165</sup> Seanad Deb 12 December 2012, National Vetting Bureau (Children and Vulnerable Persons) Bill 2012: Committee Stage.

<sup>166</sup> *ibid.*

<sup>167</sup> *ibid.*, Minister Alan Shatter TD, “...we live in an imperfect world and cannot legislate for everything ... where families make a private arrangement with an individual - not through an agency - they are entitled to some family autonomy”.

<sup>168</sup> *ibid.*

<sup>169</sup> *ibid.*, Senator Trevor Ó’Clochartaigh.

to register with a professional body or to work as part of a corporate body, through both of which they could alternatively have obtained vetting free of charge.<sup>170</sup> However, the Bill was passed without these amendments and the lacunae remain in the Act to date.

Administrative difficulties were also considered the primary bases upon which individuals were and are prevented from obtaining vetting for themselves. While administrative and fiscal constraints are, of course, a concern, and certainly were in the more straitened climate of 2012 when the Act was introduced, administrative difficulties as a catch-all excuse for inaction, particularly where there is a well-delineated, notified and significant deficiency in a piece of legislation, cannot be hidden behind indefinitely. This is a matter of prioritisation of funding. In light of the passing of the Thirty First Amendment of the Constitution in the same year that the National Vetting Bureau Act came into force, one might hope that, even symbolically, the reticence towards extending the reach of the vetting requirements in the best interests of the child might be diminished.

Despite the criteria mandating vetting, which ought to apply to CAM practitioners as members of professional bodies or those working as part of a company and dealing with children (most practitioners, if practitioner websites and professional representative bodies are to be believed), there is no mention of vetting by any of the representative bodies reviewed.<sup>171</sup>

Of significant relevance is the Children First Act 2015, a statutory implementation of the *Children First: National Guidance for the Protection and Welfare of Children*<sup>172</sup> which has, among others, the purpose of making further and better provision for the care and protection of children.<sup>173</sup> The Act came into being in the wake of the *Report of The Commission to Inquire into Child Abuse*<sup>174</sup> (hereafter “the Ryan Report”), which urged the placement of the Children First guidelines on a statutory footing.<sup>175</sup>

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<sup>170</sup> Chapter 7 provides a model for statutory registration of all CAM practitioners, with Garda vetting as a condition of registration.

<sup>171</sup> Site searches were undertaken for the terms “Criminal”, “Vetting”, “Garda”, “Declaration”, and “Declare” on five of the most prominent CAM professional bodies (Acupuncture Council of Ireland, Reiki Federation of Ireland, Chiropractic Association of Ireland, Irish Society of Homeopaths, and the Osteopathic Council of Ireland). The Irish Society of Homeopaths requires a declaration that a prospective member has “no criminal record in any State”. It does not specify a particular system or standard of declaration and may merely require a statement provided by the prospective member themselves. The Osteopathic Council of Ireland states that a member must not have a criminal record, requires details from the applicant and requests consent to a criminal record check. These terms were not found on other sites, though this does not conclusively exclude the possibility that vetting mechanisms are in place – these would ideally be more transparent and accessible by the public.

<sup>172</sup> Department of Health and Children, *Children First: National Guidance for the Protection and Welfare of Children* (Stationery Office 2011).

<sup>173</sup> Children First Act 2015, Preamble.

<sup>174</sup> *Report of the Commission to Inquire into Child Abuse* (“The Ryan Report”) (Office of Children and Youth Affairs 2009).

<sup>175</sup> *ibid* 464.



### 3.1.3 THE CHILDREN FIRST ACT 2015

The Children First Act 2015 (hereafter “the 2015 Act”), passed but not fully enacted at the time of writing,<sup>176</sup> places significant practical obligations on relevant service providers<sup>177</sup> to put in place structures facilitating mandatory reporting, by specified persons, of child protection concerns to the Child and Family Agency (hereafter “the Agency”),<sup>178</sup> requiring the mandated persons to assist the Agency in respect of children the subject of such a report, and to produce, and make available for inspection, a child safeguarding statement. These obligations are practical in nature and require positive action and resources in establishing in-house or individual reporting mechanisms, composing appropriate statements, understanding and communicating the status and duties of all relevant persons and updating all relevant documents as required by the Act. In contrast with the National Vetting Bureau Act, which requires that providers of relevant services (subject to exclusions) obtain Garda vetting, this is a heavy burden for organisations and individuals to bear and one of which they may not be aware.

Schedule 1 of the 2015 Act sets out the relevant services, the most relevant of which for the purpose of this thesis are:

1. Any work or activity which is carried out by a person, a necessary and regular part of which consists mainly of the person having access to, or contact with, children in –
  - (c) any hospital, hospice, health care centre or other centre which receives, treats or otherwise provides physical or mental health services to children ...
- and
3. Any work or activity which consists of treatment, therapy or counselling provided to a child.

CAM practitioners who work with children may fall into either or both of these categories. Interestingly, s 9 of the Act sets out exclusions, which include any individual who

- (a) undertakes any work or activity in the course of a family relationship where the work or activity concerned is undertaken by the individual solely for the benefit of a child or other family member of that individual,

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<sup>176</sup> Children First Act 2015, signed by both Houses on 11 November 2015.

<sup>177</sup> *ibid* sch 1.

<sup>178</sup> This is without prejudice to the reporting obligations established under the Criminal Justice (Withholding Information on Offences against Children and Vulnerable Persons) 2012.

- (b) undertakes any work or activity in the course of a personal relationship for no commercial consideration, or
- (c) gives assistance on an occasional basis for no consideration at a school, sports or community event or activity.

However, it does not provide a further exclusion for “private arrangements”, nor does such a provision appear elsewhere in the 2015 Act.

There is a clear bias in the Act in favour of excluding only unpaid work or work undertaken in the course of a personal or family relationship,<sup>179</sup> as well as occasional voluntary assistance as discussed in relation to other Acts. This implies that those individuals exempted from the vetting requirement under the National Vetting Bureau Act, are nonetheless obligated to fulfil the requirements of the 2015 Act. To some extent, this weakens the “administrative burden” excuse proffered for maintaining the “private arrangements” exclusion in the 2012 Act. Those organisations and individuals required to comply with the 2015 Act will endure a significant additional administrative burden in the name of better child protection. The State should see fit to allocate the appropriate funds so as to fulfil its responsibility.

Surprisingly, for a popular commercial sector dealing frequently and closely with children, the protection offered by modern legislative provisions for children treated with CAM is questionable. There are no CAM practitioners designated under the Health and Social Care Professionals Act 2005, as amended, and many may find themselves unable to apply for vetting under the National Vetting Bureau (Children and Vulnerable Persons) Act 2012, or with no impetus to. The Children First Act 2015 should place numerous new obligations on providers of CAM to safeguard children, though it is conceded that other legislative provisions which ought to have affected the CAM sector in the past seem to have left the sector untouched.<sup>180</sup>

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<sup>179</sup> As defined in the National Vetting Bureau (Children and Vulnerable Persons) Act 2012, s 3(2).

<sup>180</sup> Consumer Protection Act 2007, ss 41-43.

## CONCLUSION

*Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children.*<sup>181</sup>

Much of this thesis focusses on the legal implications of permitting the free availability of CAM therapies. However, issues arising from the failure of legislators to officially acknowledge these therapies, products and practitioners extend beyond consumer rights and even beyond ethical obligations.

The way in which we regulate or fail to regulate CAM has implications for the strength of the protections we afford to children. It has the potential to give rise to constitutional issues for children and their families, finding the solution for which would require an understanding of the CAM system, which the legislature and the judiciary do not currently appear to possess. Determining whether an otherwise caring and conscientious parent is neglecting a child by failing to provide conventional medical treatment, while instead providing a CAM therapy, whether such a child within the marital family is in a worse or a better position in relation to judicial intervention and constitutional rights vindication than a child in a non-marital family, whether practitioners of a mode of therapy which is, at best, of unproven safety and efficacy, should be designated as a profession in order to facilitate comprehensive regulation of qualifications, minimum standards of practice, appropriate, standardised and transparent grievance procedures and exclusive right to title and practice, and whether CAM should be available to children at all, given their inherent vulnerability and the unproven nature of the therapies in question, are not easy tasks. So little has been achieved, academically and legally, in the area of CAM in Ireland, that attempting to surmise a potential response on the part of the courts to the nuances of their use in children is little more than blind speculation. Addressing CAM use in children necessitates its acknowledgement overall and it is regrettable that consumers and, vitally, parents, have reached this point long before those with the power to appropriately control its use.

Azmat and Razum<sup>182</sup> define medical pluralism, as “the adoption of more than one medical system or the use or integration of both conventional biomedicine and complementary and alternative medicine for health and illness”.<sup>183</sup> As medical pluralism becomes *de rigueur* in Ireland, albeit unofficially, the constitutional protection of family autonomy may potentially be taken to address, not only the making of healthcare decisions for the child in the conventional paradigm, but its expansion to encompass other potential therapies. In other words, with few legislative exceptions, the parent is free to choose inefficacious and potentially unsafe therapies to treat their child. Children in Ireland

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<sup>181</sup> *Prince v Massachusetts* (1944) 321 US 158 [21] (Rutledge J).

<sup>182</sup> Jimoh Amzat and Oliver Razum, *Medical Sociology in Africa* (Springer International Publishing 2014).

<sup>183</sup> *ibid* 207.

are presumed to have their best interests protected through the decisions of their parents. Where the decision-making capacity of parents is compromised, either by virtue of inadequate information, cognitive dissonance,<sup>184</sup> or emotional duress caused by desperation or guilt in respect of the illness of their child, external factors, in the form of legislative provisions or, in exceptional cases, intervention may provide protection. To date, any examination or consideration of this has been insufficient, unjustifiably leaving children at risk.

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<sup>184</sup> Barry Beyerstein, 'Alternative medicine and common errors of reasoning' (2001) 76 *Academic Medicine* 230, 231.

## CHAPTER 5

### OPTIMISING THE PROTECTION OF CONSUMERS BY RECONSIDERING THE FREEDOM AND RESTRICTION OF EXPRESSION IN MATTERS OF HEALTH

#### INTRODUCTION

Evelyn Beatrice Hall's quote "I disapprove of what you say, but I will defend to the death your right to say it"<sup>1</sup> is laudable in its evocative espousal of the liberal values which would later come to be recognised as universal freedoms.<sup>2</sup> However, even the most liberal in society must acknowledge the need for balance. Though "[t]he freedom of speech is guaranteed in virtually every international human rights instrument and in the constitution of every liberal democracy, and the protection of this vital freedom is generally regarded as necessary in order for democracy to flourish",<sup>3</sup> and such freedom is, in fact, crucial for advancement of the knowledge and understanding<sup>4</sup> which will continue to enhance human longevity and quality of life, where public health is adversely affected, consideration must be given to the placement of proportionate limitations on free expression, in an attempt to ensure that an optimal balance is struck and the legitimate aim of protecting public health<sup>5</sup> is vindicated.

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<sup>1</sup> Evelyn B Hall, *The Friends of Voltaire* (Smith Elder & co. 1906) 199. This quote is often misattributed to Voltaire.

<sup>2</sup> Though the sentiment was not novel. See John Milton, *Areopagitica: A Speech of Mr. John Milton for the Liberty of Unlicenc'd Printing to the Parliament of England* (Neil Douglas 1644) 35, where Milton stated, "Give me the liberty to know, to utter, and to argue freely according to conscience, above all liberties".

<sup>3</sup> Ivana Bacik, 'Free speech, the common good, and the rights debate' (2003) *The Republic* 64, 65. This was recognised much earlier in the case of *Bonnard v Perryman* [1891] 2 Ch 269. Lord Coleridge CJ stated that "The right of free speech is one which is for the public interest that individuals should possess, and, indeed, that they should exercise without impediment, so long as no wrongful act is done". For a concise summary of the centrality of freedom of expression in the vindication of other fundamental rights, see Council of Europe 'EU Human Rights Guidelines on Freedom of Expression Online and Offline' (Foreign Affairs Council Meeting, Brussels, 12 May 2014) 1-2. See also the description of freedom of expression set out by the German Constitutional Court in *Luth* (1958) 7 BVerfGE 198, that "The basic right to freedom of opinion is the most immediate expression of the human personality in society and, as such, is one of the noblest of human rights. ... It is absolutely basic to a liberal-democratic order because it alone makes possible the constant intellectual exchange and the contest among opinions that form the lifeblood of such an order; it is the matrix, the indispensable condition of nearly every other form of freedom".

<sup>4</sup> John Skoyles, 'The logic of scientific debate: Epistemological quality control practices and Bayesian inference – a neoPopperian perspective' (2008) 1, "Scientists, I argue, abide by "epistemological quality control practices" that limit the persuasive power of unsound arguments upon theory evaluation. Examples of such debate quality control practices are publicness, clarity, openness to criticism, and the collective promotion of attempts at theory conjecture and refutation"

<[http://philsci-archive.pitt.edu/4230/1/Logic\\_of\\_scientific\\_debate.pdf](http://philsci-archive.pitt.edu/4230/1/Logic_of_scientific_debate.pdf)> accessed 10 June 2016.

<sup>5</sup> Elizabeth Martin, *Concise Medical Dictionary* (OUP Oxford 2015). For the purpose of this chapter, public health is "concerned with preventing disease and improving health in populations as distinct from individuals". The definition used by the Health Service Executive, currently, was set out in Donald Acheson, *Public Health in England* (Stationery Office 1988) as "the science and art of preventing disease, prolonging life, and promoting health through the organised efforts of society".

Freedom of expression is guaranteed,<sup>6</sup> under Art 40.6.1°(i) of the Constitution,<sup>7</sup> which states:

The State guarantees liberty for the exercise of the following rights, subject to public order and morality: - The right of citizens to express freely their convictions and opinions. The education of public opinion being, however, a matter of such grave import to the common good, the State shall endeavour to ensure that organs of public opinion, such as the radio, the press, the cinema, while preserving their rightful liberty of expression, including criticism of Government policy, shall not be used to undermine public order or morality or the authority of the State. The publication or utterance of blasphemous, seditious, or indecent matter is an offence which shall be punishable in accordance with law.

This provision has been the subject of criticism, both due to the lack of definitive obligation placed upon the State by virtue of the words “the State shall endeavour to ensure that...”, and the vagueness of its qualifying language in limiting freedom of expression for the purposes of maintaining “public order and morality”. The Constitutional Review Group, in its report in 1996,<sup>8</sup> recommended that “the Oireachtas should have the right to qualify by law the right of free expression for adequate reasons of public interest” and that “the revision of Article 40.6.1°i should follow the model of Article 10(1) of the European Convention on Human Rights”.<sup>9</sup> Art 10 states as follows:

- (1) Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.
- (2) The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.<sup>10</sup>

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<sup>6</sup> The guarantee is subject to restriction as set out in Art 40.6.1°(ii), which is narrowed further by reference to the exceptions set out in Art 10(2) ECHR.

<sup>7</sup> The Irish Constitution, Art 40.6.1°(i). Irish courts have recognised, not only the right of freedom of expression, but also the unenumerated personal right to communicate, protected by Art 40.3.1°.

<sup>8</sup> Constitutional Review Group, *Report of the Constitutional Review Group* (Stationery Office 1996).

<sup>9</sup> *ibid.* Ireland was a signatory to the Convention in 1950 but it was given effect in Irish domestic law by the European Convention on Human Rights Act 2003.

<sup>10</sup> The European Charter of Fundamental Rights, Art 11(1), couches the freedom of expression in broad terms, stating “Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers”. Finally, the freedom of expression is also guaranteed by Article 19 of the International Covenant on Civil and Political Rights, which entered into force in Ireland in 1990. Article 19(1) and (2) state:

1. Everyone shall have the right to hold opinions without interference.
2. Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.

The superiority of the precise and specific wording of Art 10(2) over and above the language of Art 40.6.1° (i) has received tacit acknowledgement by its preferential use in Irish case law.<sup>11</sup> Art 10(2) sets out the exceptions to the guarantee of freedom of expression in Art 10(1), which, most pertinently, include those of protecting reputation, protecting the rights of others and protecting public health.

The right to a good name, the right to freedom of expression, the right to earn a livelihood and the protection of public health find several points of intersection where CAM is concerned. By protecting freedom of expression, the right to earn a livelihood through advertising and endorsement is also vindicated but public health may be put at risk. By protecting the right to a good name, freedom of expression may be chilled and, again, public health may be put at risk. To adequately protect public health, it seems, may involve the placement of limitations on the rights of CAM providers and proponents, which is both a distasteful prospect and one which involves a difficult and unenviable balancing act on the part of legislators and, likely, courts.

This thesis has focussed primarily, though not exclusively, on the physical, psychological and financial risks to consumers resulting from the inaction of regulators in enforcing existing consumer protection measures prohibiting misleading claims. However, this chapter aims to analyse the wider implications of freedom and restriction of expression in matters of public health, in both the commercial and non-commercial spheres. Both commercial expression and commentary or public interest expression can be limited in the interest of protecting public health, but the margin for restricting the latter is substantially narrower, creating significant scope for harm, such as arose from the Wakefield paper, which incorrectly associated the MMR vaccine with the development of autism spectrum disorder,<sup>12</sup> precipitating a sustained and disastrous public rejection of vaccination,<sup>13</sup> or the false equivalence created between proven and unproven therapies and, indeed, the unquestioning, emotive rhetoric unjustifiably used by print and broadcast media in disseminating information on unproven or dangerous ‘miracle’ therapies, particularly those claiming to treat or cure life-threatening or chronic illness.<sup>14</sup> The silencing of criticism through the use of oppressive defamation proceedings by purveyors or proponents of CAM serves only to magnify the problem, leaving the

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<sup>11</sup> *Foley v Sunday Newspapers Ltd* [2005] 1 IR 88 (HC).

<sup>12</sup> Andrew J Wakefield and others, ‘RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children’ (1998) 351 *Lancet* 637.

<sup>13</sup> JF Murphy, ‘Fallout of the enterocolitis, autism, MMR vaccine paper’ (2011) 104 *Irish Medical Journal* 36; Gregory A Poland, ‘MMR vaccine and autism: Vaccine nihilism and postmodern science’ (2008) 86(9) *Mayo Clinic Proceedings* 869.

<sup>14</sup> See, for example, Kathryn Hayes, ‘US treatment hope for little Alexandra’ *Irish Independent* (14 July 2012) <[www.independent.ie/irish-news/us-treatment-hope-for-little-alexandra-26875649.html](http://www.independent.ie/irish-news/us-treatment-hope-for-little-alexandra-26875649.html)> accessed 20 June 2016; Sylvia Thompson, ‘Fighting cancer the vegan way’ *The Irish Times* (17 June 2002), where, despite the sub-heading stating that oncologists remain sceptical that the therapy in question (Gerson therapy) is effective for cancer, only 64 out of 1,011 words in the article address this fact. The remaining 947 words discuss Gerson therapy, its origins, why the subject of the article decided to forego conventional therapy to opt for Gerson therapy instead, how she feels, what are her future plans and where to read about and access Gerson therapy, should the reader be so inclined <[www.irishtimes.com/news/health/fighting-cancer-the-vegan-way-1.1060891](http://www.irishtimes.com/news/health/fighting-cancer-the-vegan-way-1.1060891)> accessed 16 September 2016.

public to receive virtually unfettered positive content on CAM, with only a relatively restrained and tentative rejoinder from those preaching caution and warning of a lack of supporting evidence. In an effort to balance debate at all costs, the scales have been weighted too heavily on one side, creating risk for consumers by giving the impression of a level of consensus on the benefits of CAM that simply does not exist.

Chapter 5 focuses on the endorsement of CAM, as distinct from the unregulated availability of same, and examines the theoretical and practical limitations on freedom of expression in relation to CAM, acknowledging that they are not one and the same. Having provided an overview of the status of freedom of expression in domestic and European law, Part I examines the failure of the State to sufficiently restrict freedom of expression with the legitimate objective of protecting public health. This encompasses commercial expression and non-commercial ‘public interest’ expression, taking the form of internet content such as blogs or social media posts, print media, such as books, newspapers or magazines, broadcast media, and film. Restriction of these may also interfere with the constitutional right to earn a livelihood. Commercial expression is subject to greater scrutiny than expression solely in the public interest and may be restricted in a number of circumstances, including, as is currently the case, under consumer protection law.

In addition, Part I briefly analyses the effect on the right to earn a livelihood of restricting freedom of expression. Although the effect of existing limitations is negligible, as is apparent from the veritable smorgasbord of unsubstantiated claims of efficacy for various conditions apparent in the CAM sector in Ireland, full enforcement of consumer protection provisions would significantly limit the commercial claims permissible and, in the case of some therapies, would prevent any such claims being made at all.<sup>15</sup> Whether this restriction on the right to commercial expression would unduly infringe upon the right to earn a livelihood is questionable, given the alternative of knowingly permitting the public to be misled in their consumer and healthcare decision-making.

Part II of this chapter assesses the extent to which public health is threatened by the emphasis placed upon the protection of the right to a good name over and above freedom of expression. Negative statements made by journalists, scientists and various other commentators regarding particular

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<sup>15</sup> US National Center for Complementary and Integrative Health (NCCIH), ‘Homeopathy’ (2016), “There is little evidence to support homeopathy as an effective treatment for any specific condition... Several key concepts of homeopathy are inconsistent with fundamental concepts of chemistry and physics. There are significant challenges in carrying out rigorous clinical research on homeopathic remedies”

<<https://nccih.nih.gov/health/homeopathy>> accessed 8 October 2016; Australian National Health and Medical Research Council, ‘NHMRC Statement: Statement on Homeopathy’ (2015), “There was no reliable evidence from research in humans that homeopathy was effective for treating the range of health conditions considered: no good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment”; UK National Health Service (NHS), ‘Homeopathy – Does it work?’ (2016), “There has been extensive investigation of the effectiveness of homeopathy. There is no good-quality evidence that homeopathy is effective as a treatment for any health condition”

<[www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx](http://www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx)> accessed 8 October 2016. The HSE page on CAM is under construction at the time of writing.



individuals and practices associated with CAM, have repeatedly given rise to costly and protracted defamation proceedings, or threats of such proceedings, which have, in turn, undermined freedom of expression in favour of the protection of reputation. This chilling effect, while undesirable in general, is of particular concern in the field of healthcare, where the stifling of open debate may impede progress and create risk for individual consumers and public health overall.

The chapter concludes, in Part III, that the complex balance between freedom of expression, the right to earn a livelihood, the right to one's good name and the protection of public health has failed to sufficiently protect the latter. While maintaining freedom of expression is at the core of rights vindication generally and, indeed, fundamental to the promotion of public health, unfettered, it generates and has generated unacceptable risk for consumers and has undermined legitimate public health objectives.<sup>16</sup> However, where pitted against the right to a good name, the same freedom of expression has been chilled to an unacceptable extent, particularly in the field of healthcare. It is argued that, while the staunch protection of fundamental rights must be prioritised, this must not occur in a vacuum, but with an eye to the common good, of which the protection of public and individual consumer health is a vital element.

With this said, it is apt to begin by setting out the rights at the core of this chapter.

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<sup>16</sup> For an examination of this in the context of childhood obesity, see Wendy E Parmet and Jason A Smith, 'Free speech and public health: A population-based approach to the First Amendment Symposium: Food marketing to children and the law' (2006) 39 *Loyola of Los Angeles Law Review* 363.

## PART I

### BALANCING FREEDOM OF EXPRESSION AND PROTECTION OF PUBLIC HEALTH

#### 1. RESTRICTING FUNDAMENTAL RIGHTS

As a fundamental right, any proposed restriction to be placed on freedom of expression is subject to a number of specific considerations and to the fulfilment of criteria set out in the text of the relevant provisions themselves, as expanded upon by case law.

Constitutional rights may be restricted in the common good<sup>17</sup> and where they impinge upon the constitutional rights of others.<sup>18</sup> In domestic cases addressing encroachments on freedom of expression, Irish courts have seen fit to apply two different tests in defining the limits of permissible restriction: the rationality test,<sup>19</sup> and the doctrine of proportionality.<sup>20</sup> While they are distinct, they have been applied interchangeably by Irish courts.<sup>21</sup>

The rationality test was set out in the case of *Tuohy v Courtney*,<sup>22</sup> where Finlay J stated that the role of the courts is “to determine from an objective stance whether the balance contained in the impugned legislation is so contrary to reason and fairness as to constitute an unjust attack on some individual’s constitutional rights”.<sup>23</sup>

The proportionality doctrine, which is undoubtedly more detailed than the rationality test, was described in the case of *Heaney v Ireland*,<sup>24</sup> where Costello J stated that:

The objective of the impugned provision must be of sufficient importance to warrant overriding a constitutionally protected right. It must relate to concerns pressing and substantial in a free and democratic society. They must: be rationally connected to the objective and not be arbitrary unfair or based on irrational considerations; impair the right as little as possible, and be such that their effects on rights are proportional to the objective.<sup>25</sup>

Notwithstanding the similarities between these and the criteria for limiting fundamental rights provided by Art 10(2) ECHR, it is, in fact, the textual limitations of Art 40.6.1° (i), noted above, that undermine the protection of public health vis-à-vis freedom of expression in a domestic context. As

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<sup>17</sup> *Ryan v Attorney General* [1965] IR 294 (SC), 312 (Kenny J), “None of the personal rights of the citizen are unlimited; their exercise may be regulated by the Oireachtas when the common good requires this.

<sup>18</sup> Gerard Hogan and Gerry Whyte, *J.M. Kelly: The Irish Constitution* (Tottel 2006), para 7.1.53.

<sup>19</sup> *ibid* para 7.1.54.

<sup>20</sup> *ibid* para 7.1.56.

<sup>21</sup> *ibid* para 7.1.67.

<sup>22</sup> *Tuohy v Courtney* [1994] 3 IR 1 (SC).

<sup>23</sup> *ibid* 47. This approach was affirmed in the cases of *Iarnród Éireann v Ireland* [1996] 3 IR 321 (SC), 323 and in *Re Art 26 and the Employment Equality Bill 1996* [1997] 2 IR 321 (SC), 324.

<sup>24</sup> *Heaney v Ireland* [1994] 3 IR 593 (HC).

<sup>25</sup> *ibid* 607.

that Article provides for restrictions in terms of “public order and morality”, it has been left to the courts to better define the scope. They have done this by reference to the more detailed limitations set out in Art 10 ECHR.

The Art 10 restrictions were referred to in the English case of *Venables v News Group Newspapers Ltd*,<sup>26</sup> where the court was asked to determine whether the limitations on the freedom of the defendants to publish the identities of the plaintiffs were permissible. Butler-Sloss P found that

...the court, as a public authority, was obliged in such cases to act compatibly with Convention rights in adjudicating on common law causes of action... by virtue of article 10(1) of the Convention, the freedom of the media to publish could not be restricted unless the need for such restrictions fell within the exceptions in article 10(2), which were to be construed narrowly; that the onus lay on those seeking such restrictions to show that they were in accordance with the law, necessary in a democratic society to satisfy one of the strong and pressing social needs identified in article 10(2), and proportionate to the legitimate aim pursued.<sup>27</sup>

Comparable judicial deference to the specific exceptions set out in Art 10(2) of the ECHR was also seen in the Irish case of *Foley v Sunday Newspapers Ltd*.<sup>28</sup> Here, Kelly J followed the principle established in *Venables*, finding that the freedom of the defendant newspaper to publish could not be limited unless the reason for the limitation fell within the exceptions set out in Art 10(2), which were to be interpreted narrowly.<sup>29</sup> The decision in *Foley*, according to the First Report of the Joint Committee on the Constitution on Freedom of Expression,<sup>30</sup> provides “further evidence of the ability of the judiciary to give appropriate weight to the guarantee of freedom of expression, notwithstanding the inadequacies of the wording of Article 40.6.1”.<sup>31</sup>

The requirements in Art 10(2), that restrictions be provided for by law<sup>32</sup> and that they be necessary<sup>33</sup> in a democratic society, must be considered where an existing measure is impugned or where

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<sup>26</sup> *Venables v News Group Newspapers Ltd*. [2001] Fam 430.

<sup>27</sup> *ibid* 446.

<sup>28</sup> *Foley v Sunday Newspapers Ltd* (n 11).

<sup>29</sup> *ibid* 103.

<sup>30</sup> Joint Committee on the Constitution, ‘First Report Article 40.6.1.i - Freedom of Expression’ (2008).

<sup>31</sup> *ibid* para 2.43.

<sup>32</sup> Douwe Korff, ‘The standard approach under Articles 8-11 ECHR and Article 2 ECHR’ (2008) 2, “The word “law” encompasses not only primary legislation, but also subsidiary rules and judicial case law: it covers all the domestic legal rules that allow for interferences with fundamental rights. However, the word does not merely refer back to domestic law in the sense of leaving it completely up to the domestic law-making authorities (including courts) to make up the rules as they see fit. Rather, the Court examines the “quality of the law”: legal rules that do not have the relevant quality are not “law” in terms of the Convention - not even if they serve a “legitimate aim”. Specifically, the Convention requires that any domestic law authorising (or invoked as justification for) an interference with individual rights must be “compatible with the rule of law” and in particular, accessible (that usually means, published) and sufficiently clear and precise to be “foreseeable” in its application”.

<sup>33</sup> *Hertel v Switzerland* (1998) ECHR 77 [46], “The adjective “necessary”, within the meaning of Article 10 § 2, implies the existence of a “pressing social need”.

implementation is sought of a novel provision which would restrict freedom of expression. Restrictions must also be proportionate<sup>34</sup> to the legitimate aim pursued.<sup>35</sup>

The relative weights of the rights and these imitations were considered in the case of *Douglas and others v Hello! Ltd*,<sup>36</sup> where the court considered that:

It will be necessary for the court ... to bear in mind that ... the qualifications set out in article 10(2) are as relevant as the right set out in article 10(1). This means that, for example, the reputations and rights of others – not only but not least their Convention rights – are as material as the defendant's right of free expression. So is the prohibition on the use of one party's Convention rights to injure the Convention rights of others.<sup>37</sup>

In theory, the public health exception in Art 10(2) is available as a means to restrict otherwise free expression which poses a risk to public health. In practice, however, its utilisation has been somewhat limited and it is clear from the proliferation of questionable, unsubstantiated, and dangerous claims made by CAM advertisers and commentators alike that the real-world protection for public health is minimal.

## 2. COMMERCIAL EXPRESSION VERSUS EXPRESSION IN THE PUBLIC INTEREST

CAM products and services, like any others, rely on information dissemination for their commercial viability, and increasingly, support for, and endorsement of, products or practices is being derived from public interest commentary and personal testimonials, through news media, broadcast media, blogs, books, and websites.<sup>38</sup> Freedom of expression lies at the core of these, but, as noted above, restrictions must and do exist to limit it.

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<sup>34</sup> Caroline Allen, Richard Clayton and Hugh Tomlinson, *The Law of Human Rights* (Oxford University Press 2000) 278. The principle of proportionality requires that there be a reasonable relationship between a particular objective to be achieved and the means used to achieve that objective. The principle of proportionality is described in Art 5(4) TEU.

<sup>35</sup> For the purpose of restricting freedom of expression, the legitimate aims are those set out in Art 10(2).

<sup>36</sup> *Douglas and others v Hello Ltd*. [2001] QB 967.

<sup>37</sup> *ibid* [136].

<sup>38</sup> Peter A Ubel, Christopher Jepson and Jonathan Baron, 'The inclusion of patient testimonials in decision aids: Effects on treatment choices' (2001) 21 *Medical Decision Making* 60, 65, "written patient testimonials can significantly influence hypothetical treatment choices when presented in combination with statistical summary data on treatment effectiveness" and Sue Ziebland and Sally Wyke, 'Health and illness in a connected world: How might sharing experiences on the internet affect people's health?' (2012) 90 *Milbank Quarterly* 219, 220, "The value of first-person accounts, the appeal and memorability of stories, and the need to make contact with peers all strongly suggest that reading and hearing others' accounts of their own experiences of health and illness will remain a key feature of e-health". For a discussion of the impact of personal testimony in CAM, see John Reizer, *Depression-Proofing Your Chiropractic Career* (Lulu.com 2009) 127, "There is probably no better way to convince prospects that your service is valuable than by the use of testimonials. If you are not currently utilizing this marketing tool in your office you should consider using testimonials from this day forward".

Courts have seen fit to differentiate between commercial and public interest expression. Whereas Contracting States are afforded a relatively wide margin of appreciation<sup>39</sup> in determining the limits for permissible restrictions on commercial expression (such as advertising),<sup>40</sup> public interest or ‘political’ speech attracts a much narrower margin. Commercial speech, though protected under Art 10 ECHR,<sup>41</sup> is considered “to be of less value to society than political or artistic speech, [and] it accordingly receives diminished protection from the courts”.<sup>42</sup>

## 2.1 THE INTERACTION BETWEEN FREEDOM OF EXPRESSION, THE RIGHT TO EARN A LIVELIHOOD AND THE PROTECTION OF PUBLIC HEALTH

As a preliminary issue, it is important to underline the extent of the effects arising from a restriction on the freedom of expression in respect of CAM. Any interference with or restriction on the right of CAM providers to commercial expression is *prima facie* an infringement of their right to earn a livelihood under both Art 40.3 and Art 45.2(i) of the Constitution,<sup>43</sup> as it limits their ability to advertise their product or service. However, this restriction is clearly provided for by existing consumer protection legislation,<sup>44</sup> and is justifiable by reference to the exigencies of the common good,<sup>45</sup> which may refer to the protection of consumer rights<sup>46</sup> or to the protection of public health,<sup>47</sup> so long as it is not disproportionate.<sup>48</sup>

There is no right to work in a particular field<sup>49</sup> and it is questionable whether any trader should be able to provide a service based on unsubstantiated and potentially unsafe, if well-meaning, assertions. Indeed, under Article 45.4(i), the State pledges to “safeguard with especial care the economic interests of the weaker sections of the community, and, where necessary, to

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<sup>39</sup> The margin of appreciation was first described in Application no 176/56 *Greece v United Kingdom* (‘Cyprus’) (1958) 2 Yearbook of the European Convention on Human Rights 1958-1959 178. According to Greer, Contracting States have a margin of appreciation, wherein they are afforded some “room for manoeuvre ... in fulfilling their obligations under the European Convention on Human Rights”. See Steven Greer, *The Margin of Appreciation: Interpretation and Discretion under the European Convention on Human Rights* (Council of Europe 2000) 5. See also, Richard Smith, ‘The margin of appreciation and human rights protection in the “war on terror”: Have the rules changed before the European Court of Human Rights?’ (2011) *Essex Human Rights Law Review* 124. The purpose of the margin of appreciation, according to Smith, is to “allow the European Court of Human Rights to balance State sovereignty with the need to safeguard Convention rights and an individual’s rights against the general interest”.

<sup>40</sup> *Casado Coca v Spain* (1994) 18 EHRR 1.

<sup>41</sup> *Markt-Intern Verlag GmbH and Klaus Beerman v Germany* (1989) 12 EHRR 161.

<sup>42</sup> Richard Cadell, ‘Freedom of commercial speech and the UK courts’ (2005) 64 *Cambridge Law Journal* 274. See also Application No. 7805/77 *X and Church of Scientology v Sweden* (1978) 16 DR 68, 73.

<sup>43</sup> Article 45 contains the Directive Principles of Social Policy which are not cognisable by the courts but provide guidance for the Oireachtas.

<sup>44</sup> *Hand v Dublin Corporation* [1991] IR 409 (SC) and *Shanley v Galway Corporation* [1995] IR 396 (HC).

<sup>45</sup> *Guiry v Minister for the Marine* (HC, 24 July 1997).

<sup>46</sup> Article 10(2) ECHR.

<sup>47</sup> *ibid.*

<sup>48</sup> *Guiry v Minister for the Marine* (n 45) and *Cox v Ireland* [1992] 2 IR 503 (SC).

<sup>49</sup> *Attorney General v Paperlink Ltd* [1984] ILRM 373 (HC), 384 (Costello J).

contribute to the support of the infirm, the widow, the orphan, and the aged”, and (ii) “shall endeavour to ensure that the strength and health of workers, men and women, and the tender age of children shall not be abused”. Though the Directive Principles of Social Policy are not cognisable by the courts, the Oireachtas should consider these in determining whether the existing laws and their application have had the appropriate effect. It is argued that they have not.

Additional limitations placed on public interest expression also create restrictions on the right to earn a livelihood, as made clear in the case of *Hertel*, below. The influence of personal testimony and other anecdotal evidence on consumer choice is significant and those CAM providers deriving benefit from an article in a newspaper or a review on a blog may suffer where those avenues to free promotion are closed. However, it is argued that, given the very strong protections for expression in the public interest, it is neither likely nor desirable that novel limitations would be created to restrict such material, even in the interest of public health. Instead, public education campaigns and improvements in science and health literacy<sup>50</sup> and perhaps the formulation or appropriation of best practice guidelines for media providers on issues of health and science may help to counter the costs of free expression.

### 3. COMMERCIAL EXPRESSION

The wide margin of consideration afforded to Contracting States in restricting commercial expression is apparent in domestic law. Consumer protection legislation places restrictions on the claims that can be made by those selling products and services.<sup>51</sup> For example, s 55(1) of the Consumer Protection Act 2007 prohibits traders from making representations that a product is able to cure an illness, dysfunction or malformation, if it cannot, and the advertisement of prescription pharmaceutical products is prohibited under reg 9 of the Medicinal Products (Control of Advertising) Regulations 2007.<sup>52</sup> However, a more recent and controversial manifestation of the restrictions permissible on commercial freedom of expression is the advertising and packaging limitations now in place for tobacco products. These are justified as a public health measure and are a good example of how far states can go in limiting commercial expression.

The significance of the tobacco control provisions lies in the extent to which they are permitted to impinge upon the intellectual property rights and freedom of expression of tobacco companies.<sup>53</sup>

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<sup>50</sup> Billy McClune and Ruth Jarman, *Developing Scientific Literacy: Using News Media in The Classroom* (McGraw-Hill Inc 2007) 2.

<sup>51</sup> Consumer Protection Act 2007, s 55(1).

<sup>52</sup> Medicinal Products (Control of Advertising) Regulations 2007, SI 541/2007.

<sup>53</sup> These issues were raised in a report commissioned by Japan Tobacco International on the proposed European packaging and advertising restriction on tobacco products. See Martin Cave, “Better regulation’ and certain tobacco control measures’ (2010), para 4.13(g) <[www.jti.com/files/8813/4122/2664/Cave.pdf](http://www.jti.com/files/8813/4122/2664/Cave.pdf)> accessed 6 June 2016.

Current legislation prohibits:

- i. The advertisement of tobacco products to the general public<sup>54</sup>;
- ii. The display of tobacco products at point of sale<sup>55</sup>; and, most recently
- iii. Branded packaging, instead requiring plain, standardised packaging.<sup>56</sup>

The Public Health (Standardised Packaging of Tobacco) Act 2015 (hereafter “the 2015 Act”) prescribes the design to be utilised for all tobacco packaging,<sup>57</sup> and is applicable in Ireland in addition to the measures contained in the European Tobacco Products Directive 2014.<sup>58</sup> These new packaging requirements, the specifics of which are to be determined, require plain, matt packaging for all brands,<sup>59</sup> with the only identifying feature being the name of the particular brand and product name on the package<sup>60</sup> in a specified font, colour and size.<sup>61</sup> This effectively prevents producers from using their established brand identities on packaging to entice consumers to purchase their particular product. Packaging must also carry large health warnings, together with full colour images depicting the damage to health caused by smoking.<sup>62</sup> When considered together with the prohibition on wider advertising and point of sale display, the restrictions placed on freedom of expression for tobacco producers are significant, but they are justified by reference to the protection of public health. This is made clear by the preamble of the 2014 Directive<sup>63</sup> and by s 7(11) of the 2015 Act, which states:

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<sup>54</sup> Public Health (Tobacco) Act 2002, s 33.

<sup>55</sup> *ibid* s 33A, as inserted by the Public Health (Tobacco) (Amendment) Act 2004, s 5.

<sup>56</sup> Public Health (Standardised Packaging of Tobacco) Act 2015, s 7. This is yet to be fully commenced. The Act takes additional measures to those in the Directive in implementing standardised packaging, and this is permitted under art 24(2) of the Directive. The legality of the creation of additional controls on packaging was affirmed and deemed proportionate in Case C-547/14 *Philip Morris Brands SARL and Others* [2016] (ECJ, 4 May 2016).

<sup>57</sup> For a visual example of the proposed packaging, see World Health Organisation, ‘Get ready for plain packaging’ (2016) <[http://apps.who.int/iris/bitstream/10665/206456/1/WHO\\_NMH\\_PND\\_16.1\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/206456/1/WHO_NMH_PND_16.1_eng.pdf)> accessed 10 June 2016.

<sup>58</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC [2014] OJ L127/1, as implemented by the Public Health (Standardised Packaging of Tobacco) Act 2015 (awaiting part commencement).

<sup>59</sup> Public Health (Standardised Packaging of Tobacco) Act 2015, s 7(1)(a).

<sup>60</sup> *ibid* s 7(3)(a)-(b).

<sup>61</sup> *ibid* s 7(10).

<sup>62</sup> Public Health (Tobacco) (General and Combined Warnings) Regulations 2011, SI 2011/656, reg 3(2)(a)-(b). The prescribed warnings and images are set out in part 1 of the schedule.

<sup>63</sup> Directive 2014/40/EU (n 58), eighth recital to the Preamble, “In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (TFEU), a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people”.

In prescribing matters referred to in subsection (1)(a) or (b) or subsection (10), the Minister shall have regard to –

- (a) the need to decrease the appeal of cigarettes
- (b) the need to increase the effectiveness of health warnings on retail packaging of cigarettes, and
- (c) the need to reduce the ability of retail packaging of cigarettes to mislead consumers about the harmful effects of smoking.

Unsurprisingly, and notwithstanding the noble aim of protecting public health, the 2014 Directive has been the subject of criticism and of legal proceedings by tobacco companies.<sup>64</sup> In a reference for preliminary ruling by a group of tobacco companies as part of a case in the UK,<sup>65</sup> the proportionality of the measures established by the Directive was queried, together with the legitimacy of Member States creating restrictions on packaging over and above those set out in the Directive.

The ECJ, in the case of *Philip Morris Brands SARL and Others*,<sup>66</sup> found that additional measures taken by Member States in furtherance of the objective of standardising tobacco packaging for the purpose of protecting public health were permissible under art 24(2) of the Directive.<sup>67</sup> This was significant for Ireland, where exactly such measures have been taken in the 2015 Act. The Court also found that art 13(1) of the Directive prohibited the inclusion on packaging of any information covered in that article, notwithstanding that it might be factually accurate and not misleading, and that this did not infringe the principle of proportionality.<sup>68</sup>

However, most pertinently for the purposes of the issue at hand, the Court recognised the protection of public health as a legitimate aim for which the freedom of expression afforded by Art 10 ECHR can be restricted, stating

... the interference with the freedom of expression and information that has been found to exist meets an objective of general interest recognised by the European Union, namely, the protection of health. Given that it is undisputed that tobacco consumption and exposure to tobacco smoke are causes of death, disease and disability, the prohibition laid down in Article 13(1) of Directive 2014/40 contributes to the achievement of that objective in that it is intended to prevent the promotion of tobacco products and incitements to use them.<sup>69</sup>

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<sup>64</sup> Case C-547/14 *Philip Morris Brands SARL and Others* (n 56). In Ireland, in 2015, Japan Tobacco International initiated proceedings in the High Court in an attempt to block the introduction of the standardised packaging provisions set out in the Public Health (Standardised Packaging of Tobacco) Act 2015. These proceedings issued in February 2015 and were adjourned in April 2015. However, given the very recent *Philip Morris* decision, and the affirmation therein that art 24(2) of the 2014 Directive permits the implementation of additional provisions for packaging and is not disproportionate, it seems unlikely, though not impossible, that these proceedings will progress <[www.irishtimes.com/news/politics/tobacco-giant-takes-state-to-court-over-plain-cigarette-packaging-1.2159184](http://www.irishtimes.com/news/politics/tobacco-giant-takes-state-to-court-over-plain-cigarette-packaging-1.2159184)> accessed 10 June 2016.

<sup>65</sup> *R (On the Application of Philip Morris Brands (Sárl) v Secretary of State for Health* [2014] EWHC 3669.

<sup>66</sup> Case C-547/14 *Philip Morris Brands SARL and Others* (n 56).

<sup>67</sup> *ibid* para 84.

<sup>68</sup> *ibid* paras 145-162.

<sup>69</sup> *ibid* para 152.



The Court also sought to balance the right afforded to the claimants to pursue their commercial interests with the general interest in protecting public health. Again, the Court favoured the protection of public health, stating

... the discretion enjoyed by the EU legislature, in determining the balance to be struck, varies for each of the goals justifying restrictions on that freedom [of expression] and depends on the nature of the activities in question. In the present case, the claimants in the main proceedings rely, in essence, under Article 11 of the Charter, on the freedom to disseminate information in pursuit of their commercial interests.<sup>70</sup>

It must, however, be stated that human health protection — in an area characterised by the proven harmfulness of tobacco consumption, by the addictive effects of tobacco and by the incidence of serious diseases caused by the compounds those products contain that are pharmacologically active, toxic, mutagenic and carcinogenic — outweighs the interests put forward by the claimants in the main proceedings.<sup>71</sup>

Whereas the clear recognition of the legitimacy of protecting public health is of assistance in the question of whether the same objective might be applicable in attempting to limit potentially harmful expression in relation to CAM, the language used by the Court in supporting restriction of expression in this case tends to cast a measure of doubt on its applicability. The Court, here, relies upon “undisputed” facts relating to the “death, disease and disability” caused by tobacco smoke. It cites the “proven harmfulness of tobacco consumption, ... the addictive effects of tobacco and ... the incidence of serious diseases caused by the compounds those products contain that are pharmacologically active, toxic, mutagenic and carcinogenic”. There is ample evidence of significant societal harm caused by tobacco and the prevalence of its use.<sup>72</sup> There is similarly evidence of the real and potential positive effects of restrictions on the advertisement and packaging of tobacco products.<sup>73</sup> There is social and economic interest in minimising sequelae arising from the use of

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<sup>70</sup> *ibid* para 155.

<sup>71</sup> *ibid* para 156.

<sup>72</sup> Department of Health, ‘Tobacco Free Ireland – Report of the Tobacco Policy Review Group’ (DOH 2013) 4, “Smoking is the leading cause of preventable death in Ireland. Each year at least 5,200 people die from diseases caused by tobacco use. This represents almost one in five of all deaths”.

<sup>73</sup> James Nonnemaker and others, ‘Influence of point-of-sale tobacco displays and plain black and white cigarette packaging and advertisements on adults: Evidence from a virtual store experimental study’ (2016) 56 *Addictive Behaviors* 15, 21, “If virtual store experiments translate to real-world experiences, then our results suggest that policy makers should consider policies that require plain packaging and ads or enclose tobacco displays at the POS to reduce adult cigarette purchases”. See also, J Craig Andrews and others, ‘Effects of plain package branding and graphic health warnings on adolescent smokers in the USA, Spain and France’ (2016) *Tobacco Control* 1, 6, “Overall results indicate graphicness impacts quit thoughts; whereas plain packs and graphicness affect more immediate measures of craving, fear/emotion, and pack feelings ... Plain packs can independently strengthen the more instantaneous, direct effects found with the GHWs [graphic health warnings]”; Australian Department of Health, ‘Post-implementation review tobacco plain packaging 2016’ (2016) para 107, “Dr Chipty’s analysis estimated that the 2012 packaging changes reduced average smoking prevalence among Australians aged 14 years and over by 0.55 percentage points. This result was statistically significant. The model predicts that without the 2012 packaging changes average smoking prevalence in the post-implementation period would have been 17.77% as opposed to 17.21% with the 2012 packaging changes” <<https://ris.govspace.gov.au/files/2016/02/Tobacco-Plain-Packaging-PIR.pdf>> accessed 10 May 2016.

tobacco products, with significant fiscal gains to be made in reducing healthcare spending on smoking-related illnesses.<sup>74</sup> This is compelling. The strength of the available evidence and its role in justifying, or otherwise, a restriction on the ground of public health was discussed in the Opinion of Advocate General Fennelly in the case of *Germany v Parliament and Council*,<sup>75</sup> where he stated:

The evidence required to justify a restriction will depend on the nature of the claim made. We are here largely concerned with the objective assessment of the likely effects of the Advertising Directive. The legislator should not enjoy as wide a margin of appreciation as in the case, for example, of the protection of morals. However, the Community should not be prevented from acting in the public interest simply because justification of its action necessarily depends, not on 'hard' scientific studies, but on evidence of a social scientific character, which predicts, on the basis of past behaviour, the future responses of consumers to changes in their level of exposure to promotional material. Furthermore, where the Community legislator can show that it acted upon the basis of reputable specialist studies in the field, the fact that other apparently reputable studies have reached a contrary conclusion does not, in itself, show that the legislator did not have reasonable grounds for acting. In the present cases, the legislator's assessment of the effects of tobacco advertising is consistent with the Court's own statement that '[i]t is in fact undeniable that advertising acts as an encouragement to consumption'. Furthermore, most advertising cannot be so precisely focused that it addresses only existing smokers who wish to choose between brands, to the exclusion of others who might be incited either to begin smoking or to abandon plans to give up smoking.<sup>76</sup>

Advocate General Fennelly appeared to expand the evidentiary requirements for creating restrictions with the aim of protecting public health, to include those of a social scientific or predictive nature, even where contrary opinions were available. He dismissed the unrealistic stated objective of tobacco advertisers to affect the behaviour of only a small subset of smokers. However, he went on to state that:

Evidentiary requirements may be less strict where public health is at stake. The Court stated in BSE that '[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'. However, the present cases do not concern a prohibition of the marketing of tobacco products themselves, whose harmful effects on health have not been disputed, but rather a comprehensive ban on promotion of such products. The scientific debate at issue relates to the effects of such promotion on overall consumption levels (as opposed to the mere choice of brands by existing smokers), which is at one remove from the assessment of the health risks actually posed by such consumption. Furthermore, the ban at issue in BSE was temporary in nature and was subject to review after a further examination of the situation. Differences of opinion regarding the effect of tobacco advertising are of long standing and are unlikely to be resolved quickly. The standard proposed in the immediately preceding paragraph - makes allowance for the lack of unanimity in scientific circles; it would,

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<sup>74</sup> Department of Health (n 72) 20, "A health economic assessment found that for every 1,000 smokers who quit there was an average saving of Aus\$373,000 (€277,370) in healthcare costs associated with acute myocardial infarction (MI), stroke, lung cancer, and chronic obstructive pulmonary disease (COPD)".

<sup>75</sup> Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8423.

<sup>76</sup> *ibid* para 160.

in my view, be insufficiently respectful of freedom of expression to go beyond that and to permit the legislator to restrict the exercise of that right without any clear evidence that such a restriction is likely to result in changes in behaviour which, in turn, were likely to benefit public health.<sup>77</sup>

In short, despite the strength of evidence in respect of the damage caused by smoking and acknowledgement of the precautionary principle, the evidence in support of the efficacy of tobacco advertising for increasing or maintaining overall consumption and, therefore, the potential public health impact of advertising restrictions was not found to be sufficient to merit the restriction of freedom of expression. The measure to be taken could not, at that time, be rationally linked to the stated objective of protecting public health,<sup>78</sup> failing the test of necessity.

To extrapolate from this, it appears that, despite evidence of harm caused by various CAM products or practices, unless evidence can be adduced of a rational link between further restricting CAM advertising (commercial expression) and improving the protection of public health, novel, domestic measures increasing the restrictions on commercial expression in the CAM sector may not be deemed acceptable at a European level.

Restriction of commercial expression with the objective of protecting public health is therefore justifiable, albeit where the restriction is proportional and the nexus between the measure and the objective can be clearly demonstrated. However, the placement of restrictions on non-commercial ‘public interest’ expression in the name of public health protection presents a more complex issue.

#### **4. NON-COMMERCIAL ‘PUBLIC INTEREST’ EXPRESSION**

Whereas commercial expression attracts a wide margin of appreciation for the creation of restrictions by Contracting States, non-commercial, public interest expression, the facilitation and protection of which is the fundamental aim of Art 40.6.1° and of Art 10 ECHR,<sup>79</sup> is heavily guarded and subject to restriction only on the grounds set out in Art 10(2) ECHR, which must be narrowly construed.<sup>80</sup> This form of expression, which is without the direct motivation of selling a product or service to the audience but instead ostensibly addresses matters of public interest, such as politics, current affairs or health, is found in a wide range of media, encompassing the press, broadcast media, books,<sup>81</sup> film,

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<sup>77</sup> *ibid* para 161.

<sup>78</sup> Evidence has since become available of the efficacy of advertising and packaging restrictions in decreasing smoking prevalence. See Australian Department of Health, ‘Post-implementation review tobacco plain packaging 2016’ (2016), para 107.

<sup>79</sup> Application No 7805/77 *X and Church of Scientology v Sweden* (n 42) 73.

<sup>80</sup> As provided in *Venables v News Group Newspapers Ltd* (n 26), and followed in *Foley v Sunday Newspapers Ltd* (n 11).

<sup>81</sup> Books and periodicals are subject to censorship by the Censorship of Publications Board, established by s 3 of the Censorship of Publications Act 1929. Though the Office of the Censor takes a flexible, contemporary approach to restrictions, the provisions of the Act betray a particularly narrow, moralistic agenda, undoubtedly

and the internet generally. All are subject to a level restriction and oversight,<sup>82</sup> whether under a voluntary code, a statutory code, terms of use, or censorship, but this has not limited, in any meaningful way, the dissemination of incomplete, inaccurate or dangerous information on the use of CAM products or services. Each is briefly examined in an effort to determine where the greatest risk lies, and whether an attempt to utilise the public health exception in Art 10 to minimise it would be either possible or desirable. However, it is first necessary to review the approach taken by the ECHR in addressing the restriction of non-commercial expression.

#### 4.1 THE INTERACTION BETWEEN PUBLIC INTEREST EXPRESSION AND PUBLIC HEALTH UNDER THE ECHR

The cases of *Hertel v Switzerland (no 1)* and *(no 2)*<sup>83</sup> provide detailed examples of the key issues to be considered in determining whether a limitation on public interest speech is permissible under Art 10 ECHR.

These cases related to a research paper on the deleterious effects of microwave radiation on food and, later, to public comments of the same nature. The authors of the paper, being the applicant in these cases and his fellow academic,<sup>84</sup> found deleterious physiological changes arising from the use of microwave ovens, based upon which, they submitted their paper for publication in a popular science journal with a predominantly lay audience. The paper concluded that “[t]he measurable effects on human beings of food treated with microwaves, as opposed to food not so treated, include changes in the blood which appear to indicate the initial stage of a pathological process such as occurs at the start of a cancerous condition”.<sup>85</sup> The cases focussed, fundamentally, on whether the publication of these statements amounted to protected public interest expression under Art 10.

The publisher, *Journal Franz Weber*, dedicated a substantial proportion of the issue in which the applicant’s research was published (Issue 19) to discussion of the dangers of microwave

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reflective of the values of their time, and, more importantly, they fail to offer any protection for consumers from the many newspaper and magazine articles on unproven therapies, and from books promoting, in detail, such therapies.

<sup>82</sup> Though there is minimal case law on Art 40.6.1°. See Marie McGonagle, *A Textbook on Media Law* (Gill & Macmillan 1996) 23.

<sup>83</sup> *Hertel v Switzerland (no 1)* (n 33).

<sup>84</sup> The co-author on the paper was Professor Bernard Blanc. Shortly after the publication of Issue 19, Professor Blanc issued a statement dissociating himself from “the presentation and interpretation of the preliminary exploratory experiment carried out in 1989, which was published without my consent by the co-author of the study in the journals cited above”. He stated “The results obtained do not in any circumstances justify drawing any conclusions as to the harmful effects of food treated with microwaves or a predisposition to the appearance of a given pathological condition ... only one conclusion is unavoidable, namely that it is necessary to undertake, as a matter of urgency, multidisciplinary and multifactorial basic research on the effects on (certain parameters of) health of the consumption of food treated with microwaves in comparison with food prepared using other food technologies or culinary techniques”. See *Hertel v Switzerland (no 1)* (n 33), para 15.

<sup>85</sup> *ibid* para 8. This, as noted in the case report, is a translation from the French version of the journal.

radiation, with images of various dimensions depicting the Grim Reaper, accompanying the text on each relevant page.<sup>86</sup> The ECtHR, in paragraphs 12 and 13 of the decision, provided a detailed overview of the language used by the journal. Some of the text characterised the journal itself as a tireless, fearless exposé of otherwise hidden dangers and ulterior motives.<sup>87</sup> Some of the text described the evidence gleaned from the research paper as “unequivocal” or “irrefutable”, despite expert evidence to the contrary. However, most of the text in these paragraphs was composed of simplistic and, at times, sensational language (such as “Mr 80% water, beware!” and “Danger! Cell Poison”), a style not generally encountered in other academic journals. This, despite the fact that the research itself, according to the applicant’s co-author, who dissociated himself from the representation of the findings in *Journal Franz Weber* shortly after publication, concluded only that further research was urgently required.<sup>88</sup>

The Swiss court dismissed a case taken by the Swiss Association of Manufacturers and Suppliers of Household Electrical Appliances (“the MHEA”) seeking

... an interim order prohibiting Mr Franz Weber, on pain of the penalties provided in Article 292 of the Criminal Code, “from using ... the image of a man’s skeleton or any other image suggesting the idea of death ... associated with the graphic, photographic, oral or written representation of a microwave oven”, “from stating ... that microwave ovens must be abolished and their use banned”, “from stating ... that scientific research proves what a hazard food that has been exposed to radiation in a microwave oven is to health and backs up the *Journal Franz Weber*” or “from stating ... that microwave ovens must all be destroyed without exception because food is harmed by these dangerous appliances to such an extent that it causes, in those who consume it, a change in the blood count and leads to anaemia and a precancerous stage”.<sup>89</sup>

The court did so on the grounds that, *inter alia*, a connection had not been established between the article or publication of the article by *Journal Franz Weber* and “very substantial” damage to the industry. However, after a series of appeals on the basis of the Unfair Competition Act, the Swiss Federal courts found in favour of the appellants, affirming the injunction and stating that:

Anyone claiming scientific freedom is ... wholly free to expound his knowledge in the academic sphere but, where competition is concerned, he may not claim to have the truth on his side where the opinion he is putting forward is disputed. An opinion which has not been confirmed scientifically must in particular not be misused as a disguised form of positive or negative advertising of one’s own work or the work of others.<sup>90</sup>

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<sup>86</sup> *ibid* paras 9-10.

<sup>87</sup> *ibid* para 11.

<sup>88</sup> *ibid* para 15.

<sup>89</sup> *ibid* para 16.

<sup>90</sup> *ibid* para 23. This is particularly relevant to CAM and conventional medicine, which are often in competition.

The article was therefore treated as if it were a commercial communication, affording the domestic courts a greater margin of appreciation in applying an Art 10 restriction. Hertel applied to the ECtHR, alleging violation of his Art 10 rights. The Court found, by six votes to three, in his favour in this respect, stating that:

Freedom of expression constitutes one of the essential foundations of a democratic society and one of the basic conditions for its progress and for each individual's self-fulfilment. Subject to paragraph 2 of Article 10, it is applicable not only to "information" or "ideas" that are favourably received or regarded as inoffensive or as a matter of indifference, but also to those that offend, shock or disturb. Such are the demands of pluralism, tolerance and broadmindedness without which there is no "democratic society".<sup>91</sup>

The Court recognised the particular importance of the margin of appreciation in commercial matters,<sup>92</sup> but also that the margin must be narrowed in cases where commentary is not purely commercial.<sup>93</sup> Interestingly, freedom of expression as a means of protecting of public health was not a factor in the decision of the Court.

The Court also found that "It matters little that his opinion is a minority one and may appear to be devoid of merit since, in a sphere in which it is unlikely that any certainty exists, it would be particularly unreasonable to restrict freedom of expression only to generally accepted ideas".<sup>94</sup> It did not provide any detail on how the particular level of certainty was to be determined and therefore the approach taken in this respect may vary significantly between cases. Taken to an extreme, one might consider that nothing is ever certain and, therefore, expression should never be limited.

As noted above, the Court was not unanimous in its determinations. The dissenting opinion of Bernhardt J focussed on the margin of appreciation afforded to the national courts in question and the "reasonable" decision arrived at by them to restrict the freedom of expression of the applicant because "it is beyond doubt that the applicant's central assertion and the alleged scientific results do not stand up to close scrutiny".<sup>95</sup> He concluded that:

There might be good reasons to allow such statements irrespective of their correctness, but the European Court of Human Rights should not substitute its own evaluation for that of the national courts, where those courts considered, on reasonable grounds, the restrictions to be necessary.<sup>96</sup>

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<sup>91</sup> *ibid* para 46.

<sup>92</sup> *ibid* para 47.

<sup>93</sup> *ibid*.

<sup>94</sup> *ibid* para 50.

<sup>95</sup> *ibid* Dissenting Opinion of Judge Bernhardt.

<sup>96</sup> *ibid*.

Matscher J, similarly dissenting, found that the Swiss courts considered that the statements of the applicant “were not based on any scientific evidence” and implied that their response was not unduly heavy-handed or disproportionate, and that the applicant was “not prohibited from continuing his research or from publishing that research in an appropriate way”.<sup>97</sup> He also found that it was foreseeable on the part of the applicant that, by providing the research paper to *Journal Franz Weber*, a publication targeted at lay readers, it would be simplified and “exaggerated”,<sup>98</sup> a situation from which the applicant failed to dissociate himself.

As in *Germany v Parliament and Council*,<sup>99</sup> evidence supporting restriction of freedom of expression for the legitimate aim of protecting the rights of others was neither substantial nor unanimous. The domestic courts had noted the lack of an established nexus between future sales of microwave ovens and the warnings of danger published in *Journal Franz Weber*.<sup>100</sup> That journal, which was “not general in content” and was “distributed almost entirely by subscription”, had published similar pronouncements previously, using evocative language referring to microwave ovens as being “worse than the Dachau gas chambers”,<sup>101</sup> and so its endorsement of such opinions was known to their readership. In such a situation, the injunction could not have been considered “necessary”, as it would have been unlikely to have any significant effect on the choices made by readers.<sup>102</sup>

In 2002, Hertel applied once again to the ECtHR,<sup>103</sup> challenging a domestic injunction preventing him from making public statements that the risks associated with the use of microwave ovens had been scientifically proven, without also stating that there were “current differences of opinion” on the matter. Unlike in the previous case, here the ECtHR ruled his application inadmissible, due to the minimal restriction placed on the applicant’s freedom of expression, which did not substantially limit his overall ability to make such statements in public. It found that “the obligation to refer “to current differences of opinion” serves to prevent inaccurate, misleading or unnecessarily damaging and therefore unfair statements of the competitive position”.<sup>104</sup>

*Hertel (no 1)* and *Hertel (no 2)* demonstrate the importance of proportionality in restricting rights, and reiterate, once again, the difference in the margin of appreciation afforded to

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<sup>97</sup> *ibid* Dissenting Opinion of Judge Matscher.

<sup>98</sup> *ibid*.

<sup>99</sup> Case C-376/98 *Germany v Parliament and Council* (n 75).

<sup>100</sup> *Hertel v Switzerland (no 1)* (n 33), para 49, “in the present case it was not alleged that the publication in issue had a measurable effect on the sale of microwave ovens or caused actual damage to the members of the MHEA. In applying the UCA, the Commercial Court of the Canton of Berne and the Federal Court merely found that it was plausible that there had been such an effect”.

<sup>101</sup> (1989) 8 *Journal Franz Weber*.

<sup>102</sup> *Hertel v Switzerland (no 1)* (n 33), para 46, “The adjective “necessary”, within the meaning of Article 10 § 2, implies the existence of a “pressing social need”.

<sup>103</sup> Application No 53440/99 *Hertel v Switzerland (no 2)* (2002) Reports 2002-I.

<sup>104</sup> *ibid* para 39.

Contracting States in respect of commercial and public interest cases. However, what remains uncertain is how far public interest speech can go before some level of intervention and restriction is considered necessary and proportional. In the *Hertel* cases, the statements made by the applicant were made with the ostensible aim of protecting public health. These may have afforded the applicant a notional advantage over the respondents: in ensuring that his freedom of expression was vindicated, he was also protecting public health in the face of competing commercial interests. Any Art 10 case involving CAM may not be so simplistic, as opposing sides both claim to protect public health and both require that their freedom of expression be vindicated to do so. Where restricting freedom of expression is unlikely to substantially affect the level or scale of the harm, regardless of evidence in support of the existence and cause of the harm, courts appear to be reluctant to uphold a restriction.<sup>105</sup>

#### **4.2 DOMESTIC LIMITATIONS ON FREEDOM OF EXPRESSION AND THE ORGANS OF PUBLIC OPINION**

The legitimate aims in Art 10 and those in Art 40.6.1° (i) facilitate the creation of laws restricting freedom of expression in the public interest in Ireland, in areas such as harassment,<sup>106</sup> incitement to hatred, the publication or re-publication of defamatory statements,<sup>107</sup> infringement of intellectual property rights,<sup>108</sup> or the deliberate access, download, production or distribution of child pornographic material,<sup>109</sup> among many others. However, the press, along with radio and cinema,<sup>110</sup> named in Art 40.6.1(i) as “organs of public opinion”, requires strenuous protection so as to ensure that the education of public opinion is not hindered. This is so, even where:

Publication may cause needless pain, distress, and damage to individuals or harm to other aspects of the public interest. ... a freedom which is restricted to what Judges think to be responsible or are in the public interest is no freedom. Freedom means the right to publish things which government and judges however well motivated, think should not be published. It means the right to say things which ‘right thinking people’ regard as dangerous or irresponsible. This freedom is subject only to clearly defined exceptions laid down by common law or statute.<sup>111</sup>

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<sup>105</sup> Case C-376/98 *Germany v Parliament and Council* (n 75), para 161.

<sup>106</sup> Non-Fatal Offences Against the Person Act 1997, s 10.

<sup>107</sup> Prohibition of Incitement to Hatred Act 1989, s 4(1).

<sup>108</sup> Defamation Act 2009, s 6(2).

<sup>109</sup> Child Trafficking and Pornography Act 1998, s 5(1).

<sup>110</sup> This is not an exhaustive listing, but examples referenced the technology of the time. Today, these include the television and the internet. See Gerard Hogan and Gerry Whyte (n 18), para 7.5.14.

<sup>111</sup> *R v Central Independent Television Plc* [1994] Fam 192, 204 (Hoffman LJ).



Irish courts have recognised, not only the right of freedom of expression, but also the unenumerated personal right to communicate, protected by Art 40.3.1.<sup>112</sup> In *Irish Times v Ireland*,<sup>113</sup> Barrington J found that this right included the right to communicate facts, convictions, and opinions.<sup>114</sup> This broad scope for expression and communication is limited in a few specific situations, none of which can be considered to apply, at present, to the dissemination of inaccurate, incomplete or misleading information regarding the use of CAM, by the press.

### 4.3 LIMITATIONS ON PRESS FREEDOM

According to Hogan and Whyte, freedom of expression may be restricted:

- (a) in the interest of the right to life<sup>115</sup>;
- (b) in the interest of state security;
- (c) in connection with illegal organisations;
- (d) in the interests of official privacy;
- (e) in the interest of the public peace and order;
- (f) in the interest of the authority of the courts and in the interests of a fair trial;
- (g) in the interests of individual privacy; and
- (h) in the interest of public morality.<sup>116</sup>

The press, as with private individuals, has a responsibility to act within the scope of these restrictions, but is also subject to further oversight by the Press Council and the Press Ombudsman.

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<sup>112</sup> The Irish Constitution, Art 40.3.1°, “The State guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen”.

<sup>113</sup> *Irish Times v Ireland* [1998] 1 IR 359.

<sup>114</sup> *ibid* 405.

<sup>115</sup> One might expect that the right to life might include the prohibition of speech that creates risk of death through recommending or counselling in the use of unproven or dangerous treatments, particularly for an otherwise treatable illness. However, the right to life is predominantly used to restrict freedom of expression in only two cases: the provision of information on procuring a termination of pregnancy outside the State; and the counselling of another to commit or attempt to commit suicide. See Gerard Hogan and Gerry Whyte (n 18), para 7.5.19.

<sup>116</sup> *ibid* paras 7.5.18 – 7.5.75.

### 4.3.1 THE PRESS COUNCIL/OMBUDSMAN

The Press Council, established in 2008, is an independent press regulator, with a Code of Practice by which member publications must agree to abide. The Code of Practice composes ten principles, aiming to uphold the “highest professional and ethical standards” in journalism.<sup>117</sup> For the purposes of reporting or commenting on CAM, the most relevant of these are (1) Truth and Accuracy,<sup>118</sup> (2) Distinguishing Fact and Comment,<sup>119</sup> and (4) Respect for Rights.<sup>120</sup> News media, though undoubtedly striving to achieve these objectives, has, on some occasions and in some areas, fallen short. Science and health reporting are two such areas.<sup>121</sup> This is significant, because, as an “organ of public opinion”, healthcare decision-making, for better or worse, is affected by such reporting.<sup>122</sup> By failing to abide by a thorough code of practice, journalists and their publications must accept at least partial responsibility for consequences arising from the spread of misinformation. This was central to submissions made to the Leveson Inquiry in the UK in 2012.<sup>123</sup>

Before the relatively recent establishment of the Press Council, journalists who were members of the National Union of Journalists (NUJ) were also subject to a code of practice,<sup>124</sup> which is similar to that of the Press Council. However, neither code appears to have addressed the inaccurate reporting of health issues.

There are many examples of overwhelmingly positive reports on therapies which have insufficient evidence in support of their safety or efficacy, or, indeed, copious evidence that they are neither safe nor efficacious. An article appearing in the *Irish Independent*,

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<sup>117</sup> The Press Council, ‘Code of Practice’ <[www.presscouncil.ie/code-of-practice.150.html](http://www.presscouncil.ie/code-of-practice.150.html)> accessed 6 June 2016.

<sup>118</sup> *ibid*, “Principle 1 – Truth and Accuracy: 1.1 In reporting news and information, print and online news media shall strive at all times for truth and accuracy. 1.2 When a significant inaccuracy, misleading statement or distorted report or picture has been published, it shall be corrected promptly and with due prominence. 1.3 When appropriate, a retraction, apology, clarification, explanation or response shall be published promptly and with due prominence”.

<sup>119</sup> *ibid*, “Principle 2 – Distinguishing Fact and Comment: 2.1 Print and online news media are entitled to advocate strongly their own views on topics. 2.2 Comment, conjecture, rumour and unconfirmed reports shall not be reported as if they were fact. 2.3 Readers are entitled to expect that the content of a publication reflects the best judgment of editors and writers and has not been inappropriately influenced by undisclosed interests. Wherever relevant, any significant financial interest of an organization should be disclosed. Writers should disclose significant potential conflicts of interest to their editors”.

<sup>120</sup> *ibid*, “Principle 4 – Respect for Rights: 4.1 Everyone has constitutional protection for his or her good name. Print and online news media shall not knowingly publish matter based on malicious misrepresentation or unfounded accusations, and must take reasonable care in checking facts before publication”.

<sup>121</sup> This was mentioned as a specific concern in the Report of the Leveson Inquiry. See Lord Justice Leveson, *An Inquiry into the Culture, Practices and Ethics of the Press: Report* (Stationery Office 2012) 490, para 3.29.

<sup>122</sup> Irwin M Rosenstock, ‘Why people use health services’ (2005) 83 *Milbank Quarterly* Online, 13-14. The author observed, in practice, the influence of newspaper dissemination of health campaign information.

<sup>123</sup> Lord Justice Leveson (n 121) 490-491, para 3.29.

<sup>124</sup> National Union of Journalists, ‘Code of Practice’ (2011) <[www.nuj.org.uk/documents/nuj-code-of-conduct/](http://www.nuj.org.uk/documents/nuj-code-of-conduct/)> accessed 23 June 2016.

entitled ‘Relax to your heart's content’, reported on the use of chelation at a specialist private clinic in Dublin. The language is striking:

... the days of by-pass surgery may finally be numbered, thanks to a non-invasive and painless treatment known as chelation therapy. GP, Gabriel Stewart, is promoting the treatment that is leaving the scalpel obsolete in an increasing number of cases when it comes to treating arteriosclerosis. In fact, all you have to do when this man treats you is sit back, relax and take your medicine.<sup>125</sup>

Given the highly traumatic and inherently risky nature of coronary artery bypass surgery and the lasting after-effects which can include, *inter alia*, infection, atrial fibrillation, pain, and renal dysfunction,<sup>126</sup> the idea that a pain-free alternative exists is understandably attractive. However, the article in question provided only positive anecdotal evidence in support of chelation therapy and tacit appeal to the authority of the physician quoted therein, but no consideration of whether the best available evidence supported the assertions made. In fact, chelation therapy, which is utilised as part of conventional medicine in the treatment of heavy metal toxicity, has not been proven to treat or improve the status of coronary artery disease.<sup>127</sup> Twelve years after publication of the article in question, a large study (the “TACT Trial”) showed slight improvements in test subjects, but the authors of the research nonetheless noted that alterations in general clinical protocols should not be made on the basis of their outcome, as further research was required. The trial was notable, as the first of its kind<sup>128</sup> to produce results that suggested any such benefit, and so to promote chelation therapy in such an effusive

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<sup>125</sup> Aileen O'Reilly, ‘Relax to your heart's content’ *Irish Independent* (11 February 2001)

<[www.independent.ie/unsorted/features/relax-to-your-hearts-con-tent-26247143.html](http://www.independent.ie/unsorted/features/relax-to-your-hearts-con-tent-26247143.html)> accessed 10 June 2016.

<sup>126</sup> NHS Choices, ‘Coronary artery bypass graft – Risks’ (2015) <[www.nhs.uk/Conditions/Coronary-artery-bypass/Pages/Risks.aspx](http://www.nhs.uk/Conditions/Coronary-artery-bypass/Pages/Risks.aspx)> accessed July 2016.

<sup>127</sup> Antonio L Dans, Flordeliza N Tan and Essie C Villarruz-Sulit, ‘Chelation therapy for atherosclerotic cardiovascular disease’ (2002) Cochrane Database of Systematic Reviews CD002785. See also Gervasio A Lamas and others, ‘Effect of disodium EDTA chelation regimen on cardiovascular events in patients with previous myocardial infarction: The TACT randomized trial’ (2013) 309 *Journal of the American Medical Association* 1241, 1249. The TACT trial, published in 2013, showed some improvements in candidates with diabetes and in those with a history of anterior myocardial infarction, but concluded that “[t]hese results provide evidence to guide further research but are not sufficient to support the routine use of chelation therapy for treatment of patients who have had an MI”. However, the study has received criticism for the research methodology used. See Steven E Nissen, ‘Concerns about reliability in the trial to assess chelation therapy (TACT)’ (2013) 309 *Journal of the American Medical Association* 1293, 1294, “Given the numerous concerns with this expensive, federally funded clinical trial, including missing data, potential investigator or patient unmasking, use of subjective end points, and intentional unblinding of the sponsor, the results cannot be accepted as reliable and do not demonstrate a benefit of chelation therapy. The findings of TACT should not be used as a justification for increased use of this controversial therapy”. Upon this final point, the respective authors appear to agree, further undermining the premise of the article by Aileen O'Reilly (n 125) above and, indeed, the practices discussed therein.

<sup>128</sup> US National Centre for Complementary and Integrative Health (NCCIH), ‘Chelation for coronary heart disease’ (2016) <<https://nccih.nih.gov/health/chelation>> accessed 10 June 2016.

way so many years before, was to make strong and compelling assertions on the basis of no or incomplete scientific evidence.

The journalist also identifies the physician in question as a “GP”, which, though undoubtedly accurate, gives the impression that the physician was acting in the course of this role when providing chelation therapy. Chelation does not form part of common practice for general practitioners and, in this case, the physician in question was not providing general medical services. This is misleading, as it normalises for readers this unproven treatment.

It is noted, as an aside, that the same clinic currently states that “intravenous EDTA has been shown to significantly reduce the incidence of cancer”,<sup>129</sup> despite the fact that the European Communities (Protection of Workers) (Exposure to Lead) Regulations 1988 state “The prophylactic use of chelating agents, sometimes called 'preventive therapy' is medically and ethically unacceptable. Many chelating agents may be considered nephrotoxic when administered for long periods”.<sup>130</sup>

The journalistic practice discussed above fails to meet the standards of the first two Principles of the Press Council Code, set out above, and, at the time of publication, of Principles 2, 3, and 4 of the NUJ code.<sup>131</sup> However, similar practice continues unabated.

A more recent example of this is a series of articles published in the *Daily Mail* and in the *Irish Independent* newspapers, among others,<sup>132</sup> reporting on the decision made by various people diagnosed with cancer to attend the Burzynski Clinic in Texas.<sup>133</sup> There,

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<sup>129</sup> Chelation Ireland, ‘Our Treatments’ <[www.chelationireland.com/#!/treatments/ct4q](http://www.chelationireland.com/#!/treatments/ct4q)> accessed 27 June 2016.

<sup>130</sup> European Communities (Protection of Workers) (Exposure to Lead) Regulations 1988, SI 219/1988, sch 4, art 5.

<sup>131</sup> National Union of Journalists (n 124), “A journalist: 2) Strives to ensure that information disseminated is honestly conveyed, accurate and fair, 3) Does her/his utmost to correct harmful inaccuracies 4) Differentiates between fact and opinion” <[www.nuj.org.uk/documents/nuj-code-of-conduct/](http://www.nuj.org.uk/documents/nuj-code-of-conduct/)> accessed 23 June 2016.

<sup>132</sup> Danielle Wrate, ‘British woman given just 18 months to live after being diagnosed with cancer defies doctors to marry after raising £200,000 to have controversial treatment in the US’ *Daily Mail* (10 December 2015) <[www.dailymail.co.uk/femail/article-3351404/Cancer-survivor-diagnosed-rare-brain-tumour-defies-doctors-marry-partner-tracked-controversial-treatment-US.html](http://www.dailymail.co.uk/femail/article-3351404/Cancer-survivor-diagnosed-rare-brain-tumour-defies-doctors-marry-partner-tracked-controversial-treatment-US.html)> accessed 21 June 2016. See also ‘Young mother with brain cancer given just a year to live BEATS the disease and gets married after having controversial treatment in the US’ *Daily Mail* (8 November 2013) <[www.dailymail.co.uk/health/article-2492871/Young-mother-brain-cancer-given-just-year-live-BEATS-disease-gets-married-having-controversial-treatment-US.html](http://www.dailymail.co.uk/health/article-2492871/Young-mother-brain-cancer-given-just-year-live-BEATS-disease-gets-married-having-controversial-treatment-US.html)> accessed 6 June 2016. The *Daily Mail* is not the only publication to partake in this practice. In 2012, the *Irish Independent* published an article, which described the Burzynski treatment as “advanced” and as bringing “hope”, providing a brief overview of the fundraising efforts, along with details for readers who wish to make donations. See Kathryn Hayes (n 14). In addition, there is evidence of an *Irish Times* article covering the same issue, describing the Burzynski treatment as “pioneering”, and “advanced”, and providing details for donations. The article and all references to it have since been removed from the *Irish Times* website, but is discussed, with screenshots, on various other sites. See Kathryn Hayes, ‘Appeal for ill child to travel to us for pioneering treatment’ *Irish Times* (14 July 2012) <<http://cf.broadsheet.ie/wp-content/uploads/2012/07/Screen-Shot-2012-07-16-at-11.10.24.jpg>> accessed 20 June 2016. This is reproduced in Appendix VII for ease of reference.

<sup>133</sup> The Burzynski Clinic <[www.burzynskiclinic.com/](http://www.burzynskiclinic.com/)> accessed 20 June 2016.

Dr Stanislaw Burzynski provides antineoplaston therapy, an alternative to conventional chemotherapy, administered on a trial basis as it is currently not approved by the US Food and Drug Administration. Prospective patients must raise a substantial amount of money to pay for the treatment, which has never been proven to be efficacious for cancer.<sup>134</sup> There is, in some of the articles in question, a smattering of cursory references to the fact that the treatment is a source of “controversy”, but these are far outweighed by other information on diagnosis, home and family life, and details of fundraising efforts, for readers who wish to make donations. Not only does this type of report act to disseminate information on an unproven and potentially dangerous ‘only hope’ treatment, but it relies on sentiment and human empathy to encourage readers to fund such treatment, despite the fact that it is unproven. The publications, in these cases, use misleading omissions to create a distorted and imbalanced version of the facts, behaviour which is in contravention of both the Press Council and the NUJ codes of practice, and which may give or have given rise to both physical and financial harm, or false hope for readers relying on it. Despite the creation of further oversight for the press, the problem persists, leaving potential patients and donors vulnerable.

The questionable reporting on matters of health and science formed one aspect of a large inquiry undertaken in the UK in the wake of a series of controversies involving members of the press. This was the Leveson Inquiry.<sup>135</sup>

#### **4.3.2 INADEQUACIES IN PRESS GOVERNANCE AND SCIENCE/HEALTH REPORTING - RECOMMENDATIONS FROM LEVESON**

The Report on The Leveson Inquiry into the Culture, Practices and Ethics of the Press was published in 2012. The Inquiry was established to investigate, among other things, the relationship between the press and the public.<sup>136</sup> The issue of health and science reporting formed part of the investigation.

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<sup>134</sup> Saul Green, ‘Antineoplastons: An unproved cancer therapy’ (1992) 267 *Journal of the American Medical Association* 2924, 2927, “treatment for cancer with substances called antineoplastons actually involves the use of two simple commercially available organic chemical compounds, PA and PAG, which are marketed under the names A-10, AS 2.1, and AS 2.5. None is a peptide, none has been shown to “normalize” tumor cells, none has been shown to actually intercalate DNA, and none has been proven to be active against cancer in experimental tumor test systems”. See also, Barrie Cassileth, ‘Alternative and complementary medicine’ (1999) 86 *Cancer* 1900.

<sup>135</sup> Lord Justice Leveson (n 121).

<sup>136</sup> The Leveson Inquiry, ‘About the Inquiry’

<<http://webarchive.nationalarchives.gov.uk/20140122145147/http://www.levesoninquiry.org.uk/about/>> accessed 10 May 2016.

(a) *Influence*

According to a 2011 report by the UK Department for Business Innovation and Skills,<sup>137</sup>

People hear or read about science most often through traditional media, such as television (54%) and print newspapers (33%). A fifth (19%) say one of their two most regular sources of information is the internet, though very few (2%) use science blogs specifically as one of their most regular sources.<sup>138</sup>

The Inquiry acknowledged the public influence and significance of science reporting. It noted the improvements in science reporting, the majority of which, it said, was “responsible and accurate”.<sup>139</sup>

However, in submissions from various science organisations,<sup>140</sup> the Inquiry heard of the real-world impact of science reporting on public health choices, citing “press reporting on the MMR vaccination following the publication of a case study in the *Lancet* in 1998 as an example of how journalism that ... was [allegedly] both inaccurate and unbalanced led to a media generated health scare”,<sup>141</sup> and evidence was presented of the significant and dangerous decline in vaccine uptake in the immediate aftermath of general publication.<sup>142</sup> Not only does this sensationalist style drive readers away from such vital public health measures, but it drives them, by extension, to seek alternatives, where some practitioners are happy to reinforce this misconception.<sup>143</sup> As noted above, the reporting on these is no less problematic.

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<sup>137</sup> Department for Business Innovation and Skills, ‘Public Attitudes to Science 2011’ (2011) <[www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/32567/sri-pas-2011-main-report.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32567/sri-pas-2011-main-report.pdf)> accessed 24 June 2016.

<sup>138</sup> *ibid* 3.

<sup>139</sup> Lord Justice Leveson (n 121) 688-689, para 9.57.

<sup>140</sup> *ibid* 490-491, para 3.29. Submissions were provided by Sense about Science, The Wellcome Trust, Science Media Centre, and Cardiff University Brain Imaging Centre, among others.

<sup>141</sup> *ibid*.

<sup>142</sup> *ibid*. In the submission from the Science Media Centre, Fiona Fox stated that “The potential of the media to influence and inform the public on science comes with a huge responsibility. When the media gets it wrong the impact is devastating and causes real harm to individuals and society. The furore over the measles, mumps and rubella (MMR) vaccine, which started in 1998 after a rogue doctor claimed a link between the vaccine and autism, is the best-known example of how poor media reporting can cause harm. Vaccination rates before the story stood at about 92% but dropped down to 80% after the scare, and it has taken close to 15 years to get over the damage. Cases of measles in England and Wales rose from 56 in 1998 to 1,370 in 2008”. See Fiona Fox, ‘Evidence from the Science Media Centre to the Leveson Inquiry’ (5 December 2011) 1 <[www.sciencemediacentre.org/wp-content/uploads/2012/09/Science-Media-Centre-Written-Evidence-to-the-Leveson-Inquiry.pdf](http://www.sciencemediacentre.org/wp-content/uploads/2012/09/Science-Media-Centre-Written-Evidence-to-the-Leveson-Inquiry.pdf)> accessed 23 June 2016.

<sup>143</sup> Edzard Ernst, ‘Rise in popularity of complementary and alternative medicine: Reasons and consequences for vaccination’ (2001) 20(Suppl 1) *Vaccine* S90, “much of the motivation to turn to CAM pertains to a deeply felt criticism of mainstream medicine - many people (are led to) believe that conventional interventions, including immunisation, are associated with the potential to do more harm than good. Thus, it is hardly surprising that CAM also lends support to the “anti-vaccination movement”. In particular, sections of the chiropractors, the (non-medically trained) homoeopaths and naturopaths tend to advise their clients against immunisation...The negative attitude of some providers of CAM towards immunisation constitutes an important example of indirect risks associated with this form of healthcare”.

(b) *Balance*

The Inquiry emphasised repeatedly the need for balanced science reporting, noting that it was particularly important “as the press is considered a reliable and responsible source of information”.<sup>144</sup> Without this reputation, it said, the need would not be as pressing. Significantly, the report briefly addressed the concept of balance and false equivalence in science reporting, differentiating between treating both sides of a debate as being equal, on the one hand, and ensuring that the appropriate weight be applied to each side in accordance with the evidence in support of it, on the other,<sup>145</sup> finding that the latter was the appropriate practice. Failure to do so, it stated, could “have a widespread and harmful impact”.<sup>146</sup>

In evidence submitted to the Inquiry, the Association of Medical Research Charities, Cancer Research UK, and the Wellcome Trust summarised the issue thus:

The media often has a tendency to pursue balance in its stories, by countering one claim with another, and allowing alternative viewpoints a right of reply. This is perfectly proper in, for example, political reporting. Yet in science, the practice can often lead to distortions of its own. In science, it is often the case that a mainstream opinion about the interpretation of known data is shared overwhelmingly by professionals in that field, for example with the safety of the MMR vaccine or the link between greenhouse gases and global warming... When this is the case, the effect of balancing opinion to stoke debate can be to create a misleading impression that dissent from the mainstream view is more widespread and serious than it actually is. Readers of many newspapers, for example, would have formed an incorrect view that a significant proportion of doctors and scientists believed MMR to be harmful, and took decisions about vaccinating their children accordingly.<sup>147</sup>

As noted in Chapter 2, this is a particular problem in the treatment of CAM by the media, where ostensible fairness and open-mindedness are prioritised (as liberal, pseudo-progressive values),<sup>148</sup> while fact and reason lose out.

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<sup>144</sup> Lord Justice Leveson (n 121) 491, para 3.31.

<sup>145</sup> *ibid.*

<sup>146</sup> *ibid.*

<sup>147</sup> *ibid* 689-690, para 9.60. See also Wellcome Trust, ‘Leveson inquiry: Culture, practice and ethics of the press: Response by the Association of Medical Research Charities, Cancer Research UK and the Wellcome Trust’ (2012), paras 12-13 <<https://wellcome.ac.uk/sites/default/files/wtvm054159.pdf>> accessed 27 June 2016.

<sup>148</sup> Association SCA, *The Smith Alumnae Quarterly* (Alumnae Association of Smith College 1938) 153, “Let us keep our minds open, by all means, as long as that means keeping our sense of perspective and seeking an understanding of the forces which mould the world. But don’t keep your minds so open that your brains fall out! There are still things in this world which are true and things which are false; acts which are right and acts which are wrong, even if there are statesmen who hide their designs under the cloak of high-sounding phrases”.

The Inquiry acknowledged the inherent difficulties for journalists in reporting accurately, where the research in question is performed by a prominent academic, and published in a respected medical journal.<sup>149</sup> It would be patently unfair, in such circumstances, to expect the press to accept all responsibility for the adverse consequences of publishing. However, in the case of the MMR vaccine, the evidence submitted to the Inquiry found that the press must share responsibility, “primarily because a single doctor’s research, based on a small case study, which conflicted with all other research in the field and conflicted with the great majority of medical opinion, was unjustifiably given front page prominence”.<sup>150</sup>

Evidence was also submitted on the issue of reporting on ‘miracle cures’ and the raising of false hopes by journalists.<sup>151</sup> Again, the Association of Medical Research Charities, Cancer Research UK, and the Wellcome Trust found that “[t]his can lead patients to spend life savings on treatments that are most unlikely to work, or on occasion to eschew the most effective known therapies in favour of alternatives that are untested or disproved”.<sup>152</sup> Reports on the Burzynski treatment, discussed above, provide an excellent example of this type of journalism, and one which is both Irish and contemporary.

Helpfully, the Inquiry concluded on the issue of the treatment of science by the press, by referring to a list of guidelines created by the Science Media Centre, which are reproduced below.

The Science Media Centre calls on the Leveson Inquiry to consider the following recommendations: -

1. New guidelines for the reporting of science – these guidelines would be drawn up by science journalists and used primarily by news editors and general reporters. They could also be used by a newly strengthened PCC [in an Irish context, the Press Council of Ireland] to help adjudicate on complaints;
2. Encourage newspapers to appoint at least one news editor and sub editor with a background in science reporting;
3. Encourage newspapers to ensure that all science stories are checked by specialist science reporters and that news editors defer to their specialists' judgment on the quality or otherwise of science stories;
4. Headlines on important public health stories should be agreed by the relevant science reporter;
5. Basic science training should be offered as a matter of course as part of the overall training of journalists;

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<sup>149</sup> Lord Justice Leveson (n 121) 689, para 9.58.

<sup>150</sup> *ibid.*

<sup>151</sup> *ibid* 692 [9.72].

<sup>152</sup> *ibid.*



6. Scientists and organisations representing them who have been misrepresented should have a right to reply;
7. Corrections of serious inaccuracies should be as prominent as the original story, including in how they are promoted (e.g. via social media);
8. The PCC must immediately change the rule that states that only an individual scientist can complain about an inaccurate story. The scientific community must be able to make complaints about inaccurate articles which damage the public interest.<sup>153</sup>

These guidelines, if adopted in Ireland, could act to attenuate the potential for harm arising from reports on health issues and on CAM in particular, where such reports are likely to impact on healthcare decision-making. They would not unduly restrict freedom of expression for the press, but would merely seek to protect public health and welfare by improving the quality of science journalism overall. The adoption of these pre-existing guidelines is administratively expedient, as well as being particularly fitting to one of the core themes of this thesis - making use of what is already available.

#### 4.4 EXPRESSION THROUGH BROADCAST MEDIA

The Broadcasting Authority of Ireland, established under s 6(1) of the Broadcasting Act 2009, regulates broadcasting in Ireland, including, *inter alia*, monitoring and enforcing complaints and compliance with broadcasting codes.<sup>154</sup> The establishment of such codes are provided for under ss 23(1) and 42 of the Act. Of the documents created as part of the BAI Code, two are of particular relevance in considering the protection of public health: (a) the Code of Fairness, Objectivity and Impartiality on News and Current Affairs; and (b) the Code of Programme Standards.

##### (a) *The Code of Fairness, Objectivity and Impartiality on News and Current Affairs*

This Code introduces four principles: Fairness; Objectivity & Impartiality; Accuracy & Responsiveness; and Transparency & Accountability, with rules applicable under each. Healthcare is a stalwart of current affairs and, as such, falls within the remit of the Code.

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<sup>153</sup> Fiona Fox (n 142) 9.

<sup>154</sup> See also Directive 2010/13/EC of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) [2010] OJ L95/1. This Directive is a codification of Council Directive 89/552/EC of the European Parliament and of the Council of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services [1989] OJ L298/23, as amended.

Under the rules of the Fairness principle, broadcasters must ensure that both news<sup>155</sup> and current affairs<sup>156</sup> content, which is, by its nature, factual, is provided in a way that is objective and impartial, without any expression of the broadcaster's own views, and with an even-handed approach to questioning and interviewing.<sup>157</sup> Individuals, either the subject of news or who are contributors, must be treated fairly and honestly.<sup>158</sup> However, "[t]he principle of fairness does not necessarily require that all possible opinions on a subject are addressed or that they should receive equal air-time".<sup>159</sup> Instead, the principle demands that the approach to broadcasting be guided by ensuring "equitable, proportionate coverage".<sup>160</sup>

The principle of Objectivity and Impartiality requires that news and current affairs content be presented with "due accuracy, having regard to the circumstances and the facts known at the time of preparing and broadcasting the content",<sup>161</sup> and that "[v]iews and facts shall not be misrepresented or presented in such a way as to render them misleading".<sup>162</sup>

In theory, the first and second principles allow broadcasters to avoid the problem of false equivalence, enabling them to afford time and emphasis according to best available evidence on the facts. In reality, however:

- (i) Where a significant or vocal group of viewers is unhappy with the lack of apparent respect or equality of representation for their honestly held beliefs, it may be easier to simply concede, and to afford equal time from the planning stage for future programming, regardless of the best available evidence;
- (ii) Editorial decision-making is also subject to human bias, however minor and no matter how adamantly it is denied, and this may inadvertently skew the direction or weighting of coverage;
- (iii) Broadcasters, in their role as an 'organ of public opinion', have a duty to probe and, where necessary, to challenge the behaviour and policies of the

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<sup>155</sup> Broadcasting Act 2009, s 39(1)(a).

<sup>156</sup> *ibid* s 39(1)(b).

<sup>157</sup> Broadcasting Authority of Ireland, 'Code of Fairness, Objectivity and Impartiality in News and Current Affairs' (2013) 5 <[www.bai.ie/en/download/129469/](http://www.bai.ie/en/download/129469/)> accessed 27 June 2016.

<sup>158</sup> *ibid* 9, r 3.

<sup>159</sup> *ibid* 5.

<sup>160</sup> *ibid* 6. For a recent example of false equivalence in action, see Roy Greenslade, 'Scientist complains to BBC about being misled over Radio 4 interview' *The Guardian* (30 June 2016) <[www.theguardian.com/media/greenslade/2016/jun/30/scientist-complains-to-bbc-about-being-misled-over-radio-4-interview](http://www.theguardian.com/media/greenslade/2016/jun/30/scientist-complains-to-bbc-about-being-misled-over-radio-4-interview)> accessed 1 July 2016.

<sup>161</sup> *ibid* 11, r 17.

<sup>162</sup> *ibid* 11, r 19.

political establishment, and this must extend to healthcare, it being intrinsic and indispensable to the wellbeing and prosperity of the State.

Therefore, broadcasters must decide if this duty extends only to discussion of differing opinions within the conventional medical paradigm, or whether it should also include discussion of complementary or alternative therapies, and what weight or emphasis is placed on each aspect of the discussion.<sup>163</sup> This should vary according to the context. Where, for example, winter programming includes a discussion on home treatment for coughs and colds, references to available CAM therapies present a lower risk of physical harm than they would during a discussion on treatments for cancer.<sup>164</sup> In other words, despite the existing guidance provided by the Code and the 2009 Act, news and current affairs programming concerning matters of health requires closer scrutiny to ensure appropriate balance and broadcasting that reflects the broad scope of therapies available to consumers,<sup>165</sup> while communicating the best available evidence at the time of development and broadcast, regardless of whether this favours the hegemony or its alternative. As communicators of fact, accuracy is a most important objective for those involved in creating and delivering news and current affairs content, and this is reinforced by the principle of Accuracy and Responsiveness.<sup>166</sup>

To ensure that audiences receive, and can trust, that the news and current affairs content they access from broadcast media,<sup>167</sup> the approach taken by broadcasters must be founded in fact. While multifaceted discussions on issues of health are both necessary and desirable in the public interest, broadcasters must remain cognisant of the evidence supporting the assertions made on all sides, and for which it is most compelling. In this way, the potential for harm to viewers may be minimised, while freedom of expression is vindicated.

#### (b) *Code of Programme Standards*

The BAI Code of Programme Standards provides detailed provisions which aim, *inter alia*, to promote responsible broadcasting, to acknowledge and cater to the diversity of

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<sup>163</sup> *ibid* 12, r 22. See generally, Aristotle, Ernest Barker and RF Stalley (eds), *The Politics* (OUP Oxford 1998) ch III, 1282b14, “those who are equal must have assigned to them equal things”. Where two parties to a discussion are unequal in the evidence in support of their assertions, it would be unjust to treat them as being equal.

<sup>164</sup> However, the potential for breaches of consumer protection, leading to financial harm, are the same. Where a decision is made to include content on a particular CAM therapy or therapies, weighting based on best evidence should still apply.

<sup>165</sup> Broadcasting Authority of Ireland (n 157) 12, r 22.

<sup>166</sup> *ibid* 6.

<sup>167</sup> *ibid*.

contemporary Irish taste, and to provide guidance for audiences and broadcasters on what is to be expected from broadcasting services.<sup>168</sup> This Code takes a broad perspective on programming, and places particular emphasis on protecting viewers from harm. Principles 2 (Importance of Context), 3 (Protection from Harm), and 6 (Protection of the Public Interest) are of particular relevance.

The Code itself begins by distinguishing between offence and harm. Viewers, it states, do not have a right not to be offended. The subjectivity of offensiveness would render broadcasting unsustainable, were broadcasters obligated to avoid offending anyone, at any time. This would also be a hindrance to free speech and would interfere with the function of the broadcaster as an organ of public opinion. However, viewers do have a right not to be harmed by broadcast content,<sup>169</sup> and should be given the necessary information to make an informed choice in respect of whether to view particular content.<sup>170</sup> Principle 3 notes that “Some viewers and listeners may require protection from content that purports to be one thing when it is another, for example, something seemingly factual that is actually fictional or controversial”. The potential inability of a viewer to discern between what is and is not established fact ought not limit the content created by the broadcaster, but ought to be a consideration during planning. The context and tone in which the content is delivered may assist the viewer in their discernment.<sup>171</sup> This is important in addressing issues of health care. For example, in an episode of RTE’s Documentary on One, entitled ‘The Cure at Hand’,<sup>172</sup> various patrons of a faith healer provided accounts of their positive experiences of treatment for epilepsy, cancer and haemorrhage, among other conditions. The documentary, which was, by its nature, factual, predominantly provided positive anecdotal evidence of the popularity and effectiveness of faith healing, with little by way of discussion of the existing evidence in favour of the efficacy of such a therapy<sup>173</sup> or of the risk of future attendees opting to place complete faith in the healer and in nothing else.<sup>174</sup> While attendees were not told

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<sup>168</sup> Broadcasting Authority of Ireland, ‘BAI Code of Programme Standards (2015) 9

<[www.bai.ie/en/download/128555/](http://www.bai.ie/en/download/128555/)> accessed 27 June 2016.

<sup>169</sup> *ibid* 9, “Harmful material is material that has an ‘effect’ - content that causes mental, psychological or physical harm”.

<sup>170</sup> *ibid* Principle 3.

<sup>171</sup> *ibid*.

<sup>172</sup> RTE, ‘Documentary on One – The Cure at Hand’ Broadcast 6 July 2013 at 2pm

<[www.rte.ie/radio1/doconone/2013/0627/647454-documentary-podcast-faith-healer-belief-cures-prayer/](http://www.rte.ie/radio1/doconone/2013/0627/647454-documentary-podcast-faith-healer-belief-cures-prayer/)> accessed 16 October 2016.

<sup>173</sup> Leanne Roberts and others, ‘Intercessory prayer for the alleviation of ill health’ (2009) Cochrane Database of Systematic Reviews CD000368, “These findings are equivocal and, although some of the results of individual studies suggest a positive effect of intercessory prayer, the majority do not and the evidence does not support a recommendation either in favour or against the use of intercessory prayer. We are not convinced that further trials of this intervention should be undertaken and would prefer to see any resources available for such a trial used to investigate other questions in health care”. See also, David R Hodge, ‘A systematic review of the empirical literature on intercessory prayer’ (2007) 17 *Research on Social Work Practice* 174.

<sup>174</sup> William F Simpson, ‘Comparative longevity in a college cohort of Christian Scientists’ (1989) 262 *Journal of the American Medical Association* 1657

to stop conventional treatment, the documentary nonetheless contained an interview with a woman who stated that she suffered from epilepsy but, having attended the healer in question, considered herself cured, discontinuing all conventional medication, despite medical advice to the contrary, without exception and without negative consequences. Audience members motivated to take the same approach may not be so lucky, according to the available evidence, which is equivocal. This lack of balance creates unnecessary risk and flies in the face of Principle 3 of the BAI Code.

Finally, Principle 6 acknowledges that the “public interest can also be adversely affected by the omission of material and/or the inadequate representation of information or viewpoints”,<sup>175</sup> and that broadcasters may, in the public interest, broadcast content that, *inter alia*:

- a) protects public health and safety;
- b) exposes false or misleading claims made by individuals or organisations; discloses incompetence of individuals or organisations that affect the public;
- c) exposes breaking of the law;
- d) encourages and facilitates debate and understanding of social and political topics; or
- e) informs the public, or raises a debate, on matters of public interest.<sup>176</sup>

In addition to the obligations created by the other Principles to protect viewers from harm, Principle 6 may be interpreted as placing a positive onus on broadcasters to produce content which will inform the public on matters affecting them.

Broadcasters are obligated by the broadcasting codes to consider the impact and reach of their programming and to ensure that the public are not misled as to the weight of evidence underlying views put forward by the various sides in a debate or discussion. This is of particular importance in the context of healthcare and matters of science. The creation of guidelines, similar to those recommended by the Science Media Centre in the UK, or, indeed, the use of those guidelines, would help to support programming presenting a wide range of views, while minimising false equivalence and the potential from harm arising from it.

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<sup>175</sup> Broadcasting Authority of Ireland (n 168) Principle 3.

<sup>176</sup> *ibid.*

## 4.5 EXPRESSION THROUGH FILM

Films are subject to censorship under the Censorship of Films Acts 1923 to 1992, as amended. The office of Official Censor of Films, now known as the Irish Film Classification Office (IFCO),<sup>177</sup> was created by s 1(1) of the Censorship of Films Act 1923. Section 7(2) of the Act states

...the Official Censor shall certify the picture unless he is of the opinion that such picture or some part thereof is unfit for general exhibition in public by reason of its being indecent, obscene or blasphemous or because the exhibition thereof in public would tend to inculcate principles contrary to public morality or would be otherwise subversive of public morality.

While IFCO takes a relatively flexible approach based on contemporary social values,<sup>178</sup> classifying films (including film, video and DVD),<sup>179</sup> by providing an age rating based on their theme, the language used, the level of violent and sexual content and any treatment of drug use depicted,<sup>180</sup> it remains clear that the protection of public morality trumps other concerns. The dynamic confines of what is considered by regulators to be immoral makes no impact on disseminators by film of information on matters of health, however inaccurate or unproven.

Notwithstanding the lack of power on the part of the IFCO to limit such films, there is at least one recent example of public sentiment affecting the promotion of a film deemed to bear harmful information on a matter of public health.

### 4.5.1 VAXXED - FROM COVER-UP TO CATASTROPHE

Film censorship rarely provides a source for discussion relevant to this thesis. However, in March 2016, the Tribeca Film Festival announced the premier showing of a film entitled “Vaxxed – From Cover-Up to Catastrophe”. The film, directed by Dr Andrew Wakefield, whose research paper, published in, and subsequently retracted by, *The Lancet*,<sup>181</sup> precipitated a global MMR scare and the rise of anti-vaccination movement, addresses the topic of vaccination and, more specifically, the work of Dr Wakefield

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<sup>177</sup> Civil Law (Miscellaneous Provisions) Act 2008, s 71(1).

<sup>178</sup> Irish Film Classification Office, ‘Guidelines’, “The role of IFCO was established under the Censorship of Films Act, 1923 and expanded upon in the Video Recordings Act, 1989. This legislation is framed so as to allow IFCO reflect the prevailing social values of the day”  
<[www.ifco.ie/website/IFCO/ifcoweb.nsf/web/classcatintro?opendocument&type=graphic](http://www.ifco.ie/website/IFCO/ifcoweb.nsf/web/classcatintro?opendocument&type=graphic)> accessed 29 June 2016.

<sup>179</sup> IFCO may also prohibit a video game under s 3(1) of the Video Recordings Act 1989, if it considers that it is unfit for viewing.

<sup>180</sup> For example, see Irish Film Classification Office, ‘16 Certificate – Guidelines’  
<[www.ifco.ie/website/IFCO/ifcoweb.nsf/web/16guidelines?OpenDocument&type=graphic](http://www.ifco.ie/website/IFCO/ifcoweb.nsf/web/16guidelines?OpenDocument&type=graphic)>

<sup>181</sup> Andrew J Wakefield and others (n 12).

himself. The film claims to expose corruption, including the destruction of documents relating to vaccination, on the part of the US Centre for Disease Control (CDC), and resurrects, once again, the discredited MMR-autism link.

Shortly after the announcement of its inclusion in the Tribeca Film Festival, and in the wake of an outcry by scientists, healthcare professionals, members of the public and the media itself, the film was removed from the listing, albeit with clear reluctance on the part of some organisers.<sup>182</sup> The film-makers, too, were predictably unhappy with the decision, claiming that it constituted an undue interference with freedom of speech.<sup>183</sup> Despite this, the victory for public health was not particularly significant. Although the decision not to screen the film at this private festival prevented the film-makers from gaining publicity from the discussion panels and reviewers which invariably accompany such screenings, it generated a tremendous amount of publicity by virtue of the controversy,<sup>184</sup> bolstering the image of the film-makers and their supporters as downtrodden advocates for real healthcare, and playing into the hands of those who claim conspiracy on the part of the medical establishment. As one commentator noted, “the opportunity to create a substantial critical context for it within the context of the Festival is lost”.<sup>185</sup> The film has since seen selective public release, demonstrating the very limited effect that its removal from Tribeca truly had. It will, however, undoubtedly be made available to a much wider audience through internet sites such as YouTube, and this is of greater, if redundant, concern.

#### 4.6 EXPRESSION ON THE INTERNET

There are, in Ireland, few restrictions placed upon internet content. Freedom of expression is treated as paramount, albeit subject to a number of general limitations pertaining to, for

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<sup>182</sup> Alan Yuhas, ‘Robert De Niro pulls anti-vaccination film from Tribeca film festival’ *The Guardian* (March 2016) <[www.theguardian.com/film/2016/mar/27/robert-de-niro-pulls-vaccination-film-tribeca-vaxxed](http://www.theguardian.com/film/2016/mar/27/robert-de-niro-pulls-vaccination-film-tribeca-vaxxed)> accessed 26 June 2016. See also Steven Zeitchik, ‘Robert De Niro reverses course, yanks anti-vaccine film from Tribeca lineup’ *The LA Times* (26 March 2016) <[www.latimes.com/entertainment/movies/moviesnow/la-et-mn-robert-de-niro-tribeca-andrew-wakefield-movie-cancels-20160326-story.html](http://www.latimes.com/entertainment/movies/moviesnow/la-et-mn-robert-de-niro-tribeca-andrew-wakefield-movie-cancels-20160326-story.html)> accessed 26 June 2016, and Donald Clarke, ‘Robert De Niro vexed by ‘Vaxxed’ *The Irish Times* (9 April 2016) <[www.irishtimes.com/culture/tv-radio-web/robert-de-niro-vexed-by-vaxxed-1.2612104](http://www.irishtimes.com/culture/tv-radio-web/robert-de-niro-vexed-by-vaxxed-1.2612104)> accessed 26 June 2016.

<sup>183</sup> Nigel Smith, ‘Director of controversial Vaxxed film calls Tribeca snub a free speech issue’ *The Guardian* (31 March 2016) <[www.theguardian.com/film/2016/mar/30/vaxxed-andrew-wakefield-tribeca-robert-de-niro-free-speech](http://www.theguardian.com/film/2016/mar/30/vaxxed-andrew-wakefield-tribeca-robert-de-niro-free-speech)> accessed 26 June 2016.

<sup>184</sup> Michael O’Sullivan, ‘Vaxxed: From Cover-Up to Catastrophe’: Closer to horror film than documentary’ *The Washington Post* (19 May 2016) <[www.washingtonpost.com/goingoutguide/movies/vaxxed-from-cover-up-to-catastrophe-closer-to-horror-film-than-documentary/2016/05/19/7129aaf4-1c5d-11e6-8c7b-6931e66333e7\\_story.html](http://www.washingtonpost.com/goingoutguide/movies/vaxxed-from-cover-up-to-catastrophe-closer-to-horror-film-than-documentary/2016/05/19/7129aaf4-1c5d-11e6-8c7b-6931e66333e7_story.html)> accessed 28 June 2016.

<sup>185</sup> Svetlana Mintcheva, ‘The case against nixing Vaxxed’ (2016) <<http://ncac.org/blog/the-case-against-nixing-vaxxed>> accessed 29 June 2016.

example, harassment,<sup>186</sup> incitement to hatred,<sup>187</sup> the publication or re-publication of defamatory statements,<sup>188</sup> infringement of intellectual property rights,<sup>189</sup> or the deliberate access, download, production or distribution of child pornographic material.<sup>190</sup> Debate or commentary on medical issues and health products or services, particularly where not in the promotion of a product or service for commercial purposes,<sup>191</sup> goes virtually ungoverned, under the guise of resource limitations, the protection on free expression, or a lack of external impetus. Internet service providers have a number of specific responsibilities in respect of disclosure where illegal activity has taken place,<sup>192</sup> but, as the gateway to the internet for individual users, compulsion to limit access to legal content should be non-existent. Instead, there is potential for individual websites, in their terms of service or community guidelines, to create and enforce a policy specific to health content, requiring, for example, that content providers refrain from making claims that are unsubstantiated and may lead to harm if relied upon. This may create difficulties depending on the platform,<sup>193</sup> it may be difficult or even impossible to enforce if the platform attracts heavy traffic, and it may prove unpopular where users have become accustomed to freely expressing their views. Nonetheless, with a policy in place, sites would, at a minimum, have the discretion to restrict content, where it is deemed to carry a particular risk of harm for users, howsoever this was determined.

#### 4.6.1 SITE-SPECIFIC TERMS OF USE

Many sites publish terms of use that incorporate aspects of user protection. YouTube is an extremely popular video-sharing service, owned by Google.<sup>194</sup> Users upload content, which is made available to, and searchable by, the public. This includes content

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<sup>186</sup> Non-Fatal Offences Against the Person Act 1997, s 10.

<sup>187</sup> Prohibition of Incitement to Hatred Act 1989, s 4(1).

<sup>188</sup> Defamation Act 2009, s 6(2).

<sup>189</sup> For example, Patents Acts 1992-2006, Trademarks Act 1996 and Copyright and Related Rights Acts 2000-2007.

<sup>190</sup> Child Trafficking and Pornography Act 1998, s 5(1).

<sup>191</sup> Even where products or services are promoted for commercial purposes, there is little by way of effective measures to enforce removal. The Advertising Standards Agency of Ireland (ASAI) is a voluntary regulator with limited means of enforcement.

<sup>192</sup> In *Sony Music Entertainment (Ireland) Limited v UPC Communications Ireland Limited (No 1)* [2015] IEHC 317 [232], Cregan J considered the potential application of a *Norwich Pharmacal* order to compel disclosure of details of subscribers by ISPs to rights-holders. See *Norwich Pharmacal v Customs and Excise* [1974] AC 133, 175, “If through no fault of his own a person gets mixed up in the tortious acts of others so as to facilitate their wrongdoing, he may incur no personal liability but he comes under a duty to assist the person who has been wronged by giving him full information and disclosing the identity of the wrongdoers”.

<sup>193</sup> For example, Twitter restricts tweets to 140 characters, limiting the opportunity to provide balance and detail. However, it is arguable that, as such, Twitter is unsuitable as a medium for complex discussions of healthcare.

<sup>194</sup> YouTube is used here as a site with established and comprehensive terms of service, together with the resources necessary for monitoring, flagging, and enforcement. Nonetheless, it provides an example of the deficiencies apparent, even in an optimised system. Clearly, most websites do not or cannot provide the same level of protections for users.



covering topics ranging from the so-called HIV/AIDS hoax,<sup>195</sup> and the cancer conspiracy,<sup>196</sup> to the evils of ‘Big Pharma’,<sup>197</sup> and how psychiatry is “an industry of death”.<sup>198</sup> These are freely and instantly accessible on YouTube, often have excellent production values, typically feature confident, assured medical professionals, industry experts, and bereft family members, combined with horrific, graphically re-enacted accounts of human suffering at the hands of various subsections of conventional medicine. This content is acceptable under YouTube’s Terms of Service<sup>199</sup> and under its Community Guidelines,<sup>200</sup> which, although it appears to prohibit the use of “content that intends to incite violence or encourage dangerous or illegal activities that have an inherent risk of serious physical harm or death”,<sup>201</sup> accedes to the uploading of such content “if the primary purpose is educational, documentary, scientific or artistic (EDSA), and it isn’t gratuitously graphic”.<sup>202</sup> Uploaders, then, have significant scope for making inaccurate claims and directly or indirectly providing dangerous advice, with the onus placed on viewers, some of whom may be ill or vulnerable, to discern between fact and undoubtedly compelling fiction. This is made clear by section 7.9 of the YouTube Terms of Service, which states:

You further understand and acknowledge that in using the Service, you may be exposed to Content that is factually inaccurate, offensive, indecent, or otherwise objectionable to you. You agree to waive, and hereby do wave, any legal or equitable right or remedies you have or may have against YouTube with respect to any such Content.<sup>203</sup>

This is as much a matter of practicality as one of free expression. YouTube and similar sites rely heavily on reports from users to alert them to a potential problem with

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<sup>195</sup> Stephen Allen, ‘HIV=Aids – Fact or Fraud?’ (1996)

<[www.youtube.com/watch?v=JTxvmKHYajQ&list=PL9129996C4B990236](http://www.youtube.com/watch?v=JTxvmKHYajQ&list=PL9129996C4B990236)> accessed 16 June 2016.

<sup>196</sup> ‘Documentary - The Cancer Conspiracy’ <[www.youtube.com/watch?v=Tx7W662gd8M](http://www.youtube.com/watch?v=Tx7W662gd8M)> accessed 16 June 2016.

<sup>197</sup> Media Education Foundation, ‘Big Bucks Big Pharma: Marketing Disease and Pushing Drugs’ (2006) <[www.youtube.com/watch?v=c7ke4RT9aAY](http://www.youtube.com/watch?v=c7ke4RT9aAY)> accessed 29 June 2016.

<sup>198</sup> Citizen’s Commission on Human Rights (CCHR), ‘Psychiatry – An Industry of Death’ <[www.youtube.com/watch?v=TE36wS\\_HIVQ](http://www.youtube.com/watch?v=TE36wS_HIVQ)> accessed 26 June 2016. See Citizen’s Commission on Human Rights, ‘What is the Citizen’s Commission on Human Rights?’, “The Citizens Commission on Human Rights (CCHR) is a nonprofit mental health watchdog, responsible for helping to enact more than 150 laws protecting individuals from abusive or coercive practices ... The CCHR was co-founded in 1969 by the Church of Scientology and Professor of Psychiatry Emeritus Dr. Thomas Szasz” <[www.cchr.org/about-us/what-is-cchr.html](http://www.cchr.org/about-us/what-is-cchr.html)> accessed 26 June 2016.

<sup>199</sup> YouTube, ‘Terms of Service’ <[www.youtube.com/static?gl=IE&template=terms](http://www.youtube.com/static?gl=IE&template=terms)> accessed 29 June 2016.

<sup>200</sup> YouTube, ‘Community Guidelines’

<[www.youtube.com/yt/policyandsafety/communityguidelines.html](http://www.youtube.com/yt/policyandsafety/communityguidelines.html)> accessed 29 June 2016.

<sup>201</sup> YouTube, ‘Community Guidelines – Harmful or Dangerous Content’

<<https://support.google.com/youtube/answer/2801964>> accessed 29 June 2016.

<sup>202</sup> *ibid.*

<sup>203</sup> YouTube, ‘Terms of Service’ (2010) <[www.youtube.com/t/terms](http://www.youtube.com/t/terms)> accessed 10 June 2016.

content.<sup>204</sup> This does not always happen immediately upon upload, and it may not happen at all. The sheer number of uploads<sup>205</sup> on that and other sites renders instant detection of problematic content virtually impossible, despite the range and calibre of the technology available for this purpose.

Twitter, a well-known micro-blogging site, similarly disclaims liability for content posted by users,<sup>206</sup> and states that it “may not monitor or control the Content posted via the Services”.<sup>207</sup> The television presenter and DJ, Noel Edmonds, has provided a timely example of the potential issues arising from this lack of oversight and from the lack of any means of intervention on matters of health. At the time of writing, a tweet by Edmonds promoting an electromagnetic pulse device has received criticism, after he claimed that it “slows ageing, reduces pain, lifts depression and stress and tackles cancer. Yep, tackles cancer!”.<sup>208</sup> If this were considered to be an advertisement,<sup>209</sup> it would be in contravention of s 4(1)(a) of the UK Cancer Act 1939<sup>210</sup> and of consumer law generally.<sup>211</sup> In addition, such a post would require prior approval from Twitter under their advertising policy.<sup>212</sup> However, the UK Advertising Standards Authority has determined that the tweet does not fall within their remit,<sup>213</sup> and so, as non-commercial content, Edmonds’ post attracts greater protection, notwithstanding that the effect on

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<sup>204</sup> BBC Newsbeat, ‘YouTube launches scheme to offer rewards to users who report videos’ (2016), “the website has relied on users to report inappropriate content amongst this for many years” <[www.bbc.co.uk/newsbeat/article/37439673/youtube-launches-scheme-to-offer-rewards-to-users-who-report-videos](http://www.bbc.co.uk/newsbeat/article/37439673/youtube-launches-scheme-to-offer-rewards-to-users-who-report-videos)> accessed 6 October 2016.

<sup>205</sup> BBC Newsbeat, ‘YouTube launches scheme to offer rewards to users who report videos’ (2016), “400 hours of video are uploaded to YouTube every minute” <[www.bbc.co.uk/newsbeat/article/37439673/youtube-launches-scheme-to-offer-rewards-to-users-who-report-videos](http://www.bbc.co.uk/newsbeat/article/37439673/youtube-launches-scheme-to-offer-rewards-to-users-who-report-videos)> accessed 6 October 2016.

<sup>206</sup> Twitter, ‘Twitter Terms of Service’ (2016) 4, 11 <<https://twitter.com/tos?lang=en>> accessed 28 June 2016.

<sup>207</sup> *ibid.*

<sup>208</sup> Ian Sample, ‘Noel Edmonds in Twitter row after claims that electronic box ‘tackles cancer’ *The Guardian* (7 June 2016) <[www.theguardian.com/science/2016/jun/07/noel-edmonds-in-twitter-row-after-claims-that-electronic-box-tackles-cancer?CMP=share\\_btn\\_tw](http://www.theguardian.com/science/2016/jun/07/noel-edmonds-in-twitter-row-after-claims-that-electronic-box-tackles-cancer?CMP=share_btn_tw)> accessed 7 June 2016.

<sup>209</sup> UK Cancer Act 1939, s 4(8), “In this section, the expression “advertisement” includes any notice, circular, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting sounds”.

<sup>210</sup> *ibid* s 4(1)(a), “No person shall take any part in the publication of any advertisement— (a) containing an offer to treat any person for cancer, or to prescribe any remedy therefor, or to give any advice in connection with the treatment thereof”.

<sup>211</sup> For example, the UK Consumer Rights Act, ss 9-11.

<sup>212</sup> Twitter Policies and Reporting, ‘Health and pharmaceutical products and services’ <<https://support.twitter.com/articles/20170441>> accessed 7 June 2016.

<sup>213</sup> ‘Noel Edmonds ‘cancer box’ claim dismissed by firm *BBC News* (8 June 2016) “The Advertising Standards Authority said it was aware of concerns about Mr Edmonds’s claims but after contacting the company was satisfied that no rules had been broken. A spokesman said: “They were not aware of and didn’t have control of the tweet and as such it’s not an ad for the purposes of our rules. We will, however, be reviewing marketing claims on EMP Pad’s own website to ensure they are sticking to the strict medical devices advertising rules that are in place” <[www.bbc.com/news/uk-36470979](http://www.bbc.com/news/uk-36470979)> accessed 8 June 2016.

the consumer or user is the same (or potentially greater, considering that the power of personal testimony is so significant, as noted above).<sup>214</sup>

Ireland does not have a statutory equivalent of the UK Cancer Act. While s 55(1)(g) of the Consumer Protection Act 2007 prohibits the making of representations by a trader “that a product is able to cure an illness, dysfunction or malformation, if it cannot”,<sup>215</sup> this would not apply to the statement made by Edmonds, if he is not considered a trader.

YouTube’s Terms of Service and Community Guidelines prohibit only a narrow range of content, and this does not appear to include information which may create a health risk, either by encouraging patients, for example, to avoid or to cease conventional (and potentially lifesaving) medical treatment,<sup>216</sup> or by failing to mention the dangers associated with their alternative treatment. It seems unlikely that this will change to facilitate further restrictions, or that, on balance, such change would be desirable. However, this and other sites might consider retaining, through an addition to its terms, the discretion to flag content which poses a particular risk to users and requires substantiation.

#### 4.7 POTENTIAL IMPROVEMENTS

It is neither societally nor constitutionally desirable to place novel or expanded limitations on freedom of expression. Progress, particularly in the fields of health and science, requires openness, transparency, and the sharing of information. Ideally, the public (like the notional average consumer),<sup>217</sup> would be reasonably well-informed, reasonably observant and circumspect, and would possess the basic skills to critically appraise, even at a fundamental level, claims made by experts of all sorts, based on the quality and quantity of evidence supporting them. Ideally, this evidence would, in all circumstances, be made available to those who wished to do so. However, neither of these are the case. While the public remain uninformed on matters of health and science, they must rely, almost exclusively, on the organs

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<sup>214</sup> Peter A Ubel, Christopher Jepson and Jonathan Baron (n 38) 65, “written patient testimonials can significantly influence hypothetical treatment choices when presented in combination with statistical summary data on treatment effectiveness” and Sue Ziebland and Sally Wyke (n 38) 220, “The value of first-person accounts, the appeal and memorability of stories, and the need to make contact with peers all strongly suggest that reading and hearing others’ accounts of their own experiences of health and illness will remain a key feature of e-health”. For a discussion of the impact of personal testimony in CAM, see John Reizer, *Depression-Proofing Your Chiropractic Career* (n 38) 127, “There is probably no better way to convince prospects that your service is valuable than by the use of testimonials. If you are not currently utilizing this marketing tool in your office you should consider using testimonials from this day forward”.

<sup>215</sup> Consumer Protection Act 2007, s 55(1)(g).

<sup>216</sup> Appendix VIII. These charts demonstrate an overall increase in intervention in all three cancer treatment modalities) surgery, chemotherapy and a corresponding decrease in cases for which no treatment was given, from 2000 to 2009. These correlate overall with an increase five-year survival rate.

<sup>217</sup> Case C-210/96 *Gut Springenheide and Tusky* [1998] ECR I-4657, para 31.

of public opinion. Where there is no specific guidance available for those organs, or there is neither the will on the part of the relevant organs, nor the pressure from the public or political establishment to actively implement such guidelines, neither the continued public trust, nor their wellbeing, can be assured.

While the implementation of a code similar to that provided by the Science Media Centre would be most helpful in this respect for broadcasters and journalists, its application for books and film would be inappropriate. The lack of guidance in these two categories is unlikely to have such profound effects on behaviour, however, with most consumers reading or watching with some knowledge of the topic in question. This is not the case for material on television or in the press and, for this reason, greater care is needed to avoid creating a risk of harm.

The internet remains a highly fertile breeding ground for good and bad ideas, but limiting their negative impact is legally and socially complex. The measures required to effectively restrict potentially damaging health or science (or almost any other) content would be so draconian as to be impermissible under Irish constitutional and international law.<sup>218</sup> However, an all-or-nothing approach would be unnecessarily defeatist. Though it is neither a quick nor an easy (nor an inexpensive) solution, it is necessary to educate the public, beginning at a young age, in critical thinking<sup>219</sup> and basic scientific literacy. These skills will assist in the negotiation of information in all its forms. In the meantime, individual websites should be encouraged, rather than compelled, to review and update their terms of service, where available, to include a discretion to limit or remove potentially harmful content relating to health. Where terms of service are not available, site owners should simply be cognisant of the potential issues arising from such content.

Ideally, it would not be necessary to create hard restrictions on free expression. Rather, the public would dismiss dangerous or inaccurate assertions before allowing them to influence their behaviour.

With this somewhat-restrained approach to protecting public health from potentially harmful expression, which aims both to respect the fundamental nature of free expression and to improve upon the minimal protections already available, the potential for conflict is, if not eliminated, then limited. However, numerous individuals and groups in the CAM sector have attempted to restrict negative opinion and commentary in a manner that is both questionable and potentially harmful for public health, for scientific progress and for the fundamental

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<sup>218</sup> *Heaney v Ireland* (n 24) 607. This would constitute a failure to “impair the right as little as possible”.

<sup>219</sup> Richard Paul and Linda Elder, *Critical Thinking: Tools for Taking Charge of Your Professional and Personal Life* (Financial Times/Prentice Hall 2002) 316. Critical thinking is defined by the authors as “the art of thinking about your thinking while you are thinking in order to make your thinking better: more clear, more accurate, more defensible”.

principle of free expression, by the threat or issuing of defamation proceedings. It is to these that we now turn.

## PART II

### FREEDOM OF EXPRESSION AND THE RIGHT TO A GOOD NAME

*It can be argued that a ... general concern both with the value of freedom of expression and with the pursuit of truth would support the view that speech should only ever be restricted on a minimalist basis and never where what is published is true.*<sup>220</sup>

As noted above, a restriction is placed on freedom of expression by Article 40.3.2° of the Constitution, which provides that “The State shall, in particular, by its laws, protect as best it may from unjust attack (and, in the case of injustice done, vindicate) the life, person, good name and property rights of every citizen”. Similarly, noted above, Article 10(2) ECHR subjects this freedom to such restrictions “...as are necessary ... for the protection of health or morals” and “for the protection of the reputation or rights of others”.<sup>221</sup>

The balance between freedom of expression and the right to a good name has become a prominent issue in science and healthcare in the wake of a number of costly and high-profile defamation cases taken against journalists and commentators in the UK, prompting reform of the libel regime there. Each of the commentators in question had criticised particular CAM providers, proponents, practices, or organisations, in such a manner as to allegedly undermine their reputation. However, many of the cases were dropped before the defendants were afforded the opportunity to submit evidence justifying their statements. Despite the lack of a determination, and the award of costs against the plaintiffs in such cases, the defendants nonetheless suffered significant negative financial and personal impacts arising from the proceedings.<sup>222</sup>

This potential for unduly restricting freedom of expression is a serious concern for commentators on both sides of the conventional medicine/CAM divide. It is of even greater concern, however, for public health and for consumers, who will ultimately bear the brunt of restricted debate and the curtailment of relevant healthcare information. Where freedom of expression is used to protect the making of unsubstantiated claims in matters of health and science, existing consumer protection laws,

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<sup>220</sup> Neville Cox and Eoin McCullough, *Defamation: Law and Practice* (Clarus Press 2014), para 5.06.

<sup>221</sup> Reputation and the right to a good name is also protected under Art 8 of the ECHR, albeit cloaked in the language of the right to privacy, limiting its utility in the matters at hand.

<sup>222</sup> Sense About Science, ‘A Quick Guide to Libel Laws in England and Wales’, “Science journalist Ben Goldacre was sued for libel in 2007 along with the Guardian, over an article in which he criticised the activities of vitamin pill salesman Matthias Rath. Rath was promoting vitamin pills as a cure for AIDS in South Africa and denouncing conventional therapies as toxic and harmful. Although Rath eventually dropped his libel suit, the case cost the Guardian £535,000 to defend and lasted 19 months. Only £365,000 of this was ever recovered from Rath which meant that for Goldacre and The Guardian, the cost of winning was £170,000”

<[www.senseaboutscience.org/data/files/A\\_quick\\_guide\\_to\\_libel\\_laws\\_in\\_England\\_and\\_Wales.pdf](http://www.senseaboutscience.org/data/files/A_quick_guide_to_libel_laws_in_England_and_Wales.pdf)> accessed 26 June 2016. This type of litigation has been labelled “strategic lawsuit against public participation”, or SLAPP, and has given rise to the development in the US of anti-SLAPP statutes, which provide a means of challenging the merit of a plaintiff’s claim early in proceedings in order to avoid the drawn-out and financially ruinous situation set out above. See for example, the California Anti-SLAPP Law, Code of Civil Procedure, § 425.16.

set out in detail in Chapter 3, go unenforced, and criticism is stifled with both the threat and the issuing of prohibitively costly legal proceedings, making it inevitable that the balance so desperately needed in such matters will be skewed.

It is argued that reputation is unduly protected to the detriment of freedom of expression, negatively impacting upon public health, despite the fact that the protection of such is a legitimate aim in both the ECHR and the ICCPR. Finding a balance whereby both reputation and public health are sufficiently protected requires fresh consideration of the rights in question.

## 5. DEFINING DEFAMATION

Defamation, a tort of strict liability, is defined in s 6(2) of the Defamation Act 2009 (hereafter “the 2009 Act”) as “the publication, by any means, of a defamatory statement concerning a person to one or more than one person (other than the first-mentioned person...)”. To ground a successful case in defamation, the elements of publication,<sup>223</sup> defamatory meaning,<sup>224</sup> and identification<sup>225</sup> must be present,<sup>226</sup> and the claim or claims must not be subject to any of the defences specified in Part 3 of the 2009 Act.

Part 3 of the 2009 Act sets out the defences available to defendants where a statement made by them has been found to be defamatory. Of particular relevance to those dealing with defamation in the sphere of healthcare are the defences of truth<sup>227</sup> and honest opinion.<sup>228</sup> Defendants may also offer to make amends,<sup>229</sup> or issue an apology.<sup>230</sup> A brief overview of these is set out below, although, in most of the cases addressed, the defendants did not have the opportunity to substantively utilise the defences (or their English equivalent), highlighting the key issue – defamation law, here, is primarily used to chill speech, rather than to protect reputation.

It should be noted that, in the wake of libel reform and the UK Defamation Act 2013, the defences available in English law reflect those in the Irish 2009 Act. However, at the time at which the cases discussed were taken, the defence of ‘truth’ was known as ‘justification’ and the defence of ‘honest opinion’<sup>231</sup> was termed ‘fair comment’.<sup>232</sup>

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<sup>223</sup> Neville Cox and Eoin McCullough (n 220), para 2.06, “The concept of publication simply requires that one party (A) conveys to another person (B) a defamatory statement in respect of a third party (C)”.

<sup>224</sup> Defamation Act 2009, s 2, “defamatory statement” means a statement that tends to injure a person’s reputation in the eyes of reasonable members of society, and “defamatory” shall be construed accordingly”.

<sup>225</sup> *ibid* s 6(3), “A defamatory statement concerns a person if it could reasonably be understood as referring to him or her”.

<sup>226</sup> Neville Cox and Eoin McCullough (n 220) 19.

<sup>227</sup> Defamation Act 2009, s 16.

<sup>228</sup> *ibid* s 20.

<sup>229</sup> *ibid* s 22.

<sup>230</sup> *ibid* s 24.

<sup>231</sup> UK Defamation Act 2013, s 3.

<sup>232</sup> UK Defamation Act 1952, s 6.

## 5.1 TRUTH

Section 16 of the 2009 Act establishes the defence of truth, stating, “It shall be a defence (to be known and in this Act referred to as the “defence of truth”) to a defamation action for the defendant to prove that the statement in respect of which the action was brought in all material respects”. Cox and McCullough note that the defence of truth applies only to assertions of fact, whereas the defence of honest opinion applies only to opinion, though there may be some difficulty in discerning between the two. This has been central to some of the defamation actions taken by CAM proponents in the UK in the past ten years.<sup>233</sup> The defendant may opt to prove the truth of that which is asserted to be an opinion where the all of the elements of the defence of honest opinions are not available to him or her.<sup>234</sup> Unlike in most other actions, once it is established that the defendant issued a defamatory statement concerning the plaintiff, the burden of proof is on the defendant to show that the statement made is, in fact, true<sup>235</sup> in all material (though not necessarily all) respects.<sup>236</sup> Where a defendant tries, but fails, to prove the truth of his or her defamatory statement in a way that further aggravates the injury caused by the original statement, he or she may be ordered to pay aggravated damages.<sup>237</sup>

## 5.2 HONEST OPINION

Opinion, as part of expression, is given protection under Art 40.6.1(i), Art 40.3.1°, Art 10 ECHR, and Art 19 ICCPR, and is frequently referenced in case law.<sup>238</sup> In the German constitutional case of *Luth*,<sup>239</sup> the court found that:

The basic right to freedom of opinion is the most immediate expression of the human personality in society and, as such, is one of the noblest of human rights. ... It is absolutely basic to a liberal-democratic order because it alone makes possible the constant intellectual exchange and the contest among opinions that form the lifeblood of such an order; it is the matrix, the indispensable condition of nearly every other form of freedom.

Given the centrality of the free communication of opinion to the maintenance of a functioning liberal democracy,<sup>240</sup> it is only fitting that the defence of honest opinion be set out in broad terms.

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<sup>233</sup> See for example, *British Chiropractic Association v Singh* [2009] EWHC 1101 QB.

<sup>234</sup> Neville Cox and Eoin McCullough (n 220), para 5.03.

<sup>235</sup> Defamation Act 2009, s 16(1).

<sup>236</sup> *ibid* s 16(2).

<sup>237</sup> *ibid* s 32(1).

<sup>238</sup> See, for example, *Irish Times v Ireland* (n 113) 405 (Barrington J).

<sup>239</sup> *Luth* (n 3).

<sup>240</sup> Neville Cox and Eoin McCullough (n 220), para 6.01. It is also vital for scientific and medical progress.



Section 20(1) of the 2009 Act states “It shall be a defence (to be known, and in this section referred to, as the “defence of honest opinion”) to a defamation action for the defendant to prove that, in the case of a statement consisting of an opinion, the opinion was honestly held”.

Section 20(2) goes on to describe the criteria for an opinion honestly held, stating that the defendant must have believed in the truth of the opinion at the time the statement was made,<sup>241</sup> and the opinion must have been based on facts included<sup>242</sup> or referred to<sup>243</sup> in the statement in question. Where the facts are referred to but not included, the receiver of the statement must know or reasonably be expected to know the facts referred to.<sup>244</sup> The opinion must be related to a matter of public interest.<sup>245</sup>

According to s 21, in determining whether a statement was one of fact or opinion, the court must consider:

- (a) the extent to which the statement is capable of being proved;
- (b) the extent to which the statement was made in circumstances in which it was likely to have been reasonably understood as a statement of opinion rather than a statement consisting of an allegation of fact; and
- (c) the words used in the statement and the extent to which the statement was subject to a qualification or a disclaimer or was accompanied by cautionary words.

However, as Cox and McCullough make clear, the lack of a disclaimer does not necessarily mean that the statement cannot be considered an opinion.<sup>246</sup>

As with the defence of truth, where a defendant tries, but fails, to prove that his or her defamatory statement was an opinion honestly held and based on fact, in a way that further aggravates the injury caused by the original statement, he or she may be ordered to pay aggravated damages.<sup>247</sup>

Determining whether a statement is fact or honest opinion is complex and, despite the rules set out in s 21, fundamentally intuitive and subjective.<sup>248</sup>

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<sup>241</sup> Defamation Act 2009, s 20(2)(a).

<sup>242</sup> *ibid* s 20(2)(b)(i)(I).

<sup>243</sup> *ibid* s 20(2)(b)(i)(II).

<sup>244</sup> *ibid* s 20(2)(b)(i)(II).

<sup>245</sup> *ibid* s 20(2)(c).

<sup>246</sup> Neville Cox and Eoin McCullough (n 220), para 6.16.

<sup>247</sup> Defamation Act 2009, s 32(1).

<sup>248</sup> Neville Cox and Eoin McCullough (n 220), para 6.17.

## 6. CASE LAW

*[Plaintiffs] cannot, by simply filing suit and crying 'character assassination!', silence those who hold divergent views, no matter how adverse those views may be to plaintiffs' interests. Scientific controversies must be settled by the methods of science rather than by the methods of litigation. ... More papers, more discussion, better data, and more satisfactory models – not larger awards of damages – mark the path towards superior understanding of the world around us.*<sup>249</sup>

Much of the specific jurisprudence relating to defamation cases taken by proponents or providers of CAM comes from the UK, though the same cases could have been taken in Ireland, where the relevant statements were also published here. These cases provide examples of what might be considered to be poorly chosen or even inflammatory, if not inaccurate, language used by commentators, and an unsettling eagerness for issuing costly, lengthy, and oppressive defamation proceedings on the part of CAM proponents or providers.

In *McKeith v News Group Newspapers*,<sup>250</sup> *The Sun* newspaper, one of those owned by the defendant newsgroup, published an article on the celebrity nutritionist, Dr Gillian McKeith, claiming that “she has NO medical background. She holds a ‘worthless’ PhD in holistic nutrition gained via a postal course at a backwater US college”.<sup>251</sup> The article went on to include comments from other experts calling into question the practices and the theories upon which the plaintiff based her work, closing with the statement, “DEGREES in a variety of subjects – including those in which McKeith was said to have qualified – can easily be bought on the internet. An MSc in Nutrition from top US college Belford University costs less than £250”. Dr McKeith sued for libel.

The defendants put forward four meanings: two relating to the qualifications of McKeith and two relating to the merits of her nutritional advice,<sup>252</sup> to which the plaintiff responded that the defamatory statement for which the case was taken related only to the plaintiff’s allegedly dishonest representations in relation to her qualification (the “real issue”),<sup>253</sup> and that there was no need to enter into a debate over the validity or otherwise of her nutritional advice, as there was “room for debate in relation to nutritional issues”.<sup>254</sup> The court agreed, finding that there was no common sting among all four meanings and that it would be unacceptable to broaden the scope from examining the qualification claims to include a “wide-ranging inquiry into the validity of her “theories and

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<sup>249</sup> *Underwager v Salter* 22 Fed 3d 730 (1994) (Easterbrook J).

<sup>250</sup> *McKeith v News Group Newspapers Ltd* [2005] EWHC 1162 (QB).

<sup>251</sup> “DR? NO - TV You Are What You Eat expert Gillian has dodgy nutrition degree ... via post from a small US college” *The Sun* (3 August 2005).

<sup>252</sup> *McKeith v News Group Newspapers Ltd* (n 250) [11].

<sup>253</sup> *ibid* [12]. See also [8], where Dr McKeith claimed only the meaning “... that [she] is a charlatan since she dishonestly claimed to have a genuine nutritionist degree from a respectable American college, when in truth she has only a highly dubious and inferior nutritional degree that she simply purchased off-the shelf by post from a worthless US college, and has thereby made a fortune by deliberately deceiving the general public in this way”.

<sup>254</sup> *ibid* [10].

advice”.<sup>255</sup> This was most unfortunate for the public interest, but a smart tactic on the part of the plaintiff. Had the plaintiff taken issue, not only with the claim as to the legitimacy of her qualification, but also with the claims in respect of her nutritional advice, the defendants would undoubtedly have sought to prove the truth of their statements, something which would have damaged the plaintiff’s reputation as a nutritionist to a far greater extent than using the title ‘doctor’ in a legitimate, if slightly ambiguous, manner.<sup>256</sup> A valuable opportunity to bring to public attention the dubious or harmful claims made by some practitioners, and for the courts to gain experience in this complex and important area, was lost.<sup>257</sup>

In *Rath v Goldacre*,<sup>258</sup> *The Guardian* newspaper had published three articles about Dr Matthias Rath, a research physician,<sup>259</sup> advocate for, and producer of, natural and vitamin-based medicine,<sup>260</sup> and, most pertinently, a staunch opponent of the use of antiretroviral (ARV) drugs in the treatment of HIV/AIDS. Rath had established a business, VitaCell, which sold vitamins and micronutrient products through retail outlets and online, and Rath distributed these free of charge as an alternative treatment for HIV/AIDS in South Africa during an AIDS epidemic, denouncing the pharmaceutical industry as a “cartel” selling products that were “toxic and dangerous”.<sup>261</sup> Much of the content in question was concerned with the political context in which the campaign opposing antiretrovirals was thriving, and the fate of HIV/AIDS campaigner Zackie Achmat, himself an AIDS sufferer and an advocate of ARVs, who had met with significant resistance from those asserting the superiority of vitamins and micronutrients as a treatment.

Rath initiated proceedings against *The Guardian* and against Dr Ben Goldacre, a physician, an epidemiologist, and the author of the articles in question, on the grounds that the articles in question carried the meaning that:

20 January 2007 (“the first article”):

“... that the Claimant was a vitamin peddling Aids denialist who falsely claimed that his vitamin pills are a more effective treatment for AIDS than antiretroviral drugs”.

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<sup>255</sup> *ibid* [16].

<sup>256</sup> *ibid* [15]. A sample list of the unfounded or inaccurate claims made by the plaintiff in the course of her work were submitted by the defendant.

<sup>257</sup> However, in 2007, Gillian McKeith voluntarily agreed to stop using the title “Doctor” in promotional materials, by way of avoiding publication of a preliminary finding by the UK Advertising Standards Authority, that her use of the term was “likely to mislead”. See Ben Goldacre, ‘What’s wrong with Gillian McKeith’ *The Guardian* (12 February 2007) <[www.theguardian.com/media/2007/feb/12/advertising.food](http://www.theguardian.com/media/2007/feb/12/advertising.food)> accessed 2 July 2016. See also India Knight, ‘Fools, damn fools, and ‘experts’ *The Sunday Times* (18 February 2007) <[www.thesundaytimes.co.uk/sto/news/Features/Focus/article59950.ece](http://www.thesundaytimes.co.uk/sto/news/Features/Focus/article59950.ece)> accessed 2 July 2016.

<sup>258</sup> *Matthias Rath v (1) Guardian News and Media Ltd (2) Ben Goldacre* [2008] EWHC 398 QB.

<sup>259</sup> Sarah Boseley, ‘A global business built on vitamins - and the claim to kill all disease’ *The Guardian* (12 September 2008).

<sup>260</sup> *ibid*.

<sup>261</sup> Sarah Boseley, ‘Fall of the doctor who said his vitamins would cure Aids’ *The Guardian* (12 September 2008) <[www.theguardian.com/world/2008/sep/12/matthiasrath.aids2](http://www.theguardian.com/world/2008/sep/12/matthiasrath.aids2)> accessed 10 May 2016.

27 January 2007 (“the second article”):

“... that the Claimant was selling ridiculous vitamin pills on the back of his false claim that they were better than antiretroviral drugs in treating HIV and AIDS.”

and

17 February 2007 (“the third article”):

“... that the Claimant was a vitamin-peddling anti-medication salesman who was guilty of exploiting vulnerable Aids victims in South Africa by selling them ridiculous vitamin pills on the back of his false claim that his pills were better than antiretroviral drugs in treating HIV and AIDS and was thereby substantially responsible for the needless deaths of hundreds of thousands of people”.<sup>262</sup>

Among the various inclusions and exclusions sought, Rath sought to have excluded from the action, evidence that an associate of his, in an alleged reprisal for campaigner Achmat successfully securing the free provision of antiretrovirals for patients in South Africa, had made an allegation to the International Criminal Court, accusing Achmat of genocide for his promotion of and campaigning for ARVs. Rath argued that the sting of the statement being that he was promoting vitamins and claiming that they were safer and more effective than ARVs, to the detriment of HIV/AIDS sufferers. He claimed that he had distanced himself from said associate.<sup>263</sup> However, Rath had previously issued a press release, expressly endorsing the action taken by his associate as being “entirely valid and long overdue”.<sup>264</sup> The defendants argued that “the allegation of genocide against Achmat is part of the campaign to discredit ARVs to which the Claimant is a party, which the Defendants assert operates on false premises”,<sup>265</sup> something with which the court agreed.<sup>266</sup> It found that the submission on the allegation of genocide was a particular instance of the wider allegation made on the campaign against ARVs in South Africa.

It is worth noting that the counsel for Rath had argued, in attempting to have the evidence in relation to Zackie Achmat excluded, that “The trial of this case will involve a complicated and detailed assessment of medical and scientific evidence as to the relative efficacy of vitamins and micronutrients and ARVs and the foundation for and honesty of the Claimant’s claims in relation to this relative efficacy. Against this, the episode relating to Mr Brink’s complaint against Mr Achmat

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<sup>262</sup> *Matthias Rath v (1) Guardian News and Media Ltd (2) Ben Goldacre* (n 258).

<sup>263</sup> *ibid* [22].

<sup>264</sup> Dr Rath Health Foundation Africa, ‘Press Release - Criminal Complaint by the Treatment Information Group against Treatment Action Campaign Leader “Zackie” Achmat’ (15 January 2007)

<[www4.dr-rath-foundation.org/pdf-files/TIG\\_Achmat\\_pressrelease-20070115.pdf](http://www4.dr-rath-foundation.org/pdf-files/TIG_Achmat_pressrelease-20070115.pdf)>accessed 26 June 2016.

<sup>265</sup> *Matthias Rath v (1) Guardian News and Media Ltd (2) Ben Goldacre* (n 258) [23].

<sup>266</sup> *ibid* [26].

is peripheral”.<sup>267</sup> Sadly, this was not to be. The case was later dropped by Rath, who was ordered to pay costs, and, once again, the “complicated and detailed assessment of medical and scientific evidence as to the relative efficacy”<sup>268</sup> of an unproven treatment and, indeed, a serious threat to public health, was denied its day in court.

However, one of the highest profile of this class of defamation cases was that of the *British Chiropractic Association v Singh*.<sup>269</sup>

In his article, published in *The Guardian* on 19 April 2008 and entitled ‘Beware the Spinal Trap’, Simon Singh, discussing the claims made by chiropractors in relation to the efficacy of chiropractic for various conditions, stated:

The British Chiropractic Association claims that their members can help treat children with colic, sleeping and feeding problems, frequent ear infections, asthma and prolonged crying, even though there is not a jot of evidence. This organisation is the respectable face of the chiropractic profession and yet it happily promotes bogus treatment.<sup>270</sup>

The British Chiropractic Association (BCA) issued proceedings for libel, opting to sue Singh as an individual, rather than as a co-defendant with *The Guardian* newspaper, who were also publishers.<sup>271</sup> At preliminary hearing, Eady J found in favour of the meaning ascribed by the BCA to Singh’s statement, that the BCA:

- (a) claims that chiropractic is effective in helping to treat children with colic, sleeping and feeding problems, frequent ear infections, asthma and prolonged crying, although it knows that there is absolutely no evidence to support its claims; and
- (b) by making those claims, knowingly promotes bogus treatments.<sup>272</sup>

He ruled that the alleged libellous statement was one of fact, not one of opinion, as claimed by Singh. Singh would thus be prevented from relying on the defence of fair comment. He was denied an appeal. However, Singh and his legal team successfully petitioned for one, with Laws J stating during the course of the hearing that it was arguable that “the result of the judge’s findings risk striking the

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<sup>267</sup> *ibid* [19]. This was one of the rules set out in *Polly Peck*, and it applies in an attempt limit the length of proceedings and the costs involved.

<sup>268</sup> *ibid* [19].

<sup>269</sup> *British Chiropractic Association v Singh* [2010] EWCA Civ 350. This case was taken while The Guardian and Ben Goldacre were defending the case taken by Mathias Rath. It was taken against Singh personally.

<sup>270</sup> Simon Singh, ‘Beware the spinal trap’ *The Guardian* (19 April 2016)

<[www.theguardian.com/commentisfree/2008/apr/19/controversiesinscience-health](http://www.theguardian.com/commentisfree/2008/apr/19/controversiesinscience-health)> accessed 6 May 2016.

<sup>271</sup> A full right of reply of equal prominence to the allegedly defamatory statement was offered to the plaintiffs, but this was rejected in lieu of an apology, which the defendant was unwilling to offer. See Ben Goldacre, ‘Libel laws: A lethal muzzle of medicine’ *The Guardian* (15 April 2010)

<[www.theguardian.com/commentisfree/2010/apr/15/simon-singh-libel-medical-review](http://www.theguardian.com/commentisfree/2010/apr/15/simon-singh-libel-medical-review)> accessed 26 June 2016.

<sup>272</sup> *British Chiropractic Association v Singh* (n 233) [5] (Eady J).

Strasbourg balance between the right of reputation and the right of free expression too far in favour of the former and against the latter”.<sup>273</sup> He found that Singh’s statement was capable of being comment. The case progressed to the Court of Appeal, where it was then dropped by the BCA in April 2010. The BCA cited mounting costs as a rationale.<sup>274</sup> Costs were awarded to Singh, who nonetheless bore a significant financial burden in the aftermath.<sup>275</sup> Once again, the evidence pertaining to the treatment in question was never heard.

Laws J’s reference to the Strasbourg balance was reflective of increasing public distaste for the chilling effect of British libel laws on journalism and public debate, in particular in the field of science, where transparency is sorely needed. This was reinforced by the Court of Appeal, which stated:

It is now nearly two years since the publication of the offending article. It seems unlikely that anyone would dare repeat the opinions expressed by Dr Singh for fear of a writ. Accordingly this litigation has almost certainly had a chilling effect on public debate which might otherwise have assisted potential patients to make informed choices about the possible use of chiropractic. If so, quite apart from any public interest in issues of legal principle which arise in the present proceedings, the questions raised by Dr Singh, which have a direct resonance for patients, are unresolved.<sup>276</sup>

This paragraph concisely summarises the real-world impact of oppressive defamation regimes. While both Ireland and the UK have reformed their laws on defamation (Ireland with the Defamation Act 2009 and the UK with the Defamation Act 2013), the potential for spurious claims giving rise to unjust and crippling legal costs for defendants has not been satisfactorily limited, leaving commentators who are unwilling to backpedal or apologise for an honest opinion or a statement of fact, at risk of financial harm.

More recently, though proceedings never issued, Boiron, a major manufacturer of homeopathic medicinal products, took issue with an article written by Samuele Riva, an Italian blogger for the site Blogzero.it.<sup>277</sup> In two articles entitled “Homeopathy: Myth and Legend”, published in parts 1 and 2 on the blog on 13 July 2011 and on 27 July 2011, Riva, it was alleged in a letter sent to his internet service provider, made statements that were “untrue and derogatory both of homeopathy and [the]

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<sup>273</sup> *British Chiropractic Association v Singh* [2010] EWCA Civ 1154 (Laws J) [8].

<sup>274</sup> Tim Castle, ‘Chiropractors drop science writer libel case’ *Reuters* (15 April 2010) <<http://uk.reuters.com/article/uk-britain-libel-idUKTRE63E37P20100415>> accessed 16 June 2016.

<sup>275</sup> Robert Sharp, ‘Press Release - BCA drop libel case against Simon Singh’ (15 April 2010), “On April 15th The British Chiropractic Association dropped its libel case with science writer Simon Singh. This followed the Court of Appeal ruling on 1st April that Singh’s article on chiropractic was comment not fact. Simon Singh has been fighting his case for two years and has spent more than 200,000 pounds. He will never recover all his costs” <[www.libelreform.org/component/content/article/2-uncategorised/452-bca-drop-libel-case-against-simon-singh?Itemid=101](http://www.libelreform.org/component/content/article/2-uncategorised/452-bca-drop-libel-case-against-simon-singh?Itemid=101)> accessed 16 June 2016.

<sup>276</sup> *British Chiropractic Association v Singh* (n 269) [11].

<sup>277</sup> Fabio Turone, ‘Homoeopathy multinational Boiron threatens amateur Italian blogger’ (2011) 343 *British Medical Journal* 343.

company ... “tarnishing the company’s reputation and causing “serious damage,” which it could seek to recover in court”.<sup>278</sup> The blog posts had included images of Boiron’s popular homeopathic preparation, Oscillococcinum, with a tagline underneath that stated “The Nothing-at-all that according to Boiron treats flu... diluted 200K it doesn’t contain any molecule of active principle!”.<sup>279</sup> Riva duly removed the images and references to the company but maintained the other statements about homeopathy generally. Boiron dropped the issue a month after the first letter was sent,<sup>280</sup> amid widespread public outcry.<sup>281</sup>

The statements made by Riva, though perhaps inconvenient, vexing or offensive to Boiron, were not untrue.<sup>282</sup> However, the mere threat of costly litigation, even where it was unjustified and short-lived, was sufficient to curb the author’s expression.

Finally, civil and criminal proceedings were issued against Italian scientist and television presenter, Piero Angela, by the Italian Association of Medical Homeopathy and the Italian Federation of Associations of Medical Homeopathy,<sup>283</sup> after “guests on a popular-science television programme called *Superquarks*, hosted by ... Angela, described how homeopathy could, if used in place of conventional therapies, constitute a risk for patients with serious or progressive illnesses. They also indicated that clinical benefits are due to a placebo effect”.<sup>284</sup> The plaintiffs sued the defendant for, among other things, failing to represent their viewpoint during the broadcast. However, the court found against the plaintiffs, holding that homeopathy was “not a serious therapy” but was “substantially a medicine of emotions”.<sup>285</sup>

This example is anomalous, not for its outspoken defendant, who unapologetically stated that “Science is not like philosophy, where viewers can listen to both sides and decide for themselves ... Science cannot be decided on by the vote of viewers”,<sup>286</sup> nor for the decision of the television network to broadcast a programme that was one-sided, albeit supported by the current best evidence,<sup>287</sup> but for the fact that the court was offered, and seized upon, the opportunity to make a qualitative finding on a CAM therapy. This is significant, because, as noted repeatedly above, the defendants in

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<sup>278</sup> *ibid.*

<sup>279</sup> The original posts were in Italian, but the details and the letter are translated by Fabio Turone, ‘The English translation of the letter sent by Boiron threatening the Italian blogger’ (18 August 2011) <<https://presenteduepuntozero.wordpress.com/2011/08/18/the-english-translation-of-the-letter-sent-by-boiron-threatening-the-italian-blogger/>> accessed 2 July 2016.

<sup>280</sup> Samuel Riva, ‘Bioron: The End!’ (24 August 2011) <[www.blogzero.it/2011/08/24/boiron-the-end/](http://www.blogzero.it/2011/08/24/boiron-the-end/)> accessed 2 July 2016.

<sup>281</sup> Known as the Streisand Effect, and cited in Fabio Turone (n 279).

<sup>282</sup> Robert T Mathie and others, ‘Homeopathic Oscillococcinum® for preventing and treating influenza and influenza-like illness’ (2015) Cochrane Database of Systematic Reviews CD001957, “There is insufficient good evidence to enable robust conclusions to be made about Oscillococcinum® in the prevention or treatment of influenza and influenza-like illness”.

<sup>283</sup> Alison Abbott, ‘Disgruntled homeopaths seek remedy in court’ (2001) 412 *Nature* 261.

<sup>284</sup> News in brief, ‘Homeopathy group loses lawsuit against TV science show’ (2004) 429 *Nature* 334.

<sup>285</sup> *ibid.*

<sup>286</sup> Alison Abbott (n 283).

<sup>287</sup> A situation which, as discussed above, is uncommon in broadcasting generally, where false equivalence, creating the perception of balance, has become popular.

defamation proceedings involving CAM are consistently deprived of the opportunity to justify their statements, opinions or comments by the submission of empirical evidence on the safety and efficacy of the treatment itself, leaving the entire, substantial body of evidence unexplored in the court setting and further limiting the information available to the public.

## 6.1 UNCERTAINTY FOR IRISH COURTS

Irish courts have not yet had to address cases such as these. Other European jurisdictions have a more established relationship with CAM and a longer tradition and are therefore more likely to address issues of defamation in relation to it. However, complacency is most unwise. In 2013, the UK undertook libel reforms, replacing their outmoded libel laws with the Defamation Act 2013. There is ongoing debate as to whether Ireland has become a more attractive forum than the UK as a result.<sup>288</sup> If this is the case, Irish courts may soon be asked to address proceedings similar to those set out above.

However, there is an issue of greater concern, albeit one of uncertain effect at this time. On 23 June 2016, the United Kingdom voted to leave the European Union (a departure informally known as “Brexit”),<sup>289</sup> which may affect its use as a preferred forum in which to take a case under art 7(2) of the Brussels Recast Regulation.<sup>290</sup> With the UK potentially inaccessible to aggrieved citizens of EU Member State, Lugano Convention States, or to third states for whom England and Wales is not established as being “clearly the most appropriate place in which to bring an action in respect of the statement”,<sup>291</sup> Ireland, with its hard-earned reputation for awarding damages substantially larger than its EU peers,<sup>292</sup> may, as a result, become the new forum of choice, broadening the scope of issues on which Irish courts must develop a level of expertise.

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<sup>288</sup> Hugh McCarthy, ‘Libel tourism may become our newest cottage industry’ *The Irish Times* (10 November 2014) <[www.irishtimes.com/news/crime-and-law/libel-tourism-may-become-our-newest-cottage-industry-1.1992393](http://www.irishtimes.com/news/crime-and-law/libel-tourism-may-become-our-newest-cottage-industry-1.1992393)> accessed 16 October 2016.

<sup>289</sup> Michael White, ‘What is Brexit and why does it matter? The EU referendum guide for Americans’ *The Guardian* (18 June 2016) <[www.theguardian.com/politics/2016/jun/18/eu-referendum-brexit-explainer-for-americans](http://www.theguardian.com/politics/2016/jun/18/eu-referendum-brexit-explainer-for-americans)> accessed 26 June 2016.

<sup>290</sup> Regulation 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) [2012] OJ L351/1. In the wake of the decision in Joined Cases C-509/09 and C-161/10 ECJ *eDate Advertising GmbH v X and Martinez v MGN Limited* [2011] ECR I-10269, where there is proof of internet publication, the rule in Case C-68/93 *Shevill v Presse Alliance* [1995] ECR I-415, providing that a plaintiff defamed in a number of EU Member States may choose to take a composite action in defamation in the state in which the publisher is domiciled or to take individual actions in each Member State in which the defamatory material was published, will apply, but the plaintiff will also have the option to take the case in their own centre of interests. See also Neville Cox and Eoin McCullough (n 220), para 2.106.

<sup>291</sup> Defamation Act 2013, s 9(2).

<sup>292</sup> Patsy McGarry, ‘Defamation laws ‘out of line with Europe’, says newspaper body’ *The Irish Times* (3 May 2016) <[www.irishtimes.com/news/social-affairs/defamation-laws-out-of-line-with-europe-says-newspaper-body-1.2632562](http://www.irishtimes.com/news/social-affairs/defamation-laws-out-of-line-with-europe-says-newspaper-body-1.2632562)> accessed 6 July 2016.



## 6.2 THE CHILLING EFFECT

Plaintiffs must have access to the courts to ensure that their rights are vindicated.<sup>293</sup> However, in the cases discussed above, among others, there is a pattern of proceedings:

- (a) initiated on the grounds of an alleged defamatory statement issued by the defendant; which are
- (b) maintained up to the point at which a substantive defence would be delivered, requiring, *inter alia*, the submission of expert evidence as to the safety or efficacy of a treatment or product offered or promoted by the plaintiff; and then
- (c) dropped before that defence can be delivered.

This strategy discourages any future publications along similar lines, costs defendants personally and financially, denies them the opportunity to defend their statements or to have the case decided in their favour, and still manages to protect the reputation of both the plaintiff and the products or practices with which they are associated. Use of the courts in this way is cynical. It impacts unduly upon the fundamental rights of others, and it needlessly increases the burden on an already-overloaded legal system. Reforms may be required to ameliorate this situation. The chilling effect impacts public health by limiting public debate and, as a result, diminishing the profile of the issues in question in the eyes of law and policy-makers.

### 6.2.1 ATTEMPTING TO LIMIT THE CHILLING EFFECT

In an attempt to limit the adverse effects for defendants in defamation cases, legislators might consider:

- (a) Alternative dispute resolution or preliminary review in specific categories of cases<sup>294</sup>;
- (b) Expedited processing or other controls on costs; and

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<sup>293</sup> This right of access was recognised as a personal right under Art 40.3 of the Constitution, in the case of *Macauley v Minister for Posts and Telegraphs* [1966] IR 345 (HC), 348 (Kenny J).

<sup>294</sup> Lord Justice Leveson (n 121) 1770, paras 5.4-5.5. This may, for example, take the form of anti-SLAPP provisions, as provided by law in some US states, such as California Code of Civil Procedure, § 425.16. See Legal Information Institute, 'SLAPP Suit', "Strategic Lawsuit Against Public Participation. Lawsuit filed strategically by a corporation against a group or activist opposing certain action taken by the corporation, usually in the realm of an environmental protest. Typical claims underlying a SLAPP suit are libel, slander or restraint of business. Many states have adopted anti-SLAPP statutes in the interest of protecting free speech that provide for speedy hearings of the claims and the possibility of the defendant recovering legal fees and punitive damages" <[www.law.cornell.edu/wex/slapp\\_suit](http://www.law.cornell.edu/wex/slapp_suit)> accessed 16 October 2016. Similar provisions were recommended but not implemented as part of libel reform in the UK. See Alastair Mullis and Andrew Scott, 'Something rotten in the state of English libel law? A rejoinder to the clamour for reform of defamation' (2009) 14(6) Communications Law 173, 181.

(c) Removal of the jury.<sup>295</sup>

Consideration should also be given, in a general sense, to the reputation of CAM and its proponents in Ireland, which is somewhat different to that in the rest of the EU and in the UK. Where a case does reach the decision stage, this may have a significant effect on assessment of damages.

Ideally, the apparent strategy used by the plaintiffs in the cases under discussion would be discouraged. Under Ord 19, r 28 of the Rules of the Superior Courts,

The Court may order any pleading to be struck out, on the ground that it discloses no reasonable cause of action or answer and in any such case or in case of the action or defence being shown by the pleadings to be frivolous or vexatious, the Court may order the action to be stayed or dismissed, or judgement to be entered accordingly, as may be just.

In the case of *Farley v Ireland*,<sup>296</sup> Barron J defined ‘frivolous’ and ‘vexatious’ thus:

So far as the legality of the matter is concerned frivolous and vexatious are legal terms, they are not pejorative in any sense ... It is merely a question of saying that so far as the Plaintiff is concerned if he has no reasonable chance of succeeding then the law says that it is frivolous to bring the case. Similarly, it is a hardship on the defendant to have to defend something which cannot succeed and the law calls that vexatious.

However, each of the cases brought contained a valid question to be determined. They were not *prima facie* without merit, although, it is suggested, the hardship for the defendants and the chilling effect brought about by the proceedings themselves appeared to be the primary objective, rather than the protection or restoration of the plaintiff’s good name. They would not, therefore, have satisfied the definition of vexatious litigation provided by Barron J. It may also be difficult for courts to recognise this type of case when it comes before them.

The case law from the UK demonstrates the heavy burden placed on defendants to a defamation action, regardless of outcome, and the apparent ease with which such costly actions have been taken by some of those within the CAM community. This has contributed to the undermining of both freedom of expression and the protection of public health. While commentators should, of course, choose their language with care so as not to unduly damage the reputations of others, their message should not be

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<sup>295</sup> Though this would not assist the defendants in the cases under discussion to any great extent, as they were never decided.

<sup>296</sup> *Farley v Ireland* (SC, 1 May 1997) (Barron J).

otherwise restricted to any significant extent. Measures mitigating the burden on defendants in cases such as these, where the objective of an action appears to lean more towards punishing the defendant than restoring the reputation of the plaintiff, ought to be considered as a matter of urgency.

## CONCLUSION

CAM, at first glance, appears an unlikely source of fundamental rights infringement. However, this is deceptive. The liberal ideological underpinnings of freedom of expression and the protection of reputation have found uneven application and balance in respect of CAM, resulting in risk to public health that has been left virtually unchecked, particularly outside the commercial sphere.

The public health exception afforded by Art 10 ECHR is underutilised in Irish law, as evidenced by the plethora of commercial and non-commercial claims relaying information on CAM that is either incomplete, inaccurate or dangerous. The suite of consumer protection mechanisms available in this jurisdiction provide an actionable ground upon which to restrict the claims made in a commercial setting, but, as noted throughout this thesis, its utilisation and enforcement has been sorely lacking.

Where the margin of appreciation afforded to Contracting States in determining the appropriate level of protection for commercial expression is relatively wide,<sup>297</sup> *Hertel* has demonstrated the very narrow margin afforded to states in attempting to limit non-commercial expression. This, it has been argued, is because “commercial expression is not regarded as so worthy of protection as political or even artistic expression and ... some considerations which make expression valuable in the political context may not apply in quite the same way in the commercial environment”.<sup>298</sup> However, this also assumes that all contribution in such political discussion or debate (and this may be considered to encompass discussion or debate relating to public health, which is a persistent feature across media platforms) is equal, an assumption which is both fallacious and dangerous, as noted in Chapter 2. It is asserted that a more active approach to utilising the available limitations is required to minimise, if not to entirely remove, the risk to public health arising from the dissemination of inaccurate and unsubstantiated scientific and healthcare information.

It is nonetheless necessary to refrain from impinging unduly on the freedom of expression. In this respect, an approach which supports and encourages improved quality of authorship, reporting or commentary, in combination with a longer-term strategy to improve critical thinking and scientific literacy from early years, may protect the public to a greater degree than the existing model. Publishers, broadcasters and websites should consider the modification and amalgamation of the guidelines<sup>299</sup> submitted by the Science Media Centre as part of the Leveson Inquiry, into their existing codes of conduct or terms of service. Websites should consider adding a term providing them with a discretion to intervene and restrict or remove content which they deem to represent a risk to health, though it may never be actioned.

The collaborative, communitarian approach may not be quite so appropriate where issues of defamation arise. The cases in the UK, brought by proponents of CAM, provide evidence of

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<sup>297</sup> Application no 7805/77, *X and Church of Scientology v Sweden* (n 42).

<sup>298</sup> David Harris and others, *Law of the European Convention on Human Rights* (London 1995) 402.

<sup>299</sup> Fiona Fox (n 142) 9.

oppressive litigation with the primary intention of chilling expression, rather than restoring reputation. Defendants face a heavy personal and financial burden where proceedings are issued against them, regardless of the outcome. Courts in Ireland, which are likely to face similar claims in the future, must be aware of these and other cases, and of the peculiarities of strategy common to them. Reforms of procedure, for example, expediting or limiting the length of proceedings or employing alternative dispute resolution in specific circumstances,<sup>300</sup> may be of some assistance to defendants, though further intervention may be merited, given the marked disadvantage involved and the public importance of addressing and minimising the negative effects of oppressive litigation.

The existing situation, whereby positive commentary or public interest content on CAM products or services is protected by freedom of speech provisions, while negative commentary is chilled under the guise of protecting reputation, is one which fails to protect the public interest and the public health and has perhaps given rise to the confusion among consumers in respect of safety, efficacy and regulation of CAM therapies in Ireland, observed in the short research study that follows, in Chapter 6.

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<sup>300</sup> Lord Justice Leveson, (n 121) 1770, paras 5.4-5.5.



## **SECTION C**





## CHAPTER 6

### PUBLIC UNDERSTANDING OF AND ATTITUDE TOWARDS COMPLEMENTARY AND ALTERNATIVE THERAPIES: A SHORT QUESTIONNAIRE

#### INTRODUCTION

CAM is popular in Ireland,<sup>1</sup> but is not addressed meaningfully by legislation and it has not been dealt with in Irish courts, leaving significant uncertainty as to its status. This uncertainty creates fertile ground for confusion among consumers, which, in turn, creates risk. This thesis focuses on the assessment and optimisation of the protections afforded to consumers of CAM products. It is argued that greater public awareness of the demonstrated risks and benefits of CAM should facilitate better consumer decision-making and the provision of properly informed consent.

The purpose of this questionnaire was to determine the general public understanding of CAM and its regulation, to assess the prevalence of usage and procurement for those under the age of 18, and to detect areas of potential vulnerability for consumers, which may be ameliorated through changes in policy or in law. Though some of this data has been gleaned from a secondary analysis of existing data obtained through a large general study,<sup>2</sup> and from a small study of patients in a GP surgery, both published in 2010,<sup>3</sup> the importance of contemporary and focussed data cannot be overestimated. It was hoped that the results could demonstrate whether consent given for CAM treatment is truly informed, which would, in turn, inform discussion on the potential risk to consumer and public health, a key factor in any debate on regulation and in the enhancement of public policy. Specifically, the questionnaire sought to determine:

- (a) The age range, educational and occupational background of the participant;
- (b) Whether the participant had used CAM therapies or procured them for another person;
- (c) Whether the person for whom the participant procured the CAM therapy was over the age of 18 years;
- (d) The participant's reasons for use or procurement;
- (e) How the participant assessed the efficacy and safety of a therapy prior to use; and
- (f) The participant's general understanding of the way or ways in which CAM is regulated in Ireland.

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<sup>1</sup> Patricia Fox and others, 'Complementary alternative medicine (CAM) use in Ireland: A secondary analysis of SLAN data' (2010) 18(2) *Complementary Therapies in Medicine* 95.

<sup>2</sup> Karen Morgan and others, *SLAN 2007: Survey of Lifestyle, Attitudes & Nutrition in Ireland. Main Report* (Department of Health and Children 2008).

<sup>3</sup> Patricia Fox and others (n 1); Fiona Mc Kenna and Fionnuala Killoury, 'An investigation into the use of complementary and alternative medicine in an urban general practice' (2010) 103 *Irish Medical Journal* 205.

Although a large response was obtained, the representative cross-section was suboptimal, particularly in terms of age and education. This limits the generalisability of the results. However, in areas where the questions were comparable, the results obtained were similar to those obtained in previous studies, both domestically and internationally.

This study is descriptive in nature<sup>4</sup> and seeks to establish the situation for consumers as it stands.

## **1. METHODOLOGY**

This research was carried out exclusively through use of a short online questionnaire, with 17 questions in total, disseminated through email and social media. As this process was not funded, neither the time nor the resources were available to obtain the necessary responses otherwise. The questionnaire was designed to address the adult population living in Ireland (3,434,587, based on the latest available information from the Central Statistics Office),<sup>5</sup> for which the minimum sample size was calculated at 385 for a confidence level of 95% and a margin of error of 5%.

### **1.1 ETHICAL CONSIDERATIONS**

The potential for ethical implications arising from this questionnaire was quite limited. Respondents were required to be 18 years of age or older and no specific identifying information was requested. In addition, no personal medical history was requested and participants were free not to answer any particular question and to exit the questionnaire before submitting.

The questionnaire did not seek to obtain ‘sensitive personal data’ under s 1 of the Data Protection Act 1988, as amended by s 2 of the Data Protection (Amendment) Act 2003. Data protection and confidentiality was the primary ethical concern for this research project.

The approval of the Faculty of Arts, Humanities and Social Sciences Ethics Committee was sought and was received on 3 May 2016.

### **1.2 PARTICIPANT RECRUITMENT METHOD**

A broad cross-section, across gender, age, and education categories, was sought. Due to the short data collection period of one month, it was hoped that dissemination through college email and social networks would find sufficient candidates across demographic profiles. Although social media is

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<sup>4</sup> Don E Ethridge, *Research Methodology in Applied Economics* (Wiley 2004) 24.

<sup>5</sup> Central Statistics Office, ‘Population by age group, 2011’

<[www.cso.ie/multiquicktables/quickTables.aspx?id=cna15](http://www.cso.ie/multiquicktables/quickTables.aspx?id=cna15)> accessed 10 March 2016.

undoubtedly popular among those in younger age groups,<sup>6</sup> according to a report entitled ‘Social Media Usage: 2005-2015’, 51% of people aged 50-64 and 35% of people aged 65 and over currently use social media.<sup>7</sup> Similar rates of usage were observed across both genders<sup>8</sup> and for those with any third level education, but usage was lower for those with an educational career ending before third level.<sup>9</sup> However, this study was carried out in the US and Irish patterns show significantly lower levels of internet usage generally for those over 65, and this is particularly stark for social media use,<sup>10</sup> decreasing the likelihood of obtaining the cross-section desired. Facebook and email were initially used to disseminate the questionnaire, both carrying a request for onward referrals from participants to increase the potential for obtaining a representative cross-section. Some secondary dissemination occurred through Twitter.

### 1.3 SCOPE

While information was sought from all participants as to why they did or not use CAM, the questionnaire focussed predominantly on those who had used CAM and on their decision-making process. Those who are not and have not been consumers of CAM have not received any of its purported benefits and are not or have not been at risk of physical, psychological or financial harm, direct or indirect, by virtue of its use. These participants are less likely to be affected by any change in its regulation and were not positioned to provide information on motivation for use and subjective effectiveness, both of which are key in refining consumer education.

The questionnaire was restricted to adult participants who were capable of providing informed consent. Irish participants were not specifically requested, rather it was specified that participants should be resident in Ireland at the time of participation. The rationale for this was that such residents are subject to the same lack of regulation as Irish citizens and, more worryingly, if their country of origin has an established system of regulation, they may assume the same standards in Ireland, risking harm as a result.

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<sup>6</sup> Pew Research Centre, ‘Social media usage: 2005-2015’ (2015) <[www.pewinternet.org/2015/10/08/social-networking-usage-2005-2015/](http://www.pewinternet.org/2015/10/08/social-networking-usage-2005-2015/)> accessed 10 August 2016

<sup>4</sup> The report shows 90% usage for 19-29 year olds and 77% usage for 30-49 year olds.

<sup>7</sup> *ibid.*

<sup>8</sup> *ibid* 5.

<sup>9</sup> *ibid* 6. College graduates and those with some college education showed social media usage of 76% and 70% respectively, and those with education below college level showed a usage rate of 54%.

<sup>10</sup> Eurostat, ‘NewsRelease 166/2015 - International Day of Older Persons’ (29 September 2015). 37% of people in Ireland aged 65 to 74 are internet users. Of these, 78% send and receive email and only 22% participate in social networks.

#### **1.4 LIMITATIONS AND DELIMITATIONS**

While dissemination of an online questionnaire through email and social media was an efficient distribution method, it was undermined by its failure to reach older demographics.

However, another significant limitation for this small study arose from its primary distribution among staff and students in a single academic institution. While there clearly exists some variation in demographic and social background between members of the college community, there also exists common characteristics which vary from those outside the community, effectively restricting the generalisability of conclusions to staff and students of Trinity College Dublin.

In constructing the questionnaire, questions of a sensitive nature were avoided, though, clearly, information on, for example, the health conditions for which CAM was used, would have added significant value. However, the potential discomfort for participants in answering such questions may have discouraged completion or submission and the increased the level of risk associated with any potential data breach, together with the availability of similar data from existing studies, rendered such a line of questioning unnecessary on balance.

#### **1.5 PRELIMINARY QUESTIONNAIRE DISSEMINATION AND FEEDBACK**

The questionnaire was initially provided to a small sample group of 20 people in order to gain feedback on its structure and function.

The initial wording of the questionnaire differentiated between complementary and alternative therapies. However, preliminary feedback showed confusion among participants regarding the terms “complementary” and “alternative”, as many therapies are considered to fall into both categories depending on the consumer in question. Although it would have been preferable to separate these categories in the questionnaire, for the purpose of legibility, ease of use for participants and coalescence with the thesis as a whole, it was considered most appropriate to create a single category encompassing both in the final questionnaire.

In addition, the extensive list of therapies initially provided for participants to choose from nonetheless did not provide all possible therapies and so it was determined that a short sample list would be provided in the final questionnaire, with a text box for individual specification of any unlisted therapies used. While some participants felt that this demonstrated a lack of awareness of a particular therapy on the part of the researcher, this was the optimal way to obtain data on the extensive range and of therapies currently offered to consumers.<sup>11</sup>

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<sup>11</sup> Of some of which, the researcher/author is undoubtedly unaware. The author is, however, aware of the availability of massage as a CAM therapy, something which was queried by one respondent.

## 1.6 DATA RETRIEVAL AND ANALYSIS

Data was retrieved and analysed using Excel.

## 2. RESULTS

### 2.1 PARTICIPANT DEMOGRAPHICS

#### (a) Response Rate

The final response rate was significantly higher than expected. In total, 1,959 responses were obtained. Of these, 1,887 responses (96.3%) were completed and submitted. For the purposes of this study, the total completed responses are referred to as the total responses throughout.

#### (b) Gender

64.4% (n=1,214) of participants identified as female, 32.0% (n=604) as male, and 3.6% consisted of a range of responses including 0.3% (n=6) transgender/intersex (T/I).

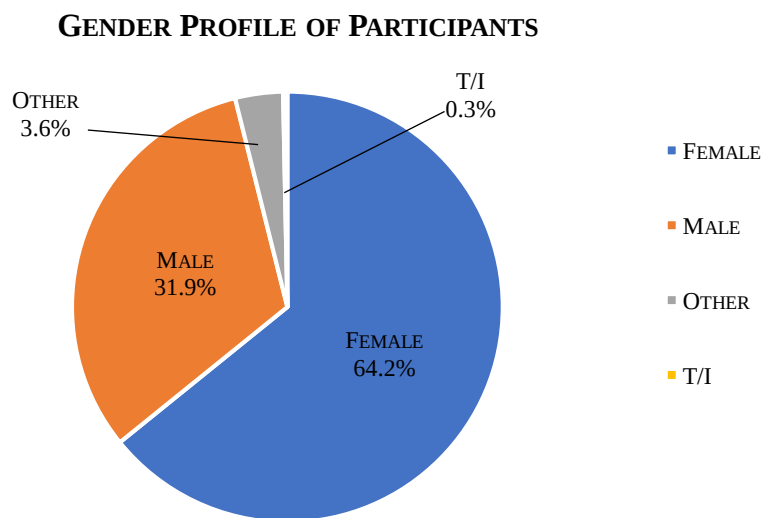


Figure 7 - Gender profile of participants

(c) Age

The age profile of participants was young overall, with over 79.9% of respondents in the 18-44 age range. This was projected to be a likely outcome based on the method of dissemination used for this questionnaire, via internal undergraduate, postgraduate and staff email lists and on social media.

| AGE              | 18-24 | 25-34 | 35-44 | 45-54 | 55-64 | 65-74 | 75 + | UNKNOWN |
|------------------|-------|-------|-------|-------|-------|-------|------|---------|
| PARTICIPANTS (n) | 843   | 311   | 354   | 211   | 133   | 26    | 6    | 3       |
| % OF TOTAL       | 44.7  | 16.5  | 18.8  | 11.2  | 7.0   | 1.4   | 0.3  | 0.2     |

Table 3 - Age profile of participants

(d) Gender Division by Age

For participants between the ages of 18 and 54, between 61.8% and 69.7% of participants were female. When combined, these age-brackets constitute 91.1% of respondents (n=1,719). Female participants constitute 65.4% of this combined category.

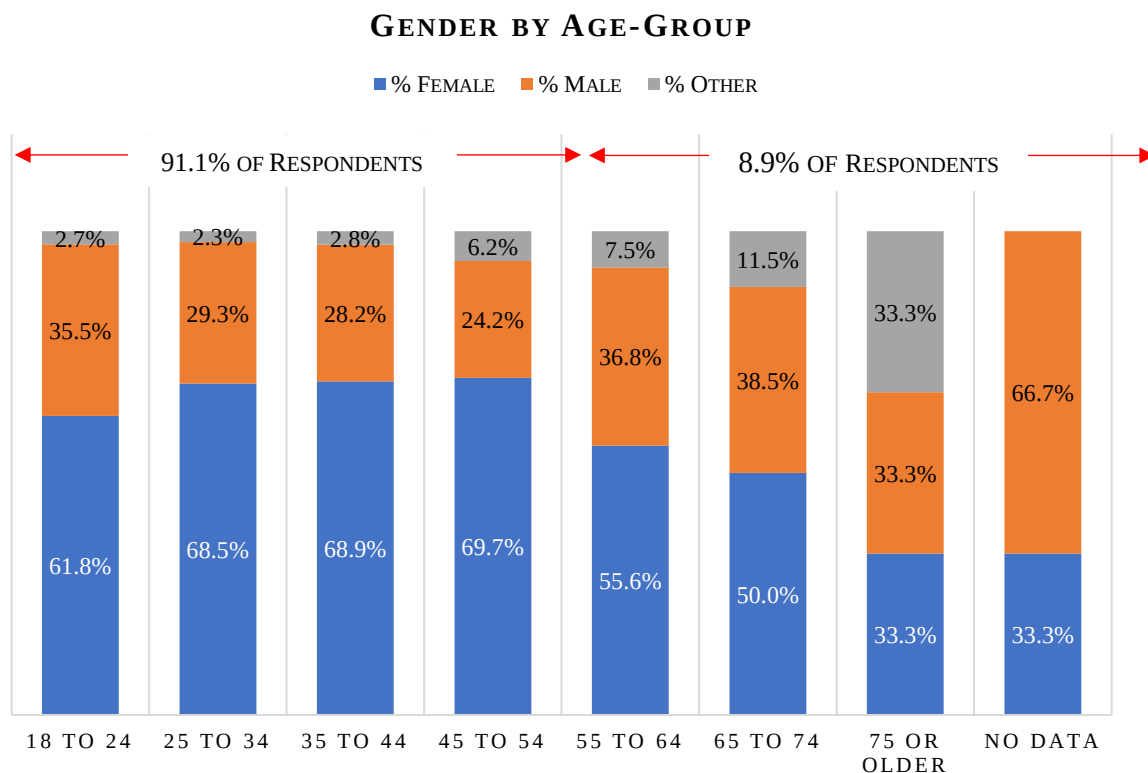


Figure 8 - Participant gender by age group

(e) *Nationality*

Participants were overwhelmingly Irish, at 80.0% (n=1,509), with broader Europeans forming the next largest group, at 10.5% (n=198). The remaining participants, encompassing America, the Asia-Pacific region (APAC), Middle East and Africa, formed 3.7% (n=70) in total. 5.9% of participants opted not to disclose their nationality.

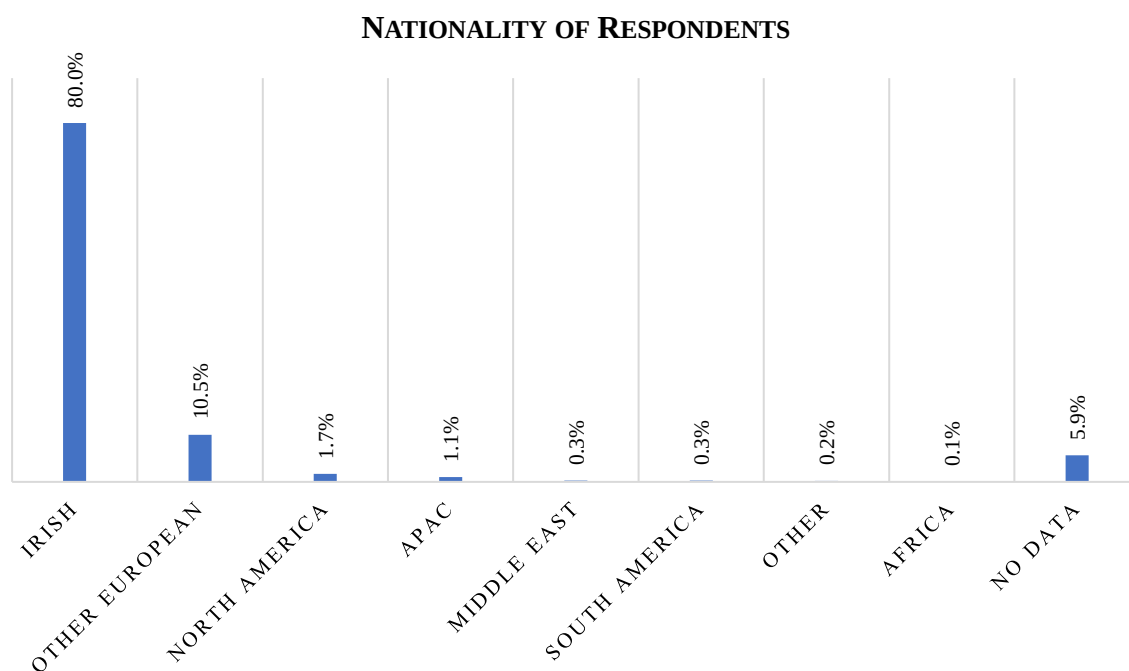


Figure 9 - Nationality profile of respondents

(f) *Education*

Unsurprisingly, given the chosen method of distribution (through university email, to students, the majority of whom are undergraduate, and staff members), the largest groups of participants were those whose highest level of education was the leaving certificate, at 35.8%, and those who held a postgraduate qualification, at 31.9%.

| HIGHEST ED       | PRIMARY | SECONDARY | LC   | CERT/DIP | UG   | PG   | OTHER | UNKNOWN |
|------------------|---------|-----------|------|----------|------|------|-------|---------|
| PARTICIPANTS (n) | 5       | 23        | 676  | 201      | 358  | 602  | 11    | 11      |
| % OF TOTAL       | 0.3     | 1.2       | 35.8 | 10.7     | 19.0 | 31.9 | 0.6   | 0.6     |

Table 4 - Education profile of respondents.

(g) Occupation

52.8% of respondents indicated a connection to healthcare, the pharmaceutical industry, applied sciences, chemical engineering or the medical device industry.

| OCCUPATION                                             | RESPONDENTS |
|--------------------------------------------------------|-------------|
| Healthcare                                             | 691         |
| Pharmaceutical research, design, manufacture or retail | 179         |
| Applied or academic sciences                           | 366         |
| Chemical engineering                                   | 40          |
| Medical device research, design, manufacture or retail | 128         |
| None of the above                                      | 891         |

Table 5 - Occupational association with relevant professions

## 2.2 CAM USE

Of the 1,887 respondents, 44.8% (n=845) stated that they had never used CAM, while 48.9% stated that they had used or procured CAM.

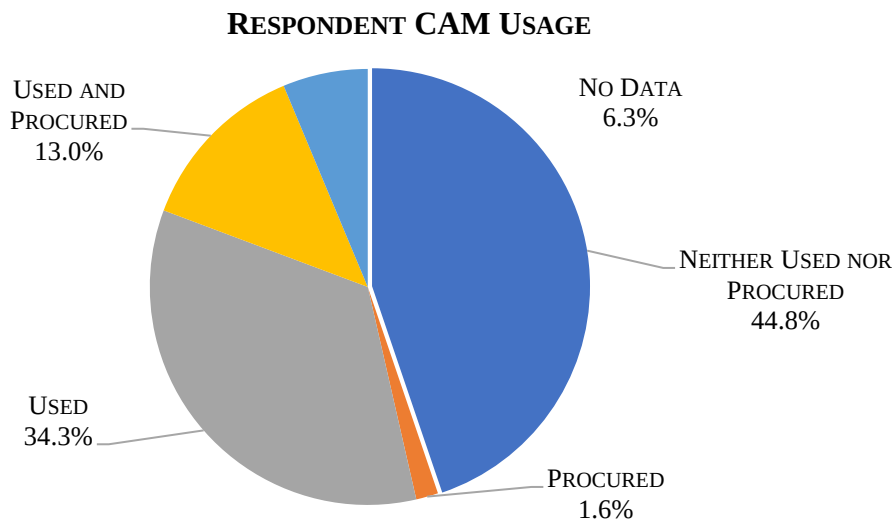


Figure 10 - CAM use or procurement among participants



For the purposes of this section, those who have used and/or procured CAM are considered CAM users and those who have not are considered non-users. CAM users tend to be older, with 55.4% of users aged 35 years or over. By contrast, only 22.4% of non-users were over the age of 35.

### AGE PROFILE OF CAM USERS VS NON-USERS

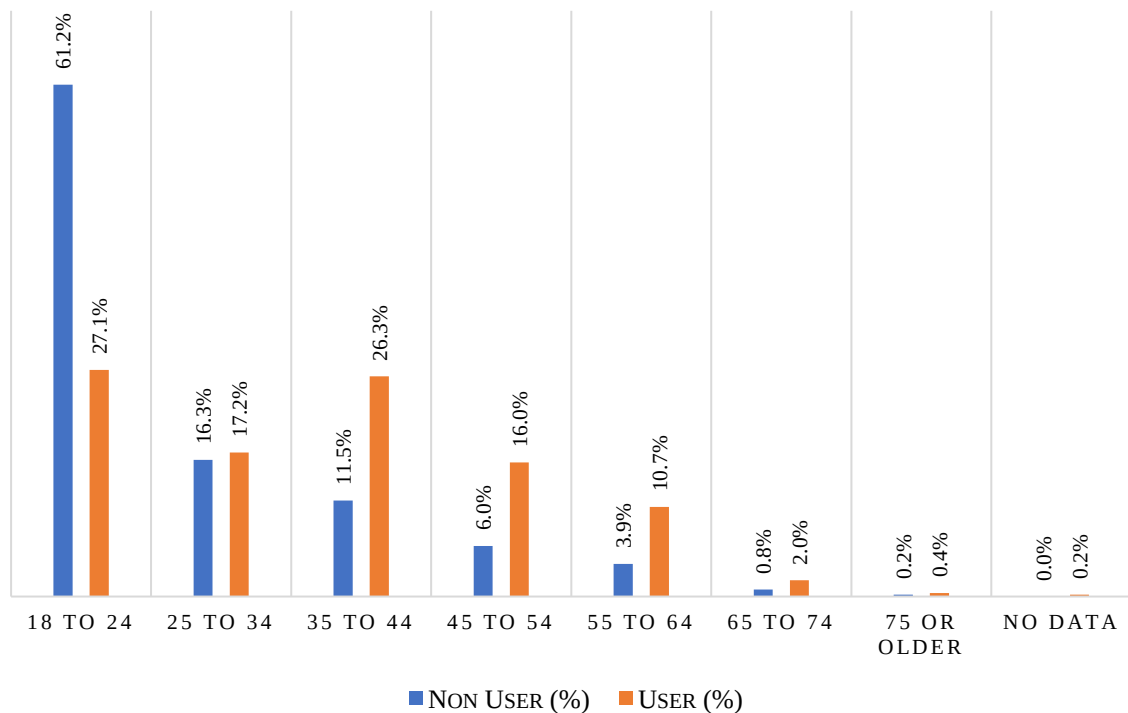


Figure 11 - Age profile of CAM users versus non-users

Figure 12 shows the clear rise in CAM usage with age (orange bars). However, the number of CAM users per age category for this questionnaire, represented by the blue line, varies substantially, with the very low numbers of respondents in higher age groups undermining the significance of the outcome.

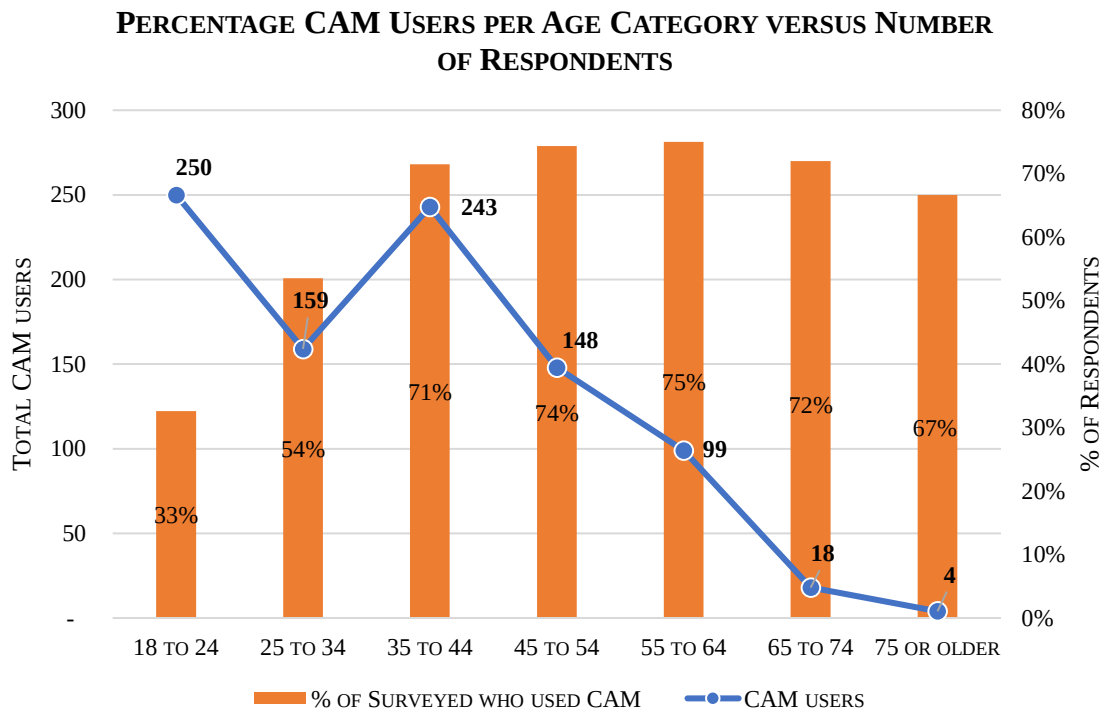


Figure 12 - CAM users as a percentage of total respondents per age group versus number of respondents per age group

Of CAM users, 73% were female and 23% were male.

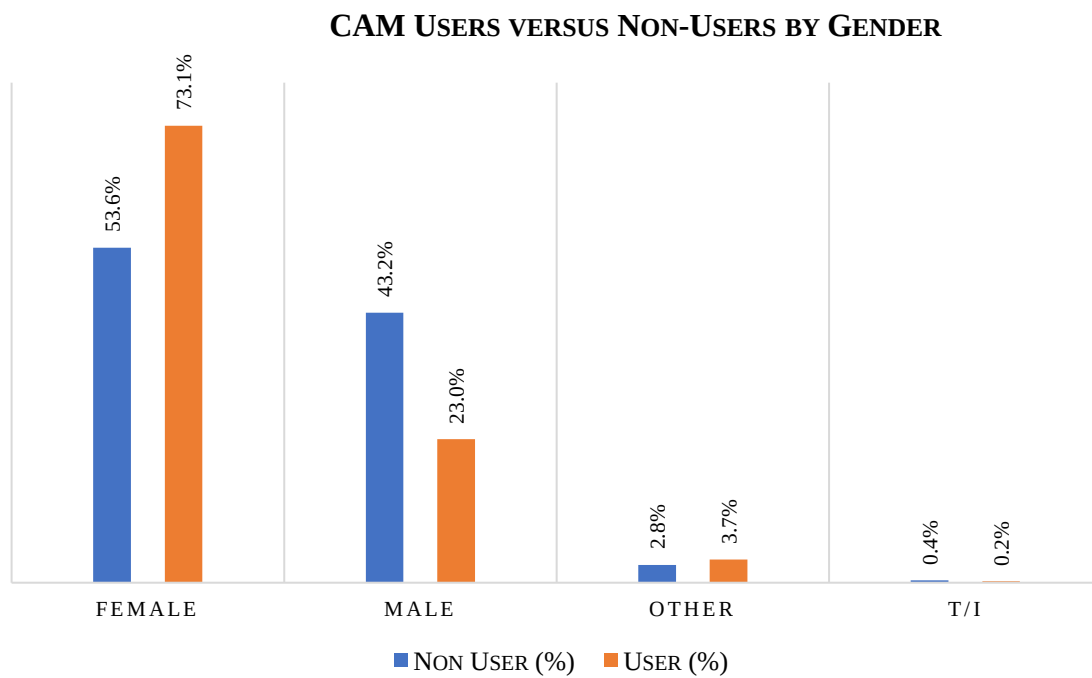


Figure 13 - CAM users versus non-users by gender

40.1% of CAM users held a post-graduate qualification, whereas only 25.6% of the non-users did, though this is likely also a function of the older demographic.

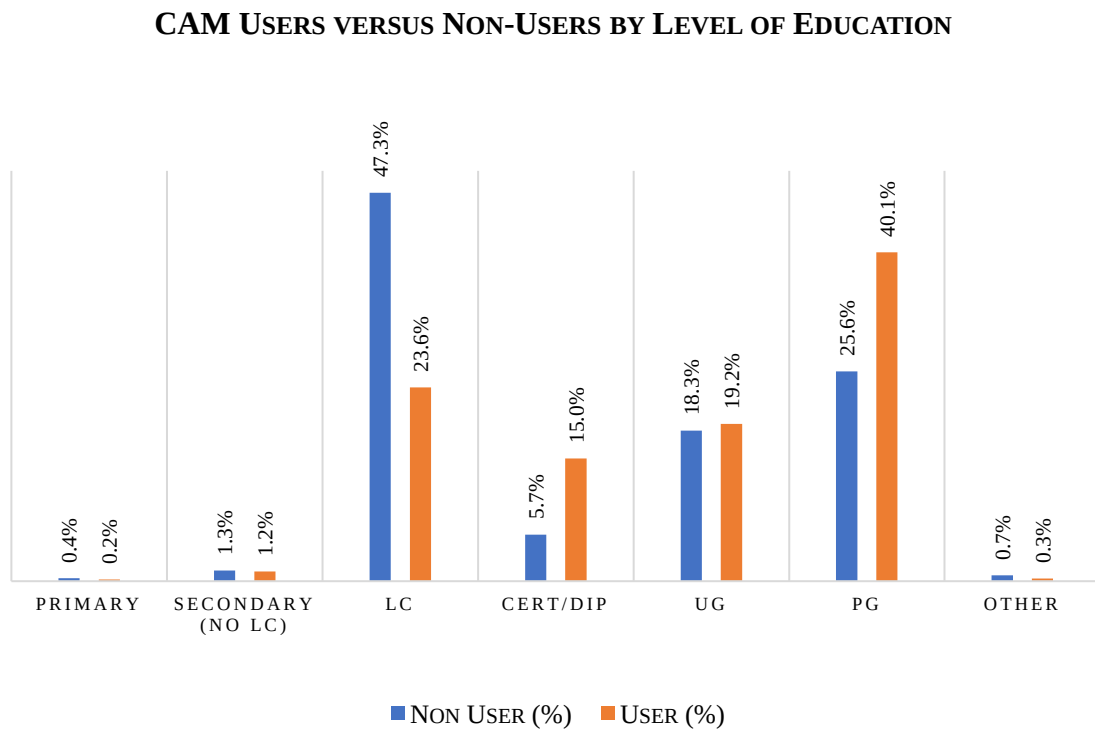


*Figure 14 - CAM users versus non-users by level of education*

As younger respondents are less likely to suffer health complaints and are therefore less likely to seek out healthcare of any kind, it was instructive to focus briefly on participants aged 35 years or over to ascertain if there were any demographic differences in this category. 73% of participants aged 35 or over had used or procured CAM.

Maintaining focus on this grouping, it is apparent that, apart from a higher percentage of postgraduate users overall, there is minimal difference in education levels between users and non-users.

### CAM USERS VS NON-USERS (OVER 35) BY LEVEL OF EDUCATION

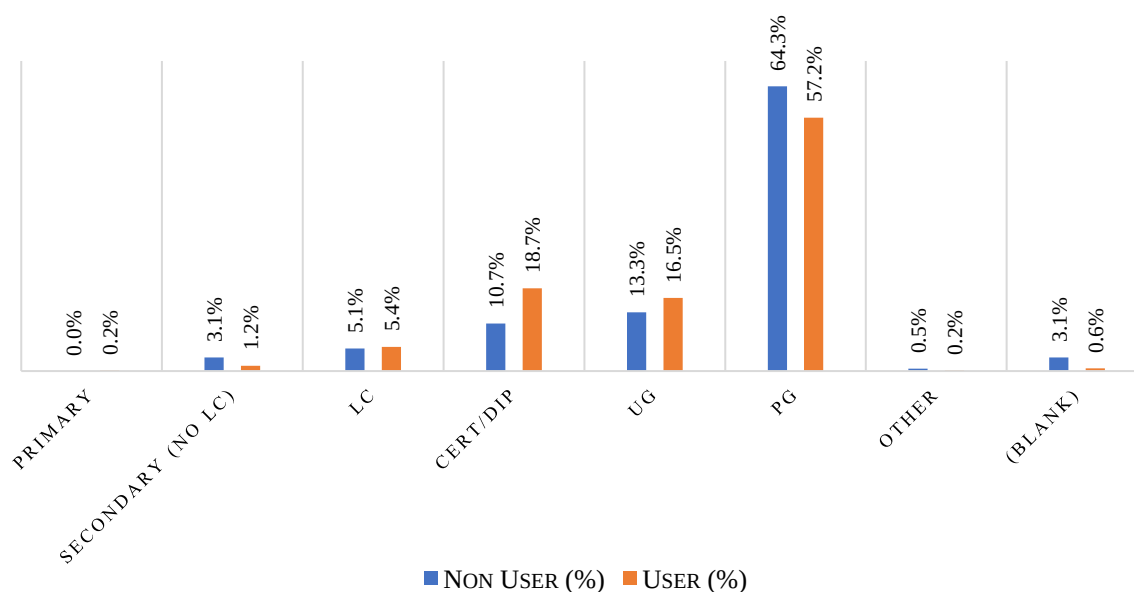


Figure 15 - Education profile of CAM users vs non-users aged 35 years and over

### 2.3 CAM PROCUREMENT FOR MINORS

Of the 276 participants who had procured CAM for another, 46.0% of these had procured a therapy for a person under the age of 18. As one might expect, this was most apparent in the 35-44 age group, with procurers predominantly female and with a higher education level than the average respondent.

### PROCURERS OF CAM FOR PERSONS UNDER 18 BY AGE GROUP VERSUS PARTICIPANTS OVERALL

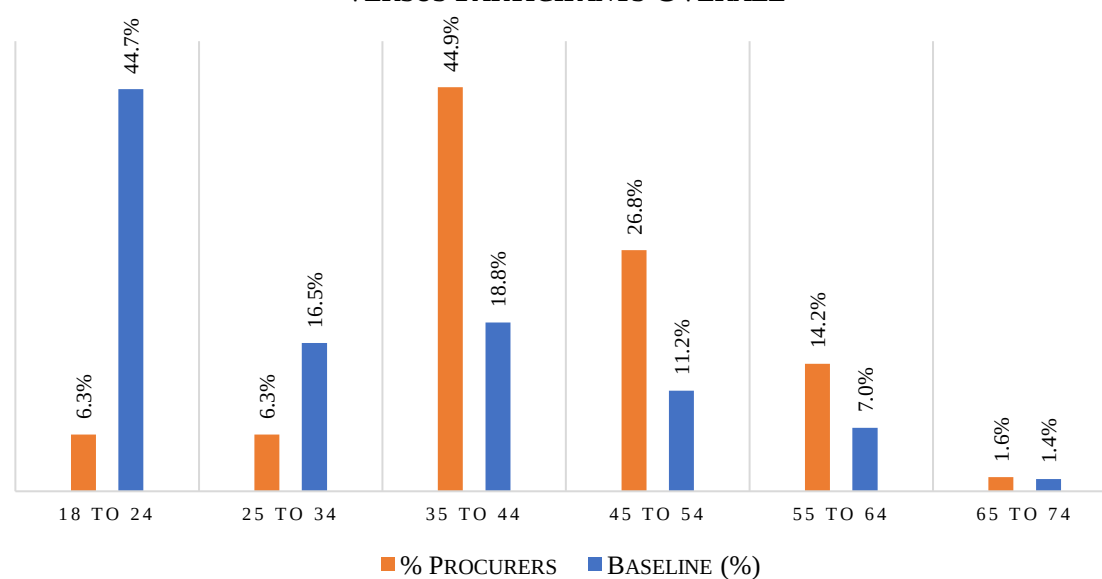


Figure 16 - Procurers of CAM for persons under 18 by age group versus participants overall

### PROCURERS OF CAM FOR PERSONS UNDER 18 BY GENDER VERSUS PARTICIPANTS OVERALL

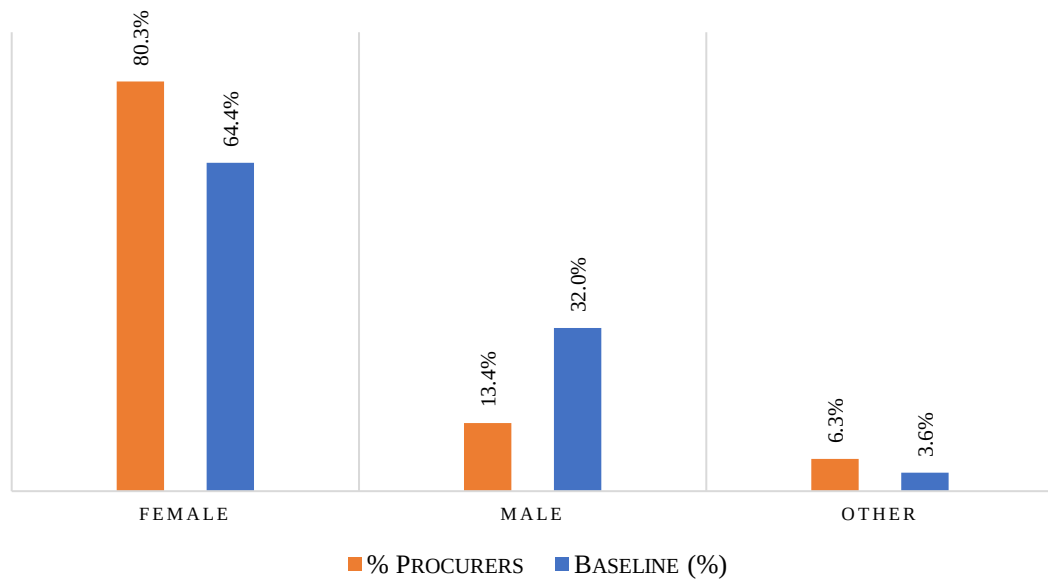


Figure 17 - Procurers of CAM for persons under 18 by gender versus participants overall

### PROCURERS OF CAM FOR PERSONS UNDER 18 VERSUS PARTICIPANTS OVERALL

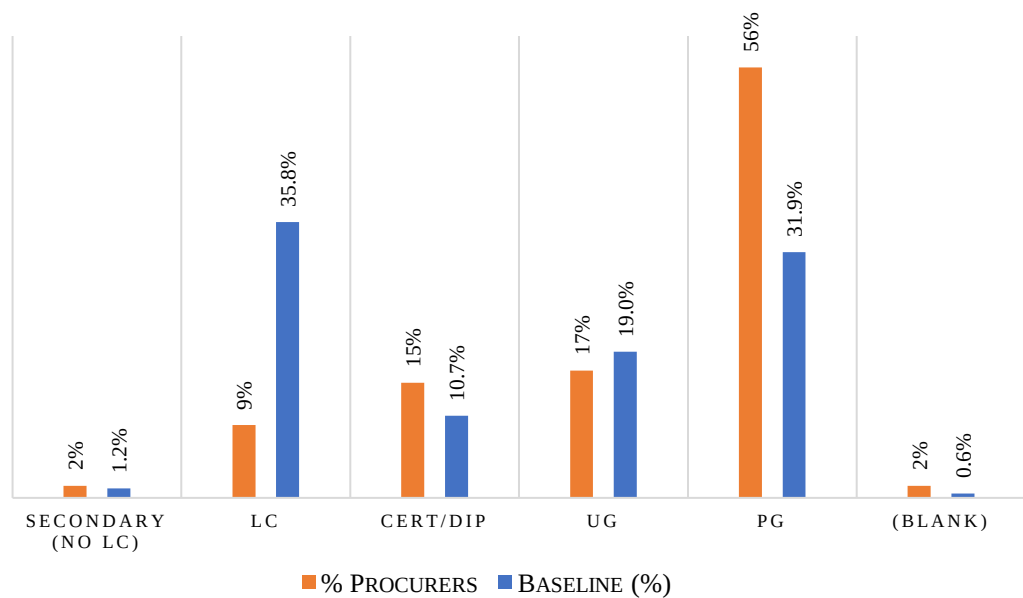


Figure 18 - Procurers of CAM for persons under 18 by level of education versus participants overall

## 2.4 RELATIONSHIP BETWEEN EDUCATION / OCCUPATION AND CAM USAGE

While higher levels of education are positively associated with CAM use,<sup>12</sup> this questionnaire sought to ascertain whether a higher level of scientific literacy predicted a lower rate of CAM use. This focussed on the areas of education and occupation. In respect of academic discipline, those with no scientific academic background and those who had studied biology were more likely than average to use or procure CAM, whereas those who had studied any other scientific discipline were equally as likely or less likely and those who had studied math or chemistry were least likely. However, given the small numbers of respondents in these groups, this result cannot be said to be significant.

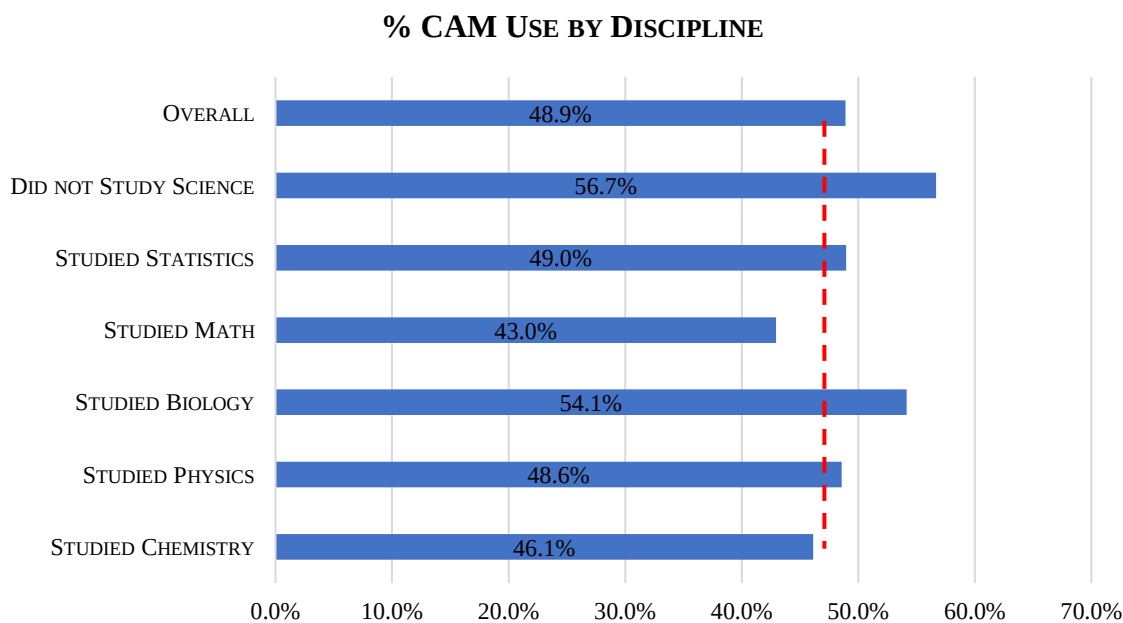


*Figure 19 - CAM use versus scientific or non-scientific academic discipline. The dashed red line represents the overall average*

In respect of occupation, those who worked in healthcare appeared significantly more likely than average to use or procure CAM, whereas those working in medical device design or manufacture and chemical engineering were much less likely than average. Overall, in all described scientific occupations except healthcare, participants were less likely than average to use CAM. However, as above, the significance of these results is limited by the small numbers of respondents in these groups.

<sup>12</sup> Patricia Fox and others (n 1) 97-98.

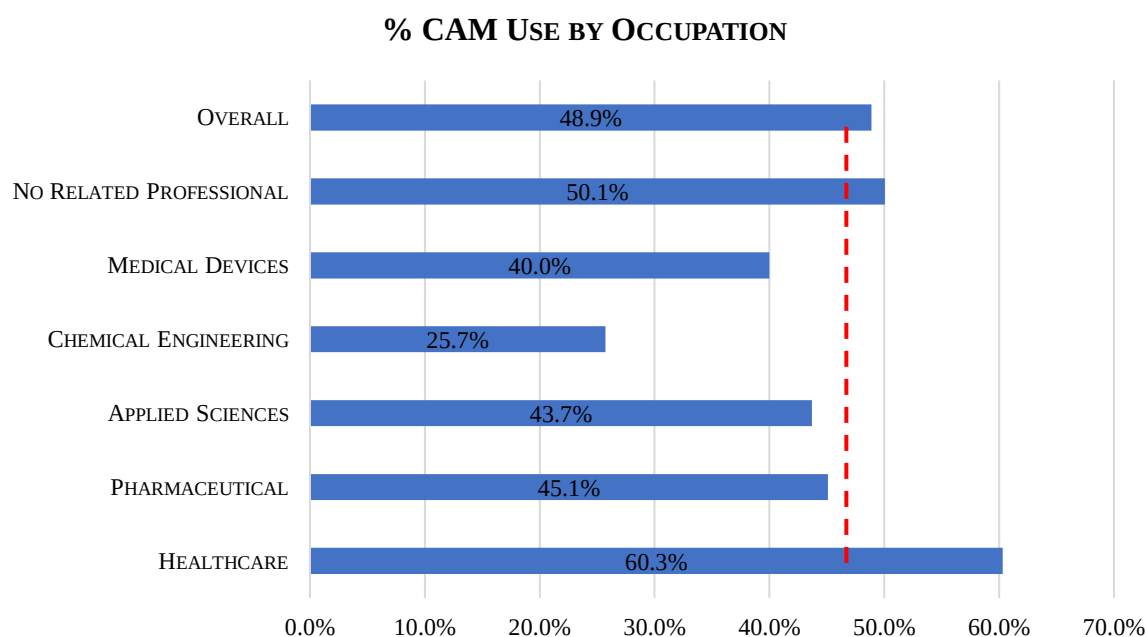


*Figure 20 - CAM use versus scientific or non-scientific occupation. The dashed red line represents the overall average*

## 2.5 CHOICE OF THERAPY

Participants used a wide range of therapies, the most popular of which were homeopathic remedies, acupuncture and chiropractic (data in respect of the ten most popular therapies are set out in *Table 6*). This coalesces with other domestic studies,<sup>13</sup> though there is some slight variance in order of preference between studies. The most popular therapies tend to vary between countries. Users typically used two or fewer different therapies.

<sup>13</sup> Patricia Fox and others (n 1), “The most popular therapies in 2002 were acupuncture (7.8%), reflexology (7%), homeopathy (6.2%), chiropractic (3.3%) and osteopathy (1.2%)”. This reflected yearly and not lifetime prevalence.

### USE OR PROCUREMENT OF INDIVIDUAL CAM THERAPIES AMONG PARTICIPANTS

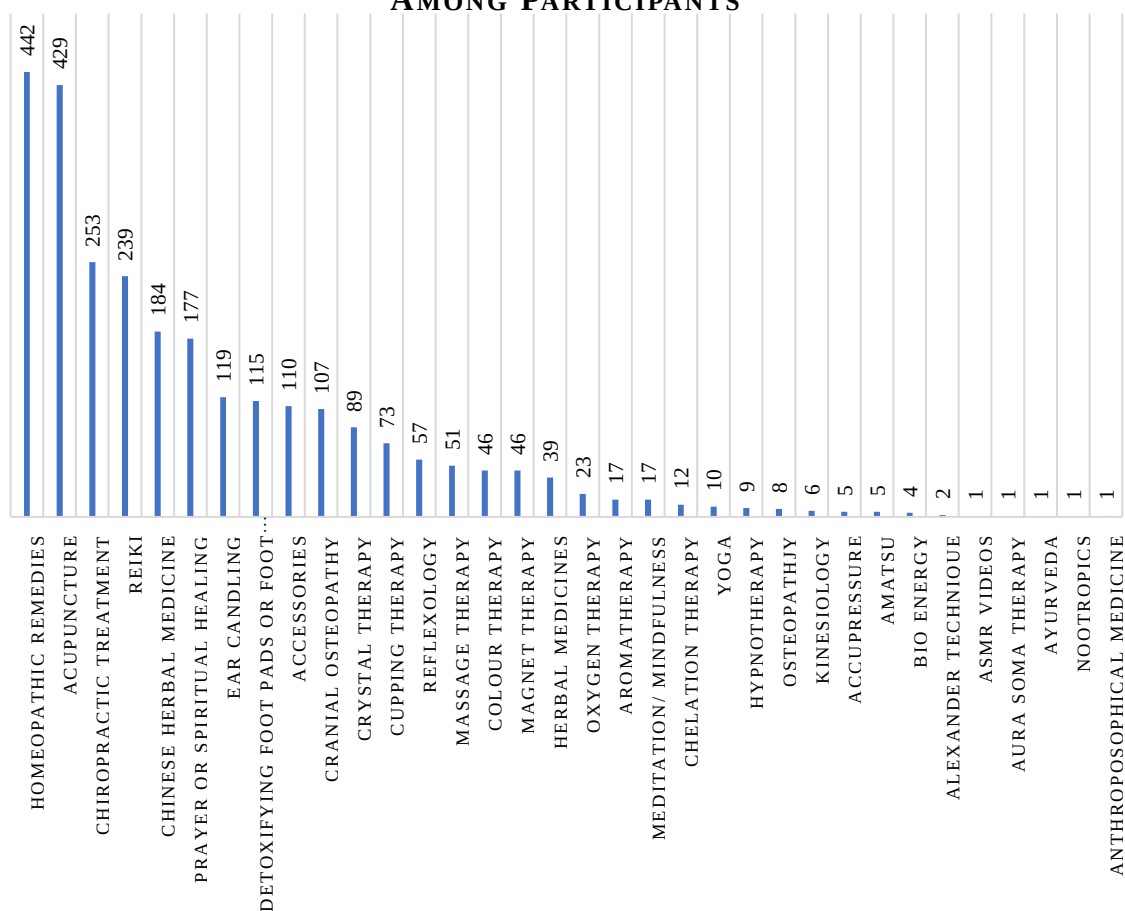


Figure 21 - Therapies by participant use or procurement

| TREATMENT                          | TOTAL | USERS (%) |
|------------------------------------|-------|-----------|
| Homeopathic remedies               | 442   | 47.9%     |
| Acupuncture                        | 429   | 46.5%     |
| Chiropractic treatment             | 253   | 27.4%     |
| Reiki                              | 239   | 25.9%     |
| Chinese herbal medicine            | 184   | 19.9%     |
| Prayer or spiritual healing        | 177   | 19.2%     |
| Ear candling                       | 119   | 12.9%     |
| Detoxifying foot pads or foot bath | 115   | 12.5%     |
| Accessories                        | 110   | 11.9%     |
| Cranial osteopathy                 | 107   | 11.6%     |

Table 6 - Most commonly used treatments among participants



## 2.6 RATIONALE FOR USE OR PROCUREMENT

The most influential factors for participants deciding to use or procure CAM were recommendations or advice from friends or family and the fact that the therapy chosen was perceived as being natural. Perceived effectiveness, the holistic nature of the therapy and a general interest in the various aspects of healthcare on the part of the participant were also common motivators.

| FACTORS INFLUENCING INITIAL USE OF CAM                                 | USERS (n) | USERS (%) |
|------------------------------------------------------------------------|-----------|-----------|
| Therapy recommended by friend, family member or other acquaintance     | 438       | 47%       |
| Therapy perceived as natural                                           | 427       | 46%       |
| Therapy perceived as effective                                         | 373       | 40%       |
| Therapy uses a holistic approach                                       | 353       | 38%       |
| Interested in many aspects of health / like to try new treatments      | 348       | 38%       |
| Therapy perceived as safe                                              | 285       | 31%       |
| Therapy perceived as best fit for healthcare needs                     | 273       | 30%       |
| Therapy recommended by conventional healthcare worker                  | 220       | 24%       |
| Wary of conventional medicine / aware of significant harm caused by it | 175       | 19%       |
| Exhausted all conventional medical options                             | 169       | 18%       |
| Unaware treatment was CAM                                              | 37        | 4%        |

Table 7 - Motivations for CAM use

## 2.7 PERCEPTIONS OF EFFICACY AND SAFETY

As perceived efficacy played an influential role in choice of a particular CAM therapy (*Table 7*), it was, by extension, important to understand the bases on which the perception of efficacy was formed. Again, advice from friends or family members played the most significant role in determining the participant's perception of efficacy, with research a close second. The inherent judgment of the participant, a referral from a conventional healthcare provider and a conversation with the CAM provider in relation to the therapy in question were similarly influential in the participant's perception of efficacy.

| REASON FOR BELIEVING CAM TO BE EFFECTIVE PRIOR TO USE                                                                                                  | USERS (n) | USERS (%) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------|
| Therapy recommended by friend, family member or other acquaintance                                                                                     | 477       | 52%       |
| Read studies and other literature on relevant therapy and, on that basis, was satisfied that it would be effective                                     | 331       | 36%       |
| Trusted own judgement - would know if a therapy was ineffective                                                                                        | 234       | 25%       |
| Therapy recommended by conventional healthcare worker                                                                                                  | 217       | 24%       |
| Spoke with retailer or service provider about experience with relevant therapy and, on that basis, was satisfied that it would be effective            | 211       | 23%       |
| Read literature provided by retailer or service provider in relation to relevant therapy and, on that basis, was satisfied that it would be effective. | 164       | 18%       |
| Therapies were freely available and could therefore be considered safe                                                                                 | 48        | 5%        |
| Worth experimenting                                                                                                                                    | 38        | 4%        |

Table 8 - Reason for believing CAM to be effective prior to use

Participant assessment of safety was similarly influenced, with advice from friends and family being the most persuasive factor, followed by existing research, the participant's inherent judgment, referral by a registered conventional physician and interaction with the retailer. The wording of these two questions was almost identical and so it is possible that some participants thought that the question was repeated and, for this reason, gave the same answer for both.

| REASON FOR BELIEVING CAM TO BE SAFE PRIOR TO USE                                                                                                 | USERS (n) | USERS (%) |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------|
| Therapy recommended by friend, family member or other acquaintance                                                                               | 514       | 56%       |
| Read studies and other literature on relevant therapy and, on that basis, was satisfied that it would be safe                                    | 364       | 39%       |
| Trusted own judgement - would know if a therapy was unsafe                                                                                       | 231       | 25%       |
| Therapy recommended by conventional healthcare worker                                                                                            | 225       | 24%       |
| Spoke with retailer or service provider about experience with relevant therapy and, on that basis, was satisfied that it would be safe           | 223       | 24%       |
| Read literature provided by retailer or service provider in relation to relevant therapy and, on that basis, was satisfied that it would be safe | 148       | 16%       |
| Therapies were freely available and could therefore be considered safe                                                                           | 69        | 7%        |
| Safety was not a consideration                                                                                                                   | 11        | 1%        |

Table 9 - Factors influencing patient perception of safety prior to CAM therapy use

## 2.8 PERCEIVED EFFECTIVENESS POST USE

Participants were asked to rate the effectiveness of the therapies they used, stating that they were completely effective, mostly effective, slightly effective or ineffective for the condition in question. Across the most popular therapies, (which give the most significant results due to the size of the sample groups), an average of 57% of participants found the therapy or therapies used completely or mostly effective.

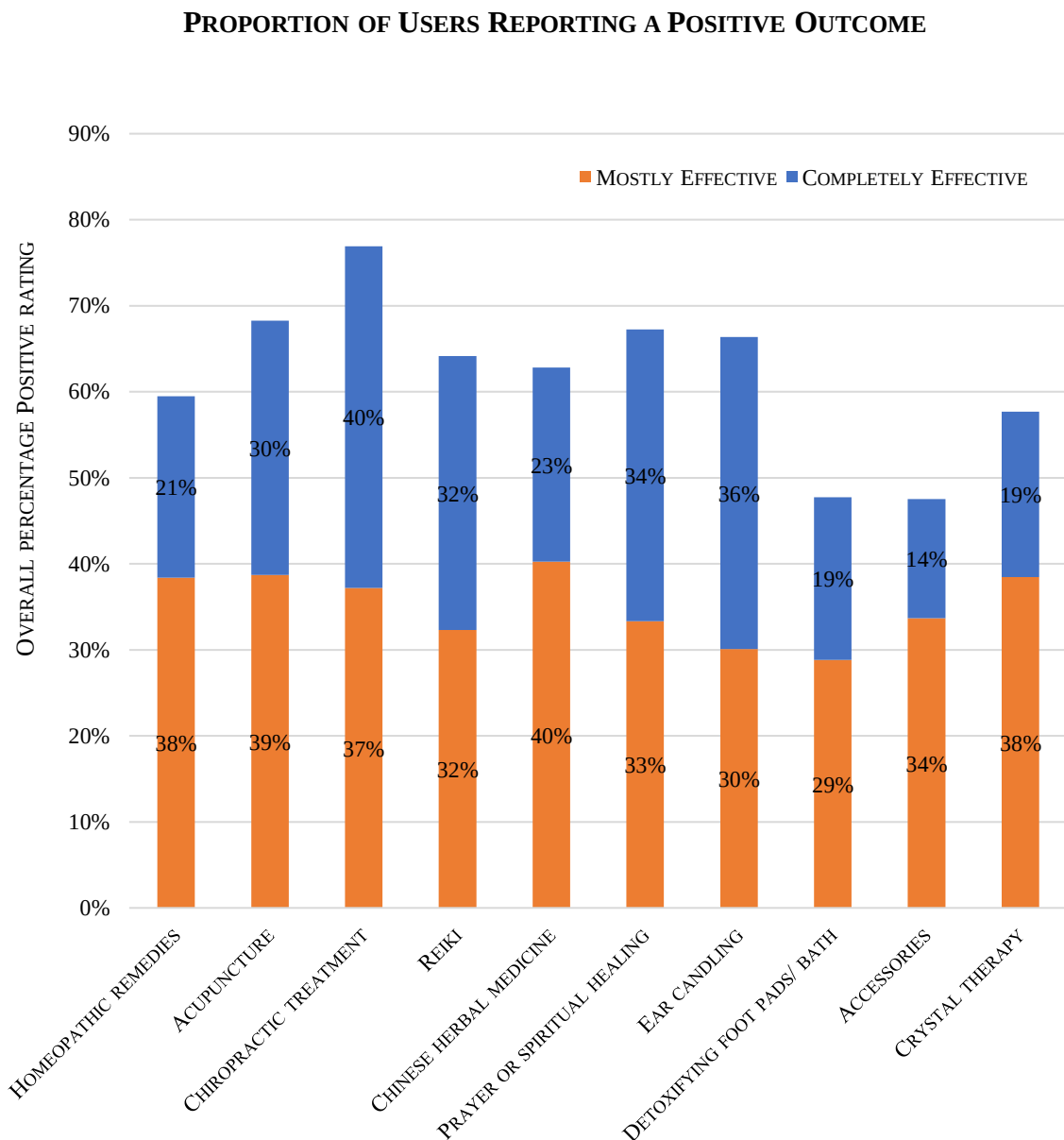


Figure 22 - Percentage positive outcome (therapy rated “completely effective” or “mostly effective”) experienced by users

## 2.9 CONSUMER PROTECTION AND CAM USE

Participants were asked about their understanding of how CAM users were protected by law in Ireland. *Table 8* shows the responses provided by users and non-users of CAM.

Overall, 44% of respondents stated that they did not know how CAM users were protected, with 57.2% of these being non-users. There is an apparent disparity between CAM user and non-user understanding of the way in which CAM is regulated. CAM users appear to perceive a higher standard of protection than non-users. Of those participants who perceived there to be one or more positive protections in place for consumers of CAM (grey), these were significantly more likely to be users than non-users. Participants who perceived no protections for consumers of CAM (orange) were quite evenly distributed across users and non-users.

| CONSUMER PROTECTION FOR CAM USERS IN IRELAND                                                                                                                                       | OVERALL | NON-USER | USER  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|----------|-------|
| Practitioners must be licenced and registered with a self-regulatory body provided for by statute, similarly to conventional doctors                                               | 5%      | 27.6%    | 71.3% |
| In the case of consumer grievances, practitioners in Ireland are subject to review and potential sanction by self-regulatory bodies provided for by statute                        | 4%      | 27.0%    | 73.0% |
| CAM medicinal products for human use are required to meet the same standards of safety and efficacy as conventional medicinal products in order to be approved for sale in Ireland | 5%      | 36.3%    | 63.7% |
| Practitioners must be registered with a voluntary professional body or association in order to practice in Ireland                                                                 | 6%      | 25.0%    | 75.0% |
| Practitioners must hold a recognised qualification to practice legally, but need not be registered with any professional or statutory body                                         | 9%      | 26.1%    | 73.9% |
| No particular qualification or registration is required to work as a CAM practitioner                                                                                              | 18%     | 48.8%    | 50.9% |
| There is no regulation specifically addressing CAM medicinal products in Ireland - general consumer protection laws are applicable                                                 | 22%     | 48.4%    | 51.3% |
| There is no regulation specifically addressing CAM practices or practitioners - general consumer protection laws are applicable                                                    | 21%     | 44.0%    | 55.8% |
| I don't know                                                                                                                                                                       | 44%     | 57.2%    | 42.3% |

*Table 10 - Participant understanding of protections – users and non-users. The answers are not mutually exclusive*

### 3. DISCUSSION

The clarification provided by this small study is limited in terms of sample group, which, though large, was heavily populated in particular age, education and gender groups. It is necessary to view the results in this light.

Overall, the results obtained from this questionnaire reflect those obtained from similar research performed domestically and internationally.<sup>14</sup> While they provide a contemporary outline of consumer motivation and general understanding of CAM in Ireland, given the significant limitations of the questionnaire overall, particularly in representativeness, it will be considered in conjunction with other domestic and international research in forming any conclusions or offering recommendations. Future research would benefit from a broader national cross-section, with data obtained through one-to-one interviews, by phone and in writing, rather than limiting it to those with internet access. Additional sociodemographic and medical information would also enhance the utility of future research.

The magnitude of the response was unexpected, with 1,887 completed questionnaires submitted. This provides some indication of the interest in CAM itself and in the debate surrounding it,<sup>15</sup> taking in issues of freedom in healthcare, self-determination, consumer protection and regulation. The questionnaire received significantly more female responses than male, which may perhaps be attributed to the influence of gender on online behaviour,<sup>16</sup> to differing levels of interest in CAM specifically, which is apparent from the clear gender division in usage, or to differences between genders in the level of interest taken in health-related issues generally.<sup>17</sup>

#### 3.1 USER DATA

CAM user data obtained from this questionnaire reinforce those from previous similar research performed domestically and internationally,<sup>18</sup> with CAM users tending to be female, aged 35 years

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<sup>14</sup> Patricia Fox and others (n 1); Fiona Mc Kenna and Fionnuala Killoury (n 3).

<sup>15</sup> Alex Meehan, 'Alternative therapies: What's fact, what's fiction' *Irish Independent* (12 October 2016) <[www.independent.ie/life/health-wellbeing/health-features/alternative-therapies-whats-fact-whats-fiction-35118638.html](http://www.independent.ie/life/health-wellbeing/health-features/alternative-therapies-whats-fact-whats-fiction-35118638.html)> accessed 14 October 2016.

<sup>16</sup> Linda A Jackson and others, 'Gender and the internet: women communicating and men searching' (2001) 44 *Sex Roles* 363, 374. According to the authors, the online behaviour of women reflects an information exchange preference, whereas the behaviour of men demonstrates an information seeking preference. As the completion of an online questionnaire constitutes an exchange of information, this was likely to attract more female responders.

<sup>17</sup> Stefan Ek, 'Gender differences in health information behaviour: A Finnish population-based survey' (2015) 30(3) *Health Promotion International* 736, "The results show that women were more interested in and reported much more active seeking of health-related information, paid more attention to potential worldwide pandemics and were much more attentive as to how the goods they purchase in everyday life affect their health than men did. Women also reported receiving far more informal health-related information from close family members, other kin and friends/workmates than men did".

<sup>18</sup> Felicity Bishop and GT Lewith, 'Who uses CAM? A narrative review of demographic characteristics and health factors associated with cam use' (2010) 7 *Evidence-based Complementary and Alternative Medicine*

or over and third-level educated. As established previously, this particular group also tend to have disposable income to spend on self-care.<sup>19</sup>

The CAM usage data focussed on lifetime rather than one-year prevalence, and the figure obtained, being 48.9%, is within the range of previous studies undertaken in the UK.<sup>20</sup> However, as noted above, this is unreliable due to the limited cross section of the sample group accessed.

One unexpected consideration arising was that of participant gender. Whereas, traditionally, questionnaires provided a binary 'male/female' option and more recently a "male/female/other" option, the recent shift in societal attitude<sup>21</sup> supported a more inclusive approach, which, after some consideration, resulted in the use of a text box, with the question "With which gender do you currently identify?". This aimed to encourage those who were transgender<sup>22</sup> or intersex<sup>23</sup> to give their views,<sup>24</sup> as distinct groups with their own particular health needs<sup>25</sup> and with distinct consumer and social contexts.<sup>26</sup> It also facilitated those who identified as female or male to express this, avoiding the transgender or intersex categorisation if they wished. While the numbers of participants identifying as falling within the T/I category was too small to reliably identify significant trends in the broader population, this may prove to be an interesting area for future research.

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11, "The evidence suggests that people who use CAM tend to be female, of middle age and have more education".

<sup>19</sup> Roger Jones, *Oxford Textbook of Primary Medical Care* (Oxford University Press 2004) 118.

<sup>20</sup> Paul Posadzki and others, 'Prevalence of use of complementary and alternative medicine (CAM) by patients/consumers in the UK: Systematic review of surveys' (2013) 13(2) *Clinical Medicine* 126, 127, where lifetime prevalence here was found to be 58.7%; Katherine J Hunt and others 'Complementary and alternative medicine use in England: Results from a national survey' (2010) 64 *International Journal of Clinical Practice* 1496, where lifetime prevalence was found to be 44%.

<sup>21</sup> This shift is visible, albeit within a very limited remit, in the enactment of the Gender Recognition Act 2015.

<sup>22</sup> Craig Forsyth and Heith Copes, *Encyclopedia of Social Deviance* (SAGE Publications 2014) 740, "Transgender is an umbrella term for people whose gender identities, gender expressions, and/or behaviors are different from those culturally associated with the sex to which they were assigned at birth".

<sup>23</sup> Agnes Higgins and others, *The LGBTIreland Report: National Study of the Mental Health and Wellbeing of Lesbian, Gay, Bisexual, Transgender and Intersex People in Ireland* (GLEN and BeLonG To 2016) 19, "Intersex stands for the spectrum of variations of sex characteristics that occur within the human species. It is a term used to describe individuals who are born with sex characteristics (chromosomes, genitals, and/or hormonal structure) that do not belong strictly to male or female categories, or that belong to both at the same time".

<sup>24</sup> The particular terms "transgender" and "intersex" were chosen as umbrella terms to reflect their use in Agnes Higgins and others (n 23). However, notwithstanding their well-intentioned use in this questionnaire, such terms are rarely exhaustive. The omission of any groups or individuals identifying as falling outside these two umbrella terms is inadvertent.

<sup>25</sup> World Health Organisation/ Pan American Health Organisation, 'Addressing the causes of disparities in health service access and utilization for lesbian, gay, bisexual and trans (LGBT) persons (Concept paper)' (2013), paras 10-14. In 1999, the American Public Health Association, in their paper 'The need for acknowledging transgender individuals within research and clinical practices', addressed the specific public health requirements of transgender people.

<sup>26</sup> *ibid*, para 14(f), "Transgender individuals have a high prevalence of HIV/STIs, victimization, mental health issues, and suicide and are less likely to have health insurance than heterosexual or LGB persons. Trans individuals are also at higher risk of being unemployed, experiencing discrimination in the workplace, and being victims of violence in the community".

### 3.2 AGE

CAM use appears to increase with participant age. This may reflect a number of factors, including the increased likelihood of illness with age, greater potential for exposure to negative experiences in conventional medicine, or to publicity surrounding the negative experiences of others, and greater potential for exposure to other cultures and ideas. There may also be some association with parenthood, when parents consider afresh the risks they are willing to accept, including those arising from conventional medicine, seeking, instead, therapies that they perceive as being safer or more natural.<sup>27</sup> However, according to Brinig, this risk aversion is a function of age and gender, rather than parenthood per se, with female risk aversion peaking at age 30.<sup>28</sup> By happy coincidence, this is the average age of a first-time mother in Ireland.<sup>29</sup>

### 3.3 EDUCATION/OCCUPATION

Although CAM use was most significant in those without third level education or occupation in a scientific field, the difference between the two groups was, in reality, minimal, due to the small numbers of respondents in each group. Nominally, the difference observed may be due to lower levels of scientific or research literacy within this group, or to the principled or reasoned rejection of theories or practices considered unviable within strict scientific orthodoxy on the part of those with scientific training, though it is likely to be a mix of these and other factors. If verified by further research, this may be significant for those considering regulation or policy changes, as general improvements in scientific literacy may help consumers to make improved healthcare choices in all sectors.<sup>30</sup>

In both the scientific education and occupation groups, although those who had not studied science or worked in a scientific occupation were most likely to use CAM, there were also outliers in the form of those who had studied biology and those working or hoping to work in healthcare respectively. Respondents in both groups had a higher than average rate of CAM use. For those in front-line healthcare occupations, this may be due to a broad interest in many types of healthcare,<sup>31</sup> or to a real-world understanding of the important role played by interpersonal skills in healthcare and in the patient experience. Where a healthcare professional does not perceive a direct risk, they may be happy to use a therapy or, indeed, to recommend it to a patient. 24% of respondent CAM users in

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<sup>27</sup> Edward O Wilson, *On Human Nature* (Harvard University Press 1978) 86-87, 124.

<sup>28</sup> Margaret F Brinig, 'Does mediation systematically disadvantage women?' (1995) 2 *William & Mary Journal of Women and the Law* 1, 16-17.

<sup>29</sup> Central Statistics Office, 'Vital Statistics: Yearly Summary 2015' (2016), "The average age of first time mothers in 2015 was 30.7 years, up 0.2 years from 2014" <[www.cso.ie/en/releasesandpublications/ep/p-vs/vitalstatisticsyearlysummary2015/](http://www.cso.ie/en/releasesandpublications/ep/p-vs/vitalstatisticsyearlysummary2015/)> accessed 14 October 2016.

<sup>30</sup> Billy McClune and Ruth Jarman, *Developing Scientific Literacy: Using News Media in The Classroom* (McGraw-Hill Inc 2007) 2.

<sup>31</sup> Table 7, Motivations for CAM use. 38% of users stated that this was a contributing factor in their use of a CAM therapy.

this study stated that they had used a CAM therapy on the recommendation of a conventional healthcare provider.<sup>32</sup> Healthcare professionals may also be aware of the limitations of the particular CAM therapy and be able to use their own skill and judgment to seek assistance in the conventional sector when necessary, though this would not be the case for the referred patient left to their own devices to negotiate the parameters of their use. This highlights the key benefit of increased public scientific literacy overall<sup>33</sup>; reliance on the information obtained from less reliable sources would likely not be as significant for those with good science or healthcare literacy as it might be for those with no or poor science or healthcare literacy.

Third level education in biology, as the second outlier, may be considered as a pre-emptor to a healthcare occupation or may suggest an interest in biological systems generally, though this is difficult to determine with any certainty.

### **3.4 PROCUREMENT OF CAM FOR PERSONS UNDER THE AGE OF 18**

6.7% of respondents (n=127) had procured CAM for a person under the age of 18. The use of CAM for children, as noted in Chapter 4, creates additional risks to those undertaken by adult users.<sup>34</sup> A child cannot consent<sup>35</sup> and the consent by proxy given by parents may not be valid if not adequately informed. Given the inherent vulnerability of children, the clear confusion among participants as to the available protections for consumers of CAM in Ireland (*Table 10*), the difficulty in discerning accurate from inaccurate information on CAM generally and, in many cases, the absence of a proven favourable risk-benefit balance in any cohort, the protection of children from therapies unsupported by high quality evidence of safety and efficacy must be prioritised. The voluntary self-regulatory system has not performed adequately in this respect and the carte blanche afforded to parents under the Constitution in respect of the care of their child has only served to magnify the risk.

### **3.5 INFORMATION SOURCES**

The data obtained showed significant reliance on anecdotal evidence, in the form of advice or recommendations from friends, family or other acquaintances. Though this is considered an

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<sup>32</sup> *ibid.*

<sup>33</sup> Hilda Bastian, Thomas Kaiser, Sindy Matschewsky, 'Promotion of general health and scientific literacy via consumer and patient information: The role of the IQWiG' (2005) 99(6) *Zeitschrift für Ärztliche Fortbildung und Qualitätssicherung* 379, "The promotion of general health- and scientific knowledge (critical health information, or health literacy) is strongly associated with good health outcomes and patient empowerment in several ways. Unlike other factors that determine health outcome and patient empowerment, health literacy is modifiable".

<sup>34</sup> See Chapter 4, Part I.

<sup>35</sup> A person between the ages of 16 and 18 can consent to some medical procedures though it is uncertain whether this applies to CAM.



unreliable source of evidence, its influence is disproportionate.<sup>36</sup> Improvement in scientific and healthcare literacy, as mentioned above, may reduce reliance on lower quality information sources and enhance healthcare decision-making.

## CONCLUSION

CAM is popular among consumers in Ireland, despite inconsistent understanding of how and to what extent it is regulated and the differences in standards between it and conventional medicine.

As noted throughout this thesis, apart from regulation of medicinal products for human use, addressing traditional herbal and homeopathic remedies,<sup>37</sup> and the applicability (though not, it seems, the application)<sup>38</sup> of consumer law generally, there is an absence of regulation specifically addressing the provision of CAM therapies in Ireland. This has created a fertile space in which claims overstating the safety and efficacy of products and services have flourished. Nonetheless, there is a strong perception of effectiveness among consumers (*Figure 22*), which, though in many cases in conflict with the best available evidence, cannot and should not be dismissed out of hand. Instead, there is the potential to use this information, albeit, perhaps, on a larger scale, to inform patient care across the healthcare spectrum. By improving conventional care, supported by evidence, there is the potential to increase effectiveness and patient satisfaction.

The lack of reliable information available to and recognisable by consumers is problematic and is reflected, in part, in the reliance on anecdotal evidence among participants. Most consumers do not have access to medical journals, which often use a subscription model, but were this not the case, consumers may still not be capable of discerning reliable journals from unreliable or high quality research from low. This is a failure in education from primary school onwards, with those setting the school curricula neglecting to recognise the need to adapt to deal with an increasingly data-driven society. As noted in Chapter 5, information disseminated by the media in its various formats can be unreliable, preferring eye-catching headlines or emotive human interest points over pertinent scientific fact, presenting a skewed perspective on what is safe and, indeed, what is possible in conventional medicine and in CAM, as well as in science generally. Though efforts have been made by, for example, the Cochrane Collaboration to bring accessible and objective systematic reviews to the public realm, its effects are nonetheless limited in a lay population, where people are not necessarily aware of the value of such endeavours. It is argued, however, that it is not the primary responsibility of these organisations to attempt to influence individual health behaviours but to

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<sup>36</sup> Hans Hoeken, 'Anecdotal, statistical, and causal evidence: Their perceived and actual persuasiveness' (2001) 15 *Argumentation* 425, 428. The author asks whether this is because "anecdotal evidence usually presents an anecdote to support the claim; statistical evidence consists mainly of statistics. In general, an anecdote is easier to imagine than statistics. A vivid argument would be more convincing than a more pallid one".

<sup>37</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67.

<sup>38</sup> See, for example, Chapter 3.

provide high quality and objective information upon which local health policy can be formulated and an official stance taken on various aspects of healthcare, which could then be relied upon by consumers in their decision-making and by those tasked with enforcing the applicable laws.

Ireland is in an advantageous position, relative to some other jurisdictions in this respect, as no particular stance has been taken previously and therapies have not been funded by the State. By contrast, the UK National Health Service is now in the position of acknowledging the lack of proven efficacy of some therapies, such as homeopathy, while continuing to fund them, albeit to a reduced extent.<sup>39</sup>

The use of high quality global research in the development of an official stance on CAM therapies, both individually and overall, would provide greater certainty for consumers and should include special consideration of the use of CAM for minors. A model regulatory framework for these purposes, together with an alternative set of individual considerations are set out in detail in Chapter 7.

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<sup>39</sup> NHS Choices, 'Homeopathy' (2015), "Does it work? There has been extensive investigation of the effectiveness of homeopathy. There is no good-quality evidence that homeopathy is effective as a treatment for any health condition... It is available on the NHS? Homeopathy is not available on the NHS in all areas of the country. Two NHS hospitals provide homeopathy, and some GP practices also offer it" <[www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx](http://www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx)> accessed 10 September 2016.

## CHAPTER 7

### IMPROVING PROTECTION FOR CONSUMERS OF CAM IN IRELAND

#### INTRODUCTION

Having researched for and written this thesis over four years, it is a source of both convenience and of frustration that little of substance has changed for the regulation of CAM in Ireland: there are still no minimum standards for education or training, professional registration is voluntary, grievance procedures are opaque and existing consumer protections are not appropriately enforced in the sector, leaving unsafe or inefficacious therapies freely available and high quality information difficult to find and easily contradicted by providers, albeit acting in good faith. Freedom of expression is used by some in the CAM sector to disseminate misleading information and to chill dissenting opinion. Children treated with CAM remain unprotected from what may be objectively suboptimal or potentially life-threatening healthcare choices of their otherwise caring and conscientious parents. Whether this is because of the inherent complexities of implementing a regulatory regime for the sector, which are apparent, not only from domestic consultation,<sup>1</sup> but also from international commentary,<sup>2</sup> or due to general lack of recognition of the importance of regulation of the sector, the relevant state actors have been either neglectful, cowardly or, given the popularity and visibility of CAM in Ireland, wilfully ignorant, placing the public at risk of physical, psychological or financial harm. ‘Fiscal restraint’ is likely to provide a large shield behind which would-be legislators can hide and certainly it is both appropriate and necessary to adopt a cautious approach to novel spending in a previously undemanding sector. Difficulties in wrangling the many factions and facets of the broad expanse of CAM in order to gain assent on regulation or the likely political backlash from some members of the public<sup>3</sup> and from unhappy practitioners may also create a viable excusatory pretext. These are not, however, justification for the continued failure to act to protect the public as a whole in this sector.

Change is required to protect consumers of CAM, to protect public health by guarding veracity, transparency and openness in healthcare and scientific debate and to protect children subjected to unsafe or inefficacious therapies at the behest of their parents. Whether the model changes set out in Part II of this chapter would provide the protection needed and whether they would be acceptable to legislators, to practitioners, to proponents, and to consumers, remains to be seen, although, due to the contentious nature of the topic in question, consensus seems unlikely. Strong opinions are not in

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<sup>1</sup> Teri Garvey, *Report of the National Working Group on the Regulation of Complementary Therapists to the Minister for Health and Children* (Stationery Office 2005).

<sup>2</sup> Council of Europe Parliamentary Assembly, Resolution 1206 (1999), ‘A European approach to non-conventional medicines’ [5].

<sup>3</sup> The topic of CAM is a source of impassioned debate, as noted in Chapter 6.

short supply, but this should not and cannot prevent regulators from meeting their duty to protect the public.<sup>4</sup>

Chapter 7 is divided into two substantive parts, with one overall conclusion. Part I considers the system of voluntary self-regulation currently in place. This has clearly proven unsatisfactory, given all that has been discussed before. However, this system has been favoured in many jurisdictions, it was the predominant one recommended to be maintained by the National Working Group on the Regulation of Complementary Therapists (albeit in a more robust form and with some statutory regulation for therapies bearing particular risks) and the Irish Government has not seen fit to deviate from it.

Part I briefly examines the European recommendations arising from the 1997 and 1999 Resolutions on non-conventional medicine.<sup>5</sup> These documents emphasise the importance of standardisation of various CAM practices in the protection of consumers travelling between Member States and in the realisation of the fundamental freedoms but return time and again to the subsidiarity of healthcare policy and regulation to Member States,<sup>6</sup> despite a number of European instruments which fly in the face of this (none of which directly address CAM), eventually recommending voluntary harmonisation of standards between Member States and encouraging them to “model their approach on their neighbours’ experiments and, whenever possible, to co-ordinate their position with regard to these medicines”.<sup>7</sup> Although this has yet to come to fruition (and it is argued that, due to the difficulty in finding consensus within one individual therapeutic modality in Ireland, let alone among myriad international counterparts, it is highly unlikely to), it is instructive to consider examples of regulatory frameworks in other jurisdictions, if not to harmonise, then simply to understand what has succeeded and what has failed. For this purpose, the UK, Australia and Minnesota in the United States are examined.<sup>8</sup> These were selected as established regimes with varying but not completely alien cultures of CAM use and ones which have had to address challenge, both from consumers and proponents and from the conventional medical or scientific community. However, Part I concludes that the cultural and political entanglements with CAM in these and other jurisdictions render any potential contribution to the formation of a novel regime for CAM subject to its malleability for the Irish context. Treatment culture and context is not a matter of cut-and-paste and nowhere has its importance been more apparent than in the delivery of CAM services.<sup>9</sup>

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<sup>4</sup> This was reinforced in Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2) [5], “Establishing a legal framework for non-conventional medicine is a difficult undertaking, but it is preferable to being too liberal”.

<sup>5</sup> European Parliament Resolution on the status of non-conventional medicine (1997) OJ C182/67 and Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2).

<sup>6</sup> Consolidated version of the Treaty on European Union (2012) OJ C326/13, Art 168.

<sup>7</sup> Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2) [6].

<sup>8</sup> CAM is regulated at a state and local level in the US. See NCCIH, ‘Credentialing, Licensing, and Education’ (2015) <<https://nccih.nih.gov/health/decisions/credentialing.htm>> accessed 15 October 2016.

<sup>9</sup> See Chapter 2.

Having considered the existing domestic regime and some of its international counterparts, Part II presents model recommendations for broad changes to be made to the existing regime in Ireland. Three potential approaches are offered, one which requires simply that existing legislation on consumer protection be fully enforced in the CAM sector, one which adds to this numerous other novel provisions, some of which may be considered controversial or draconian but all of which have the objective of improving protection for consumers generally and particularly for vulnerable groups such as children, and a final, compromise position which calls for moderate improvements including the implementation of a regime similar to that of Government Sponsored Self-Regulation, described by Michael Weir,<sup>10</sup> combined with restrictions on specific procedures considered to be high risk, concerted efforts to improve public health and research literacy, and the improvements in consumer protection enforcements described above. None of these approaches are perfect but they demonstrate the potential for action. Part II concludes by attempting to address some outstanding issues which may have fallen, if not outside the scope of this thesis, then at its outer perimeters, or which it was not possible to address in detail but which present a basis for further study, analysis or consideration, particularly by future regulators.

Part III concludes the thesis with a final call for change. The risk at which consumers (particularly vulnerable consumers) find themselves is unacceptable but is open to improvement and attenuation. Ignorance, reticence and avoidance are no longer satisfactory. Action is long overdue.

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<sup>10</sup> Michael Weir, 'Regulation of Complementary and Alternative Medicine Practitioners' (2006) 23(2) *Law in Context* 179-80.

## PART I

### APPRAISING THE FAILED SYSTEM AND CHANGING DIRECTION

#### 1. A BRIEF NOTE IN SUPPORT OF THE IMPUGNED SYSTEM

At present, CAM operates within a voluntary self-regulatory framework, whereby practitioners are required to act within the parameters of the law as it applies generally and as it applies to all traders, but are bound by no greater duty arising by virtue of their particular area of commerce. The specific and far-reaching inadequacies of this type of regulation in this context have been discussed at length throughout this thesis. However, consensus on a move to statutory regulation is not forthcoming. Various commentators have rightfully acknowledged the potential issue in replacing the voluntary system with an expensive statutory system that confers official recognition and status on therapies potentially lacking supportive scientific evidence of safety or efficacy, obliquely endorsing their use in the eyes of the public.<sup>11</sup> This is a serious concern and not one that is easily addressed by the recommendations set out in Part II. In addition, the voluntary system is relatively inexpensive, ostensibly politically neutral<sup>12</sup> and resource-unintensive, with the state taking no part whatsoever in the setting of educational standards, the development of codes of practice and ethics, administration, or discipline. The same cannot be said for the proposed system.

In 2005, the National Working Group on the Regulation of Complementary Therapists reported that:

The general thrust of public policy, here and in the EU, is towards minimising statutory regulation i.e. by law. The policy generally is only to regulate by statute when there is an overriding public interest for an activity to be regulated.

The trend internationally in the regulation of complementary therapists is away from statutory regulation and towards a robust system of voluntary self-regulation policed by one overall body for each therapy.<sup>13</sup>

Whereas the current voluntary system could not be considered robust, consideration should be given to this proposition.

The existing voluntary self-regulatory system for CAM in Ireland does not feature one representative body for each practice, but, in some cases, numerous bodies. An acupuncturist in Ireland, for example, may become a member of one or more of the Professional Register of Traditional Chinese Medicine (PRTCM), the Acupuncture Council of Ireland (ACI) or the Acupuncture Foundation

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<sup>11</sup> For example, Julie Stone and Joan Matthews, *Complementary medicine and the law* (Oxford University Press 1996) 92. See also, Edzard Ernst, 'Regulation of complementary and alternative medicine' (2003) 8 Focus on Alternative and Complementary Therapies 291, 292.

<sup>12</sup> Although this is less of a definitive choice than a fortunate default position.

<sup>13</sup> Teri Garvey (n 1) 39.

Professional Association (AFPA).<sup>14</sup> While this provides scope for practitioners to determine which body aligns best with their own personal healthcare ethos, it may also encourage a race to the bottom, as bodies with lower educational standards, registration requirements, membership fees, or a laxer approach to enforcement of codes of conduct may attract more members than others. A single, consolidated body, if one could be formed, would permit the development of unified standards for education and practice in a particular therapeutic modality and would provide a single grievance mechanism for consumers. In addition, it would be easier to educate the public to choose practitioners accredited by a single, named body than by a mixture of different bodies with varying standards.

Budd and Mills<sup>15</sup> set out a number of criteria for an effective voluntarily self-regulating professional body, which may be useful for those attempting to bolster the existing voluntary self-regulatory system in this way. Such a body, they say:

- (a) maintains a register of individual members or member organisations;
- (b) sets educational standards and runs an accreditation system for training establishments;
- (c) maintains professional competence among its members with an adequate programme of Continuing Professional Development;
- (d) provides codes of conduct, ethics and practice;
- (e) has in place a complaints mechanism for members of the public;
- (f) has in place a disciplinary procedure that is accessible to the public;
- (g) requires members to have adequate professional indemnity insurance;
- (h) has the capacity to represent the whole profession;
- (i) includes external representation on executive councils to represent patients or clients and the wider public interest.<sup>16</sup>

Many of the representative bodies for CAM in Ireland *prima facie* meet some of these criteria, although the grievance mechanisms are far from transparent and the outcome reports of such evade even Google.<sup>17</sup> Where such mechanisms are properly utilised and reports written, their lack of public accessibility renders them less than meaningful, a classic case of abiding by the word of the law but not the spirit. Calling upon a single, unified representative body to improve transparency in this respect would undoubtedly be simpler than attempting to petition numerous separate bodies, with

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<sup>14</sup> Practitioners may alternatively eschew membership of any representative body.

<sup>15</sup> Sarah Budd and Simon Mills, *Regulatory Prospects for Complementary and Alternative Medicine: Information Pack* (University of Exeter 2000).

<sup>16</sup> *ibid.*

<sup>17</sup> For the purpose of sourcing reports on grievance proceedings, the websites of five prominent CAM representative associations (Irish Society of Homeopathy, Acupuncture Council of Ireland and Chiropractic Association of Ireland, Osteopathic Council of Ireland and Reiki Federation of Ireland) were searched for the words, “report”, “disciplin”, “disciplinary”, “grievance”, “complaint” and “fitness”. No relevant results were returned.

what may be variable success. However, this bolstered system still does not, by its nature, require any individual practitioner to subscribe to it, undermining its protections for consumers overall.

Voluntary self-regulation in its current form is not an appropriate method of regulating practices with the potential to cause harm, direct or indirect, physical, psychological or financial, to consumers. While encouraging the development and maintenance of high standards through recommendations, guidelines and incentives is admirable and appropriate for all sectors, stronger protections are required where risk is involved. Despite the potential for undue validation and perceived endorsement by the state, the CAM sector requires more than voluntary regulation to appropriately protect consumers from physical, psychological or financial harm.

## **2. COMPARATIVE ANALYSIS**

In determining how best to alter the existing situation to protect consumers, it is instructive to undertake a short comparative examination of regimes for governance in other jurisdictions.<sup>18</sup> For this purpose, the United Kingdom, Australia and the United States (specifically Minnesota) were chosen, as jurisdictions with diverse but potentially compatible attitudes to CAM. However, the European Union, as a potential source of overarching law, must be considered as a matter of priority.

### **2.1 THE EUROPEAN PERSPECTIVE**

As Ireland seeks to re-emphasise its place in the EU in advance of the forthcoming British departure,<sup>19</sup> consideration must first be given to any proposed system or guidance for CAM regulation at a European level. Guidance was given in the form of two Resolutions in 1997 and in 1999,<sup>20</sup> and there has been little addressing CAM generally since.<sup>21</sup>

The freedom of movement afforded by membership of the EU has exposed the Irish market to practices previously unknown, but long-established in other Member States and farther afield. While the broadening and liberalisation of the healthcare market generally is considered, at least at a European level, to be most positive for patients,<sup>22</sup> the weighting of patient choice

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<sup>18</sup> See generally, Solveig Wiesener and others, 'Legal Status and Regulation of Complementary and Alternative Medicine in Europe' (2012) 19(suppl 2) *Forschende Komplementärmedizin* 29.

<sup>19</sup> Informally known as 'Brexit'.

<sup>20</sup> European Parliament Resolution on the status of non-conventional medicine (1997) OJ C182/67 and Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2).

<sup>21</sup> There have been measures addressing various aspects of health and healthcare, the recognition of professional qualifications, and two Directives specifically addressing homeopathic and traditional herbal medicinal products for human use, both of which are discussed at length in Chapter 2.

<sup>22</sup> Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2) [3].



against the best available evidence on the balance of safety and efficacy appears suspect,<sup>23</sup> particularly as the best available evidence does not support the use of CAM for very many medical conditions. Although the Resolutions mentioned above give the impression of enthusiasm for regulation, this appears to be with a view to making services available, rather than fulfilling the Treaty obligation of ensuring a high level of consumer protection.<sup>24</sup> The call, in the 1999 Resolution, for ‘allopathic’ (conventional medical) doctors to be trained to deliver CAM therapies (as opposed to advising patients on their use) is, in the opinion of the author, misjudged.<sup>25</sup> The clear confusion among consumers as to the line between conventional medicine and CAM, what evidence supports CAM and how it is regulated<sup>26</sup> does not call for the statutorily regulated and state-funded conventional system to further blur the ethical and consumer protection principles by integrating unproven therapies into its repertoire. There is a clear onus on conventional medical practitioners to provide safe, evidence-based care<sup>27</sup> and this cannot currently be reconciled with the use of CAM to treat patients.<sup>28</sup>

The development of university courses in various CAM disciplines as a means of creating appropriately high standards of education and training was also recommended in the 1999 Resolution. This did, in fact, come to fruition in a number of universities internationally.<sup>29</sup> However, it was and is not without controversy.<sup>30</sup> Objections continue to be raised in respect of evidence supporting the therapies at the core of many of these university courses and, at the time of writing, some have been disbanded.<sup>31</sup> The Resolution in question came into being 17 years ago and it is suggested that a different approach might be taken in any updated document.

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<sup>23</sup> As discussed in the introduction to this thesis, direct physical risk as a whole is almost impossible to assess in terms of rate of adverse events, though evidence of individual incidents been gleaned through systematic reviews. However, the indirect and financial risks are consistently present.

<sup>24</sup> Consolidated version of the Treaty on European Union (2012) OJ C326/13, Art 169(1), “In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests”.

<sup>25</sup> Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2) [7].

<sup>26</sup> See Chapter 6.

<sup>27</sup> Medical Council, *A Guide to Professional Conduct and Ethics for Registered Medical Professionals* (8th edn, Medical Council 2016) [42.5] “As far as possible, you should make sure that any treatment, medication or therapy prescribed for a patient is safe, evidence-based and in the patient’s best interests ... You should weigh up the potential benefits with the risks of adverse effects and interactions when deciding what to prescribe. You should review patients’ treatment regimes periodically”.

<sup>28</sup> This situation is considered below, as a potential future development. It is nonetheless objectionable.

<sup>29</sup> Zoe Corbyn, ‘Unwelcome complements’ *Times Higher Education* (30 October 2008).

<sup>30</sup> *ibid*, “David Colquhoun, professor of pharmacology at University College London, is among those at the forefront of a growing campaign of opposition to what critics call “pseudo-science degrees” on the grounds that the vast majority are not based on empirical evidence. Colquhoun calls it “quite incredible” that the subjects are being taught in universities, and the labels of BSc and MSc for such degrees are, he says, “particularly offensive”. With the focus on training CAM practitioners rather than producing critical thinkers, students are also being taught “gobbledegook” mechanisms to explain their therapies that have “no plausible scientific basis”, he says. Colquhoun campaigns, he says, because he believes it is “worth it” to defend what universities should be doing, and adds that many scientists share his view. “No respectable university should provide a course that preaches the mumbo-jumbo of meridians, energy flows and Qi (the principles on which acupuncture is based) as though they were science,” he argues”.

<sup>31</sup> Anthea Lipsett, ‘Homeopathy degree suspended after criticism’ *The Guardian* (27 August 2008).

While it might be an unpopular sentiment, the fact that large swathes or even entire populations of people support or use a particular therapy, even for many years, does not make or prove it efficacious. Cognitive dissonance is not the exclusive preserve of individuals.

The 1999 Resolution notes that although the subsidiarity of healthcare policy-making and regulation to EU Member States has been made clear (most recently by Art 168(7) of the Treaty of Lisbon)<sup>32</sup> the core objective of creating an ‘ever closer union’<sup>33</sup> requires appropriate harmonisation of standards to facilitate free movement of workers within the single market. While recognition of qualifications has been achieved for many medical and other professions<sup>34</sup> (itself an interference with domestic health policy in Member States) this has not extended to CAM practitioners. Many of the recommendations offered below seem unlikely to contribute to harmonisation, though it is argued that this is because the standards of evidence of safety and efficacy demanded of individual CAM therapies in other Member States are perhaps suboptimal for the purpose of protecting consumers. Whether raising the bar instead of lowering or maintaining existing low standards will be considered admirable and progressive or quixotic is likely to depend on the audience.

There is no clear, contemporary guidance from Europe in respect of CAM, and what exists favours expanding choice in healthcare over protecting consumers. However, the 1999 Resolution called upon “member states to model their approach on their neighbours’ experiments and, whenever possible, to co-ordinate their position with regard to these medicines”,<sup>35</sup> a reminder that a novel system of regulation for Ireland need only be novel to Ireland and can take inspiration and guidance from other jurisdictions, both positive and negative. To this end, we first turn to the United Kingdom.

## 2.2 UNITED KINGDOM

The UK has a strong history of CAM use and recognition, with high profile proponents, such as the British royal family,<sup>36</sup> public funding of some CAM therapies and statutory regulation of two, chiropractic and osteopathy, through the General Chiropractic Council (GCC) and the General Osteopathic Council (GOsC) respectively. Despite the apparent Euroscepticism in the UK,<sup>37</sup> the substantial healthcare choice afforded to patients under their socialised health system

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<sup>32</sup> Consolidated version of the Treaty on European Union (2012) OJ C326/13, Art 168.

<sup>33</sup> Council of Europe Parliamentary Assembly, Resolution 1206 (1999) (n 2) [6].

<sup>34</sup> Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22, as implemented in Ireland by the Recognition of Professional Qualifications (Directive 2005/36/EC) Regulations 2008, SI 2008/139.

<sup>35</sup> Under the UK Chiropractors Act 1994 and the UK Osteopaths Act 1993 respectively.

<sup>36</sup> Tom Heller and others, *Perspectives on Complementary and Alternative Medicine* (Taylor & Francis 2005) 376.

<sup>37</sup> Charles Grant, ‘Why is Britain Eurosceptic?’ (2011)

(the NHS), the university offerings for CAM study,<sup>38</sup> the practice of, and referral of patients for, some CAM therapies by conventional physicians<sup>39</sup> and the minimal statutory regulation of the sector overall is surprisingly close to what was envisioned by the 1999 Resolution. As a model system with which to harmonise, it might be argued that Ireland could do worse. However, the UK system places undue emphasis on safety<sup>40</sup> and choice and not enough on whether there is evidence of efficacy. Aside from the obvious implications for consumer law, set out in detail in Chapter 3, this approach fails to consider whether indirect harm might eventuate from a patient choice to use a therapy with no proven efficacy, instead of an effective conventional therapy for which the risks, though likely greater than those for the CAM therapy, are known and considered to be outweighed by its benefits.

Considerations of efficacy as part of funding allocation assessment have recently come to the fore in respect of homeopathy and acupuncture, both of which are voluntarily regulated and both of which are funded, to some extent, by the NHS.

#### *(a) Homeopathy*

As has been stated, explained and demonstrated at length throughout this thesis, there is no high-quality evidence that homeopathy is efficacious for any condition. This is explicitly recognised by the NHS, which states, “There has been extensive investigation of the effectiveness of homeopathy. There is no good-quality evidence that homeopathy is effective as a treatment for any health condition”.<sup>41</sup> Not only does this raise questions in respect of ongoing funding, but of the significant sums of money that have been expended on it to date. Nonetheless, homeopathy cost the NHS over

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<[www.cer.org.uk/sites/default/files/publications/attachments/pdf/2011/essay\\_euroseptic\\_19dec08-1345.pdf](http://www.cer.org.uk/sites/default/files/publications/attachments/pdf/2011/essay_euroseptic_19dec08-1345.pdf)> accessed 16 November 2016.

<sup>38</sup> Although many were disbanded in 2012, courses in general CAM practice (including aromatherapy, massage and reflexology), acupuncture, chiropractic, osteopathy and Chinese medicine and herbal medicine are still available through universities in the UK. See, for example, Wrexham Glyndwr University, ‘BSc (Hons) Complementary Therapies for Healthcare’ (2016)

<[www.glyndwr.ac.uk/en/Undergraduatecourses/ComplementaryTherapiesforHealthcare/](http://www.glyndwr.ac.uk/en/Undergraduatecourses/ComplementaryTherapiesforHealthcare/)> accessed 17 September 2016, or University of Westminster, ‘Complementary Medicine’ (2016)

<[www.westminster.ac.uk/courses/subjects/complementary-medicine](http://www.westminster.ac.uk/courses/subjects/complementary-medicine)> accessed 17 September 2016.

<sup>39</sup> British Medical Association General Practitioners Committee, ‘Referrals to complementary therapists Guidance for GPs’ (2006)

<[www.essexlmc.org.uk/wp-content/uploads/2014/04/Ref\\_comp\\_therapists\\_mar06.pdf](http://www.essexlmc.org.uk/wp-content/uploads/2014/04/Ref_comp_therapists_mar06.pdf)> accessed 10 September 2016.

<sup>40</sup> Although this, too, is questionable. See Edzard Ernst, ‘Complementary and alternative medicine: What the NHS should be funding?’ (2008) 58 British Journal of General Practice 208, 208-209, where the author found that “spinal manipulation ... has been shown to be as effective (or ineffective) as standard care for alleviating back pain, but it is associated with frequent, moderately severe adverse effects and less frequent, serious risks”. That it is regulated does not effectively dissolve the inherent risks of the practice. In addition, ‘safety’ in relation to CAM is narrowly defined and tends to refer only to direct physical harm, effectively ignoring indirect harm, longer-term harm, and psychological and financial harm.

<sup>41</sup> NHS Choices, ‘Homeopathy’ (2015) <[www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx](http://www.nhs.uk/Conditions/Homeopathy/Pages/Introduction.aspx)> accessed 10 September 2016.

£5million in 2014,<sup>42</sup> a not-inconsiderable sum of money in an oversubscribed public health system.

### *(b) Acupuncture*

Recent narrowing of the scope for public funding of acupuncture has also taken effect in light of new evidence showing a lack of efficacy for lower back pain, which was formerly considered to derive benefit from it<sup>43</sup> and for which funding was therefore available. It is unknown whether this will continue to be funded, and to what extent, by the NHS.

The willingness to revise policy based on updated evidence is admirable and follows good scientific practice. However, the perpetually shifting sands of UK public spending on CAM, the doublethink inherent in explicitly dismissing something as ineffective but paying for patients to receive it and the fact that the vast majority of CAM therapies available in the UK (including homeopathy and acupuncture) are under voluntary self-regulation, just as in Ireland, render the UK regulatory system of little use as a positive point of reference. Following the UK regime would be expensive, culturally ill-fitting, likely ineffective given the stated objective of protecting consumers, not only from direct and immediate physical harm but from longer term, indirect physical harm and from psychological and financial harm, and would undermine the science and evidence-based paradigm towards which Irish health and other sectors are slowly moving and upon which we, as a country, are attempting to build an international reputation.<sup>44</sup> The UK, it seems, should not act as a model for novel Irish regulation.

## **2.3 AUSTRALIA**

Most CAM therapies are regulated voluntarily under Australian law. However, three (chiropractic, osteopathy and Chinese medicine) are regulated statutorily under the umbrella of the Australian Health Practitioner Regulator Authority (AHPRA),<sup>45</sup> which “supports the 14

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<sup>42</sup> Good Thinking Society, ‘NHS homeopathy spending’ (2015) <<http://goodthinkingsociety.org/projects/nhs-homeopathy-legal-challenge/nhs-homeopathy-spending/>> accessed 10 October 2016.

<sup>43</sup> National Institutes of Health and Care Excellence, ‘Low back pain in adults: Early management’ (2009), “1.6.1 Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks”. By contrast, see National Institutes of Health and Care Excellence, ‘Low back pain and sciatica: Management of non-specific low back pain and sciatica: Invasive treatments’ (2016) 8, “13. Do not offer acupuncture for managing non-specific low back pain with or without sciatica”.

<sup>44</sup> Department of Jobs, Enterprise and Innovation, ‘Minister Halligan announces research investment of €22.3 million in next generation of research talent’ (2016) <[www.djei.ie/en/News-And-Events/Department-News/2016/October/18102016a.html](http://www.djei.ie/en/News-And-Events/Department-News/2016/October/18102016a.html)> accessed 20 October 2016.

<sup>45</sup> As established by the Health Practitioner Regulation National Law Act, enacted 2009-2010 throughout the various territories.

national boards responsible for regulating the health professions”.<sup>46</sup> These therapies were registered under the Australian National Registration and Accreditation Scheme, selected as requiring statutory regulation in order to comply with the objectives of the Scheme, namely:

- To help keep the public safe by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered;
- To facilitate workforce mobility for health practitioners;
- To facilitate provision of high quality education and training for practitioners;
- To facilitate the assessment of overseas qualified practitioners;
- To facilitate access to services provided by health practitioners; and
- To enable the continuous development of a flexible Australian health workforce.<sup>47</sup>

Again, safety,<sup>48</sup> workforce mobility and choice in healthcare are prioritised and acknowledgement of the potential for indirect harm or of the need for consumer protection are absent. This approach is also visible throughout the scant provisions addressing CAM in Ireland.<sup>49</sup>

Australia was chosen as a potential model for Ireland as AHPRA serves a similar function to CORU, the Irish umbrella body for health regulatory boards established under the Health and Social Care Professional Act 2005. However, AHPRA provides a centralised support for regulatory bodies including those governing conventional medical practitioners, nurses and midwives, dentists, physiotherapists and other conventional healthcare providers alongside those regulating chiropractors, osteopaths and those practicing Chinese medicine. CORU represents only conventional health and social care providers at this time, and many, such as conventional medical practitioners, nurses and midwives and dentists, are sufficiently regulated in their own right. These do not fall under the remit of CORU, leaving members of the public to negotiate between what may be several different representative bodies and several different grievance mechanisms, depending on where their issue lies.

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<sup>46</sup> AHPRA, ‘Who are we?’ (2016) <[www.ahpra.gov.au/About-AHPRA/Who-We-Are.aspx](http://www.ahpra.gov.au/About-AHPRA/Who-We-Are.aspx)> accessed 12 October 2016.

<sup>47</sup> *ibid.*

<sup>48</sup> This appears to be concerned with protection from physical harm, not from, for example, psychological harm.

<sup>49</sup> For example, Medicinal Products (Control of Placing on the Market) Regulations 2007, SI 2007/540, reg 11(2)(d) and (e). Standards for demonstrating safety for homeopathic medicinal products for human use are prescribed but to demonstrate efficacy, producers must only show that “the particular class of homeopathic medicinal product has been in use in the State as a homeopathic treatment for the indication sought”.

The streamlined approach taken by AHPRA is more appealing and appears more accessible than what is currently available to Irish consumers. Unfortunately, AHPRA ostensibly affords the three CAM therapies under its remit parity of esteem with conventional practices that is, at the time of writing, unsupported by high quality scientific evidence. This creates risk of consumer confusion and harm that undermines the explicitly protective objective of the Agency and its usefulness as a model for novel Irish regulation.

Although the potential for adding a register for a particular, narrow group of CAM practitioners under the CORU umbrella is considered below, it is unlikely to provide the desired effect of protecting Irish consumers from harm and may, conversely, create further confusion, increasing risk.

## **2.4 UNITED STATES**

Regulation of CAM providers in the US varies between states, with some requiring that particular CAM professionals be licensed or registered in order to practice.<sup>50</sup> The piecemeal approach, though certainly more organised than in Ireland, may create issues for consumers and for practitioners working or moving between states. However, the so-called ‘health freedom’ law of one state, Minnesota,<sup>51</sup> on CAM practices is of particular interest and, it is argued, may provide a framework upon which Irish regulation might be developed.

### **2.4.1 MINNESOTA HEALTHCARE FREEDOM ACT 2001, 146A**

Chapter 146A of the Minnesota Statutes is entitled ‘Complementary and Alternative Healthcare Practices’<sup>52</sup> and it provides for the creation of the Office of Unlicensed Complementary and Alternative Health Care Practice.<sup>53</sup> The purpose of the Office is:

... to investigate complaints and take and enforce disciplinary actions against all unlicensed complementary and alternative health care practitioners for violations of prohibited conduct, as defined in section 146A.08. The office shall also serve as a clearinghouse on complementary and alternative health care practices and unlicensed complementary and alternative health care practitioners through the dissemination of objective information to consumers and through the development and performance of public education activities, including outreach, regarding the provision of complementary and alternative health care practices

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<sup>50</sup> David M Eisenberg and others, ‘Unconventional medicine in the United States - prevalence, costs, and patterns of use’ (1993) 328(4) *New England Journal of Medicine* 246.

<sup>51</sup> Similar laws are in place in New Mexico and in Rhode Island.

<sup>52</sup> Minn. Stat. § 146A

<sup>53</sup> Minn. Stat. § 146A.01, subd 5.

and unlicensed complementary and alternative health care practitioners who provide these services.<sup>54</sup>

The statute applies to all CAM services provided by practitioners who are not licenced or registered by a relevant health licensing board or commissioner, to the public for remuneration.<sup>55</sup> Of relevance to Irish regulators, it provides the following:

- A parent who obtains complementary and alternative health care for the parent's minor child is not relieved of the duty to seek necessary medical care<sup>56</sup>;
- A complementary or alternative health care practitioner who is providing services to a child who is not receiving necessary medical care must make a report<sup>57</sup>;
- A complementary or alternative health care provider is a mandated reporter<sup>58</sup>;
- State and other healthcare agencies or institutions and professional societies are required to report disciplinary proceedings or changes in registration status relating to an unlicensed CAM practitioner to the Office<sup>59</sup>;
- Licensed health professionals are required to report personal knowledge of behaviour which he or she believes to constitute grounds for disciplinary action under chapter 146A, including conduct suggesting that the practitioner may be incompetent or mentally or physically unable to practice safely<sup>60</sup>;
- Insurance companies must disclose quarterly figures relating to malpractice awards or settlements made against unlicensed CAM practitioners<sup>61</sup>;

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<sup>54</sup> Minn. Stat. § 146A.02, subd 1. For information on the therapies licenced or regulated in Minnesota, see Minnesota Department of Health, 'Health-Related Occupations Currently Regulated by the State of Minnesota' (2014) <[www.health.state.mn.us/divs/hpsc/hop/occupations.pdf](http://www.health.state.mn.us/divs/hpsc/hop/occupations.pdf)> accessed 12 October 2016.

<sup>55</sup> Minn. Stat. § 146A.01, subd 6.

<sup>56</sup> Minn. Stat. § 146A.025.

<sup>57</sup> Minn. Stat. § 146A.025.

<sup>58</sup> Minn. Stat. § 146A.025.

<sup>59</sup> Minn. Stat. § 146A.03, subds 2-3

<sup>60</sup> Minn. Stat. § 146A.03, subd 4.

<sup>61</sup> Minn. Stat. § 146A.03, subd 5.

- Each complaint submitted to the Office must be investigated<sup>62</sup>;
- False, fraudulent, deceptive or misleading advertising is prohibited<sup>63</sup>;
- Conduct likely to deceive, defraud, or harm the public or demonstrating a willful or careless disregard for the health, welfare, or safety of a complementary and alternative health care client; or any other practice that may create danger to any client's life, health, or safety, in any of which cases, proof of actual injury need not be established, are prohibited<sup>64</sup>;
- Use of the title "doctor," "Dr.," or "physician" alone or in combination with any other words, letters, or insignia to describe the complementary and alternative health care practices the practitioner provides is prohibited<sup>65</sup>;
- Failure to provide a complementary and alternative health care client with a recommendation that the client see a health care provider who is licensed or registered by a health-related licensing board or the commissioner of health, if there is a reasonable likelihood that the client needs to be seen by a licensed or registered health care provider, is prohibited<sup>66</sup>;
- Patients must be provided with a written copy of the complementary and alternative health care bill of rights, containing, *inter alia*, the degrees, training, experience or qualifications held by the provider, together with the statement, "THE STATE OF MINNESOTA HAS NOT ADOPTED ANY EDUCATIONAL AND TRAINING STANDARDS FOR UNLICENSED COMPLEMENTARY AND ALTERNATIVE HEALTH CARE PRACTITIONERS. THIS STATEMENT OF CREDENTIALS IS FOR INFORMATION PURPOSES ONLY"<sup>67</sup>; and
- An unlicensed complementary and alternative health care practitioner may not provide a medical diagnosis or recommend discontinuance of medically prescribed treatments.<sup>68</sup>

The Minnesota statute provides a number of minimum standards for therapies otherwise falling outside regulatory parameters, which is, at present, the situation in which all

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<sup>62</sup> Minn. Stat. § 146A.07.

<sup>63</sup> Minn. Stat. § 146A.08, subd 1(e).

<sup>64</sup> Minn. Stat. § 146A.08, subd 1(f).

<sup>65</sup> Minn. Stat. § 146A.08, subd 1(v).

<sup>66</sup> Minn. Stat. § 146A.08, subd 1(w).

<sup>67</sup> Minn. Stat. § 146A.11, subd 1(2).

<sup>68</sup> Minn. Stat. § 146A.11, subd 1(2).



CAM practitioners in Ireland find themselves. Although this statute loosely forms the basis for the second set of model recommendations set out below, it lacks a number of fundamental elements that would appropriately address the domestic consumer protection issues; namely, that it does not sufficiently delineate between medicine and what is on offer under the statute,<sup>69</sup> it does not require that the practitioner hold any particular qualification in order to provide services to the public, and it does not place limitations on the types of therapy that can be provided so long as they fall within the “broad domain of complementary and alternative healing methods and treatments”.<sup>70</sup> Some issues of particular importance are left on the shoulders of potentially unqualified therapists, such as determining whether a child is receiving “necessary medical care”.<sup>71</sup> The overestimation of skill and scope of practice and the underestimation or wholesale dismissal of the proven benefits of conventional medicine, together with the financial interest in preserving the exclusive domain of treatment create the potential for serious consequences for children treated under this regime. That unlicensed CAM practitioners registered under the Act are made mandatory reporters is positive, but this does not provide real-world protection unless the practitioner realises that a problem exists.

The Minnesota statute provides a novel approach to regulation in comparison to those seen in the UK and Australia. Although unsuitable for wholesale adoption, a number of provisions, adapted for the Irish market and appropriately enforced, would provide significantly better protection for consumers than currently exists. This is described in Part II.

The Minnesota statute was suggested as a potential model for Irish regulation in the 2002 *Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland*,<sup>72</sup> though, predictably, no action has been taken to implement this or any other scheme since.

Given the cost, complexity, and likely political unpopularity of implementing a *de novo* regulatory framework, it is apt to first consider utilising and augmenting the existing statutory and common law protections and enhancing public education to better safeguard consumers, before making more dramatic changes.

No approach is ideal and none will satisfy all stakeholders, but all nonetheless aim to improve upon the unenforced protections currently in place for consumers.

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<sup>69</sup> Being therapies which lack high-quality evidence in support of their safety, efficacy or both.

<sup>70</sup> Minn. Stat. § 146A.01, subd 4.

<sup>71</sup> Minn. Stat. § 146A.025.

<sup>72</sup> Tim O’Sullivan, *Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland* (Stationery Office 2002), para 3.4.

## PART II

### OPTIMISING CAM REGULATION TO BETTER PROTECT CONSUMERS

#### 3. VOLUNTARY OR STATUTORY REGULATION?

In 2005, the National Working Group on the Regulation of Complementary Therapists published the *Report of the National Working Group on the Regulation of Complementary Therapists to the Minister for Health and Children*.<sup>73</sup> This provided eight recommendations for a novel regulatory regime for CAM in Ireland,<sup>74</sup> which focussed primarily on statutory regulation of the most high risk practices (specifically, acupuncture, Traditional Chinese Medicine and herbal medicine – strangely, not chiropractic or osteopathy, as in so many other jurisdictions) and improved voluntary self-regulation of all other therapies. The Working Group advocated for unification of professional bodies for each distinct therapy with the objective of offering a single standard of information on each to consumers and to conventional practitioners.<sup>75</sup> While this was most useful for guidance, it failed (a) to consider that the voluntary self-regulatory structure, no matter how fortified, does not provide the standard of protection consumers should expect from their healthcare, and (b) to sufficiently consider evidence and consumer protection overall in its designations for statutory regulation. Statutory self-regulation, as noted above and by Salter in Chapter 1,<sup>76</sup> is a privilege that must be earned. It engenders public trust and confers status, as with conventional medicine. The recommendations for the trio of therapies put forward for statutory self-regulation were selected on the basis of their risk profile but the Working Group failed to consider what positive attributes entitled them to this elevated status. While it is acceded that statutory regulation in some form is necessary in lieu of a better alternative, it is necessary to consider scientific evidence of efficacy alongside safety when regulating. Not only is this a consumer protection issue but the ethical provision of healthcare demands that the risks and benefits of a given treatment be balanced against each other to determine whether it should be used. The consistent failure of regulators in Ireland and elsewhere to consider this is not only disappointing and perplexing, but it flies in the face of what are otherwise strong, comprehensive and long-established systems of consumer protection and ethical healthcare practice. CAM is the exception to the rule.

A number of the model recommendations provided below aim to distinguish between therapies with supporting evidence of efficacy and those without, in addition to the existing consideration of safety. Clarity and transparency are required if the consumer confusion in respect of CAM in Ireland is to be ameliorated.

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<sup>73</sup> Teri Garvey (n 1).

<sup>74</sup> These are provided in Appendix IX.

<sup>75</sup> Teri Garvey (n 1) 43.

<sup>76</sup> Brian Salter, *The New Politics of Medicine* (Palgrave Macmillan 2004) 6-7.

However, it is necessary to turn, first, to the least expensive and easiest to implement recommendation provided herein: enforcing Ireland's existing consumer protection provisions.

#### **4. RECOMMENDATIONS**

##### **4.1 ENFORCEMENT OF EXISTING CONSUMER PROTECTION LAWS**

The first and simplest of the three schemes proposed in this thesis is to use the existing consumer protection suite to its full extent, actively monitoring sellers and service providers to ensure compliance and proactively investigating complaints.

However, it is undoubtedly blunt and is less than comprehensive. It relies heavily on public reporting and on authorities having the resources necessary for market surveillance. It cannot account for the private nature of CAM, which makes consistent oversight next to impossible, particularly given the voluntary status of regulation and the unknown number of CAM providers working in Ireland at this time.

##### **4.2 CREATION OF NEW STRUCTURES TO IMPROVE PROTECTIONS FOR CONSUMERS**

Although likely to be unpopular, difficult, and expensive, it may be necessary to provide a more comprehensive answer to how CAM consumers can best be protected in Ireland than that set out above. To that end, a number of model recommendations are offered.

Two model registers could be established which would set mandatory minimum standards of practice for all providers of complementary and alternative therapies:

- (a) Register of Complementary and Alternative Medical Practitioners; and
- (b) Register of Wellness Therapists.

Each is described in turn, together with a brief discussion of the need for the establishment of a Research Assessment Panel.

###### **4.2.1(a) MODEL REGISTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICAL PRACTITIONERS**

The Register of Complementary and Alternative Medical Practitioners (hereafter "Register I"), which might be implemented as a stand-alone statutory body or perhaps under the auspices of CORU under the Health and Social Care Professionals Act 2005, would require the following:

| <b>MODEL REGISTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICAL PRACTITIONERS</b>                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Therapies in the registered modality must be proven safe                                                                                                                                                                                                                  |
| Therapies in the registered modality must be proven efficacious, through evidence of satisfactorily high quality, for any claimed condition                                                                                                                               |
| Practitioners must meet specified education, training, practice and continuing professional development standards – this may include elements of conventional clinical diagnosis to ensure established scope of practice is respected                                     |
| Practitioners must behave ethically, in accordance with the code of ethics established by their regulatory body – this includes only providing therapies for which likely benefit outweighs risk and this, as noted above, should be based on the best available evidence |
| Practitioners must be subject to a publicly accessible and transparent grievance and disciplinary procedure                                                                                                                                                               |
| Practitioners must fulfil all statutory child protection requirements                                                                                                                                                                                                     |
| Practitioners must not act or advise consumers so as to undermine established public health objectives                                                                                                                                                                    |
| Practitioners may coordinate with conventional healthcare providers                                                                                                                                                                                                       |
| Practitioners should be made mandatory reporters under the Children First Act 2015.                                                                                                                                                                                       |
| <b>REGISTRANTS WOULD BE ENTITLED TO:</b>                                                                                                                                                                                                                                  |
| Protection of title, eg ‘Medical Acupuncturist’                                                                                                                                                                                                                           |
| Accept referrals from conventional healthcare providers                                                                                                                                                                                                                   |
| Receive public funding as part of primary care                                                                                                                                                                                                                            |

*Table 11 – Model Register of Complementary and Alternative Medical Practitioners*

The public validation provided by recognition and protection of title for practitioners on this register would be hard won and may, in fact, not be worth the effort, given the very limited scope within which many practitioners would be able to practice. Under the model recommendations set out above, a practitioner could only claim to treat conditions for which there is high quality evidence of efficacy outweighing the risk arising from treatment. As a result, many more CAM therapists would no longer be entitled to use this terminology but would fall under the remit of the second model register, described below.

While the issue of consumer confusion was raised in relation to the AHPRA system, which regulates conventional healthcare providers alongside three categories of CAM provider, the potential addition to the list of national registers under the CORU umbrella of CAM

practitioners,<sup>77</sup> very narrowly defined, should not give rise to the same cause for concern. The evidence to be demanded for this notional registration should be of sufficiently high quality as to prove, insofar as any health practice can be proven, to be efficacious.

Educational standards for registrants on Register I should be on par with those of conventional disciplines and education should focus on the treatment of conditions for which there exists high quality supporting evidence of efficacy which outweighs the risks of treatment. The integration of basic training in conventional clinical diagnostic methods (but not treatment methods) into any educational programmes established to fulfil the requirements of the model registration criteria ought to be encouraged, as it would help to establish in the minds of registered practitioners the parameters of their scope of practice, as well as ensuring that conditions falling outside the scope of practice, which require immediate conventional medical attention or which present a longer-term risk to the patient if left untreated, would be referred to a conventional medical professional in a timely manner.

This undoubtedly presents as harsh and restrictive and would effectively limit successful registrants, having jumped through the numerous hoops set out above, to treating one or two conditions for which there is good evidence of efficacy and minimal risk. However, being able to provide good evidence that a therapy works and that the therapist in question can provide it safely is a fundamental aspect of delivering high quality healthcare across the spectrum. This model aims to protect consumers from some of the worst failings in the current system, arising predominantly from the lack of any minimum standards for practice and appropriate enforcement of consumer protection law as it relates to unfair or misleading claims,<sup>78</sup> and provide the potential for protected title and for recognition by the State and by conventional medicine. Determination of whether to permit medical claims based on the best available evidence would likely require the establishment of a specialist research assessment panel.

As part of the proposed CAM register (Register I), a Research Assessment Panel would evaluate available evidence in favour of the safety and efficacy of each registered CAM therapy for a specific condition. Such a panel would comprise epidemiologists, other experienced healthcare or scientific researchers and representatives of the practice in question. Each claim for which high quality evidence of safety and efficacy was offered would be placed on a publicly accessible list and the registered practitioners would be permitted to make the approved claims in the course of their business. The panel would focus on existing research, with the possibility of performing systematic reviews and meta-analyses where necessary. Given the research expertise of panel members, it would ideally not be necessary to involve registered members of the Medical Council, minimising the perception of conflict of interest

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<sup>77</sup> These would likely be regulated by separate boards for each discipline, not simply under the heading of 'CAM practitioners'.

<sup>78</sup> Consumer Protection Act 2007, ss 41-43.

and avoiding at least some ill-feeling between the two sectors. The Research Assessment Panel composition need not be fixed and the panel would be prepared to maintain a contemporaneous list of evidence for all registered therapies.

Being unable to fulfil the demands of healthcare regulation should not be considered a reason to change the demands, but an opportunity to increase standards. However, where CAM practitioners are unable or unwilling to meet these standards, there ought to be another option. This should not default to voluntary self-regulation, but instead, might simply require a lower standard of statutory self-regulation than the one set out above.

#### **4.2.1(b) REGISTER FOR WELLNESS THERAPISTS**

This second model register, based loosely on the mechanism provided under Chapter 146A of the Minnesota Statutory Code, would be available to all providers currently falling within the broad category of CAM, but for whose therapy there is a lack of high quality evidence of efficacy, leaving them outside the scope of the Register for CAM Practitioners (Register I).<sup>79</sup> Registration might require the following:

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<sup>79</sup> Or those who do not wish to undergo the demanding registration process.

| <b>MODEL REGISTER FOR WELLNESS THERAPISTS</b>                                                                  |
|----------------------------------------------------------------------------------------------------------------|
| Therapies in the registered modality must be proven safe                                                       |
| Therapists must not make medical claims of any kind                                                            |
| Therapists must meet specified education, training, practice and continuing professional development standards |
| Therapists must not use medical terminology                                                                    |
| Therapist must not make any medical diagnosis                                                                  |
| Therapists must behave ethically, in accordance with the code of ethics established by their registering body  |
| Therapists must be subject to a publicly accessible and transparent grievance and disciplinary procedure       |
| Therapists must fulfil all child protection requirements                                                       |
| Therapists must not act or advise consumers so as to undermine established public health objectives            |
| <b>REGISTRANTS WOULD BE ENTITLED TO:</b>                                                                       |
| Provide services to the public for the purposes of improving or maintaining wellbeing                          |

*Table 12 – Model Register for Wellness Therapists*

This register (hereafter “Register II”) would not fall under the auspices of CORU or any similar body associated with conventional healthcare practitioners, to ensure that there was no public confusion in respect of the two separate systems. Instead, it may require a separate umbrella body, with registers for individual wellness therapies to enforce minimum ethical and safety standards, which, in conjunction with the investigative and enforcement powers of the CCPC,<sup>80</sup> may provide considerable consumer protection, while drawing a clear dividing line between evidence-based medicine and services to enhance general wellbeing.

Language used for and by the umbrella body ought to be carefully chosen so as not to represent the potential to cure any disease or condition for which there is no empirical evidence. ‘The Irish Register for Wellness Therapists’ is one such example, avoiding use of the word “medicine” or “health”.

An argument might be made for permitting medical claims to be made by Wellness Therapists where these have been proven through high quality research accepted by the Research Assessment Panel, described above. It is argued, however, that without also establishing that the Wellness Therapist making the claim has met the educational, training, professional and ethical demands necessary to be placed on Register I, he or she has not been proven to possess

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<sup>80</sup> If properly utilised.

the knowledge or skill to effectively and safely treat the condition claimed. Wellness Therapists may refer a patient to a CAM Practitioner for treatment of a medical condition falling within their scope of practice or advise them to seek conventional medical advice.<sup>81</sup>

One outstanding matter is the availability of therapies or procedures whose risks outweigh their proven benefit. These, it is asserted, would not be made available to consumers until high quality evidence suggests that this balance had been redressed. This might require that novel research be carried out or that a systematic review of existing research be undertaken, which may be time consuming, expensive or simply not possible. This should not present sufficient reason to permit the provision of such therapies to consumers.<sup>82</sup>

In effect, given the current dearth of high quality evidence of efficacy for most CAM therapies for most conditions, registration on Register I as a CAM Practitioner, with all that this requires, permits and provides, would significantly restrict the claims permissible by practitioners in promoting their practice. Those on Register II may also find themselves frustrated by their change in status and in their scope of permitted practice. These measures are unlikely to be popular among practitioners but, given their public protection imperative, their rational basis and, lest it be forgotten, their concordance with existing consumer law, potential legislators would be wise to at least consider the implications of opting, instead, for inaction or the introduction of measures with similarly low standards in the name of political expediency. However, given the likely reticence on many fronts, there may be a more palatable, moderate position available to legislators.

#### **4.3 THE MODERATE APPROACH**

Direct physical or psychological risks noted throughout this thesis tend to relate to specific behaviours or actions carried out by a CAM practitioner as part of a therapy and not the therapy in its entirety.<sup>83</sup> A more moderate approach to regulation might consider focusing the most restrictive measures on these. Michael Weir places considerable emphasis on this point,<sup>84</sup> recommending that, rather than speaking broadly of which therapies require restriction, the performance of individual higher-risk practices be limited to regulated professionals.<sup>85</sup> These include, for example:

- the use of high velocity, low amplitude thrusts on the cervical spine;

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<sup>81</sup> Similarly, many experienced conventional healthcare professionals can diagnose a particular medical condition and know how to treat it safely and effectively but they are not permitted to do so if this is outside their scope of practice.

<sup>82</sup> However, a less restrictive option is offered in the third recommendation.

<sup>83</sup> Though, as noted previously, the consumer protection risk and the indirect risk arises from CAM therapies in general.

<sup>84</sup> Michael Weir (n 10) 171.

<sup>85</sup> *ibid* 193.



- piercing of the skin or the performance of surgical procedures ordinarily performed by medical doctors<sup>86</sup>;
- administration of a substance by injection or inhalation;
- placement of an instrument, hand or finger beyond specific orifices including the ear canal, anal verge and labia majora;
- prescription or dispensing for vision or eye problems;
- management of labour or delivery of a baby; or,
- allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.<sup>87</sup>

The list is not exhaustive and must, if adopted, be tailored for the Irish context. Appropriate recognition, regulation and oversight would require establishment in order to implement Weir's recommendations, reintroducing, to some extent, cost and complexity that is likely to be unpopular across the board. To this end, along with the restriction on practices carrying increased risk, Weir recommends the establishment of Government Sponsored Self-Regulation (GSSR). According to Weir,

GSSR is a form of self-regulation where a government representative is actively involved, along with representatives of the profession, consumers and legal profession ... The inclusion of a government representative is said to assure the consumer that the self-regulatory process is credible and accountable. Under GSSR the government does not control the self-regulatory process...<sup>88</sup>

GSSR would require the formation of panels comprised as set out above, which would develop a code "in consultation with all industry representatives; and government legal and consumer representatives. This code would include provision for practitioner accreditation; course accreditation; funding [and] an annual report". The effectiveness of these panels and the level and quality of oversight they might provide is unknown and would depend, to some extent, on

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<sup>86</sup> Weir creates an exception for acupuncturists here but this may not be relevant in Ireland, where there is no regulation or protection of title for any CAM practitioner.

<sup>87</sup> This particular practice led to the death of a patient in Ireland in 2006. See G O'Halloran, 'Man died an hour after being treated for peanut allergy' *Independent* (25 April 2009) <[www.independent.ie/irish-news/courts/man-died-an-hour-after-being-treated-for-peanut-allergy-26531233.html](http://www.independent.ie/irish-news/courts/man-died-an-hour-after-being-treated-for-peanut-allergy-26531233.html)> accessed 10 September 2017. The chiropractor and applied kinesiologist treating the patient used the NAET (Nambudripad's Allergy Elimination Technique) protocol for nut allergy desensitisation outside a controlled healthcare setting and the patient developed a fatal anaphylactic reaction shortly after. "Professor of histopathology at the Royal College of Surgeons and at Beaumont Hospital, Mary Leader, told the inquest that in (allopathic) medicine such desensitisation would not be carried out without strict supervision in a hospital where drugs, IV access, oxygen and a doctor were immediately available and she said no person should be tested for nut allergy without these. "If a patient has an acute anaphylactic reaction like this they are immediately treated with drugs to stop the reaction", she said".

<sup>88</sup> Michael Weir, 'Regulation of Complementary and Alternative Medicine Practitioners' (2006) 23(2) *Law in Context* 171, 179. This option was put forward for the regulation of Traditional Chinese Medicine in Australia.

their members and the powers afforded to them, but Weir notes that the proposal appears “comparatively low cost and not unduly anti-competitive”.<sup>89</sup>

There is a level of external accountability associated with this approach and it would, it appears, impinge to a lesser extent upon the freedom of CAM practitioners to practice and upon the healthcare choices of consumers, making it more politically attractive than the approaches set out previously. It is suggested that the implementation of Weir’s broad recommendations on restricted practices and the establishment of GSSR-type panels, combined with deliberate, determined application of existing consumer protection law, noted above, and substantive improvements in public health and research literacy, would result in a moderate approach which would improve protection in all three risk categories,<sup>90</sup> while also satisfying the criteria of the proportionality test, should a challenge be brought. Irish regulators would, of course, be free to determine, on the basis of existing international data on risk and benefit, which restricted practices could be permitted to be used by which CAM practitioners and which ones should remain part of conventional medical practice only.

However, in the likely event of reluctance to implement formal, systemic change, general recommendations for CAM regulation and consumer protection are set out in detail below.

#### **4.4 GENERAL PROVISIONS FOR APPLICATION IN LIEU OF A NOVEL REGIME**

##### *(a) Fully Informed Consent*

At present, as discussed in Chapter 1, consent to all medical procedures must be adequately informed, with detail provided to the patient in question based on what the reasonable patient in the circumstances would want to know and what the particular patient giving consent would want to know.<sup>91</sup> Minor or trivial medical procedures, such as stitching a small wound, requires only that basic information be provided on the procedure, for example, whether it will be painful or uncomfortable, whether there will be scarring, what is the risk of infection or whether the patient will be required to remove the stitches afterwards. Consent in such situations is often given informally.

However, this thesis argues that, where the recommendation above mandating tiered registration are not implemented, consent given by CAM consumers to all procedures must be

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<sup>89</sup> *ibid.*

<sup>90</sup> Risk of direct physical and psychological harm, risk of indirect harm caused by inefficacious therapies and the avoidance of effective conventional care, and risk of financial harm.

<sup>91</sup> *Geoghegan v Harris* [2000] 3 IR 536 (HC) (Kearns J), citing *Canterbury v Spence* (1972) 464 F. 2d 772, 788, on materiality, “A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summons discussion with the patient. There is no bright line separating the significant from the insignificant; the answer in each case must abide a rule of reason”. The reasonable patient test is now applicable in Irish law.

fully informed,<sup>92</sup> in line with the recommendations provided in the National Consent Policy,<sup>93</sup> reproduced in Chapter 1. This should include all practitioners formally disclosing that the best evidence at the time of treatment suggests that the treatment provided is not efficacious for a particular condition/ that the treatment provided has been shown to be efficacious in some trials but that the overwhelming evidence suggests that it is inefficacious/ that it has been found to be somewhat efficacious in very limited circumstances/ that high quality evidence shows efficacy for the patient's particular condition. As noted above, if there is no demonstrated benefit and there is any risk at all, ethically, the therapy should not be made available.

*(b) Restrictions on Claims Permissible by Practitioners*

Practitioners should not be permitted to claim, directly or indirectly, in person or through advertising, that their therapy can be utilised for the treatment of a disease or condition, where the best available evidence at the time the claim is made does not support this. Such claims are prohibited at present under ss 41-43 of the Consumer Protection Act 2007, but are not adequately enforced. Strict enforcement is necessary if consumer protection is to be improved, as uneven application will increase confusion and consequent risk.

*(c) Public Information Campaign*

Public information campaigns should advise consumers to research before they seek out CAM services and a website should be established to provide guidance for consumers, along with up-to-date information on the status of evidence available in support of various CAM therapies for particular conditions. This may necessitate the establishment of a Research Assessment Panel, discussed above.

*(d) Prohibition on Sales of CAM Products in Pharmacies*

CAM products, including medicinal products, should not be sold in pharmacies where no high-quality evidence supports their efficacy, as this violates several provisions in the existing statutory Code of Conduct established under the Pharmacy Act 2007.<sup>94</sup>

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<sup>92</sup> Subject to the wishes of the consumer, although basic information on their diagnosis, risks and benefits should be given, in a way that is easily understandable by the patient. See Medical Council, *A Guide to Professional Conduct and Ethics for Registered Medical Professionals* (8th edn, Medical Council 2016) 16.

<sup>93</sup> National Consent Advisory Group, *National Consent Policy* (HSE 2014) 24.

<sup>94</sup> See Chapter 3.

(e) *Revision of Labelling Requirements*

The scheme for labelling and marketing homeopathic medicinal products should be revised to ensure that packaging reflects the actual composition of the product within. This recommendation is based on three principles:

(i) *There is often no active ingredient present in the remedy as sold*

At present, remedies are labelled with the base substance from which the remedy is made, but often there is not even one mole of that substance present in the product at the time of purchase.<sup>95</sup> This is misleading for consumers, contrary to the fundamental principles of consumer law.

(ii) *Archaic or unintelligible units of measurement are in contravention of the wording and the spirit of consumer law generally*<sup>96</sup>

The units of measurement used for homeopathic preparations, a scale of X(D), C, L, or M based on level of dilution, are archaic, counterintuitive, and should be changed to standardised units of measurement in order to be comprehensible to consumers. Perhaps if consumers were aware of the concentration of the substances they were purchasing, it would encourage both further research and broader debate on the scientific, economic and practical viability of such therapies.

(iii) *Remedies with no indication and no active ingredient present beyond sugar and water may potentially be considered and regulated as a food product*

Were the homeopathic remedies in question sold as a food product, labelling declaring the presence of an ingredient that was, in fact, absent from the product, would be in contravention of art 7(1)(a) of the Food Information Regulation, which states:

Food information shall not be misleading, particularly: (a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production.<sup>97</sup>

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<sup>95</sup> *ibid.*

<sup>96</sup> *ibid.*

<sup>97</sup> Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 [2011] OJ L304/18.

The Food Information Regulation is decidedly consumer focused, whereas the Medicinal Products Directive,<sup>98</sup> from which the domestic labelling requirements are derived, is prescriptive for manufacturers but is not consumer focused. The former cites informed consumer choice as a core principle, mentioning it eight times in the text, whereas the same phrase does not appear in the text of the latter. This may appear irrelevant, as food and medicinal products are catered for under distinct regulatory regimes, though both are utilised for the protection of end consumers. However, we must consider that most standard homeopathic preparations do not contain an active ingredient nor, at this time in Ireland, any indication, meaning that they are composed of sugar and water and do not make a claim to cure any condition. Indeed, the Food Information Regulation defines an ‘ingredient’ as,

... any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; *residues shall not be considered as ‘ingredients’*.<sup>99</sup> (emphasis added)

Where sugar and water are the only ingredients in a product,<sup>100</sup> and the labelling carries an indication that a product is medicinal only because it is required to do so by law,<sup>101</sup> regulators might consider whether such products might be more appropriately regulated under food law and without such an indication, increasing the protection for consumers.

Homeopathy is, at present, uniquely positioned to avoid the rigors of both the Product Authorisation procedure applicable to most medicinal products in Ireland, through which a number of convenient shortcuts have been carved,<sup>102</sup> and also the strict standards of the Food Information Regulation, in what must be acknowledged to be a highly unfair, selective lowering of the bar by European regulators, and one which is

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<sup>98</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67.

<sup>99</sup> Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 [2011] OJ L304/18, art 2(1)(f).

<sup>100</sup> See David Robert Grimes, 'Proposed mechanisms for homeopathy are physically impossible' (2012) 17 Focus on Alternative and Complementary Therapies 149, 150-151 for a comprehensive discussion of the scientific and mathematical improbability of the presence of a single mole of ingredient past the 12C dilution, let alone enough to create a meaningful physiological effect.

<sup>101</sup> Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1994, SI 1994/44, sch 3 requires that the packaging of a registered homeopathic medicinal product states that the product is a (a) “homeopathic medicinal product” and (l) that it is a “homeopathic medical product without approved therapeutic indications”.

<sup>102</sup> See Chapter 3.

not justifiable on the extensive available volume of high quality scientific evidence and widespread official acknowledgement that homeopathy has not been shown to be effective for any condition.

*(f) Limited Use of CAM for Children*

CAM would ideally only be used in paediatric or incompetent populations within strict parameters, as consent on the part of the child or parent may not be fully informed and the risk benefit balance is often unfavourable. However, narrowing of choice in paediatric care in such a manner may prove unpopular among parents and practitioners, and, consequently, among politicians, and it remains uncertain, despite the inherent vulnerabilities of this consumer group whether such restriction on parental choice would be found constitutional if challenged. Use of CAM in the treatment of children for medical conditions should be supported by high-quality scientific evidence of efficacy and safety. A Research Assessment Panel or a GSSR-type panel would be desirable to assess the relevant evidence and to seek consensus on the appropriateness of treatment based on the risk-benefit profile for each intervention.

*(g) Review of the Provision of CAM by Registered Medical Practitioners*

Though outside the narrow scope of this thesis, the provision of CAM therapies for chronic or life-threatening conditions is not always by lay practitioners but also by registered medical practitioners. Physicians in Ireland are afforded significant latitude to treat their patients as they see fit, but this leaves patients vulnerable to confusion. It is reasonable for consumers to assume that treatments provided by registered medical practitioners have been subject to research with a demonstrably positive outcome and that the risk-benefit balance is favourable. Clearly, this is not the case. Chelation therapy, Gerson therapy and other invasive CAM therapies with little evidence of efficacy and serious associated risks<sup>103</sup> are administered or supervised by registered medical practitioners. The Medical Council should consider issuing specific and detailed guidance on the provision of CAM therapies by registered medical practitioners.

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<sup>103</sup> On chelation therapy, see US National Poison Control Centre, 'Chelation: Therapy or "therapy"?' (2011), "Chelation therapy is a treatment for heavy metal poisoning: iron, mercury, arsenic, and lead. Some people give chelation "therapy" for other conditions such as cardiovascular disease, autism, and Alzheimer's. This exposes patients to risks without benefit" <[www.poisson.org/articles/2011-mar/chelation-therapy](http://www.poisson.org/articles/2011-mar/chelation-therapy)> 10 September 2016. See also, Yashwant Sinha and others, 'Chelation therapy and autism' (2006) 333 British Medical Journal 756 and Arla Baxter and Edward Krenzelok, 'Pediatric fatality secondary to EDTA chelation' (2008) 46 Clinical Toxicology 1083, 1084. On Gerson therapy, see Barrie Cassileth, 'Gerson regimen' (2010) 24 Oncology 201.

*(h) Freedom of Expression and Consumer Protection*

Many of the issues for consumers arising from CAM relate to unfair or misleading claims, which have, as noted in Chapter 5, been excessively protected by the right to freedom of expression. The two-tier model regulatory regime set out above attempts to prevent the inappropriate use of freedom of expression to protect potentially harmful commercial speech or content by placing strict controls on the claims permissible by practitioners on each register. Those on Register I may only make medical claims for which high quality evidence has been submitted and accepted by the Research Assessment Panel. Those on Register II may not make medical claims of any kind. Given the existing consumer protection law in place to prevent this, such a provision would not create an undue limitation on freedom of expression, but would simply restate and strengthen the law as it stands. In the likely event that regulators do not wish to implement the two-tier scheme, strict enforcement of existing consumer protection provisions, as set out in Recommendation I above, should have a similar effect. Neither of these, however, limit non-commercial expression or commentary.

## 5. DISCUSSION

Devising and recommending the implementation of a regime to restrict the practices of an entire sector, particularly at a time when choice in healthcare is *de rigueur* and the regimes in place in other jurisdictions overwhelmingly favour the voluntary self-regulatory model, may reasonably be considered draconian and unnecessary. However, as noted above and at various points throughout this thesis, this model has failed to provide sufficiently for the protection of consumers from harm, not just physical or psychological, but financial. CAM should not continue to be treated as an exception to the demands of consumer protection law and to the requirements of medical ethics. True choice in healthcare is undermined, not promoted, in a system which permits the limitation or obscuring of the information provided to consumers, or, indeed, which permits, by omission to act in mitigation, the making of unfair or misleading claims as part of commercial practice. Healthcare, in whatever form, is not a service akin to tailoring or carpet fitting. Providers are placed in a position of trust by patients or consumers, afforded the power to make physical and psychological changes affecting consumer health for better or worse. Voluntary self-regulation, in place at the present time, does not appropriately address the risks taken by consumers, knowingly or unknowingly, when accessing a service for which there is no minimum requirement for education or training, for which there may be no high-quality evidence of efficacy or safety and for issues arising from which there may be no appropriate route of recourse. Relatively unburdened by a long and contentious history of CAM use, unlike, for example, in the UK,<sup>104</sup> Irish legislators have an opportunity to establish a *de novo* regulatory model for CAM based on the best available evidence, not just for the safety of the many and various therapies, but also for their efficacy for individual conditions. This need not restrict access to most therapies by consumers,<sup>105</sup> which may remain available without making specific claims of efficacy for any medical condition, providing protection from misleading claims and maintaining choice. A regime in this vein, as set out above, might be considered.

This said, the complexity of regulating CAM has become increasingly clear as research process has progressed. No system of regulation is without its deficiencies and this includes one which embraces the recommendations set out above. Failure to acknowledge these and also other important facets of regulation not given due attention throughout this thesis, by virtue of constraints in time, space or narrative, would give an incomplete picture of the intricacies involved. To this end, this discussion aims to address some of the outstanding uncertainties and neglected issues arising from the thesis overall and from the proposals set out above.

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<sup>104</sup> Tom Heller and others, *Perspectives on Complementary and Alternative Medicine* (Taylor & Francis 2005) 376.

<sup>105</sup> Those which are unsafe and provide no established benefit should not be made available to the public.



(a) *Human Dignity*

Fundamental but underdeveloped,<sup>106</sup> featured only in the Preamble to the Constitution,<sup>107</sup> and “invoked more as a rhetorical flourish than as a carefully defined legal principle”,<sup>108</sup> the protection and promotion of human dignity underlies the legal and ethical protections called for throughout this thesis.

(b) *Balancing Science and Philosophy*

The consideration of how and whether to regulate requires acknowledgement of the questionable scientific viability of many of the CAM therapies on offer.<sup>109</sup> Regulators must recognise different philosophies of health and healthcare and determine to what extent each of these should influence medical treatment in the State. It has been argued throughout this thesis that the State should recognise as a medical treatment that which can provide high quality scientific evidence of safety and efficacy for a particular condition, through double blind, placebo controlled trials which have been systematically reviewed or, if this is not possible (and it is acknowledged that it is not always possible) through other means satisfactory to the broad scientific research community. In *NWHB*, Keane CJ asserted that

...scientists, in common with other groups in society, can ... be arrogant and complacent. The fact remains that in our daily lives we constantly proceed on the basis that they do indeed know best. When we board an aircraft, we like to think that the captain is guided by his or her technical manuals and not by what he or she has been told by an astrologer. If we have to undergo brain surgery, we would hope that the surgeon conducts the operation in accordance with the latest state of scientific knowledge and not in accordance with the requirements of some arcane religious cult.<sup>110</sup>

Nowhere has this statement been more appropriate than in the matter of CAM. Science, not philosophy, should make the final determination on matters of safety and efficacy in all areas of consumer law, but most importantly in healthcare, where certainty and strict standards protect consumers when they are at their most vulnerable. This should apply across the healthcare spectrum.

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<sup>106</sup> Conor O'Mahony, 'The dignity of the individual in Irish constitutional law' in Dieter Grimm, Alexandra Kemmerer & Christoph Mullers (eds), *Human Dignity in Context* (Hart Publishing 2016) 3.

<sup>107</sup> Gerry Whyte, 'The role of the Supreme Court in our democracy: a response to Mr. Justice Hardiman' (2006) 28 *Dublin University Law Journal* 1, 20.

<sup>108</sup> Conor O'Mahony, 'The dignity of the individual in Irish constitutional law' in Dieter Grimm, Alexandra Kemmerer & Christoph Mullers (eds), *Human Dignity in Context* (Hart Publishing 2016) 5.

<sup>109</sup> See, for example, See David Robert Grimes, 'Proposed mechanisms for homeopathy are physically impossible' (2012) 17 *Focus on Alternative and Complementary Therapies* 149.

<sup>110</sup> *North Western Health Board v HW & CW* [2001] 3 IR 622 (SC), 706 (Keane CJ).

(c) *The Private Nature of CAM*

Although minimum standards may be established in regulating the CAM sector, the private nature of CAM will likely limit the effective enforcement of the provisions on the making of claims and, to some extent, will be unable to entirely prevent the provision of services outside the parameters of regulation. Enforcement would rely on self-reporting of prohibited practice by the CAM provider, which is most unlikely, or reporting by the consumer, whose vested interests, including financial outlay, cognitive bias in respect of the efficacy of the treatment and human unwillingness to admit to a suboptimal decision seem unlikely to encourage full and frank disclosure to the relevant authorities. Mandatory entry for all CAM providers onto one of the two registers described above would better enable regulators to detect and investigate unregistered providers and would facilitate the provision of a simpler message to consumers to check that their CAM or Wellness Therapist is registered before attending for treatment of any kind. However, this approach, as noted above, is unlikely to find favour.

(d) *Resistance on the Part of CAM Providers*

Allied to the above point, changes in regulation are unlikely to change the core beliefs of CAM providers and, where these are at variance with the revised scopes of practice, may face resistance.

(e) *Unaddressed Implications for Mental Health*

The recommendations provided above do little to address the potential mental health implications of unqualified parties effecting psychological or emotional changes in patients. Stone notes that, while patients derive benefit from the CAM experience, the time and attention afforded to them and the holistic approach taken by practitioners, many such practitioners may not possess the necessary skills or qualifications to deal with mental health care and intervention.<sup>111</sup> The potential for beneficial psychological effects arising by virtue of treatment implies a correlative potential for negative effects. With increasing recognition of the prevalence and gravity of mental health difficulties in Ireland, the need to protect mental health as we protect physical health must also be acknowledged.

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<sup>111</sup> Julie Stone, *An Ethical Framework for Complementary and Alternative Therapists* (Routledge 2002) 7, “An ethical concern borne out of the holistic model of treatment relates to the increased potential for harm when health carers claim to treat emotional and spiritual health. A practitioner who hopes to be able to bring about changes in a patient’s physical, emotional and spiritual state might also be capable of causing harm in these spheres”.

(f) *Social Concerns in Respect of Livelihood*

Although it has been acknowledged that, in formulating and implementing novel restrictions, consideration must be given to the potential for undue infringement of practitioners' right to earn a livelihood under Art 40.3, it is argued that constitutional validity will do little to assuage the concerns of practitioners who find their practice on the wrong side of enforced provisions requiring proven safety and efficacy for all claims. The social impact of such regulation would likely be significant, restricting the scope of practice of practitioners and limiting earning potential. However, consideration must be given to the broader consequences in principle of avoiding putting in place appropriate regulatory protections on this basis alone.

Taken as a mere retailer or service provider, a CAM provider must be held to the same standards of consumer protection as those in other sectors. As a healthcare provider, it is argued that the duty to protect the public is significantly greater than for a mere retailer or service provider, with the consumer or patient in a vulnerable position by virtue of their condition, by virtue of their reliance on the knowledge and skill on the provider to positively affect their health and by virtue of the direct and indirect risks associated with medical treatment generally. However, at present, CAM providers in Ireland find themselves effectively free to make unsubstantiated claims to treat medical conditions, perceiving and experiencing fewer restrictions than those imposed upon mere retailers or service providers.<sup>112</sup> This is an unacceptable situation and is made no less unacceptable by reference to the potential negative impacts of regulation on practitioner employment. A livelihood earned through the issuing of misleading and unsubstantiated claims, irrespective of whether these are made in good faith, should not, on principle, be encouraged or facilitated.

(g) *The End of Life / "Miracle Cure" Exemption*

A convincing and emotive case can be made for the making available of various unproven and often expensive therapies to terminally ill patients, under headings which range from "potential miracle cure" to "what's the worst that can happen?". As noted in Chapter 4 and in Chapter 5, desperation drives a search for hope, which is found in copious amounts on the internet, where tales of miracle cures abound. However, to provide what may be considered a heartless riposte, the therapies referred to above should not be provided to those who are terminally ill, nor should the national or local media appeal for funding for this purpose. To

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<sup>112</sup> Appendix V, Advertising Standards Authority of Ireland, 'Re: Reiki in Ireland' (Ref 26287 – 20 October 2016 final). This is an example of a claim made on the Reiki in Ireland website, for which a complaint lodged was upheld. The website claimed, among other things, that "Reiki acts as a marvellous form of drug-free pain relief". This is unsubstantiated. The claim has since been removed from the site but is representative of very many other unsubstantiated claims made by CAM providers, which remain unchallenged under any facet consumer law in Ireland.

continue the practice, even with the best of intentions, facilitates the creation of false hope in individuals, in families and in communities, encouraging similar behaviour and further entrenching the view that there are cures that “they [conventional medical practitioners] don’t want you to know about”.<sup>113</sup> The trust and communication required for a positive and beneficial doctor-patient relationship has been emphasised throughout this thesis. Further undermining it discourages attendance, appropriate disclosure and compliance, placing lives at risk.

More important, however, is the reality faced by terminally ill patients, after the initial flood of hope associated with the discovery of a so-called miracle therapy, engendering goodwill and, often, public fundraising. Patients may need to travel significant distances while extremely ill or unstable,<sup>114</sup> staying away from their families and support networks for long periods of time, and undergoing what may be invasive, unpleasant and dangerous procedures, such as coffee<sup>115</sup> or bleach<sup>116</sup> enemas, for no established benefit. The patients pass away, having suffered the indignity, through no fault of their own, of falling victim to an expensive, unnecessary, inefficacious and extremely expensive healthcare practice.

Can this, perhaps, be accepted under the guise of personal choice? The idea that the patient ‘fought the good fight’? In the opinion of the author, no. Terminally ill patients are no less deserving than any others of high-quality, evidence based medical care, consumer protection and vindication of their personal and fundamental rights. In the case of *Fleming v Ireland*,<sup>117</sup> Kearns P stated that

In the eyes of the Constitution, the last days of the life of an elderly, terminally ill and disabled patient facing death have the same value, possess the same intrinsic human dignity and naturally enjoy the same protection as the life of the healthy young person on the cusp of adulthood and in the prime of their life.

The duress of the circumstances under which a decision to try a miracle cure is made cannot be overstated, nor should the decision itself be condemned or derided. Hope and desperation

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<sup>113</sup> See, for example, Kevin Trudeau, *Natural Cures "They" Don't Want You to Know About* (Perseus Books Group 2007).

<sup>114</sup> Many popular alternative cancer clinics are located in Mexico, particularly in Tijuana, outside the purview of the US Food and Drug Administration.

<sup>115</sup> Gerson.hu, ‘Some More Details’, “This nutrition-based therapy is best known for its success in curing cancer, but it is also a highly effective treatment for a wide range of chronic degenerative conditions, which even the most advanced allopathic methods can only alleviate but not cure... Detoxification is carried out by coffee enemas and castor oil treatments” <[www.gerson.hu/some-more-details](http://www.gerson.hu/some-more-details)> accessed 26 September 2016. See, in contrast, Barrie Cassileth, ‘Gerson regimen’ (2010) 24 *Oncology* 201.

<sup>116</sup> David Cornett, ‘Autism: Potentially lethal bleach ‘cure’ feared to have spread to Britain’ *Independent* (22 November 2015) <[www.independent.co.uk/life-style/health-and-families/health-news/autism-potentially-lethal-bleach-cure-feared-to-have-spread-to-britain-a6744291.html](http://www.independent.co.uk/life-style/health-and-families/health-news/autism-potentially-lethal-bleach-cure-feared-to-have-spread-to-britain-a6744291.html)> accessed 16 September 2016.

<sup>117</sup> *Fleming v Ireland* [2013] IEHC 2.

are both powerful motivators. Rather, the fault lies at the feet of those offering hope where none exists, for significant financial gain. As observed by William Jarvis and Stephen Barrett,

...no one wants to be cheated, especially in matters of life and health. Victims of disease do not demand quack treatments because they want to exercise their "rights," but because they have been deceived into thinking that they offer hope ... complete freedom is appropriate only in a society in which everyone is perfectly trustworthy—and no such society exists. Experience has taught us that quackery can even lead people to poison themselves, their children and their friends.<sup>118</sup>

Where these so-called therapies are not legally available, where they are addressed factually in the media, minimising emotive language and imagery and where illegal provision of such therapies is investigated and exposed, the potential for the creation of false hope is diminished.

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<sup>118</sup> William Jarvis and Stephen Barrett, “Health freedom”  
<[www.quackwatch.com/01QuackeryRelatedTopics/hffreedom.html](http://www.quackwatch.com/01QuackeryRelatedTopics/hffreedom.html)> accessed 2 September 2016.

### **PART III**

#### **CONCLUSION**

##### **6. REFLECTIONS ON THE RESEARCH PROCESS AND A FINAL CALL FOR CHANGE**

During the period of substantive research, my expected conclusion of this thesis has shifted from enthusiastic “BAN THEM ALL!!” militancy, dismissed after the first week, to a broad, if qualified, determination that many consumers perceive a benefit from CAM and, to this end, many of these therapies should remain accessible, albeit within an altered framework. My starting position on the need for high-quality evidence to justify the availability of therapies claiming to effectively treat particular medical conditions has not changed. Without this, consumer protection will continue to be undermined, consent may be rendered invalid, and consumers may be harmed, physically, psychologically, or financially, directly or indirectly.

One of my initial concerns in respect of the statutory regulation of CAM was affording it validity where the best available evidence did not merit it, unduly boosting consumer confidence by virtue of a perceived state endorsement. Though unlikely to be implemented, this concern would be addressed by the second recommendation made above, whereby the novel restrictions on scope of practice and the strict registration criteria for those on the proposed Register of CAM Practitioners (Register I) would effectively minimise the disparity between the potential benefits offered by the CAM Practitioner and expected by the consumer, and those established through research. Public trust in and utilisation of these notional evidence-based and highly trained CAM Practitioners could safely be encouraged – if not, there would be little motivation for them to go to the significant effort of registering on the Register of CAM Practitioners, when the Register for Wellness Therapists (Register II) would have significantly less demanding registration criteria and permit the provision of a broader range of non-medical practices. The recommendation to establish a GSSR-type panel would likely not create the same perception of state endorsement but nor would it provide the same measure of consumer protection.

The extent of public interest in CAM and the passion with which it is discussed and debated was not a surprise, although certainly some of the ire I encountered during the course of my research, both from those who supported CAM and felt that I was unfairly seeking to disparage it and from those who perceived that I was in favour of CAM and felt that my research was therefore nothing more than irresponsible quackery, was something of a revelation. The information with which the affronted parties were provided in respect of my research was identical for all parties and was neutral by design. The reactivity displayed by both ‘sides’ of the CAM debate provides some insight into what future regulators of CAM in Ireland and those empowering them may expect to face and why this task has been avoided to date. Nonetheless, it cannot continue to be avoided.

Consumers, young and old, are placed at risk by our lax and indifferent system of voluntary self-regulation for CAM. Healthcare is not simply another service falling under the remit of consumer law, though consumer law is certainly applicable, if not actually applied to CAM. The provision of healthcare requires that consumers or patients place significant trust in the knowledge and expertise of practitioners, although no education or training of any kind is required to act as CAM practitioner in Ireland. CAM practitioners may not submit themselves to the supervision of a representative body, or to any publicly accessible grievance procedure, leaving aggrieved consumers with no route of recourse. Notwithstanding this, CAM remains popular in Ireland.

Consumers deserve better. Patients deserve better. The CAM regimes in place in other jurisdictions do not provide an answer for the Irish context. Rather, Ireland must raise the bar, ideally by implementing a considered, improved regime, which would facilitate the establishment of minimum standards, provide accountability and oversight, prohibit the use of particular practices considered high-risk as part of a broader therapy and demand that high quality evidence be provided in support of the safety and efficacy of a therapy if a therapeutic claim is made,<sup>119</sup> restricting, by enforcement of existing consumer law, the provision of any and all insufficiently substantiated therapeutic claims. This will not prevent consumers from accessing most of their chosen therapies with the objective of enhancing their general wellbeing, the concept of which is diffuse and subject to interpretation. Requirements in respect of evidence and its effect on scope of practice, in respect of education and training, of ethical practice and of compliance with child protection measures, would significantly enhance consumer protection in the sector, building trust and strengthening the reputation of CAM and its practitioners overall.

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<sup>119</sup> If no claim is made, a therapy must be demonstrated to be safe.





# **APPENDICES**



## APPENDIX I

### Seroxat/Paxil: Adolescent Depression – Position Piece on Phase III Clinical Studies (October 1998)

**SB CONFIDENTIAL - FOR INTERNAL USE ONLY**

**October 1998**

#### **SEROXAT/PAXIL ADOLESCENT DEPRESSION Position piece on the phase III clinical studies**

##### **EXECUTIVE SUMMARY**

Results from the 2 placebo-controlled, phase III clinical trials designed to assess the efficacy and safety of Seroxat/Paxil in adolescents with major depression are now available.

Study 329 (conducted in the US) showed trends in efficacy in favour of Seroxat/Paxil across all indices of depression. However, the study failed to demonstrate a statistically significant difference from placebo on the primary efficacy measures. The second study (study 377), which was conducted in Europe, South America, South Africa and the United Arab Emirates, showed a high placebo response rate and failed demonstrate any separation of Seroxat/Paxil from placebo.

Data from these 2 studies are insufficiently robust to support a label change and will therefore not be submitted to the regulatory authorities. Results from Study 329 will be presented in abstract form at the ECNP meeting (Paris, November 1999) and a full manuscript will be progressed. There are no plans to publish data from Study 377.

/

**SEROXAT/PAXIL**  
**ADOLESCENT DEPRESSION**  
**Position piece on the phase III clinical studies**  
**FOR INTERNAL USE ONLY**

**SITUATION**

2 SB sponsored, placebo-controlled, phase III clinical trials have been conducted, Study 329 (US) and Study 377 (Europe, South America, South Africa and Saudi Arabia), in order to assess the efficacy and safety of Seroxat/Paxil (up to 40mg/day) in the treatment of adolescents (aged between 13 and 18 years and 11 months) with unipolar major depressive disorder (diagnosed according to DSM IIIR, Study 329 or DSM IV criteria, Study 377).

**Study 329** was a placebo-controlled, imipramine comparator study with an 8 week acute treatment phase followed by a 6 month extension phase. The acute phase has completed and the extension phase is due to complete at the end of 1998. 275 patients were recruited to the study. Results from the acute phase of this study show that there were no statistically significant differences from placebo on either of the primary efficacy parameters (change from baseline in HAMD total scores and the proportion of responders-where response was defined as a  $\geq 50\%$  reduction from baseline in HAMD score or a HAMD score  $\leq 8$  at endpoint). However, trends in favour of paroxetine compared with placebo were seen across all the indices of depression (change from baseline in HAMD total [ $p=0.133$ ], HAMD responders [ $p=0.112$ ], CGI [ $p=0.094$ ] and K-SADS [ $p=0.065$ ] scores) and statistically significant differences from placebo were observed in the proportion of patients in remission (defined as a HAMD score of  $\leq 8$  at endpoint). In general, the response to imipramine was similar to that for placebo. The 6 month extension phase has now completed and is scheduled to report at the end of 1998.

**Study 377** was a 12 week placebo-controlled study, conducted in 276 adolescents with major depression. There was a high placebo response rate in this study and no statistically or clinically significant differences from placebo were observed on either of the primary efficacy variables (proportion of patients achieving a  $\geq 50\%$  reduction from baseline in total MADRS scores and change from baseline in the K-SADS-L depressive subscale score). The only differences from placebo (secondary efficacy variables) were seen in a subgroup of patients who were  $\geq 16$  years of age.

Possible explanations for the high placebo response include;

- 1) The large number of study visits
- 2) the duration of the assessments
- 3) The fact that concomitant psychotherapy was not excluded
- 4) Question marks about the adequacy of using currently available diagnostic criteria and rating scales in younger patients
- 5) Adolescents may be more susceptible to a placebo effect
- 6) Developmental issues. Children and adolescents may respond in a pharmacologically different manner due to quantitative and/or qualitative differences in neurotransmitter/receptor systems.

**Conclusions from these studies:**

- There were no differences in the safety profile of Seroxat/Paxil in adolescents when compared to that already established in the adult population
- The efficacy data from the above clinical trials are insufficiently robust to support a regulatory submission and label change for this patient population.

**OTHER DATA:**

**Ongoing studies:** SB France are conducting a locally funded double-blind, comparative study of Seroxat/Paxil with clomipramine in adolescents with major depression (Study 511). In addition, a study in adolescents with OCD (Study 453) is underway in the US. This study comprises a 16 week open label Seroxat/Paxil treatment phase, followed by double-blind, randomisation to paroxetine or placebo for a further 16 weeks of treatment. The regulatory acceptability of these 2 studies needs to be established.

**Published data:** A review of the literature shows that 2 studies assessing the use of paroxetine in the treatment of 34 adolescents and children with depression have been published (Rey-Sanchez and Gutierrez-Cesares, 1997; Findling et al; 1996).

The first study (Rey-Sanchez and Gutierrez-Cesares, 1997) was a retrospective survey of data from 25 adolescents (aged 13-17 years) treated with paroxetine. Patients were diagnosed according to ICD 10 criteria. In 13 of the patients unipolar major depression was not the primary diagnosis. 17 patients received paroxetine as a monotherapy, 8 also received concomitant psychotropic medications (n=7 benzodiazepines, n=1 haloperidol). Paroxetine was administered at doses of 10mg (14 patients) or 20mg/day (11 patients). No specific depression

rating scales were used, response was based on clinical judgement. 76% patients had a satisfactory response (11 complete remission, 8 improved with residual symptoms). A lack of satisfactory response was observed in 6 (24%) patients. Eight patients reported side effects (somnolence or sleep disorders n=6, asthenia n=4, nausea n=3, tachycardia n=2, diarrhea n=2, headache n=2, orthostatic hypotension n=1, restlessness n=1). Two patients were withdrawn due to one due to anxiety, one due to hypotension and dizziness)

The second study (Findling et al; 1996) was conducted in 9 patients aged between 7-15 years (children and adolescents) meeting DSM IV criteria for a major depressive disorder. Symptomatology was assessed using HAM-D for subjects aged 13 to 15 years, and the childhood depression rating scale (CDRS) subjects aged 12 or younger. Paroxetine was initially given at a dose of 10mg/day. This was escalated to 20mg/day if the patient had not responded after 4 weeks of treatment. 8/9 patients responded to treatment with paroxetine. Three patients had complete remission, 5 patients had a >50% reduction in total CDRS score from baseline. CGI improved in all patients. One patient withdrew from the study at week 2 due to an adverse experience. This patient was found to have elevated serum paroxetine levels and was a poor 2D6 metaboliser. Assessment of pharmacokinetic parameters in this study showed that paroxetine had a similar half life to that reported in the adult population (15.7h [sd 9.0h] vs 24h, respectively).

#### COMPETITOR ACTIVITIES:

Lilly are believed to be in near to completing their phase III clinical trials in adolescent depression. One relatively large placebo-controlled 8 week study with an open 12 month follow-up period conducted in 96 patients (aged 8-18 years) has recently been published (Emslie et al; 1997 and 1998). These data show that 56% (27/48) patients on fluoxetine (20mg/day) compared with 33% (16/48) patients on placebo were rated as much or very much improved on the CGI at Week 6 (p=0.02). In the 12 month follow-up period, 85% (n=74) patients recovered from the depressive episode (47 on fluoxetine, 22 on placebo and 5 on other antidepressants or lithium). Twenty nine (39%) of the patients (36% of those who had recovered on fluoxetine [17/47] and 41% of those who had recovered on placebo [9/22] had a recurrence of depression during the 12 month follow-up (a higher recurrence rate than seen in adults). Other published data on fluoxetine are from small open studies or individual case reports (Colle et al; 1994).

Pfizer already have positive data (including PK data) and are licenced in the US for the treatment of adolescent OCD. In addition, Pfizer are also believed to be

conducting clinical trials in adolescent depression. Available published data are limited, derived from small open studies in adolescent depression (McConville et al; 1996; Tierney et al; 1995)

### **TARGET**

To effectively manage the dissemination of these data in order to minimise any potential negative commercial impact.

### **PROPOSALS**

- Based on the current data from Studies 377 and 329, and following consultation with SB country regulatory and marketing groups, no regulatory submissions will be made to obtain either efficacy or safety statements relating to adolescent depression at this time. However data (especially safety data) from these studies may be included in any future regulatory submissions, provided that we are able to go on and generate robust, approvable efficacy data. The rationale for not attempting to obtain a safety statement at this time is as follows;
  - i) regulatory agencies would not approve a statement indicating that there are no safety issues in adolescents, as this could be seen as promoting off-label use
  - ii) it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine.
- Positive data from Study 329 will be published in abstract form at the ECNP (Paris, November 1998) and a full manuscript of the 329 data will be progressed.
- The regulatory acceptability of Studies 511 and 453 and any other data in this patient population will continue to be investigated.

## REFERENCES

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2. Findling R, Fiala S, Myers C et al. Putative determinants of paroxetine response in pediatric patients with major depression. *Psychopharmacol Bull*; 1996; 32 (3):446.
3. Emslie GJ, Rush AJ, Weinberg WA et al. A double-blind, randomized, placebo-controlled trial of fluoxetine in children and adolescents with depression. *Arch Gen Psychiatry*; 1997; 54 (11): 1031-1037.
4. Emslie GJ, Rush AJ, Weinberg WA et al. Fluoxetine in child and adolescent depression: acute and maintenance treatment. *Depression and Anxiety (US)*; 1998; 7 (1): 32-39.
5. Colle LM, Belair JF, DiFeo M et al. Extended open label fluoxetine treatment of adolescents with major depression. *J Child Adolesc Psychopharmacol*. 1994; 4 (4): 225-232.
6. McConville BJ, Minnery RL, Sorter MT et al. An open study of the effects of sertraline on adolescent major depression. *J Child Adolesc Psychopharmacol*. 1996; 6 (1):41-51
7. Tierney E, Joshi PT, Llinas JF et al. Sertraline for major depression in children and adolescents: Preliminary clinical experience. *J Child Adolesc Psychopharmacol*; 1995; 5 (1):13-27.



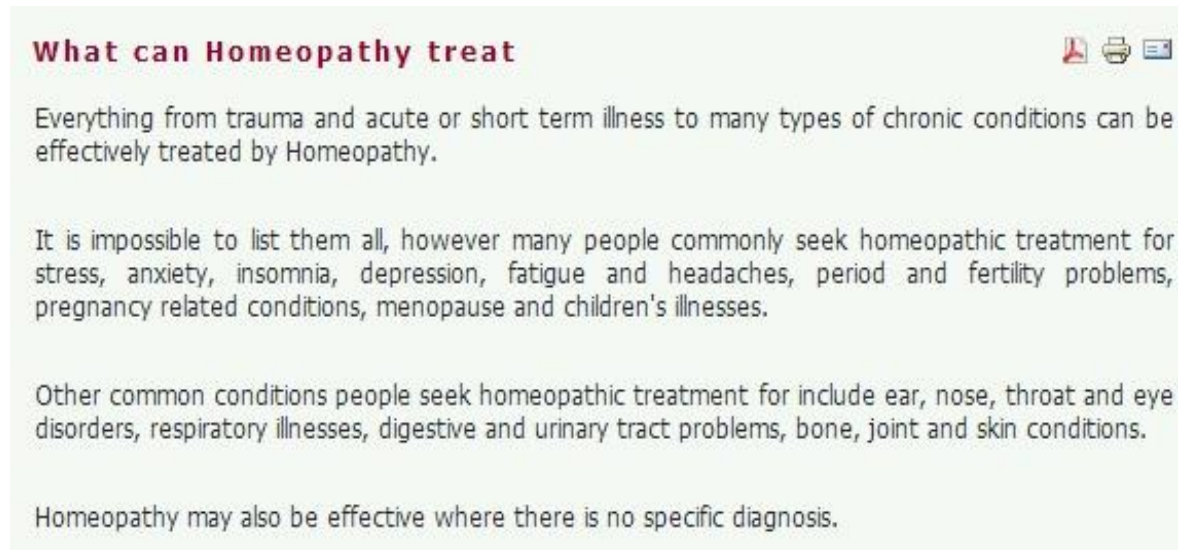
## APPENDIX II

### Non-Commercial versus Commercial Claims

#### *Non-Commercial (Representative body)*

Irish Society of Homeopaths, “What can Homeopathy treat?”

<[www.irishhomeopathy.ie/homeopaths/index.php?option=com\\_content&view=article&id=52&Itemid=70](http://www.irishhomeopathy.ie/homeopaths/index.php?option=com_content&view=article&id=52&Itemid=70)> accessed 27 November 2013.



The screenshot shows a webpage with a light green background. At the top left, the title "What can Homeopathy treat" is written in a dark red font. To the right of the title are three small icons: a red document icon, a printer icon, and a speech bubble icon. Below the title, there are four paragraphs of text in a dark grey font. The first paragraph states: "Everything from trauma and acute or short term illness to many types of chronic conditions can be effectively treated by Homeopathy." The second paragraph states: "It is impossible to list them all, however many people commonly seek homeopathic treatment for stress, anxiety, insomnia, depression, fatigue and headaches, period and fertility problems, pregnancy related conditions, menopause and children's illnesses." The third paragraph states: "Other common conditions people seek homeopathic treatment for include ear, nose, throat and eye disorders, respiratory illnesses, digestive and urinary tract problems, bone, joint and skin conditions." The fourth paragraph states: "Homeopathy may also be effective where there is no specific diagnosis."

#### *Commercial*

Dervish Dublin Holistics ‘What can Homeopathy treat?’

<[www.dervishdublinholistics.com/dublin-homeopathy-co-op.html](http://www.dervishdublinholistics.com/dublin-homeopathy-co-op.html)> accessed 6 September 2016.

## What can Homeopathy treat?

Everything from trauma and acute or short term illness to many types of chronic conditions can be effectively treated by Homeopathy. It is impossible [sic] to list them all, however many people commonly seek homeopathic treatment for stress, anxiety, insomnia, depression, fatigue and headaches, period and fertility problems, pregnancy related conditions, menopause and children's illnesses. Other common conditions people seek homeopathic treatment for include ear, nose, throat and eye disorders, respiratory illnesses, digestive and urinary tract problems, bone, joint and skin conditions. Homeopathy may also be effective where there is no specific diagnosis.

## APPENDIX III

### Commercial Claims

#### Blum Wellness – ‘Asthma’

<blum.ie/wellness\_topics/c\_7\_asthma.html> accessed 12 October 2016

# Asthma

[Home](#) > [We May Help You With](#) > Asthma



Allergies are often treated with chiropractic care. Many allergic and asthmatic reactions are caused by hypersensitivity of the immune system and/or respiratory system. Researchers have found that the immune and respiratory systems depend on normal communication from the brain and spinal cord to control and coordinate their functions properly.

Therefore, if your neck is misaligned, it could cause an imbalance in your nervous system function. This upper cervical spinal joint irritation could possibly produce or exaggerate asthmatic and allergic symptoms. For example; many asthma and allergy sufferers experienced traumas such as head injuries, auto accidents, or falls which could have injured their upper cervical spines. The good news is that we can perform an upper cervical examination to determine if chiropractic care can reduce your allergic and asthmatic reactions. Schedule an appointment today!



Many allergic and asthmatic reactions are caused by hypersensitivity of the immune system and chiropractic care can help.

## APPENDIX IV

### Chiropractic Association of Ireland, 'Prepayment for Chiropractic Services' (7 April 2006)



#### PREPAYMENT FOR CHIROPRACTIC SERVICES 7<sup>th</sup> April 2006

Some chiropractors offer prepayment options where extensive treatment is indicated. This arrangement usually involves a discount on the overall cost of treatment, but sometimes the request for prepayment can be a cause of concern for patients.

- The CAI recommends that a "pay as you go" option should also be available on request.
- Where a "pay as you go" option is not available, and the patient does not wish to agree to prepayment, the chiropractor must facilitate the patient in finding another CAI member who does offer "pay as you go".
- Some chiropractors do not subscribe to what they describe as the crisis model of healthcare – which is considered to be similar to only going to the dentist when you have acute toothache. They prefer a model where preventive care is provided leading to better overall health as a result of regular care. The option of prepayment is often offered in such circumstances.
- Chiropractors who offer prepayment plans feel it is to the benefit of the patient because it allows the patient to know in advance exactly what it will cost to complete the programme of care.
- Prepayment reduces the number of payment transactions and can make visits more convenient for the patient.
- Those chiropractors offering prepayment may also encourage discussion of the option with the patient's spouse. This allows the option to be discussed thoroughly prior to making a decision.
- The CAI recommends that written provisions be made to ensure that prepaid funds are not expended until services are provided and that patients may receive a prompt refund of unused fees upon request. The written provisions should include a clear explanation of how any refund will be calculated and should be signed by the patient. Where clinics employ more than one chiropractor, clear indications should be made in the written provisions regarding who will be responsible for providing any refund – the chiropractor, or the clinic owner?

The CAI supports the right of chiropractors to offer prepayment options, but also supports the right of patients to decline this offer yet still be able to access chiropractic care if they do not feel prepayment is suitable to their circumstances.

Prepayment agreements are subject to The European Communities (Unfair Terms in Consumer Contracts) Regulations, 1995 and must balance the rights of the chiropractor with those of the patient. Please contact us again if, after discussion with your chiropractor, you have any concerns about a request for prepayment.

#### Useful websites:

<http://www.chiropractic.ie> Chiropractic Association of Ireland. Information on chiropractic, and the register of members in Ireland, all of whom have completed a university training of at least four years duration and who are fully insured.

[http://www.bupaireland.ie/yourhealth/Realfactsheets/chiropractic\\_and\\_osteopathy.html](http://www.bupaireland.ie/yourhealth/Realfactsheets/chiropractic_and_osteopathy.html) - information from BUPA about chiropractic and osteopathy.

<http://www.vhi.ie/hfiles/hf-085.jsp> - information from VHI about chiropractic treatment, which is covered on plans A-E.

## **APPENDIX V**

### **Complaint to the Advertising Standards Authority of Ireland, 'Re: Reiki in Ireland' (Final) (20 October 2016)**

Our Ref.: 26287.dm

30th September 2016

Ms Claire O'Leary  
Apt 2 Marino House  
16 Malahide Road  
Dublin 3

#### **RE: Reiki In Ireland**

Dear Ms O'Leary

With reference to your complaint about the above advertising, I enclose a copy of a report which the ASAI Executive proposes to submit to the Complaints Committee in the matter.

This report represents the Executive's recommendation in the matter; the final decision on the case will rest with the Committee. Copies of the report are being sent to you and to the advertiser. Any additional comments you may wish to make will be carefully considered if received by 12 noon October 10th.

The final Case Report as approved by the Complaints Committee after its consideration of the matter will be included in the next Complaints Bulletin which is released to media for publication. We will write to you again confirming the findings of the Complaints Committee, or advising you of any material changes in the report. In the meantime we would be glad if you would treat the report as confidential.

Yours sincerely

Orla Twomey,

CHIEF EXECUTIVE.

Encl.

CC:11/10/16

## CASE REPORT

Batch No:237

Ref.:26287

Product: Health & Beauty

Advertiser: ReikiinIreland.com

Medium: Internet (Company Website)

Advertisement

The advertising referred to the following:

“...Reiki makes its own way to the area of the body in need of treatment. Reiki has proved to be of great benefit for a broad range of conditions. It is used as a compliment to conventional therapies in hospitals world-wide. People who suffer with migraine, asthma, skin conditions, ulcers, orthopaedic injuries and arthritis and many other ailments have noted amazing improvements in their health. Reiki has also been of benefit for some people challenged with various forms of cancer and other types of serious health challenges. The gentle Reiki energy is also effective in calming the mind and has helped many with anxiety and depression. People with low self-esteem and poor self-confidence levels have also noted remarkable differences following treatments. Very receptive people often experience Reiki as Love. Love is a uniting power which leads us forward to an even greater state of oneness with the whole of creation.

### HOW CAN REIKI HELP ME

Reiki acts as a marvellous form of drug-free pain relief

Reiki calms the mind reduces stress/worry/anxiety

Reiki boosts the immune system supports the body's natural ability to heal itself.

It minimizes the unpleasant side-effects of prescribed medication

It unblocks our creativity helping us reach our true potential

It promotes high self confidence

Reiki helps you develop successful relationships...”

### Complaint:

The complainant said that while [s]he considered that a lot of the claims made in the advertising required substantiation that the one which [s]he considered to require the most evidence was that “Reiki acts as a marvellous form of drug-free pain relief”.

### Advertisers’ Response:

The advertiser said that after much soul searching she had taken down the page from her website referenced in the complaint and copied the updated content directly from The Reiki Federation of Ireland which was her governing body. She said that while the content remained similar to that complained of that she would never wish to mislead consumers with information provided.

### Code Sections:

7th Edition

2.4 (c) Compliance with the Code is assessed in the light of a marketing communication's probable effect when taken as a whole and in context. Particular attention is paid to:

- the characteristics of the likely audience
- the media by means of which the marketing communication is communicated
- the location and context of the marketing communication
- the nature of the advertised product and the nature, content and form of any associated material made available or action recommended to consumers.

11.1 Claims about health and beauty products and treatments should be backed by substantiation. Where relevant, this should include the results of robust and reputable

2 Ref.: 26287

trials on human subjects, of sufficient rigour, design and execution as to warrant general acceptance of the results.

11.5 Advertisers should not discourage essential treatment for conditions for which medical supervision should be sought. For example, they should not offer specific advice on, diagnosis of or treatment for such conditions unless that advice, diagnosis or treatment is conducted under the supervision of a suitably qualified health professional. Accurate and responsible general information about such conditions may, however, be offered.

Conclusion:

Complaint Upheld.

The Complaints Committee considered the details of the complaint and the advertisers' response. The Committee noted that the advertiser had not offered any substantiation for the claims made in her advertising and upheld the complaint under Sections 11.1 and 11.5 of the Code.

Action Required

While the page in question had been removed from the website, the Committee advised the advertiser that such claims should not be used again without adequate substantiation.



## **APPENDIX VI**

### **Correspondence from CORU Re Upcoming Designations under the Health and Social Care Professionals Act 2005**

**(20 November 2015)**

Dear Claire,

Thank you for your recent inquiry about statutory registration and for your interest in the work of CORU.

CORU currently has registers open for the following professions:

- Dietitians
- Occupational Therapists
- Radiographers
- Radiation Therapists
- Social Workers
- Speech and Language Therapists
- Optometrists and
- Dispensing Opticians

The professions to be regulated are:

- Clinical Biochemists
- Medical Scientists
- Orthoptists
- Physiotherapists
- Podiatrists
- Psychologists
- Social Care Workers

The Minister for Health is the person responsible for deciding which professions are to be regulated. The only professions we have been asked to advise the Minister on how to potentially regulate are Counsellors and Psychotherapists.

Future decisions about regulation of additional professions are likely to be influenced by learning gained from the first phase of registration and also by looking at international experience of emerging State-recognised models of Voluntary Registration/Negative registration. It is also probable that

professions to be registered will be ranked based on the level of risk posed to the public by the profession.

We thank you again for your interest in CORU and we would encourage you to check out our website [www.coru.ie](http://www.coru.ie) for updates on developments.

Regards,

Alan Neary

Communications Officer

**CORU** - Regulating Health and Social Care Professionals



## APPENDIX VII

### Kathryn Hayes, 'Appeal for ill child to travel to US for pioneering treatment' (14 July 2012, since removed from the Irish Times website)

<<http://cf.broadsheet.ie/wp-content/uploads/2012/07/Screen-Shot-2012-07-16-at-11.10.24.jpg>>  
accessed 20 June 2016.

The Irish Times - Saturday, July 14, 2012

## Appeal for ill child to travel to US for pioneering treatment

KATHRYN HAYES

The mother of a terminally ill girl (2) is hoping a pioneering treatment in the US could help save her daughter's life.

Alexandra Burke-Costa from Effin, Co Limerick, was diagnosed with an aggressive terminal cancer last November after a large tumour was found on her face. She was treated for what doctors thought was an abscess.

However, after antibiotics failed an MRI confirmed Rhabdomyosarcoma. It is a rare cancer that forms in the soft tissues and can attack all parts of the body.

Following her diagnosis the child had seven months of intensive chemotherapy.

After being told there was no further treatment available in Ireland, Alexandra's mother contacted the Buzynski Clinic in Houston, Texas. The clinic provides advanced alternative cancer treatments. But the cost can be between €30,000 and €100,000; so far the family has raised €22,000 through local fundraising.

Contributions to the family's fundraising campaign to Bank of Ireland, sort code: 904536; account number: 96313393.

### In this section »

- ▼ Outstanding Simon keeps his Irish customers satisfied
- ▼ HSE overpaid worker €63,000 in voluntary redundancy scheme
- ▼ Inquest into child's death opens Monday
- ▼ Kenny says health cuts should be quick
- ▼ Second witness in Dublin murder trial retracts statement
- ▼ Irish doctors help at scene of avalanche

## APPENDIX VIII

Charts (a)-(e) demonstrating a correlation between increased conventional intervention and increased five- year survival rate <sup>1</sup>  
(2013)

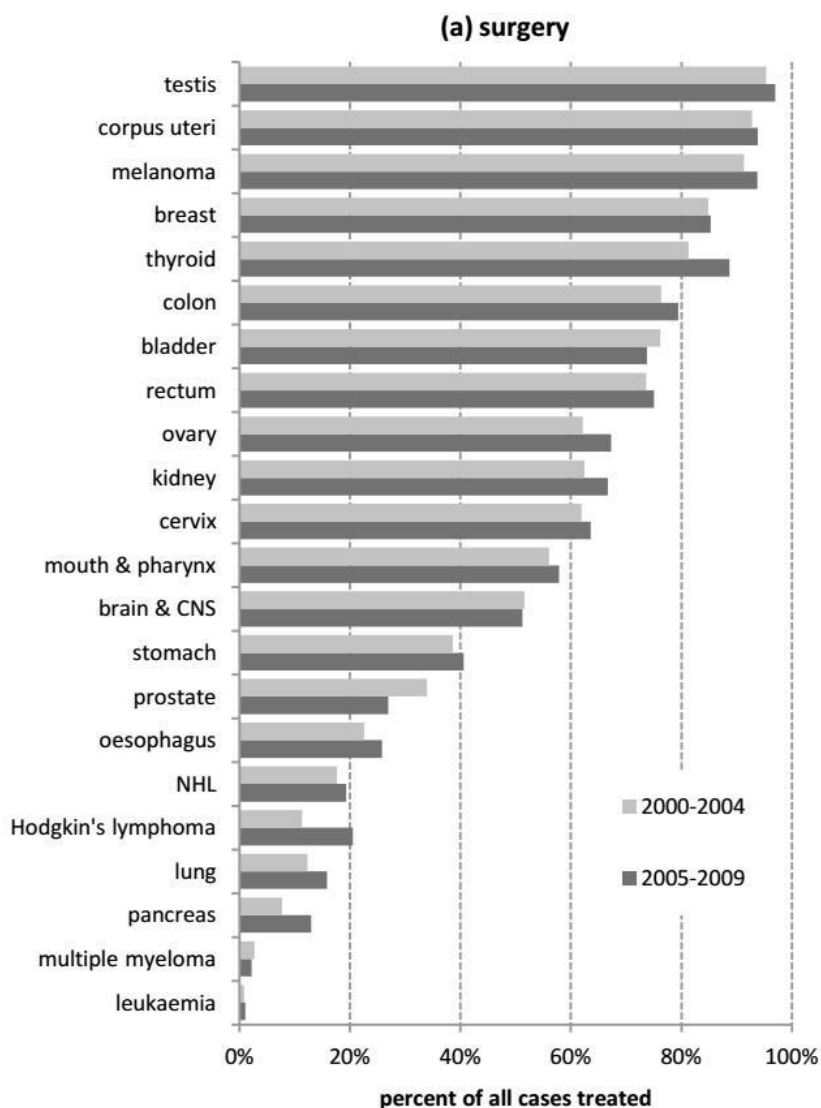


Figure (a) - Overall increase in surgical intervention, from 2000 to 2009

<sup>1</sup> Figures (a) - (e), charts demonstrating an overall increase in intervention in all three treatment modalities and a corresponding decrease in cases for which no treatment was given, from 2000 to 2009. National Cancer Registry, *Cancer in Ireland 2013: Annual report of the National Cancer Registry* (National Cancer Registry 2013) 34-36.

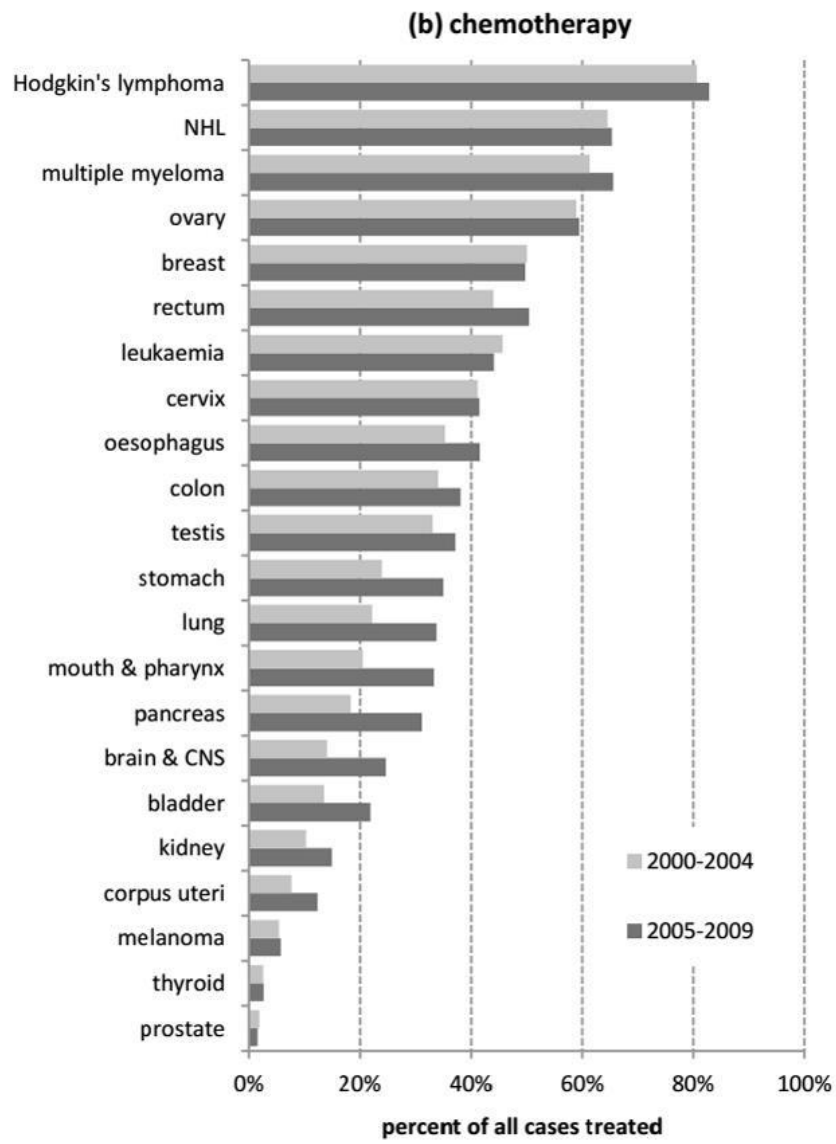


*Figure (b) - Overall increase in the use of chemotherapy, from 2000 to 2009*

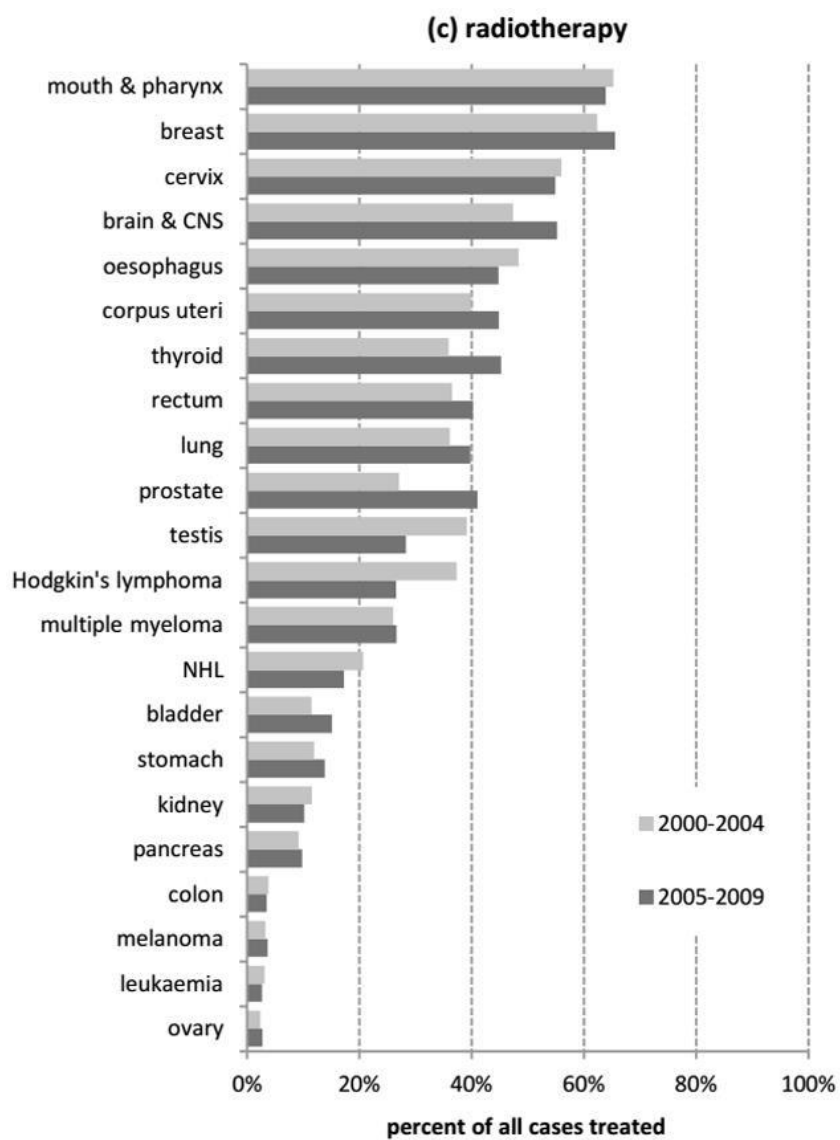


Figure (c) - Overall increase in the use of radiotherapy from 2000 to 2009

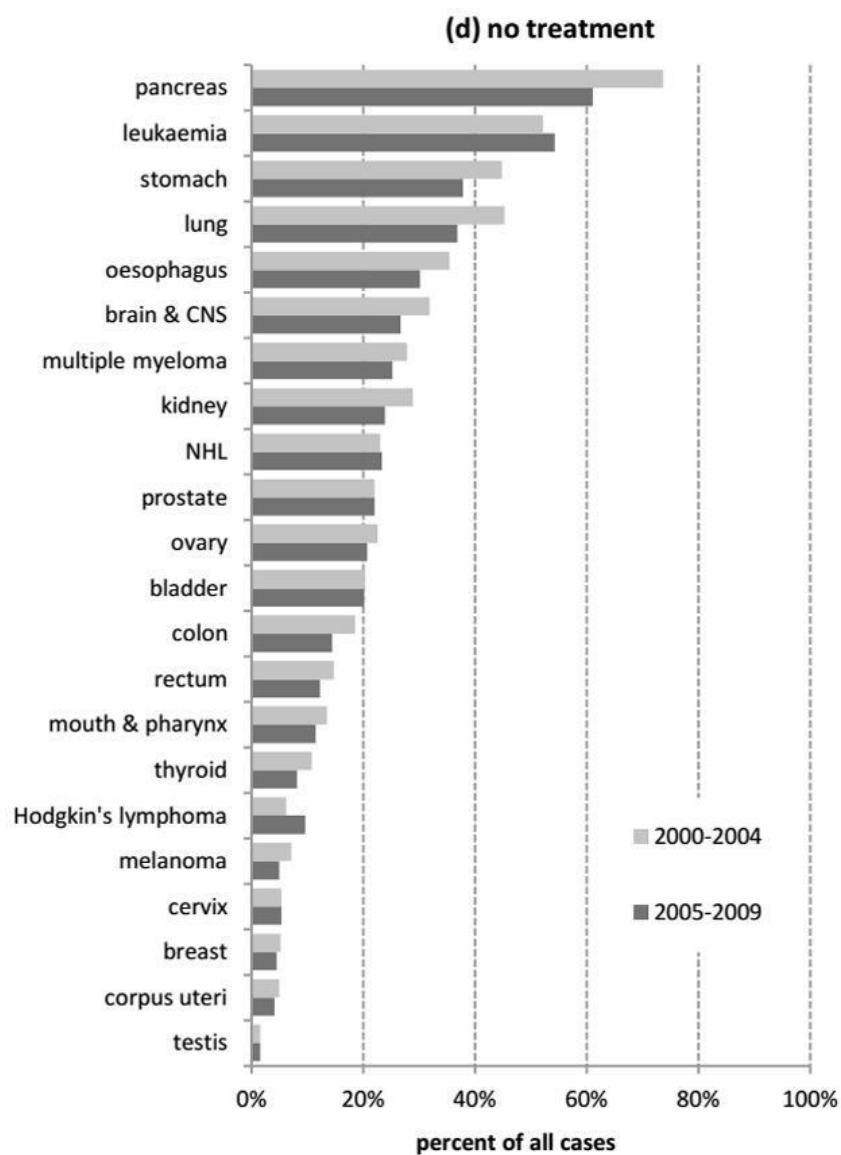


Figure (d) - Overall decrease in cases in which no treatment was provided, from 2000 to 2009

**Five-year relative survival for males and females diagnosed with all invasive cancers during the periods 1994-1999, 2000-2004, and 2005-2009 (2013)**

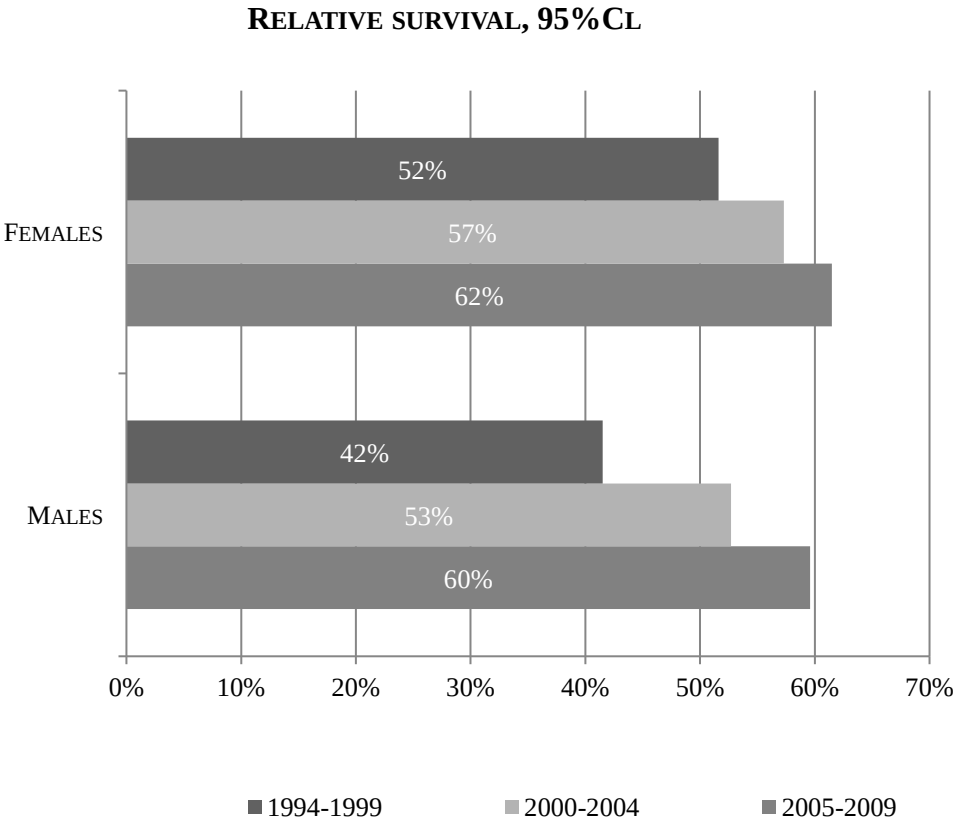


*Figure (e) - Five-year survival rates for all cancers from 1994 – 2009*

## **APPENDIX IX**

### **Report of the National Working Group on the Regulation of Complementary Therapists to the Minister for Health and Children (December 2005)**

#### **Recommendations of the National Working Group**

The following are the recommendations of the group to the Minister for Health and Children:

1. Statutory regulation for herbalists/acupuncturists/Traditional Chinese Medicine practitioners. To achieve this, it is recommended that a small, single-focus working group be established without delay to consider the complex issues and various models involved in statutory regulation.
2. For all other groups, the development of a robust system of voluntary self-regulation is recommended.
3. Facilitated work-days for various therapy organisations to progress areas of development with a view to encouraging federation into one representative organisation for that therapy. This is a necessary first step before harmonisation of advice on education standards in collaboration, as appropriate, with providers and HETAC/FETAC.
4. A report on the state of the sector following these facilitated work days.
5. Publication of a comprehensive, up-to-date information booklet incorporating a client/therapist charter for the public following the publication of the report on the state of the sector.
6. Immediate setting up of a forum for dialogue between the complementary and conventional medical sectors.
7. The establishment of a National Annual Forum for the sector to continue the momentum arising from the work of the Working Group.
8. Following the facilitated work days and the report on the sector, the establishment of a working group on the single issue of the development of a Complementary Therapies Council which would oversee issues in the complementary therapies area.

## APPENDIX X

### Claims as to indication for homeopathic medicinal products under the SRS

Weleda Gelsemium 30C - HOR0407/024/001

<<https://thehealthstore.ie/vitamin-minerals/homeopathy/weleda-gelsemium-30c>> accessed 10 October 2016



Search entire store here...

 0

Home / Vitamins & Minerals / Homeopathy / Weleda Gelsemium 30C

Previous Product



### Weleda Gelsemium 30C

For Colds; influenza; sore throat; runny nose; tight headaches; nervous anxiety. For sufferers of conjunctivitis; inflamed burning eyes; hay fever; catarrh; heavy aching muscles; flushing aching and trembling.

€8.95

Next Product

RECENTLY VIEWED PRODUCTS

 WELEDA SULPHUR 30C

ADD TO CART

### Weleda Sulfur (Sulphur) 30C - HOR0407/010/001

<<https://thehealthstore.ie/vitamin-minerals/homeopathy/weleda-sulphur-30c>> accessed 10 October 2016



Search entire store here...

 0

Home / Vitamins & Minerals / Homeopathy / Weleda Sulphur 30c

Previous Product



### Weleda Sulphur 30c

The Homoeopathic remedy can be used for Itching skin; dry skin problems, boils; inflamed, red orifices; burning sensations - e.g. hot feet in bed.

€8.95

Next Product

RECENTLY VIEWED PRODUCTS

 WELEDA GELSEMIUM 30C

ADD TO CART



## **APPENDIX XI**

### **Public Understanding of and Attitude Towards Complementary and Alternative Therapies: Questionnaire Distributed to Participants (May 2016)**

**1. I have read and understood the information provided.**

**2. What age are you?**

- 18 to 24
- 25 to 34
- 35 to 44
- 45 to 54
- 55 to 64
- 65 to 74
- 75 or older
- I do not wish to answer this question

**3. With which gender do you currently identify? If you do not wish to answer this question, please leave blank.**

**4. What is the highest level of education that you have completed?**

- Primary school
- Some secondary school, but no Leaving Certificate
- Leaving Certificate
- Certificate or Diploma
- Undergraduate degree
- Postgraduate qualification
- None of these
- I do not wish to answer this question

**5. Have you studied any of the following as part of any third level course or qualification? Tick all that apply**

- Chemistry
- Physics
- Biology
- Mathematics
- Statistics
- No, none of these
- I do not wish to answer this question

**6. Have you worked, or are you hoping to work, in any of the following fields? Tick all that apply**

- Healthcare
- Pharmaceutical research, design, manufacture or retail
- Applied or academic sciences
- Chemical engineering
- Medical device research, design, manufacture or retail
- No, none of these
- I do not wish to answer this question

**7. What is your nationality? If you do not wish to answer this question, please leave blank**

**8. Have you ever used a CAM therapy or procured the use of one for another person?**

- Yes, I have used one or more CAM therapies
- Yes, I have procured the use of one or more CAM therapies for another person
- Yes, I have used one or more CAM therapies for myself **and** have procured the use of such a therapy or therapies for another person
- No
- I do not wish to answer this question

**9. How often do you use or procure CAM therapies?**

- 12 or more times per year
- 6-12 times per year
- 3-6 times per year
- 1-3 times per year
- Less than once per year.
- I do not wish to answer this question

**10. If you have procured the use of a CAM therapy for another person, was that person...**

- Under 18 years of age
- Over 18 years of age
- I have procured such products or services for individuals both under **and** over 18 years of age
- I do not wish to answer this question

**11. Why did you choose to use or procure a CAM therapy? Tick all that apply**

- They are safe
- They are effective
- They are natural
- They are the best fit for my individual healthcare needs
- They are holistic
- I am interested in many aspects of health and like to try new treatments
- I am wary of conventional medicine and am aware of significant harm caused by it
- I had exhausted all conventional medical options
- It was recommended by a friend, family member or other acquaintance
- It was recommended to me by a member of the conventional medical profession (such as a physician, dentist, nurse, physiotherapist, pharmacist or other allied health professional)
- I was unaware at the time that the product or treatment I used or procured was not a conventional medicine/medical therapy
- I do not wish to answer this question
- Other (please specify)

**12. Why did you choose not to use or procure a CAM therapy? Tick all that apply**

- I am generally healthy, and have had no need to seek treatment of any kind
- I do not have enough knowledge to justify using them
- I have simply never considered using a CAM therapy
- I prefer to attend conventional medical practitioners, as I understand the system
- They are more expensive than conventional medicine/medical treatment
- I do not consider them to be safe
- I do not consider them to be effective
- I was advised against seeking a CAM therapy by a friend, family member or other acquaintance
- I was advised against seeking a CAM therapy by a member of the conventional medical profession, (such as a physician, dentist, nurse, physiotherapist, pharmacist or other allied health professional)
- I do not wish to answer this question
- Other (please specify)

**13. Which of the following complementary or alternative therapies have you used or procured for use by another person? Tick all that apply**

- Homeopathic remedies
- Chiropractic treatment
- Acupuncture
- Reiki
- Colour therapy
- Crystal therapy
- Chinese herbal medicine
- Ear candling
- Magnet therapy
- Accessories such as bracelets, rings or pendants, used for the treatment of joint disorders or to improve general wellbeing
- Detoxifying foot pads or foot bath
- Prayer or spiritual healing
- Cranial osteopathy
- Oxygen therapy
- Cupping therapy
- Chelation therapy
- I do not wish to answer this question
- Other (please specify)

**14. Please rate the effectiveness of the following therapies, in your experience. If you have not used or procured them, please select "Not applicable - never used"**

- Not at all effective for the purpose or purposes required
- Slightly effective for the purpose or purposes required
- Mostly effective for the purpose or purposes required
- Completely effective for the purpose or purposes required
- Not applicable - never used
  - Homeopathic remedy
  - Chiropractic treatment
  - Acupuncture
  - Reiki
  - Osteopathy
  - Colour therapy
  - Crystal therapy
  - Chinese herbal medicine
  - Ear candling
  - Magnet therapy
  - Accessories such as bracelets, rings or pendants, used for the treatment of joint disorders or to improve general wellbeing
  - Detoxifying foot pads or foot bath
  - Prayer, spiritual, or faith healing
  - Osteopathy
  - Oxygen therapy
  - Cupping
  - Chelation therapy
  - Other (please specify)

**15. Before using a selected therapy, how did you determine that it was safe for use by you or another person? Tick all that apply**

- I read studies and other literature on the relevant therapy and, on that basis, was satisfied that it was safe
- I read the literature provided by the retailer or service provider in relation to the relevant therapy and, on that basis, was satisfied that it was safe.
- I spoke with the retailer or service provider about their experience with the therapy and what I could expect, and, on that basis, was satisfied that it was safe
- I was referred by a trusted friend, family member, or other acquaintance, and, on that basis, was satisfied that it was safe
- I was referred by a member of the conventional medical profession, (physician, dentist, nurse, physiotherapist or other allied health professional) and, on that basis, was satisfied that it was safe
- I trust my judgement and would know if a therapy was unsafe
- The therapies are freely available and can therefore be considered safe
- I do not wish to answer this question
- Other (please specify)

**16. Before using a selected therapy, how did you determine that it would be effective for you or another person? Tick all that apply**

- I read studies and other literature on the relevant therapy and, on that basis, was satisfied that it would be effective
- I read the literature provided by the retailer or service provider in relation to the relevant therapy and, on that basis, was satisfied that it would be effective.
- I spoke with the retailer or service provider about their experience with the therapy and, on that basis, was satisfied that it would be effective
- I was referred by a trusted friend, family member or other acquaintance and, on that basis, was satisfied that it would be effective
- I was referred by a member of the conventional medical profession, (physician, dentist, nurse, physiotherapist or other allied health professional) and, on that basis, was satisfied that it would be effective
- I trust my judgement and would know if a therapy was ineffective
- The therapies are freely available and can therefore be considered effective
- I do not wish to answer this question
- Other (please specify)

**17. How are consumers of CAM protected by law in Ireland? Tick all that apply**

- Practitioners must be licenced and registered with a self-regulatory body provided for by statute, similarly to conventional doctors
- In the case of consumer grievances, practitioners in Ireland are subject to review and potential sanction by self-regulatory bodies provided for by statute
- CAM medicinal products for human use are required to meet the same standards of safety and efficacy as conventional medicinal products in order to be approved for sale in Ireland
- Practitioners must be registered with a voluntary professional body or association in order to practice in Ireland
- Practitioners must hold a recognised qualification to practice legally, but need not be registered with any professional or statutory body
- No particular qualification or registration is required to work as a CAM practitioner
- There is no regulation specifically addressing CAM medicinal products in Ireland - general consumer protection laws are applicable
- There is no regulation specifically addressing CAM practices or practitioners - the general consumer protection laws are applicable
- I do not wish to answer this question
- I don't know
- Other (please specify)

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