

The Pharmacist's Liability in the Tort of Negligence and Product Liability Law in Ireland

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Doctor of Philosophy

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Summary

This thesis encompasses historical and legal comparative enquiries into the pharmacy and the law affecting its practitioners. The major research themes are the possible application of the professional negligence standard to pharmacists, emerging new areas of potential liability, as pharmacists expand their role and related issues regarding causation and proof, where there is evidence of a new judicial willingness to modify traditional rules.

The work comprises seven chapters. Chapter 1 (introduction and Methodology) sets out the thesis structure, research question and applied methodology. Chapter 2 (A Concise History of Pharmacy) traces the origins of pharmacy, as a distinct profession, and the prior association of apothecaries with both branches of the emergent medical profession. The establishment during the Nineteenth Century of statutory professional bodies for pharmacy in Ireland, Britain and the US is examined. Chapter 3 (The Duty of Care) examines tortious liability with particular reference to healthcare providers. The new duties imposed on pharmacists under the Pharmacy Act 2007 and its associated legislation are analysed. Chapter 4 (Professional Negligence and the Standard of Care) deals with the professional negligence liability of pharmacists and that of medical practitioners, including legal developments in Ireland. Attention is devoted to pharmacists' role regarding psychiatric medication and to patients' contributory negligence. Chapter 5 (Causation) examines factual causation, legal causation and remoteness of damage. The Irish cases concerning disclosure of risks associated with treatment are analysed. The chapter explores the varying responses in different jurisdictions to 'loss of a chance' in healthcare litigation. Chapter 6 (Liability for Defective Products) traces developments in the US, Australia, Canada, New Zealand. The Strasbourg Convention and the European Product Liability Directive, and adaptation of the latter in Australia/Asia are studied. Chapter 7 (Emerging Issues, Conclusions and Proposals for Reform) explores the desirability of establishing a novel Healthcare Legal Forum for Ireland and the introduction of Patient Group Directions to Ireland on the United Kingdom model. The chapter draws on the thesis research outputs to recommend legal and organisational change for societal benefit to Ireland.

RECOMMENDATIONS

The thesis makes the following recommendations:

(1) The establishment of a Healthcare Legal Forum would facilitate the various health sector regulators to exchange views and information on legislative change. Such an environment would enhance the material available on which to base decisions for the Law Reform Commission, the Department of Health and other interested bodies.

(2) Ireland should legislate for the introduction of Patient Group Directions on a similar basis to the United Kingdom.

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To embark on such a project as this thesis would not have been possible with the unwavering love and support of my wife, Marie, and of our children, Aoife and David. My debt of gratitude to my family is truly incalculable. Marie's postgraduate studies came prior to my own; her accomplishments have been an invariable source of pride and inspiration to me. In my time at the Law School, Aoife and David have both completed an undergraduate degree course and are now postgraduate students themselves.

Dedication

This thesis is dedicated jointly to my mother, Jane Byrne, my first teacher, and to Prof. William Binchy, my first teacher in the law.

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Chapter 1 Introduction and Methodology

1.1 Introduction

1.2 Structure of the Thesis

The thesis comprises nine chapters. Chapter 1 (introduction and Methodology) sets out the Structure, the Research Question and Methodology for this work. The areas covered by the other chapters are described below.

1.2.1 Research Question

How ought the pharmacist's liability in the tort of negligence and in product liability law to be determined in contemporary Irish society? Addressing this question will involve examining the possible application of the professional negligence standard to pharmacists, emerging new areas of potential liability, as pharmacists expand their role and related issues regarding causation and proof, where there is evidence of a new judicial willingness to modify traditional rules.

1.2.2 Chapter 2: A Concise History of Pharmacy

Pharmacy, as a distinct profession, is comparatively new, originating generally in the Nineteenth Century. The chapter traces the prior association of apothecaries with both branches of the emergent medical profession. Professional pharmacy's foundation in Ireland, Britain and the US is described. The growing influence of European Institutions on the pharmaceutical profession is also examined.

1.2.3 Chapter 3: The Duty of Care

This chapter describes the duty of care, contractual and tortious, with particular reference to healthcare provider contracts. Breach of statutory duty is examined against the backdrop of recent Irish legislation. Physical damage to the person or to property, psychological damage, economic loss and negligent misstatement are topics covered here. Pharmacists' duties (including assumed duties) and their scope are analysed. The duty to warn the patient is considered,

including EU and US approaches to patient information provision. Pregnancy as personal injury and conscientious objection to dispensing contraceptives are also covered.

1.2.4 Chapter 4: Professional Negligence and the Standard of Care

The chapter examines the professional negligence liability of pharmacists and that of medical practitioners, including legal developments in Ireland. The standard of care, in specified settings, applicable to medical practitioners and other healthcare workers are analysed. Attention is devoted to pharmacists' role regarding psychiatric medication and to patients' contributory negligence.

1.2.5 Chapter 5: Causation

The broad areas considered in this chapter are factual causation, legal causation and remoteness of damage. The primary test of factual causation, the 'but-for' test, is examined alongside those situations in which the courts have relaxed the evidentiary burden. There is particular emphasis on the Irish cases concerning disclosure of risks associated with treatment. The thesis explores the varying responses in different jurisdictions to pleading 'loss of a chance' in healthcare litigation. Intervening causes and *res ipsa loquitur* are additional topics examined.

1.2.6 Chapter 6: Liability for Defective Products

The historical background is examined with a focus on the abolition of the privity requirement. The chapter traces developments in the US, Australia, Canada, New Zealand. Duties of manufacturers, retailers and non-retailers (including component suppliers) are analysed. General standard of care issues in products cases are considered. The learned intermediary doctrine, exceptions, and its position in various jurisdictions are analysed. Legal comparative treatment includes manufacturing defects, design defects, warning defects. The Strasbourg Convention and the European Product Liability Directive, and adaptation of the latter in Australia/Asia are studied.

1.2.7 Chapter 7: Emerging Issues, Conclusions and Proposals for Reform

This chapter draws on the thesis research outputs to recommend legal and organisational change for societal benefit to Ireland.

The author proposes the establishment of a Healthcare Legal Forum for Ireland

The author describes Patient Group Directions in the United Kingdom and advocates that a similar system be introduced in Ireland by legislation.

1.2.8 Some Issues not addressed in this Thesis

This thesis does not attempt a detailed treatment of all the factors at play in contract formation. A full exegesis on inducement to alter one's position in the tort of negligent misstatement, thus acting to one's detriment, likewise is outwith the scope of this thesis. The thesis does not explore ethical issues in any depth.

1.3 Methodology

This author is a practising pharmacist, who was also called to the Bar of Ireland in 1993. Coming from this diverse professional background, the researcher desires to elucidate the current legal position regarding pharmacists' civil liability. Through reading for this thesis, it became apparent that the traditional literature on 'professional negligence' (more recently, sometimes styled 'professional liability') has an understandable focus on the ancient liberal professions, medicine and the law. European Union legislation¹ on the professions has broadened the recognition, both legally and in the popular consciousness, now accorded to several professional callings that were formerly regarded as being occupational or vocational in character.

The thesis presents a concise historical portrait of pharmacy, a legal history tracing how negligence and product liability have evolved, an examination of the modern legal bases for pharmacists' civil liability, and proposals for law reform. The main methodological approach has been to analyse comparatively the negligence and product liability environment affecting pharmacists in Ireland, the United Kingdom, the United States of America, Canada, Australia and New Zealand. The law of contract is also studied, as it applies to the pharmacist's professional practice in the context of modern healthcare systems.

The author has utilised the many excellent subscription legal databases available through TCD Library and on a visit to the Institute of Advanced Legal Studies (2011). In addition, recourse was had to open access databases (e.g. BAILII, AustLII), and to open access journals. The resources, Google Scholar and Google Books were also instructive.

¹ For example, Directive 2005/36/EC (*Directive on the Recognition of Professional Qualifications*).

For legal historical research, the subscription database, Making of Modern Law, was particularly advantageous, as were the out-of-copyright books and other informative materials available through the Internet Archive (www.archive.org).

Chapter 2 A Concise History of Pharmacy

To consider the changing role of the pharmacist, it is necessary to consider the evolution of the profession and of its position alongside other healthcare craft groups. Emphasis is placed on the historical picture in some territories of the English speaking peoples.

2.1 Early Origins

The earliest known record of the art of the apothecary (forerunner of the pharmacist) is in Babylon (now Iran). Practitioners at this time (approximately 4600 years ago) were priests, physicians and pharmacists, rolled into one.² Some 600 years later, the Chinese also contributed to the evolution of pharmacy.

Galen, a Roman teacher of pharmacy and medicine (honoured by both professions), was the originator of compounding. The term, 'galenical' is given to a medicine prepared by extracting one or more active botanical constituents. It was not until the Roman conquest that systematic medicine, based on Greek classical writings, began to be practised in the lands that comprise modern Britain.³ Matthews notes that hospitals are reported to have existed in pagan Ireland four centuries before the Christian era.⁴ Separation of pharmacy and medicine is said to have taken place *circa* 300AD: it is illustrated by the twin brothers, Damian, the apothecary, and Cosmas, the physician.⁵

The Anglo-Saxon healing recipes or formulae were known as 'leechdoms'.⁶ Those documents, written in the vernacular, described a class of doctor and pharmacist, still without a segregation of activities.⁷

² See Kelly, WN, *Pharmacy: What it is and How it Works* (2002) CRC Press, Boca Raton (FL), 3.

³ Matthews, LG, *History of Pharmacy in Britain* (1962) E&S Livingstone, Edinburgh and London, 1. See also La Wall, CH, *Four Thousand Years of Pharmacy: an Outline History of Pharmacy and the Allied Sciences* (1927) JB Lippincott Company, Philadelphia, 82.

⁴ La Wall, CH, *op cit*, 116.

⁵ See Kelly, *op cit*, 3.

⁶ The word 'leechdom' later took on a humorous or derogatory meaning, *i.e.* the realm of doctors or medicine.

⁷ Matthews, *op cit*, 5. See also American Medical Association (Lecture Memoranda), *Anglo-Saxon Leechcraft: an Historical Sketch of Early English Medicine* (1912) American Medical Association, Atlantic City (NJ). Available from http://www.archive.org/stream/anglosaxonleechc00brituoft/anglosaxonleechc00brituoft_dj dj.txt. (Last accessed 12 January, 2012).

The Normans allowed the physician-monks of the Benedictine Order to flourish, many of whom had trained in 'physic' at Salerno,⁸ until that school lost staff and students to the medical school at the newly-established University of Bologna (the first university in Europe). Chaucer listed in the Prologue to the Canterbury Tales the books which a 'Doctour of Physik' might be expected to study.⁹ The Renaissance provided new fields of study and continents to explore. Leonardo da Vinci, polymath extraordinaire, immersed himself in the study of human anatomy. Vasco da Gama succeeded (where Columbus failed) in finding a passage to India, thereby opening up the large Asian spice trade.¹⁰ Guttenberg's printing presses turned from an output of bibles (1453-1455) to secular works. The innovation of wood-cut illustrations in printed books by the middle of the fifteenth century enhanced the description of medical herbs and obviated the tedium of manuscript copying.¹¹

2.2 Emergent Specialisation

The first organised Gild (Guild) was the Pepperers, founded in the twelfth century to organise the distribution of imported drugs and 'spicery'.¹² The Pepperers overlapped with the Spicers and were later succeeded by the Grocers (the merchants selling by weight). By the time of Henry VIII, in some towns there were mixed guilds of Barbers, Surgeons and Apothecaries.¹³ In 1617, James I granted a Royal Charter to the Society of Apothecaries that authorised their separation from the Grocers.¹⁴ The Grocers' dominant business focus (*i.e.* profit) had become a cause for concern,

⁸ For an account of the role played by Constantine the African, convert to Christianity and Benedictine monk, in Salerno's medical school, see Lindberg, DC, *The Transmission of Greek and Arabic Learning to the West*, in Lindberg, DC (Editor), *Science in the Middle Ages* (1978) University of Chicago Press, Chicago, 61, 62. See also *History Scene 13: AVICENNA - THE "PERSIAN GALEN"* in Bender, GA, (Illustrated by Thom, RA), *Great Moments in Pharmacy* (1965) Parke, Davis & Company, Rochester (MI). Reproduced in Washington State University, College of Pharmacy, *A History of Pharmacy in Pictures* (Undated Web Resource) Washington State University, Pullman (WA). Available from <http://www.pharmacy.wsu.edu/history/>. (Last accessed 12 January, 2012). Avicenna described all Greco-Roman medicine in his book, *Canon of Medicine*: see Ramawat, KG, Dass, S, Mathur, M, *The Chemical Diversity of Bioactive Molecules and Therapeutic Potential of Medicinal Plants*, Chapter in Ramawat, KG (Editor), *Herbal Drugs: Ethnomedicine to Modern Medicine* (2009) Springer-Verlag, Berlin, Heidelberg, 11.

⁹ Matthews, *op cit*, 13. See further Chaucer's *Tale of Sir Topas* in which are described some of the spices then available.

¹⁰ See Ramawat, KG, Dass, S, Mathur, M, *op cit*, 20.

¹¹ Matthews, *op cit*, 25.

¹² Matthews, *op cit*, 29. See also Daly, MH, *A Few Notes on the Gild System* (1950) 11(3) Dublin Historical Record 65.

¹³ Matthews, *op cit*, 33. See further (*op cit*, 39-40): by the early seventeenth century, the City of Lichfield, Staffordshire, had an all-embracing gild, known as the Mercer's Company, which included apothecaries and salters.

¹⁴ Matthews, *op cit*, 41-42: His Majesty was induced to grant the Charter by two Doctors of Physic, Theodore de Mayerne and Henry Atkins. See also Gillispie, CG, *Physick and Philosophy: A Study of the Influence of the College of Physicians of London upon the Foundation of the Royal Society*, Chapter in Gillispie, CG, *Essays and Reviews in History and History of Science* (2006) 96 Transactions of the American

particularly among medical men. The sole right of keeping an apothecary's shop or warehouse in the City of London and its environs was granted to those who were or would become (after a seven-year apprenticeship) Freemen of the Society.¹⁵ The London Pharmacopoeia (*Pharmacopoeia Londinensis*) of 1618 was the first to be officially adopted by any nation, "even though it bore the name of a city only".¹⁶ It was said at the time of the Plague (1665-1666) that the physicians left the city and the apothecaries stayed to help in treating the population: most ordinary people looked on the apothecary as the 'family doctor', calling in a physician in only the most serious cases.¹⁷

The Brehon Laws, which prevailed in Ireland until abolished by James I, stipulated the professional examinations and formal qualifications for physicians.¹⁸ The Guild of St. Mary Magdalene, by the end of the fifteenth century, had become one of the strongest in the City of Dublin: it comprised Apothecaries, Barbers, Perriwig-makers and Surgeons.¹⁹ The first Dublin apothecary recorded was Thomas Smith.²⁰ Smith prospered and in 1593, as Mayor of Dublin, he laid the foundation stone for the recently-chartered Trinity College. The Dublin College of Physicians (chartered in 1692) attempted unsuccessfully to prevent Apothecaries from practising medicine.²¹ There were already in force several statutes permitting the phenomenon. Nevertheless, the College obtained supplementary powers to combat quackery, "then prevalent amongst apothecaries and

Philosophical Society, New Series, American Philosophical Society, Philadelphia, 210, 212(n), citing: Barrett, CRB, *The History of the Society of Apothecaries of London* (1905) E Stock, London [Republished (1977) AMS Press, New York], pp xix-xxxix.

¹⁵ Matthews, *op cit*, 42.

¹⁶ Matthews, *op cit*, 272. The first official pharmacopoeia in Europe was the Florentine *Ricettario Fiorentino* (1498): Société d'Histoire de la Pharmacie, *Liens vers d'autres sites relatifs à la Pharmacie et son histoire* [Links to Other Sites Relating to Pharmacy and its History] (Undated Web Resource) Available from <http://www.shp-asso.org/index.php?PAGE=liens2>. (Last accessed 12 January, 2012). The London Pharmacopoeia was also preceded by those published in: Barcelona (1535); Nuremberg (1546); Zaragoza (1546); Augsburg (1564); Cologne (1565): see Fisch, MH, *Book Review: Urdang, G, Pharmacopoeia Londinensis of 1618, Reproduced in Facsimile, with a Historical Introduction (1944) State Historical Society of Wisconsin, Madison* (1945) 33 Bull Medical Library Association 541, 541.

¹⁷ Matthews, *op cit*, 112-113. See also Gillispie, CG, *op cit*, 219: After the Restoration, the literary forces of the College of Physicians were led "through a virulent battle of the books in which the Apothecaries Company incautiously engaged them."

¹⁸ Matthews, *op cit*, 57.

¹⁹ Matthews, *op cit*, 58.

²⁰ See Kerr, JJ, *Notes on Pharmacy in Old Dublin* (1942) 4(4) Dublin Historical Record 149. See also Jones, G, Malcolm, E, *Introduction: An Anatomy of Irish Medical History*, Chapter in Jones, G, Malcolm, E (Editors), *Medicine, disease and the state in Ireland, 1650-1940* (1999) Cork University Press, Cork, 4.

²¹ See Widdess, JDH, *A History of the Royal College of Physicians of Ireland, 1654-1963* (1963) E & S Livingstone, Edinburgh and London, 33-37. See also Freidson, E, *The Theory of the Professions: State of the Art*, Chapter in Dingwall, R, Lewis P (Editors) *The Sociology of the Professions* (1983) Macmillan Press, London, 23-24. The term 'status professions' has been suggested for the three original learned professions, medicine, law and the clergy, "pointing out quite accurately their marked difference from the [more] recent 'occupational professions'."

druggists".²² Marland clarifies that the 'doctor's shop' was a name applied by the indigent clientele, which description members of the Chemist and Druggist community would never themselves proclaim.²³

The College received wider powers from the Irish Parliament in 1761, in particular the right to insist on "*the disclosure of the formulae of proprietary medicines—much in advance of any legislation in Great Britain*".²⁴ The Dublin Pharmacopoeia was first published in 1807 with the third and final edition published in 1850: it was replaced by a novel British Pharmacopoeia (1864).²⁵

The Apothecaries secured their own charter of incorporation in 1745. The Apothecaries' Hall Act 1791 was enacted; this statute bore the long title, "*For the more effectually preserving the health of his majesty's subjects, for erecting an apothecaries' hall in the city of Dublin, and regulating the profession of an apothecary throughout the kingdom of Ireland*".²⁶ Under the 1791 Act, a School of Medicine was set up in Cecilia Street, Dublin: This proved very successful for some years, principally "*owing to the very distinguished men who lectured there ... Donovan, Kane, etc.*"²⁷ In the period preceding the Act of Union (1800), 'Apothecary Ware' was a significant contributor to trade, as noted in the moribund Irish Parliament.²⁸

²² Matthews, *op cit*, 58.

²³ See Marland, H, *The 'Doctor's Shop': The Rise of the Chemist and Druggist in Nineteenth-Century Manufacturing Districts*, Chapter in Curth, L, (Editor), *From Physick to Pharmacology: Five Hundred Years of British Drug Retailing* (2006) Ashgate, Aldershot, 80. See also O'Brien, E, *Conscience and Conflict: A Biography of Sir Dominic Corrigan 1802-1880* (1983) Glendale Press, Dublin, 25

²⁴ Matthews, *op cit*, 58. Matthews remarks that the Dublin Apothecaries, organised as the Guild of St. Luke, came in for criticism. In 1672, while taking up the rear of a procession of all the gilds (presumably because theirs was the most recently established), the gild members were lampooned in a trite verse. See Kerr, JJ, *op cit*, 154. This body was keen to assert its professional status: in 1766, it successfully opted out of the annual parade of craft gilds; see Corfield, PJ, *Power and the Professions in Britain, 1700-1850* (1995) Routledge, London, 155. On the position in Scotland, see, however, Phillips, AF, *Medical Liability and the Law of Negligence*, Unpublished PhD Thesis (1992) Faculty of Law, University of Edinburgh, 35-36, citing: Hamilton, D, *The Healers, A History of Medicine in Scotland* (1981) Canongate, Edinburgh, 57.

²⁵ Kremers, E, Sonnedecker, G (Editors), *Kremers and Urdang's History of Pharmacy*, Fourth Edition (1986) American Institute of the History of Pharmacy, Madison (WI), 430-431.

²⁶ Apothecaries' Hall Act 1791, 31 Geo III, c 34. See also s 73 of the Pharmacy Act 2007 (Restriction of Apothecaries' Hall Act 1791).

²⁷ See Kerr, *op cit*, 155.

²⁸ See Anonymous, *Observations on that Part of the Speaker's Speech, which relates to Trade* (1799) T Burnside, Dublin, *Mr Irving's Account, No 5, Appendix No 2*. Available from <http://www.actofunion.ac.uk/viewPamphlets.php?picNumber=title&pages=45&startPage=1&institution=&id=0474>. (Last accessed 12 January, 2012). The Catalogue of the National Library of Australia (NLA) adopts the pamphlet's attribution, in the Goldsmiths' Library Catalogue, to R Longfield, Viscount Longueville. The relevant NLA entry is available from <http://catalogue.nla.gov.au/Record/1087960> (Last accessed 12 January, 2012).

In 1820 Michael Donovan was Professor of Chemistry, Pharmacy and *Materia Medica* in the Apothecaries' Hall.²⁹ Donovan was anxious that Apothecaries should be merely compounders of medicines: “*he also tried to found an Irish College of Pharmacy, so he has [a] claim to be called the Father of Irish Pharmacy.*”³⁰ During the Famine years the number of students fell away and the School of Medicine was transferred to the Catholic University founded under Cardinal Newman.

There was no controversy in the UK Parliament that the Irish Apothecaries and the Surgeons would become “Registered Medical Practitioners” under the Medical Act 1858.³¹ The Act expressly forbade advertising by registered Medical Practitioners and imposed heavy penalties on unqualified people calling themselves Doctor.³² The Apothecaries were the only medical practitioners deemed to be qualified in pharmacy.³³ The Licentiate of Apothecaries’ Hall remained a route to registration as a pharmacist until the enactment of the Pharmacy Act 1962.³⁴

²⁹ See Kerr, *op cit*, 155. Donovan kept an apothecary's shop in Clare Street, Dublin. He was the inventor of Donovan's Solution, “*a preparation of iodine, arsenic and mercury, which [wa]s still in the Pharmacopoeia and in common use*”, at the time (1942) that Kerr's article was published. Kerr mentions another distinguished Apothecary, Robert Kane, Professor of Chemistry in Apothecaries' Hall from 1831. He published *Elements of Pharmacy* in 1831, but his fame rests chiefly on his well-known work, *The Industrial Resources of Ireland*.

³⁰ See Kerr, *op cit*, 155.

³¹ Medical Act 1858, 21 & 22 Vic c 90.

³² 21 & 22 Vic c 90, s40 (Falsely pretending to be a registered person). See also Fleetwood, J, *Some Old Dublin Medical Advertisements* (1986) 39(3) Dublin Historical Record 86, 96. On the diffuse nature of veterinary training in Ireland, see White, T, *Investing in People: Higher Education in Ireland from 1960 to 2000* (2001) Institute of Public Administration, Dublin, 11: “*As early as 1800 the Royal Dublin Society had resolved to open a public veterinary school. Eventually in 1895 a charter was granted to establish the Royal Veterinary College of Ireland. It opened in 1900*”. See further Bright, K, *Reflections on the Royal Dublin Society (1731-2001)* (2003) 56(1) Dublin Historical Record 18, 22: “[*T*]he society was forced to close its veterinary school through lack of funds in 1826.”

³³ See O'Connor, J, *The Irish Justice of the Peace: A Treatise on the Powers and Duties of Justices of the Peace in Ireland*, Second Edition (Assisted, as to Vol II, by Byrne, W) (1915) E Ponsonby Ltd, Dublin, 105 (internal citation omitted; case citations to the English Reports substituted for the original references to the Nominate Reports):

“*As distinguished from an apothecary, ‘a chemist is one who sells medicines which are asked for’ (per Cresswell J, [The Master Wardens and Society of The Art and Mystery of Apothecaries of The City of London] v Lotinga (1843) 174 ER 360); ‘a chemist may prepare and vend, but not prescribe or administer, medicine’ (per Best CJ, Allison v Haydon (1828) 130 ER 907; see also Apothecaries’ Company v Greenough (1841) 113 ER 1337).*

“*An apothecary prescribes drugs, and prepares and sells drugs that he himself has prescribed, and also prepares and sells drugs prescribed by others ([The College of Physicians, London v Rose] (1703) 2 ER 857; Woodward v Ball (1834) 172 ER 1372).*”

See also Clarke, P, *Medical Law for Medical Men: Their Legal Relations shortly and popularly explained: with Chapters concerning Dentists, Chemists, and Midwives* (1890) Balliere, Tindall, and Cox, London, 15 (Licentiate of Apothecaries Hall may be registered as, and have all the rights of, a Pharmaceutical Chemist of Ireland).

³⁴ The term ‘Master-Apothecary’ was thought to be *infra dignitatem* and gave way to the Licentiate: see Matthews, *op cit*, 60. See also the Pharmacy Act 1962 (No 14), s2 (Keeping of open shop for dispensing medical prescriptions and sale of poisons). Sub-section (3) provided *inter alia* that an “*authorised person*” included: “*...a registered medical practitioner who, before the commencement of this section, began a course of study to be gone through for the purpose of obtaining a qualifying diploma, within the meaning of the Medical Practitioners Acts, 1927 to 1961...*” See also s8, which specified date limitations to the

2.2.1 Ireland

Towards the middle of the nineteenth century some of the Apothecaries seem to have acted almost solely as dispensers of prescriptions. They founded a Society of their own, known as the Pharmaceutical Society.³⁵ Many Apothecaries acted purely as medical practitioners and did not keep open shop. This led to complaints. According to the preamble of the Pharmacy (Ireland) Act 1875³⁶: “[A] great deficiency exists throughout Ireland of establishments and shops for the sale of medicines and compounding of prescriptions, and great inconvenience thereby arises to the public in many parts of the country.” The Preamble to the Act declared the objective to enable “persons who although they do not desire to practise the art and mystery of an apothecary, desire and are qualified to open shop for the retailing, dispensing and compounding poisons and medical.” Giving effect to the Act, the Pharmaceutical Society of Ireland was founded in 1875.³⁷

The Society’s first President was Sir Dominic Corrigan, who commenced the study of medicine at the School of Physic, University of Dublin, in 1820. In his fourth year (1823-24), Dominic Corrigan attended a course in *Materia Medica* and Pharmacy given by Michael Donovan at the Apothecaries’ Hall.³⁸ Not being a member of the Established Church, Corrigan could look forward to a career in dispensary practice, which was the branch of the profession that he joined upon his return, in 1825, from Edinburgh upon graduating with the Degree of MD.³⁹ In 1828, however, Corrigan attained an appointment to The Charitable Infirmary,⁴⁰ “where he achieved international eminence in medicine.”⁴¹

Corrigan was elected a Liberal Party MP for the City of Dublin in 1870. He was mainly responsible for the passing of the Pharmacy Bill of 1875 which sought to institute a pharmaceutical society, to regulate the qualifications of pharmaceutical chemists in Ireland and to establish certain relations

provisions in s22 for the registration of licentiates of Apothecaries Hall as pharmaceutical chemists. The Pharmacy Act 1962 was repealed in its entirety by the Pharmacy Act 2007 (No 20).

³⁵ Kerr, *op cit*, 156: “This body had no official status[;] it existed to further the interests of pharmacy and chemistry instead of those of medicine.”

³⁶ 38 & 39 Vic, c 57.

³⁷ A concise rationale for the Society’s establishment is to be found at *R (Cleeland) v Pharmaceutical Society of Ireland* [1896] 2 IR 368, 381, per Johnson J: “In modern times the Ante-Union Apothecaries’ Act 1791 ... was found insufficient in many parts of Ireland for the wants of the public, which required more numerous establishments for the sale of medicines and compounding of prescriptions.”

³⁸ See O’Brien, E, *Conscience and Conflict: A Biography of Sir Dominic Corrigan 1802-1880* (1983) Glendale Press, Dublin, 27.

³⁹ See O’Brien, *op cit*, 64. The Catholic Emancipation Act was passed in 1829, although it would have been some years before Roman Catholics could have aspired realistically to a hospital appointment in Dublin.

⁴⁰ At Jervis Street, Dublin.

⁴¹ See O’Brien, *op cit*, 16.

between the Pharmaceutical Societies of Great Britain and Ireland.⁴² The Bill was introduced by Sir Michael Hicks Beach and passed after a number of modifications. The new Pharmaceutical Society in recognition of Corrigan's work made him its first president, a post he occupied from 1875-78.

The Pharmacy Act (Ireland), 1875 was the Principal Act.⁴³ The Pharmacy Act (Ireland), 1875, Amendment Act, 1890,⁴⁴ created the role of 'Assistant to a Pharmaceutical Chemist', who was empowered to act in the temporary absence of the pharmacist.⁴⁵ The operation of the Pharmacy Acts (Ireland) would appear to have received minimal parliamentary scrutiny at Westminster.⁴⁶ While that may have been so, those Acts received much closer analysis in the 1890s in the Irish Courts. The Pharmacy Act (Ireland) 1875⁴⁷ empowered the Society to make regulations regarding the examination of candidates. The regulations were to have no effect until approved by the Lord Lieutenant and the Privy Council and laid before both Houses of Parliament. Section 17 of the 1875 Act provided that rules that followed the prescribed procedure were to become "*of the like force and effect as if they had been enacted in this Act*". According to Willis, it was "*remarkable enough to find that section 17 applied to the rules of a private autonomous body ... indeed the closest analogy [was] in three instances where rules of the Bank of England in technical matters were thus dignified*".⁴⁸

In *R (Cleeland) v Pharmaceutical Society of Ireland*,⁴⁹ the applicant sought from the Court an interpretation of the rules for examination of candidates. The question of *vires* was not raised. The Court decided the statutory interpretation issue in favour of the Council on the assumption that the rules were *intra vires*. The applicant had served an apprenticeship and desired to present for the Society's examination. Regulation 3 in the Society's rules required an apprenticeship to be

⁴² See O'Brien, E, *op cit*, 266. Upon the Society's establishment, a President (Dominic Corrigan) and Vice President (Aquilla Smith) and a council of 21 were named by Government to carry out the provisions of the Act. In 1874, Hicks Beach was made Chief Secretary for Ireland; he was included in the Cabinet in 1877.

⁴³ Pharmacy Act (Ireland), 1875, 38 & 39 Vic, c 57.

⁴⁴ Pharmacy Act (Ireland), 1875, Amendment Act, 1890, 53 & 54 Vic, c 48, s19. Section 19 was among the amendments to the relevant Bill proposed in the House of Lords by the Marquess of Waterford. See Hansard, PHARMACY ACT (IRELAND) (1875) AMENDMENT BILL—(No 172), HL Deb 01 August, 1890 Vol 347 c 1523.

⁴⁵ From the mid-1980s, no further examinations were held by the Pharmaceutical Society of Ireland for aspirants to the role of pharmaceutical assistant.

⁴⁶ Merely two references (prior to 1920) to the Principal Act in Hansard were located in the course of this research: PHARMACY (IRELAND) ACT, 1875, HC Deb 21 August, 1916 Vol 85 c 2237 ("*Copy presented of Regulations with regard to the Pharmaceutical Licence Examination [by Act]; to lie upon the Table.*"); PHARMACY (IRELAND) ACT, 1875, HC Deb 01 May, 1918 Vol 105 c 1519 ("*Copy presented of Amended Regulations as to acceptance of other Examinations in lieu of the Pharmaceutical Preliminary Examination [by Act]; to lie upon the Table.*")

⁴⁷ 38 & 39 Vic, c 57, s 16.

⁴⁸ Willis, *op cit*, 70.

⁴⁹ [1896] 2 IR 368 (KBD).

completed with “a firm of legally qualified pharmaceutical chemists” In *Cleeland*, not all directors of the limited liability company that employed the applicant were pharmacists, which defeated the application for an order absolute of *mandamus*. The Court gave ‘firm’ its traditional meaning as a collective of natural persons. The members of the Court, O’Brien, Holmes and Gibson JJ, did ponder *quaere*, whether the regulations in question were not *ultra vires*.

A better-positioned applicant came before the King’s Bench Division a few years later in *R (Conyngham) v The Pharmaceutical Society of Ireland*.⁵⁰ All of the directors of what had become (in 1897) the applicant’s ‘family business’, Hayes, Conyngham & Robinson Ltd, were pharmacists. Therefore, Conyngham prevailed on the ‘firm’ argument, where *Cleeland* had failed.

The force of the House of Lords judgment in *The Institute of Patent Agents v Lockwood*⁵¹ provided the stimulus for enduring interest among legal scholars in the process of statutory interpretation that the Irish Courts had adopted.⁵² For its legal-historical content, the applicant’s submission in *R (Conyngham) v The Pharmaceutical Society of Ireland* on *The Institute of Patent Agents v Lockwood* is quoted:

“[In *Lockwood’s Case*,] Parliament had done nothing more than frame the skeleton which the rule-making body was to clothe with flesh and blood. Here Parliament has thought fit to make detailed provisions in regard to the examination—and the subjects of the examination—of persons wishing to carry on this profession, and has merely entrusted to the Council of the Society the very limited duty of making rules for the conduct of those examinations.”⁵³

The *Conyngham* Court held (per Palles CB and O’Brien J) that the regulation as to apprenticeship was repugnant to the provisions of the 1875 Act, therefore *ultra vires* when made, and that, upon the construction of that Act (s 17 notwithstanding), the Court had competence to determine its validity. The Court distinguished *Lockwood*.⁵⁴ A further holding was that the effect of the statutory

⁵⁰ *R (Conyngham) v The Pharmaceutical Society of Ireland* [1899] 2 IR 132. In 1998, Boots the Chemists plc acquired through a subsidiary the Hayes, Conyngham & Robinson pharmacy group; with 15 stores, it was the largest pharmacy chain in Ireland at that time.

⁵¹ *The Institute of Patent Agents v Lockwood* [1894] 1 AC 347.

⁵² See Willis, J, *The Parliamentary Powers of English Government Departments* (1933) Harvard University Press, Cambridge (MA), 69-73. In *R (Cleeland) v Pharmaceutical Society of Ireland* [1896] 2 IR 368, the consideration of the *Lockwood* decision was minimal, as it was not central to the *ratio decidendi*.

⁵³ [1899] 2 IR 132, 136.

⁵⁴ See, for example, [1899] 2 IR 132, 154 per O’Brien J:

“This is not a rule for the examination of intending candidates; it is a rule avowedly made for the purpose of constituting a personal status in the candidates, reaching back to a

recognition of the rules in s 10 of the 1890 Act was to render the impugned Regulation 3 valid and binding.

Because of the excellent reputation of their training, the demand for Dublin-trained pharmacists in Britain led to tensions during the first decades of the Pharmaceutical Society of Ireland's existence.⁵⁵

Pharmacy technicians emerged by the 1990s. Their training was overseen by the Society, although there was for technicians no statutory registration process as laid down for Pharmaceutical Chemists and others. Prior to the enactment of the Pharmacy Act 2007, the 'old' Society abolished under the Act, possessed the power to erase a name from the Register solely for non-payment of registration fees when due. The disciplinary machinery that developed in Britain since 1954 (*vid inf*) was not available.

The Pharmacy Act 2007 has established a 'new' Pharmaceutical Society of Ireland with significant powers to shape the duty of care and the standard of care for pharmacists. These topics will be explored in greater depth later in the thesis. The major challenges for pharmacist are: responsiveness to a regime in which guidance on professional standards will react more rapidly to an ever-changing world; the effect of more formalised practice standards can be expected to influence the standard of care in negligence.

2.2.2 Britain

Prior to the nineteenth century, the paths that pharmacy took in Ireland and in Britain were broadly similar. In 1703, the apothecaries gained a decisive victory when it was held by the House of Lords in the case of *The College of Physicians, London v Rose*⁵⁶ that "*the function of the apothecary consisted, not merely in compounding and dispensing, but also in directing and ordering the remedies to be employed in the treatment of disease.*"⁵⁷ The Pharmaceutical Society of Great Britain was founded in 1841.⁵⁸ The Society's founder, Jacob Bell, was elected MP for St

period of no less than four years prior to the time when they present themselves for examination, a thing completely ... outside the Act".

⁵⁵ See Kerr, *op cit*, at 159.

⁵⁶ (1703) 2 ER 857 (HL).

⁵⁷ See Carr-Saunders, AM, Wilson PA, *The Professions* (1933) Clarendon Press, Oxford, 73, and further (*loc cit*): "*Thenceforward the apothecaries came to form an inferior order of medical practitioners*".

⁵⁸ Uniform standards of training and examination became compulsory with the enactment of the Pharmacy Act 1868. The Pharmacy Act set up a register of people qualified to sell, dispense and compound poisons. Membership of the Society of Great Britain was not compulsory from 1841 to 1868. The Pharmaceutical Society would examine and register pharmacists, and prosecute them in cases relating to poisons.

Albans in 1850 in order to espouse the cause of the Society in Parliament. This career progression was, in one respect, the opposite of the Irish Society's founder, Sir Dominic Corrigan, who was elected to the House of Commons before the professional organisation he sought to establish had come into being. The qualification of pharmaceutical assistant was not created in Britain, as had been done in Ireland.⁵⁹ Due to the low volume of prescriptions, "[i]t can be concluded that trade with the general public was of greater importance than dealings with the medical profession for most nineteenth-century druggists."⁶⁰

The powers and purposes of the Pharmaceutical Society of Great Britain were examined in the case of *Jenkin v Pharmaceutical Society of Great Britain*.⁶¹ It was held that trade union activities and the provision of general insurance cover to members were not contemplated in the Royal Charter of 1843.⁶²

The Statutory Committee of the Royal Pharmaceutical Society of Great Britain⁶³ was established under Section 7 of the Pharmacy Act 1954. In accordance with Section 8 of that Act, the Statutory Committee considered any convictions received by, or allegations of misconduct made against, a pharmacist or a person applying for registration with the Society. Under Section 80 of the Medicines Act 1968, the Statutory Committee also considered cases against companies carrying on a retail pharmacy business where: the company had committed an offence under medicines legislation ; a director, officer or employee of the company had been convicted of an offence, or was alleged to have committed misconduct.

In 2007 new fitness to practise provisions and new fitness to practise Rules, came into force.⁶⁴ The regulation of new professions, coming under statutory control, in Scotland is a competence of the

Regulation in other areas was left to the Society. The 1868 Act also introduced a Poisons List of substances only to be sold by retail by registered Pharmaceutical Chemists and Chemists & Druggists. See also Carr-Saunders, AM, Wilson PA, *op cit*, 133: the Pharmaceutical Society of Great Britain was preceded by "*a short-lived General Association of Chemists and Druggists of Great Britain in 1829*".

⁵⁹ Under the Poison and Pharmacy Act 1908, the Society gained further powers relating to education and training. The title of Pharmacist was extended to all registered persons. The scope of the Poisons List was broadened. However, see Carr-Saunders, AM, Wilson, PA, *op cit*, 353.

⁶⁰ Marland, H, *The 'Doctor's Shop': The Rise of the Chemist and Druggist in Nineteenth-Century Manufacturing Districts*, Chapter in Curth, L, (Editor), *From Physick to Pharmacology: Five Hundred Years of British Drug Retailing* (2006) Ashgate, Aldershot, 87. See also Beckett, C, *Attitudes to Political and Commercial Endorsement in the Business Papers of Silas Mainville Burroughs, with Particular Reference to Henry Morton Stanley* (2008) 52 *Medical History* 107, 110. See also Carr-Saunders, AM, Wilson PA, *op cit*, 132: "*Mineral medicines were bought from chemists and galenicals from druggists*".

⁶¹ *Jenkin v Pharmaceutical Society of Great Britain* [1921] 1 Ch 392.

⁶² See also Carr-Saunders, AM, Wilson PA, *op cit*, 139.

⁶³ The 'Royal' designation was granted by the Monarch to mark the Society's sesquicentennial in 1991.

⁶⁴ Pharmacists and Pharmacy Technicians Order 2007, 2007 No 289, revoked by the Pharmacy Order 2010, 2010 No 231, article 58. Schedule 2 of the Pharmacy Order 2010 set out detailed transitional provisions that

Scottish Parliament under the Scotland Act 1998.⁶⁵ The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians (since July 2011)⁶⁶ and pharmacy premises in Great Britain.⁶⁷ The Royal Pharmaceutical Society of Great Britain has repositioned itself as a professional body with the mission to promote and represent the professional interests of its members.

2.2.3 United States of America

If historical scholarship is prepared to disregard the lore of Native Americans (not well documented in the medical and paramedical literature), then the American continent in the late-sixteenth and seventeenth centuries could be viewed as a healthcare *tabula rasa*. The English policy of *laissez-faire* capitalism stifled the orderly regulation of professions and permitted a chaotic multiplicity of health providers.⁶⁸ Thus successful Anglophone colonisation of the New World brought with it the incoherent healthcare paradigm of England, rather than the stability of the continental European system.⁶⁹

Other health systems also came to exist on the land mass that came to be known since 1959 as “The Lower Forty-Eight”.⁷⁰ France peaceably transferred its American possessions to the United States.⁷¹ Likewise Spain gave Florida (1819) to its northern neighbour, which took possession in 1821 (under the Adams–Onís Treaty). Mexico’s independence from Spain was also recognised in 1821. Mexico transferred territory to the US, in the aftermath of the conflict known in English as The Mexican-American War (1846-1848), and through the Gadsden Purchase (1854). The US has

apply to allegations referred to the Statutory Committee before 30 March 2007. Inquiries ordered by the Chairman of the Statutory Committee and not yet heard shall be disposed of by the Disciplinary Committee in accordance with the regulations that governed the Statutory Committee (SI 1978/20), and the Pharmacy Act 1954 (‘the old Rules’).

⁶⁵ Scotland Act 1998, c 46.

⁶⁶ The policy intention was to extend regulation to pharmacy technicians in Scotland (a devolved area) through an Order pursuant to section 60 of the Health Act 1999 (as amended) laid for approval by resolution of the Scottish Parliament and Westminster.

⁶⁷ The General Pharmaceutical Council (GPhC) Web Site is <http://www.pharmacyregulation.org/> (Last accessed 12 January, 2012). See also the Pharmacy Order 2010, 2010 No 231. Part 6 makes provision relating to the fitness to practise of registrants. The Investigating Committee has power to deal with the case by way of issuing warnings or giving advice. In addition, the Fitness to Practise Committee may suspend registrants or attach conditions to their entry in the Register and may also direct that the registrant be removed from the Register.

⁶⁸ Higby, GJ, *From Compounding to Caring: An Abridged History of American Pharmacy*, Chapter in Knowlton, CH, Penna, RP, *Pharmaceutical Care*, Second Edition (2003) American Society of Health-System Pharmacists, Bethesda (MD), 20.

⁶⁹ *Ibid.*

⁷⁰ Alaska was admitted as the Forty-Ninth State of the Union on 03 January, 1959. Hawaii became the Fiftieth State on 21 August, 1959.

⁷¹ The Louisiana Purchase (1803).

accordingly acquired to some extent francophone⁷² and hispanophone⁷³ elements of pharmaceutical history.

While physicians had become common by 1700, pharmacists were still rare. Physicians or their apprentices performed their own compounding.⁷⁴ The importance of apothecaries in the Revolutionary War was such that the Continental Congress appointed Andrew Craigie as one of the (four District) Apothecaries General. In a radical reorganisation of the Military Medical Department, Craigie was appointed 'Apothecary' in 1780.⁷⁵ In the early nineteenth century, drug stores had emerged. Physicians still operated 'doctor's shops': some employed apothecaries ('drug clerks') whose training and knowledge in medicinal products exceeded that of the doctor (who spent many years in medical training).⁷⁶

⁷² See Kremers, E, Sonnedecker, G, (Editors), *Kremers and Urdang's History of Pharmacy*, Fourth Edition (1986) American Institute of the History of Pharmacy, Madison (WI), 146-151.

⁷³ The Spanish integrated the *boticario* (apothecary) into their expeditions to the New World from an early stage. See Mena García, MdC, *Sevilla y las Flotas de Indias: la Gran Armada de Castilla del Oro (1513-1514)* Vol 37, Serie Historia y geografía (1998) Universidad de Sevilla, Sevilla, 47:

"Según era costumbre, el cargamento fue revisado por el médico de la expedición, Rodrigo Barreda, y el boticario sevillano, Solórzano, quienes constataron las calidades y utilidad de las sustancias medicamentosas que iban a ser embarcadas."

This author's translation:

"As was customary, the cargo was reviewed by the Physician to the Expedition, Rodrigo Barreda, and the Sevillian Apothecary, Solórzano, who [jointly] verified the quality and utility of the medicinal substances that were to be brought aboard ship."

In 1523, Charles V instituted in Spain and its possessions the *Protomedicato*, a Supervising Physician role (originating in the Kingdom of Sicily in 1397) in the remit of which was oversight of all branches of medicine, including the *boticarios*: see Findlen, P, *Possessing Nature: Museums, Collecting, and Scientific Culture in Early Modern Italy* (1996) University of California Press, Berkeley, 264. The *Protomedicato* was abolished by Decree in Mexico in 1830: see Garcisa Cubas, A, *Compendio de La Historia de México Y de Su Civilización* (2008) BiblioBazaar, Charleston (SC), 180. Medical and pharmacy services were sparse in *Nueva España* (including Mexico), most frequently available from Catholic Church missionaries, like the Franciscan Fathers: see Simmons, M, *Spanish Pathways: Readings in the History of Hispanic New Mexico* (2001) University of New Mexico Press, Albuquerque, 63. In 1821, an edition of the *Formulario Magistral y Memorial Farmacéutico* [Compounding Formulary and Pharmaceutical Handbook] was produced for the first time in Mexico, which was considered to be the first Mexican Pharmacopoeia. See Parliament of Mexico, Parliamentary Gazette, *Gaceta Parlamentaria, año VIII, número 1694, jueves 17 de febrero de 2005* (2005) Available from <http://gaceta.diputados.gob.mx/Gaceta/59/2005/feb/20050217.html> (Last accessed, 12 January, 2012): *"En 1821 fue editado en México, por primera vez, el 'Formulario Magistral y Memorial Farmacéutico', considerada esta obra como la primera Farmacopea Mexicana"* (original version).

⁷⁴ Higby, GJ, *From Compounding to Caring: An Abridged History of American Pharmacy*, Chapter in Knowlton, CH, Penna, RP, *Pharmaceutical Care*, Second Edition (2003) American Society of Health-System Pharmacists, Bethesda (MD), 20. By contrast, on the continent of Europe, the French Revolution did not leave pharmacists ("chemical artisans") unscathed. See Gillispie, CG, *The Encyclopédie and the Jacobin Philosophy of Science: A Study in Ideas and Consequences*, Chapter in Gillispie, CG, *Essays and Reviews in History and History of Science* (2006) 96 Transactions of the American Philosophical Society, New Series, American Philosophical Society, Philadelphia, 119-120, wherein Gillispie cites his own earlier works.

⁷⁵ Kremers, E, Sonnedecker, G (Editors), *Kremers and Urdang's History of Pharmacy*, Fourth Edition (1986) American Institute of the History of Pharmacy, Madison (WI), 164, 165.

⁷⁶ Higby, *op cit*, 22.

Higby criticises Kremers and Urdang for not adequately explaining the emergence and consolidated position in society of the corner drug store.⁷⁷ Higby puts separate reasons forward for these trends. The services of an apothecary were considered a luxury in Colonial times: by the nineteenth century, such services became viewed as a necessity. Apothecaries in hospital practice abandoned the practice of medicine in favour of pharmaceutical specialisation. Around 1815, medical education moved away from the apprenticeship model. Doctors began to write more prescriptions: some had trained in Europe where this was commonplace. Louisiana (1816) and South Carolina (1817) were the first States to regulate pharmacy.⁷⁸ The nation's first pharmacy school, Philadelphia College of Pharmacy (PCP), was established in 1821.

The United States was faced with two major armed conflicts in the nineteenth century, one foreign and one domestic. The War of 1812 was initially acute, although it rumbled on for 25 years at varying levels of intensity.⁷⁹ This intercontinental campaign pitted the new republic against the maritime superpower of the day, the United Kingdom. Clearly, some disruption of shipping occurred. By the 1840s, unscrupulous European drug exporters (whose nefarious practices had been legislatively addressed 'at home') began to ship to the US spent crude drugs: these had the majority of their active constituents prior-extracted by solvent.⁸⁰ Against such practices, physicians came to rely on the expertise of pharmacists.⁸¹ The decline in quality of imported drugs led to the federal enactment, the Drug Importation Act 1848.

The American Pharmaceutical Association (APhA) was founded in 1852. Pharmacy expanded rapidly, although many new recruits to the mass-manufacturing sector of the late 1850s were of low calibre. The onset of the Civil War "*ended much of the bickering between apothecaries and physicians.*"⁸²

⁷⁷ Higby, *op cit*, 22, citing generally Kremers, E, Sonnedecker, G (Editors), *Kremers and Urdang's History of Pharmacy*, Fourth Edition (1986) American Institute of the History of Pharmacy, Madison (WI).

⁷⁸ Kremers and Sonnedecker, *op cit*, 214: Georgia followed in 1825. In Louisiana, Louis J Dufilho, Jr was the first to pass the licensing examination, "*therefore making his pharmacy the first United States apothecary shop to be conducted on the basis of proven adequacy*": New Orleans Pharmacy Museum, *The History of Louis J Dufilho, Jr* (Undated Web Resource) Available from <http://www.pharmacymuseum.org/history.htm>. (Last accessed, 12 January, 2012).

⁷⁹ See Hickey, DR, *The War of 1812: A Short History* (1995) University of Illinois Press, Chicago, Chapter 1.

⁸⁰ Higby, *op cit*, 28: for example, bales of cinchona bark (the source of quinine) were dried of solvent and brazenly labelled '*good enough for America*'.

⁸¹ Gennaro, AR (Editor), *Remington: The Science and Practice of Pharmacy*, Twenty-First Edition (2005) Lippincott Williams & Wilkins, Philadelphia, 12.

⁸² Gennaro, *op cit*, 12.

The American Civil War

In 1861, there were only six colleges of pharmacy in the United States.⁸³ None of these establishments was located in the Southern States that formed the territory of the secessionist Confederacy. It was no accident that the Army Laboratory was established in Philadelphia. John Maisch, the talented German pharmacist who held the Chair of *Materia Medica*⁸⁴ at PCP, was appointed to head the Army Laboratory. Flannery points out that the Government's intervention was a departure from the *laissez-faire* economic system and one that raised eyebrows in the pharmaceutical industry.⁸⁵

The disease of malaria is worthy of some attention.⁸⁶ Malaria was a major health problem, particularly since most of the land under the Confederacy's control was in the endemic zone.⁸⁷ This fact was especially telling for the Southern medical services; obviously, as Union forces made greater inroads into Confederate territory, the risk of exposure to service personnel and others increased. The Union gained a remarkable advantage in producing mass quantities of quinine (and other drugs) and distributing them in the field and in hospitals. The Union was so successful at producing quinine sulphate semi-synthetically, that it was administered to those at sea⁸⁸ who, provided there were no pools of stagnant water onboard ship to harbour mosquitoes, had a theoretically-negligible,⁸⁹ immediate, exposure risk to malaria. Quinine sulphate was used also as a general purpose tonic.

⁸³ Flannery, MA, *Civil War Pharmacy: A History of Drugs, Drug Supply and Provision, and Therapeutics for the Union and Confederacy* (2004) Pharmaceutical Products Press, New York, 25.

⁸⁴ *Materia Medica* later came to be termed Pharmacognosy (the science of drug sources).

⁸⁵ Flannery, MA, *op cit*, 109.

⁸⁶ See Leland, J, *Aliens in the Backyard: Plant and Animal Imports into America* (2005) University of South Carolina Press, Columbia, 67: malaria is said to have been introduced to America by Europeans; there was no record of the disease in the New World prior to 1492. Quinine was first isolated from cinchona bark in 1820 by the French chemists, Caventou and Pelletier: see Kremers and Sonnedecker, *op cit*, 361.

⁸⁷ See Centers for Disease Control (CDC), *Elimination of Malaria in the United States (1947 — 1951)* (2010) CDC, Atlanta. Available from http://www.cdc.gov/malaria/about/history/elimination_us.html. (Last accessed 12 January, 2012). A Nineteenth-Century cartographic distribution of malaria is included. The greatest altitudes in the Appalachian Mountains were non-endemic. The Centers for Disease Control were based in Atlanta (GA) precisely because combating malaria required a sustained effort in the Southern United States, particularly, in the States of Florida, Georgia and South Carolina.

⁸⁸ Flannery, *op cit*, 156. See further, *op cit*, 232: the (Union) Surgeon General William Hammond's Circular No 6 argued against some of the most seriously inappropriate medicine prescribing and consumption, e.g. antimony and calomel (mercurous chloride). This challenged conventional medical thinking deeply, leading to his court-martial.

⁸⁹ See, however, United States Naval War Records Office, *Official Records of the Union and Confederate Navies in the War of the Rebellion, Series II - Volume 2: Navy Department Correspondence 1861-1865, with Agents Abroad* (1921) Government Printing Office, Washington (DC), 759: "... crews necessarily exposed to the action of the malaria of the freshwater rivers and swamps bordering the rice fields, but a change of locality lately made has lessened their severity."

The Southern authorities had great difficulty in obtaining cinchona bark due to the Union naval blockade.⁹⁰ The price of supplies obtained through blockade runners escalated, as the War progressed. Malaria's contribution to the South's total burden from morbidity and mortality was a significant factor in the Confederacy's eventual defeat.

Throughout the Civil War, community pharmacy practice was in much better condition in the North than in the South.⁹¹ Many Southern communities were left without physicians or pharmacists: the Southern parliament at Richmond (VA) passed a Conscription Act 1862, which exempted certain apothecaries from military service.⁹²

Twentieth-Century Pharmacy in the United States

By 1902, over the first 50 years of the APhA's existence, pharmacists had evolved from manufacturers into compounding experts.⁹³ Pharmacists could not compete in manufacturing with the pharmaceutical industry. American hospital pharmacy was until the 1920s considered the poor relation of community practice. The latter had become quite commercialized, leading some pharmacists to seek new opportunities in hospitals, industry and academia. In the US, the concept of clinical pharmacy first found practical expression in the 1960s. As manufacturing, then compounding declined in community pharmacy and more potent drugs emerged in the mid-twentieth century, hospital pharmacists took control over these substances and gained a voice in therapeutic decisions.⁹⁴ A similar pattern emerged in the UK and Ireland in the 1980s.

A new practice paradigm, Pharmaceutical Care, was proposed in 1989 by Hepler and Strand.⁹⁵ The proponents of the pharmaceutical care concept have declared that practitioners adhering to their model have the following duties: "*Practitioners who treat patients with medications have a duty to warn patients of the known risks associated with drug therapies ... Joined with the duty to warn*

⁹⁰ Flannery, *op cit*, 196.

⁹¹ Flannery, *op cit*, 172.

⁹² Flannery, *op cit*, 172: the Act had to be amended in 1864 to prevent bogus pharmacists from evading the draft—only those in specified practice on the 10th. October, 1862 could now avail.

⁹³ See Higby, GJ, *American Pharmacy's First Great Transformation, Practice, 1852-1902*, Chapter in Higby, GJ (Editor), *American Pharmacy (1852-2002): A Collection of Historical Essays* (2005) American Institute of the History of Pharmacy, Madison (WI), 4.

⁹⁴ See Higby, GJ, *The Continuing Evolution of Pharmacy Practice, 1952-2002*, Chapter in Higby, GJ (Editor), *American Pharmacy (1852-2002): A Collection of Historical Essays* (2005) American Institute of the History of Pharmacy, Madison (WI), 13-16. Clinical pharmacy was recognized in the American Pharmaceutical Association's 1969 Code of Ethics: pharmacists were exhorted to give to each patient the full measure of their ability as an essential health practitioner.

⁹⁵ Hepler, CD, Strand, LM, *Opportunities and Responsibilities in Pharmaceutical Care* (1990) 47 *American Journal of Hospital Pharmacy* 533.

is the obligation to follow-up to determine if patients experienced harmful events with drug therapy.”⁹⁶

Despite greater opportunities for some practitioners to perform pharmaceutical care in certain settings, the core distributive functions of pharmacy remain.⁹⁷

2.3 Practice of Pharmacy - Insights and Aspirations

One of the main advantages that members of the public can derive from the availability of community pharmacies is the realisation of self-care possibilities.⁹⁸ A convenient base point (in 1979) from which to gauge medical perceptions of the role of pharmacy in self-care is a book titled, *The Symptom Iceberg: a Study of Community Health*, which contains no instance of the protected title, ‘pharmacist’, and a mere seven, fleeting, references to (the contextually unambiguous term) ‘chemist’.⁹⁹ Following the original iceberg metaphor, the areas above the metaphorical surface were major illness and minor illness, with self-care below. More recently, Colin Bradley (a Professor of General Practice) has suggested that the illness iceberg is shifting, yielding more blurred divisions between illness states, in consequence of which the role of the pharmacist in self-care has become more widely acknowledged.¹⁰⁰ The International Pharmaceutical Federation (FIP) has emphasised that “[c]lose co-operation between prescribers

⁹⁶ See Cipolle, RJ, Strand, LM, Morley, PC *Pharmaceutical Care Practice: The Clinician's Guide* (2004) Second Edition, McGraw-Hill Professional, Columbus, 257-258.

⁹⁷ See Higby, GJ, *The Continuing Evolution of Pharmacy Practice, 1952-2002*, Chapter in Higby, GJ (Editor), *American Pharmacy (1852-2002): A Collection of Historical Essays* (2005) American Institute of the History of Pharmacy, Madison (WI), 16.

⁹⁸ Self-medication has been defined as “*pharmaceutical treatment undertaken by the patient on his/her own initiative without medical prescription*”: see Council of Europe, *Committee of Ministers Resolution ResAP(2001)2 concerning the Pharmacist's Role in the Framework of Health Security (Adopted by the Committee of Ministers on 21 March, 2001 at the 746th meeting of the Ministers' Deputies)*. Available from <https://wcd.coe.int/ViewDoc.jsp?id=193721&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>. (Last accessed 12 January, 2012). See also Gaughan, D, *Role of the Pharmacist in Self-Care*, in Irish Pharmaceutical Healthcare Association (IPHA) *IPHA Switch-On to Self-Care Roundtable* (25 March, 2009), Dublin. Proceedings available from <http://www.ipha.ie/alist/special-conferences.aspx?article=ccd871b6-6103-4f49-bad5-16b5c1b049f2>. (Last accessed 12 January, 2012).

⁹⁹ Hannay, DR, *The Symptom Iceberg: a Study of Community Health* (1979) Routledge, London. On the perceptual challenge that pharmacists have had to surmount, see Dingwall, R, *Essays on Professions* (2008) Ashgate Publishing, Aldershot, 77: “*Pharmacy occupies an uneasy place in the sociology of health care occupations. On the one hand, it is normally considered to be a ‘profession’, whatever that term might mean. On the other hand, it is a little tarnished by its association with ‘trade’. Professionals are gentlemen, paid for their advice and service, while tradesmen make their living by selling a product.*”

¹⁰⁰ Bradley, C, *The development of self-care and its implications for GPs*, in Irish Pharmaceutical Healthcare Association (IPHA) *IPHA Switch-On to Self-Care Roundtable* (25 March, 2009), Dublin. Proceedings available from <http://www.ipha.ie/alist/special-conferences.aspx?article=ccd871b6-6103-4f49-bad5-16b5c1b049f2>. (Last accessed 12 January, 2012).

*and pharmacists is as important in the area of self-medication as it is in relation to prescribed medicines.”*¹⁰¹

Since the 1980s, the World Health Organization (WHO) has stressed the importance of self-care in health policy.¹⁰² There was general recognition that self-care is undoubtedly the primary resource of any healthcare system. People already manage or treat a large proportion of their ailments without consulting a doctor or pharmacist. The WHO recognised that the pharmacist can play a key role in helping people to make informed choices about self-care, and in providing and interpreting the information available: “[t]his requires a greater focus on illness management and health maintenance, rather than on product selling. Indeed, self-care does not always require use of a medicine. If, however, there is a need for self-medication in self-care, then the role of the pharmacist must be extended.”¹⁰³

National pharmaceutical associations are engaged in promoting the expanding role of the pharmacist. For example, the Canadian Pharmacists Association has produced a document on this topic, building on: who the pharmacist is (“*the health professional who focuses on the patient’s drug therapy*”); what the pharmacist’s current role is (“[t]he role most people associate with a pharmacist is dispensing medications). However, pharmacists have an equally important role in meeting the needs of their patients as the medication management experts”); what is needed to allow pharmacists’ role to expand.¹⁰⁴ The Canadian Pharmacists Association states that “[d]rugs are now the most commonly used intervention to improve health, and only the pharmacist has extensive training devoted primarily to drugs and their use. Pharmacists’ expertise lies in how medications should be used, how to maximize benefits and minimize adverse effects of drug

¹⁰¹ See International Pharmaceutical Federation / Fédération internationale pharmaceutique (FIP), *FIP Statement of Principle - Self-Care Including Self-Medication - The Professional Role of the Pharmacist* (1996) FIP, The Hague, [3]. Available from http://www.fip.org/www/uploads/database_file.php?id=204&table_id= (Last accessed 12 January, 2012).

¹⁰² See World Health Organization Regional Office for Europe *EUR/HFA, Target 13 Healthy Public Policy*, in Kickbusch, I, (Editor) *A Strategy for Health Promotion* EUR/ICP/HSC 615 4534r (1990) World Health Organization Regional Office for Europe, Copenhagen. Available from http://whqlibdoc.who.int/euro/-1993/EUR_ICP_HSC_615.pdf. (Last accessed 12 January, 2012).

¹⁰³ World Health Organization Report WHO/DAP/98.13, *The Role of the Pharmacist in Self-Care and Self-Medication* (1998) Report of the 4th WHO Consultative Group on the Role of the Pharmacist, The Hague, The Netherlands 26-28 August, 1998, World Health Organization, Geneva, [10]. Available from <http://apps.who.int/medicinedocs/pdf/whozip32e/whozip32e.pdf>. (Last accessed 12 January, 2012).

¹⁰⁴ Canadian Pharmacists Association, *Expanding the Role of Pharmacists* (2008) Canadian Pharmacists Association, Ottawa. This publication (first researched in 2010) is no longer retrievable on the Publisher’s Web Site; located in January 2012 through the Web Site of the Ontario Pharmacists’ Association, Toronto. Available from the URL: <http://www.opatoday.com/documents/ExpandingtheRoleofPharmacists.pdf> (Last accessed 12 January, 2012): “*Canadians rate pharmacists as the most trusted health professional.*” See, in particular, the section on “*What Needs to Happen to Allow Pharmacists’ Role to Expand?*”.

therapy, and how prescription drugs interact with other medications.”¹⁰⁵ Kinsella (2009) noted that Irish Government policy aims to strengthen the primary care system as central and first point of contact for patients with health system, with a change in emphasis from secondary care to primary care.¹⁰⁶

Pharmacists participate in minor ailment services in Northern Ireland and in Scotland.¹⁰⁷ The Pharmaceutical Society of Ireland has welcomed such initiatives: “[e]xamples of increased pharmacy services which are currently happening in other jurisdictions ... are minor ailment schemes, medicines management reviews and immunisation programmes. Introduction of schemes such as these into the Irish healthcare system would provide significant benefits to patients and would lead to significant savings to the public purse.”¹⁰⁸

The Royal Pharmaceutical Society of Great Britain, in 2002, proposed *inter alia* that pharmacists can address sub-optimal prescribing by providing information for prescribers, participating in (hospital or community) formulary development and conducting prescribing reviews.¹⁰⁹

The Pharmaceutical Society of Ireland commissioned the Report, *Pharmacy Ireland 2020*, in 2008. One of the report’s aims was to examine possibilities for pharmacies provide a range of diagnostic and screening services, that have traditionally been carried out in a medical setting, including tests for Prostate Specific Antigen, *Helicobacter pylori* (a bacterium implicated in most gastric and duodenal ulcers), Cholesterol, Blood Pressure, Body Mass Index, Blood Glucose, International

¹⁰⁵ *Ibid.*

¹⁰⁶ See Kinsella, M, *From primary care to self-care - the Government Health Strategy* in Irish Pharmaceutical Healthcare Association (IPHA) *IPHA Switch-On to Self-Care Roundtable* (25 March, 2009), Dublin. Proceedings available from <http://www.ipha.ie/alist/special-conferences.aspx?article=ccd871b6-6103-4f49-bad5-16b5c1b049f2>. (Last accessed 12 January, 2012). Kinsella cites: Department of Health and Children, *Primary Care, A New Direction, Quality & Fairness – A Health System for You* (2001) Department of Health and Children, Dublin.

¹⁰⁷ See Health and Social Care in Northern Ireland (HSCNI) *NI Minor Ailments Scheme* (Undated Web Resource) HSCNI Business Services Organisation, Belfast. Available from <http://www.hscbusiness.hscni.net/2055.htm>. (Last accessed 12 January, 2012). See also NHS National Services Scotland, Information Services Division, *Minor Ailment Service (MAS)* (2011) Information Services Division, NHS National Services Scotland, Edinburgh. Available from <http://showcc.nhsscotland.com/isd//5033.html>. (Last accessed 12 January, 2012).

¹⁰⁸ See Pharmaceutical Society of Ireland, *Submission from the Pharmaceutical Society of Ireland to the Expert Group on Resource Allocation and Financing in the Health Sector* (2009) Pharmaceutical Society of Ireland, Dublin, [3]. Available from http://www.thepsi.ie/Libraries/Submissions/DoHC_Expert_group_Resource_Allocation_Health_Sector.sflb.ashx. (Last accessed 12 January, 2012).

¹⁰⁹ Royal Pharmaceutical Society of Great Britain, *Realising the Potential of Pharmacists* (2002) Royal Pharmaceutical Society of Great Britain, London, 3.

Normalised Ratio (a standardised method of monitoring blood clotting).¹¹⁰ Support for the pharmacist's role in Ireland has come from the Economic and Social Research Institute (ESRI).¹¹¹

The Council of Europe (CoE), Committee of Ministers (CM) has instigated the preparation of performance indicators for pharmaceutical care.¹¹² The CM has also stressed the real dangers that counterfeit pharmaceuticals pose, to which a comprehensive response is required through co-operation between governmental, intergovernmental and non-governmental organisations.¹¹³ Manufacturers must *inter alia* develop packaging that makes falsification difficult and pharmacists must take due care in choosing their suppliers. Patients must be made aware of the inherent dangers of counterfeit medicines - in which the role of the pharmacist is crucial. In 2010, the CoE Parliamentary Assembly submitted a Draft Convention Counterfeit Medicines for consultation among the relevant CoE organs.¹¹⁴ Notably, the European Union (EU) Commission has promulgated a Falsified Medicines Directive.¹¹⁵

¹¹⁰ Pharmaceutical Society of Ireland *Pharmacy Ireland 2020 Working Group, Interim Report April 2008* (2008) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/Libraries/Publications/Interim_Report_of_the_Pharmacy_Ireland_2020_Working_Group.sflb.ashx. (Last accessed 12 January, 2011).

¹¹¹ Layte, R, *Coping with Population Change in Ireland: The Implications for Healthcare* ESRI Research Bulletin 2009/4/3 (2009) Economic and Social Research Institute, Dublin, Ireland, [2]. Available from <http://www.esri.ie/UserFiles/publications/20091218105452/RB20090403.pdf>. (Last accessed 12 January, 2011). See also the Pharmacy Regulator's response to the ESRI document: *Pharmaceutical Society of Ireland, PSI Says Role of Other Health Professions Should Be Examined to Reduce Further Pressures* (2009) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/tns/news/archive-2009/09-10-21/PSI_Says_Role_of_Other_Health_Professions_Should_Be_Examined_to_Reduce_Further_Pressures.aspx. (Last accessed 12 January, 2011).

¹¹² See, for example, Council of Europe, Committee of Ministers (CM) Documents, CM(2008)91 (11 June, 2008), *1032 Meeting, 9 July 2008, 6 Social cohesion, 6.2 European Pharmacopoeia (EDQM) – European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)*, Available from https://wcd.coe.int/ViewDoc.jsp?id=1305367#P12_103. (Last accessed 12 January, 2011).

¹¹³ Council of Europe, *Committee of Ministers Resolution ResAP(2001)2 concerning the Pharmacist's Role in the Framework of Health Security (Adopted by the Committee of Ministers on 21 March, 2001 at the 746th meeting of the Ministers' Deputies)*, [Para. 8]. Available from <https://wcd.coe.int/ViewDoc.jsp?id=193721&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>. (Last accessed 12 January, 2011).

¹¹⁴ Council of Europe, Parliamentary Assembly, Doc 12130 (26 January, 2010), *Draft Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health, Request for an Opinion from the Committee of Ministers*, Available from <http://assembly.coe.int/Documents/WorkingDocs/Doc10/EDOC12130.pdf>. (Last accessed 12 January, 2012). See also Council of Europe, Parliamentary Assembly, Doc 12160 (08 February, 2010), *Draft Convention of the Council of Europe on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health, Report by the Social, Health and Family Affairs Committee*. Available from <http://assembly.coe.int/Documents/WorkingDocs/Doc10/EDOC12160.pdf>. (Last accessed 12 January, 2012).

¹¹⁵ EU Commission, *DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products*. Available from http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf. (Last accessed 12 January, 2012). Further information is available from European Commission, DG Health & Consumers,

The UK Department of Health has produced a working definition of 'supplementary prescribing', which is "a voluntary partnership between an independent prescriber (a doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific Clinical Management Plan with the patient's agreement".¹¹⁶ In the UK, pharmacists are now involved in 'independent prescribing'.¹¹⁷ In Ireland, since 2007, nurse prescribing is possible through a Collaborative Practice Agreement (CPA), which is an agreement between the nurse/midwife, registered medical practitioner and health service employer which outlines the parameters of the prescriptive authority of the nurse/midwife.¹¹⁸

2.4 Thesis Perspectives on Pharmacy's Future

In the UK and Ireland particularly, given the largely public environment in which pharmacists practice their profession, contract law is unlikely to generate a great volume of litigation, instigated by patients or consumers of medicines.

Tort is undoubtedly the branch of the law of obligations, which has greatest relevance for pharmacists.¹¹⁹ From a theoretical perspective, tort may be viewed as either a medium of corrective justice (redressing a wrong) or of distributive justice (a system of compensation). It is

Public health, Medicinal products for human use, *Pharmaceutical package* (Undated Web Resource) Available from http://ec.europa.eu/health/human-use/package_en.htm. (Last accessed 12 January, 2012).

¹¹⁶ Department of Health, *Supplementary Prescribing by Nurses, Pharmacists, Chiropodists/Podiatrists, Physiotherapists and Radiographers within the NHS in England: a guide for implementation* - updated May 2005 (2005) Department of Health, London. Available from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4110032. (Last accessed 12 January, 2012). See also Department of Health, *Review of Prescribing, Supply and Administration of Medicines (the Crown Report)* (1999) Department of Health, London. Available from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4077151. (Last accessed 12 January, 2012). See also NHS National Prescribing Centre, *MeReC Briefing No. 23: Supplementary Prescribing and Patient Group Directions* (2004) National Prescribing Centre, Liverpool. Available from http://www.npc.nhs.uk/merec/other_non_clinical/resources/merec_briefing_no23.pdf. (Last accessed 25 March, 2012).

¹¹⁷ Department of Health, *Improving Patient's Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England* (2006) Department of Health, London. Available from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4133743. (Last accessed 12 January, 2012).

¹¹⁸ Under the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 and the Misuse of Drugs (Amendment) Regulations 2007, a Registered Nurse Prescriber is authorised to prescribe only if employed by a health service provider. In addition, the Nurses Rules 2010 (made by An Bord Altranais in the exercise of powers conferred under the Nurses Act 1985) require a person whose name is entered in the Nurse Prescriber's Division of the Register to notify the Board of any change in the name or address of the employer or the location of the place of employment.

¹¹⁹ The third branch of the law of obligations, restitution, would appear more relevant to fields of endeavour like the financial services sector.

the latter vision that the author submits is applicable to the pharmacist's environment. Distributive justice is concerned with loss allocation on grounds of social justice or social policy. Pharmacy's 'in-house' manufacturing activities are waning and will continue to do so, as the medical and pharmaceutical professions have become ever more reliant upon the medicinal products manufactured by the (government-regulated) pharmaceutical industry. Manufacturers are singularly well positioned to factor in the potential costs of compensation into their pricing structure. Product liability law should therefore achieve the societal goal of compensating for injuries caused by pharmaceutical products. Unless the pharmacist acts in such a manner as to disentitle her to the protection that product liability law affords her, the injured patient/consumer will have the manufacturer/distributor as the target for compensation.

The Pharmacy Act 2007 has established a 'new' Pharmaceutical Society of Ireland with significant powers to shape the duty of care and the standard of care for pharmacists. The major challenges for pharmacist are: responsiveness to a regime in which guidance on professional standards will react more rapidly to an ever-changing world; the effect of more formalised practice standards can be expected to influence the standard of care in negligence.

The existing and emerging roles of the pharmacist are governed by the principles and policies of professional negligence. This is especially the situation with respect to advice provision for a professional group that can claim to be uniquely qualified to impart information on medicinal products.

With an aging population, nursing home facilities become more numerous and larger in size in Ireland. While unquestionably belonging to the medical and pharmaceutical sectors for services provided in the community, residency in a nursing home can represent somewhat of a barrier to direct pharmacist-patient contact. Depending on the intention of the parties entering into a pharmacy consultancy arrangement, a consulting pharmacist role may embrace a relationship with patients as third parties. This is an area of the law the contours of which have yet to be mapped.

This thesis examines, from a pro-active perspective, two significant emerging issues in Irish pharmacy. These emerging issues are: (1) the establishment of a broad-based Healthcare Legal Forum to which pharmacists may contribute their professional expertise for the benefit of Irish society; (2) Introduction of Patient Group Directions to Ireland.

Chapter 3 The Duty of Care

3.1 Introduction

Historically the role of the pharmacist was centred on the management of the pharmacy and the accurate dispensing of drugs.¹²⁰ Pharmacists are now involved *inter alia* in monitoring patient medication profiles and patient profiles, searching for drug-drug and drug-food interactions.¹²¹ There is a dearth of case law from the Irish courts because most cases involving pharmacists' liability would appear to be settled prior to hearing. Compromised legal proceedings naturally have no precedential value since the very opportunity for judicial analysis and decision-making will have been removed by the parties' agreement to terminate their legal proceedings.

Zammit remarks that the courts have held that "*architects, doctors and lawyers do not render work but provide a service. Therefore, it is not their duty to carry out all that is requested by their client, but to do all that is within their capacity to achieve the proper end result.*"¹²²

The legislature and the courts will determine the scope of the respective duties of care for the medical profession, professions allied to medicine and institutional healthcare providers, in their various manifestations. With the development of other professions, the traditional leadership role of the medical profession in healthcare delivery will be transformed.¹²³ Some professional competencies in the non-medical professions may have evolved or may yet evolve so that it would no longer be appropriate for a medical viewpoint to prevail. A health professional is unlikely to deny the existence of a duty of care to a patient, because the circumstances of their interaction, in a healthcare delivery situation, tend to make negation unfeasible and tactically

¹²⁰ Pozgar, GD, *Legal Aspects of Health Care Administration*, Ninth Edition (2012) Jones & Bartlett, Sudbury (MA), 266. Pozgar, GD, Santucci, N, Pinnella, JW, *Legal and Ethical Issues for Health Care Professionals*, Second Edition (2010) Jones & Bartlett Publishers, Sudbury (MA), 289. See also: McCormick, III, HB, *Ferguson v Williams: The Pharmacist: Bean Counter or Learned Professional* (1992) 1 Journal of Pharmacy & Law 245 [Case Comment on *Ferguson v Williams* (1991) 399 SE2d 389 (NC App)].

¹²¹ Pozgar, GD, Santucci, N, Pinnella, JW, *loc cit*.

¹²² Zammit, A, *Medicine, healthcare, pharmacy and the law* (2012) Journal of the Malta College of Pharmacy Practice, Iss 18, 31, 32.

¹²³ Naturally, non-lawyerly, professional, viewpoints on the 'duty of care' also exist; describing the legal, ethical and clinical responsibilities of clinical care. For example, see Howard, P and Bowen, N, *The challenges of innovation in the organization of home enteral tube feeding* (2001) 14 Journal of Human Nutrition and Dietetics, 3.

unsound.¹²⁴ The common law does not recognise ethereal duties: a duty must be owed directly to the plaintiff.¹²⁵

The nature of the duty requirement in negligence “[as commonly understood] is that [of] a control device that enables courts to check the propensity of juries to award damages in situations where matters of legal policy would dictate otherwise.”¹²⁶ A control device, like duty and causation, is a “way of keeping the negligence principle within practical bounds”.¹²⁷ The negligence principle demands that the tortfeasor pays for the foreseeable harm caused through his fault. The breadth of the negligence principle has been compared to that of “having to disgorge an unjust enrichment”.¹²⁸ “Sober tort lawyers” can remain grounded (in the colloquial sense) by invoking the “duty” concept to deny liability where imposing it would bring about a result that is not “fair, just and reasonable”.¹²⁹ The duty of care element of negligence has one positive aspect (specifying when people are subject to a legal obligation to take care) and one negative aspect (specifying the limits of the law’s requirement for care to be exercised).¹³⁰ Balkin and Davis remark that the concept of duty of care is a “comparatively modern one, but is now so firmly rooted that there can be no doubt that actions in negligence must fail where duty is not established.”¹³¹ Courts have been reluctant to recognise a duty of care in some areas with pure economic loss and failure to act the principal ones remaining.¹³²

3.1.1.1 Application to Pharmacists in Ireland

This chapter outlines modern developments in the law on duty of care. The legal position of the position of the pharmacist in Ireland has been transformed through the regime introduced by the Pharmacy Act 2007.

¹²⁴ Denial of a duty may carry a distinctive quality of unethical behaviour, leading to disciplinary sanctions.

¹²⁵ “A man is entitled to be as negligent as he pleases to the whole world, if he owes no duty to them.” For this famous dictum and more, see *Le Lievre v Gould* [1893] 1 QB 491, 497, per Lord Esher MR (CA).

¹²⁶ Binchy, W, *Torts* (1973-1974) 6 *Ottawa Law Review* 511, 511; McMahon, B and Binchy, W, *Irish Law of Torts*, Third Edition (2000) LexisNexis Butterworths, Dublin. For a contrary view, see Neethling, J, Potgieter, PM, Visser, PJ, *Law of Delict*, Second Edition (1994) Butterworths, Durban, 140.

¹²⁷ Weir, T, *The Staggering March of Negligence*, Chapter in Fleming, JG, Cane, P, Stapleton J (Editors), *The Law of Obligations: Essays in Celebration of John Fleming* (1998) Oxford University Press, Oxford, 98.

¹²⁸ Weir, T, *loc cit*.

¹²⁹ Weir, T, *op cit*, 98-99.

¹³⁰ Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 464.

¹³¹ Balkin, RP, Davis, JLR, *Law of Torts* Third Edition (2004) LexisNexis Butterworths, Chatswood (NSW), 201, citing *inter alia*: *Heaven v Pender* (1883) 11 QB 503, 507 per Brett MR (CA); *Le Lievre v Gould* [1893] 1 QB 491, 497, per Lord Esher MR (CA); (*Hay or Bourhill v Young* [1943] AC 92 (HL).

¹³² McMahon, B and Binchy, W, *Irish Law of Torts* Third Edition (2000), LexisNexis Butterworths, Dublin, 115.

It has been reported (reticently) in parliamentary proceedings that “*at least two [English] High Court decisions where liability for harm caused has been assigned, proportionately to the extent of their individual contributory negligence, to both the pharmacist and the prescriber.*”¹³³ The UK Department of Health has pointed out, validly: “[*i>n practice, within the NHS, the existence of a duty of care is seldom challenged and so the individual who has been harmed.*”¹³⁴ In most cases, the court’s attention is devoted to three components: negligence, causation and injury. Emergencies serve as an example of exceptional cases in which a duty of care issue may arise.¹³⁵

The Pharmaceutical Society of Ireland (PSI) has stated, without immediate differentiation of the legal from other aspects, the requirement to meet the duty of care.¹³⁶ The PSI document goes on to specify actions to be taken (or shortcomings to be avoided) consistent with observing the legal duty of care:

*“A pharmacist should only engage in activities which are within their normal scope of practice and for which they have the required skills and competencies. ... Any pharmacist who is unable to assist a patient by virtue of this provision should source an alternative accessible practitioner for the patient to attend.”*¹³⁷

To be *unable* does not expressly include the state of being *unwilling* (e.g. through conscientious objection), although in Ireland’s colloquial speech the former word is sometimes used to connote

¹³³ United Kingdom Parliament, *Healthcare across EU borders: a safe framework*, European Union Committee, Memorandum by the Royal Pharmaceutical Society of Great Britain (2008), Paragraph 7.6. Available from <http://www.publications.parliament.uk/pa/ld200809/ldselect/ldcom/30/08111305.htm>, (Last accessed 12 January, 2012).

¹³⁴ Department of Health, *Making Amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS* (2003) Department of Health, London, [51]. Available from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4010641 (Last accessed 12 January, 2012).

¹³⁵ See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 42-43.

¹³⁶ Pharmaceutical Society of Ireland (Standards and Practice Unit), *Pharmacy Practice Guidance Manual A self-audit tool for pharmacists and pharmacy owners* (May 2008) Pharmaceutical Society of Ireland, Dublin, [2]. Available from http://www.thepsi.ie/Libraries/Publications/Pharmacy_Practice_Guidance_Manual.sflb.ashx. (Last accessed 12 January, 2012). US jurisdictions are generally reluctant to find that pharmacists owe a duty of confidentiality or a fiduciary duty to a patient or customer. See, for example, *Evans v Rite Aid Corp* (1996) 478 SE2d 846 (SC Sup Ct) (The Code of Ethics of the American Pharmaceutical Association does not create for pharmacists a statutory or common law duty of confidentiality for pharmacists). In *Griffin v Pharm-Mor Inc* (1992) 790 FSupp 1115 (SD Ala), the court held that a pharmacist has a duty of disclosure toward the customer. It declined to reach the issue of whether a confidential relationship exists between a pharmacist and the customer.

¹³⁷ Pharmaceutical Society of Ireland, *op cit*, [14]. (Emphasis supplied).

the latter.¹³⁸ There is also a clear duty to stay abreast of developments.¹³⁹ The PSI is implementing the continuing professional development (CPD) programme mandated by the Pharmacy Act 2007. Currently, the PSI requires at annual registration a declaration that a pharmacist engages in CPD and a description of relevant activities undertaken.

The general nature of a duty of care analysis is stated in the Canadian case, *Stewart v Pettie*.¹⁴⁰ Major J stated: “*The question of whether a duty of care exists is a question of the relationship between the parties, not a question of conduct. The question of what conduct is required to satisfy the duty is a question of the appropriate standard of care.*”¹⁴¹ One speaks of duty of care in the context of particular relevant action or culpable inaction: the foregoing *dicta* in *Stewart v Pettie* would appear to lack focus in that regard. Regarding omissions, it is difficult to conceive of a scenario in which pharmacist could escape liability for failure to act, since a health professional is both ethically and legally bound to act in the patient’s best interests.¹⁴²

3.2 Modern Developments in the Law on Duty of Care

In a critique of the celebrated product liability case, *MacPherson v Buick Motor Co*, Goldberg and Zipursky highlighted the inhibitory effect of *Winterbottom v Wright*¹⁴³ on development of the duty concept.¹⁴⁴ The courts recognised early that liability for negligence must not become unbounded: *Ultramares Corporation v Touche Niven & Co.*¹⁴⁵ The extract, with emphasis supplied, within the following passage from that New York case is renowned: “*If liability for negligence exists, a thoughtless slip or blunder, the failure to detect a theft or forgery beneath the cover of deceptive entries, may expose accountants to a liability in an indeterminate amount for an indeterminate*

¹³⁸ See also Brushwood, DB, *Professional Capabilities and Legal Responsibilities of Pharmacists: Should Can Imply Ought, The Symposium on the Evolving Jurisprudence: Changing the Law for a Changing Profession* (1995-1996) 44 Drake Law Review 439.

¹³⁹ One recent development is nurse prescribing: Office of the Nursing Services Director, Health Service Executive, *Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland* (2008) Health Service Executive, Dublin.

¹⁴⁰ *Stewart v Pettie* [1995] 1 SCR 131, 1995 CanLII 147 (SCC).

¹⁴¹ *Stewart v Pettie* [1995] 1 SCR 131, 1995 CanLII 147 (SCC), [32].

¹⁴² Analogies with factual, non-therapeutic, circumstances giving rise to either, no *prima facie* general duty to rescue, or, some feature to trigger a duty in occupiers’ liability, are not realistic. In healthcare, a feature for duty imposition already exists. See also Balkin, RP, Davis, JLR, *Law of Torts Third Edition* (2004) LexisNexis Butterworths, Chatswood (NSW), 216-217.

¹⁴³ *Winterbottom v Wright* (1842) 152 ER 402.

¹⁴⁴ Writing on the case of *MacPherson v Buick Motor Co* (1916) 111 NE 1050 (NYCA); Goldberg, JCP, Zipursky, BC, *The Moral of MacPherson* (1998) 146 University of Pennsylvania Law Review 1733, 1743. See also Clarke, SH, *Unmanageable Risks: MacPherson v Buick and the Emergence of a Mass Consumer Market* (2005) 23 Law and History Review 1.

¹⁴⁵ (1931) 174 NE 441 (Cardozo J).

time to an indeterminate class.”¹⁴⁶ An often-quoted rationalisation of the duty concept is found in *Donoghue v Stevenson*¹⁴⁷ as Lord Atkin’s renowned ‘neighbour principle’, which to him appeared “to be the doctrine of *Heaven v Pender*.”¹⁴⁸

Proximity was not intended to be confined to mere physical proximity.¹⁴⁹ *Donoghue v Stevenson* has singular importance in that “the categories of negligence are never closed.”¹⁵⁰ Quill recounts the first reported (albeit guarded) approval of Lord Atkin’s *dicta* in an Irish Court.¹⁵¹ In *Kirby v Burke & Holloway*, Gavan Duffy J fortified the principle in *Donoghue v Stevenson* with the views of the celebrated American jurist, Oliver Wendell Holmes:¹⁵² In cases of physical injury, Quill states that the proximity concept is “generally subsumed within the concept of reasonable

¹⁴⁶ *Ultramares Corporation v Touche Niven & Co* (1931) 174 NE 441, 444. For the original context of “Cardozo’s cogent aphorism”: Feinman, JM, *Liability of Accountants for Negligent Auditing: Doctrine, Policy, and Ideology* (2003) 31 Florida State Law Review 17, 24.

¹⁴⁷ [1932] AC 462 [HL(SC)]. Winfield, PH, *Duty in Tortious Negligence* (1934) 34 Columbia Law Review 41, 56: “*Heaven v Pender* is the historical point at which duty was clinched in the law of negligence. Later cases are concerned not so much with emphasizing the necessity for proving duty as with the exploration of its scope and the tests for ascertaining its existence.”

¹⁴⁸ *Donoghue v Stevenson* [1932] AC 562, 580, per Lord Atkin (HL), citing *Heaven v Pender* (1883) 11 QBD 503, and summarising [[1932] AC 562, 581] the remarks of Brett MR [(1883) 11 QBD 503, 509.

¹⁴⁹ *Donoghue v Stevenson* [1932] AC 562, 581. See also: Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 469, citing: *Home Office v Dorset Yacht Co Ltd* [1970] AC 1004 (HL). Trindade and colleagues discuss how physical proximity was at the heart of *Home Office v Dorset Yacht Co Ltd*: liability was imposed for property at special risk of damage by escaped young offenders, seeking to evade timely recapture by those warders who brought the boys to an island, on a training exercise. By the same token, owners of properties at a greater remove from the escape zone would not have been in such proximity. See also Kodilinye, G, *Commonwealth Caribbean Tort Law*, Fourth Edition (2009) Routledge-Cavendish, London, 63-65, citing: *Austin v AG* (1986) High Court, Barbados, No 1209 of 1985 (Unreported). (Sufficient relationship of proximity did not exist between the Superintendent of Prisons and the plaintiff to impose a duty of care in respect of an escaped prisoner who inflicted serious knife injuries on the plaintiff).

¹⁵⁰ Carty, H, *An Analysis of the Economic Torts* (2001) Oxford University Press, Oxford, 238. Hazel Carty devoted a chapter to *Negligence and Pure Economic Loss* in her First Edition; this approach was not repeated in Carty, H, *An Analysis of the Economic Torts*, Second Edition (2010) Oxford University Press, Oxford.

¹⁵¹ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 21: *Kirby v Burke & Holloway* [1944] IR 207, Gavan Duffy J.

¹⁵² *Kirby v Burke & Holloway* [1944] IR 207, 215. See also: Heuston, RFV, *Donoghue v Stevenson in Retrospect* (1957) 20 Modern Law Review 1, 8, (n 6): “Oddly enough, apart from *Trinity, Oxford*, the only place in which this has been produced as a ground for doubting the authority of the decision has been the Irish High Court: *Kirby v Burke*”. *Mustapha v Culligan of Canada Ltd* [2008] 2 SCR 114 was a case in which the plaintiff sought to recover damages for a psychiatric injury he suffered as a result of seeing dead flies in a bottle of water supplied by Culligan. The question of whether Culligan owed a duty of care to Mustapha was determined solely on the basis of their manufacturer-consumer relationship, rather than on the basis of any unusual susceptibility on the part of the plaintiff. See also Handford, P, *Recovery for psychiatric illness in Canada: a tale of two cases* (2011) 19 Tort Law Review 18, 18: “*Mustapha v Culligan of Canada Ltd* [2008] 2 SCR 114 was the Supreme Court of Canada’s first opportunity for more than 50 years to restate the principles of liability for psychiatric injury as applied in Canada. However, McLachlin CJ’s economically worded judgment did not go into the issues in any detail.”

foreseeability".¹⁵³ In prosaic terms, if a wrongdoer gets close enough to a potential plaintiff to cause physical damage and causes such damage, 'that's proximity'.

In *Anns v Merton London Borough Council*, Lord Wilberforce propounded a two-step inquiry process.¹⁵⁴ The *Anns* formula found favour in Canada in *Nielsen v Kamloops (City)*.¹⁵⁵ Professor Klar has criticised the *Anns* formula adoption: "Duty was based on foreseeability limited by policy; the question of whether there was sufficient proximity between the parties to make it just and fair to recognize a duty was not a part of the vocabulary of the judgment."¹⁵⁶

In the case of *Caparo Plc v Dickman*, there was a significant retreat from the *Anns* policy-based approach and a re-assertion of principle as crucial to judicial decisions.¹⁵⁷ The *Caparo* case is contrasted with *Smith v Eric S Bush*,¹⁵⁸ in *Morgan Crucible Co plc v Hill Samuel & Co Ltd*,¹⁵⁹ based on the different economic relationships between the parties and the nature of the markets in which they were operating.¹⁶⁰ The auditors in *Caparo* were sued for economic loss due to negligent misstatement.¹⁶¹ The court said that liability was confined to cases where the statement or advice had been given to a known recipient for a specific purpose of which the maker was aware and upon which the recipient had relied and acted upon to his detriment.

Giliker and Beckwith underline the usefulness of identifying a number of factors that the courts will take into account when applying the *Caparo* criteria: (1) the type of harm the claimant has

¹⁵³ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 55.

¹⁵⁴ *Anns v Merton London Borough Council* [1978] AC 728, 751, per Lord Wilberforce.

¹⁵⁵ *Nielsen v Kamloops (City)* [1984] 2 SCR 2 (SCC).

¹⁵⁶ Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 180. See also: *Hill v Van Erp* (1997) 188 CLR 159, 176-177, per Dawson J: "proximity is neither a necessary nor a sufficient criterion for the existence of a duty of care."

¹⁵⁷ *Caparo Plc v Dickman* [1990] 2 AC 605 (HL). At [1990] 2 AC 605, 617, Lord Bridge made reference to the following authorities: *Governors of Peabody Donation Fund v Sir Lindsay Parkinson & Co Ltd* [1985] AC 210, 239f-241c; *Yuen Kun Yeu v Attorney-General of Hong Kong* [1988] AC 175, 190e-194f; *Rowling v Takaro Properties Ltd* [1988] AC 473, 501d-g; *Hill v Chief Constable of West Yorkshire* [1989] AC 53, 60b-d. In *Customs and Excise Commissioners v Barclays Bank plc*, at [2007] 1 AC 181, 190, Lord Bingham of Cornhill, supported an incremental approach, citing: *Sutherland Shire Council v Heyman* (1985) 157 CLR 424, 481, approved by Lord Bridge of Harwich in *Caparo Industries plc v Dickman* [1990] 2 AC 605, 618. See also Stapleton, J, *Legal Cause: Cause-in-Fact and the Scope of Liability for Consequences* (2001) 54 Vanderbilt Law Review 941, 944: "... 'traditional' cases or 'simple running down' cases, are not the most important in the challenges they present to modern tort doctrine. Of much greater significance are non-traditional claims, such as those alleging a negligent failure to control a third party, which test the limits of the contours of the map of torts."

¹⁵⁸ *Smith v Eric S Bush* [1990] 1 AC 831 (HL).

¹⁵⁹ *Morgan Crucible Co plc v Hill Samuel & Co Ltd* [1991] 1 Ch 295.

¹⁶⁰ [1991] 1 Ch 295, 302 (CA) per Hoffmann J.

¹⁶¹ Whether statutory strict liability would have applied on the *Caparo* facts under the Trade Practices Act 1974 (Cth) in the Trans-Tasman setting: see Fleming, J, *The Law of Torts*, Ninth Edition (1998) LBC Information Services, Sydney, 717 (n).

suffered (physical, financial, or psychiatric), (2) whether the damage in question is caused by a positive act or an omission, (3) the type of defendant sued.¹⁶²

Support for the *Caparo v Dickman* three-stage formulation has come in the Irish Supreme Court from Keane CJ, albeit as *obiter dicta*, in *Glencar Explorations v Mayo County Council (No 2)*.¹⁶³ The Supreme Court in *Glencar (No 2)* suggested that, if it had been called upon to do so, it would have approved the *Caparo* three-stage test. Keane CJ stated that the decisions in both *Donoghue v Stevenson* and *Hedley Byrne & Co Ltd v Heller and Partners Ltd* unquestionably represent the law in this jurisdiction.¹⁶⁴ The learned Chief Justice said that although the decision in *Ward v McMaster* has been “*treated by some as an unqualified endorsement by this court of the two stage test adopted by Lord Wilberforce in Anns v Merton London Borough ... , it is by no means clear that this is so.*”¹⁶⁵

¹⁶² Giliker, P, Beckwith, S, *Tort*, Third Edition (2008) Sweet & Maxwell, London. See also Witting, C, *Duty of Care: An Analytical Approach* (2005) 25 Oxford Journal of Legal Studies 33, 35, where the author has remarked that the three-stage test presents a conceptual framework for resolving duty questions: the courts have not explained the significance of each element in the test (particularly that each element has a different function in the duty enquiry). *Caparo* has been disapproved, at least partially, in Australia in the High Court decision in *Sullivan v Moody* (2001) 207 CLR 562 (HCA). See Luntz, H, Hambly, D, *Torts: Cases and Commentary*, Sixth Edition (2008) LexisNexis Butterworths, Sydney, 149. The *Caparo* approach appealed to Kirby J (alone) in *Pyrenees Shire Council v Day* (1998) CLR 330, *Perre v Apand Pty Ltd* (1999) 198 CLR 180 and *Crimmins v Stevedoring Industry Finance Committee* (1999) 200 CLR 1 – all decided prior to *Sullivan v Moody*.

¹⁶³ *Glencar Explorations plc v Mayo County Council (No 2)* [2002] 1 IR 84, 139, per Keane CJ, citing these authorities: “... as held by Costello J at first instance in *Ward v McMaster* [1985] IR 29, by Brennan J in *Sutherland Shire Council v Heyman* (1985) 157 CLR 424 and by the House of Lords in *Caparo plc v Dickman* [1990] 2 AC 605. As Brennan J pointed out, there is a significant risk that any other approach will result in what he called a ‘massive extension of a prima facie duty of care restrained only by undefinable considerations ...’” *Ward v McMaster* [1988] IR 337, 347 McCarthy J. The line of argument including the following *dicta* by McCarthy J was described by the *Glencar* Court (Keane CJ) as not forming part of the *Ward v McMaster ratio decidendi*: “*The elaborate analysis of Brennan J. in the High Court of Australia in Sutherland Shire Council v Heyman (1985) [157 CLR 424] led to the verbally attractive proposition of incremental growth in this branch of the law; such a proposition, however, suffers from a temporal defect - that rights should be determined by the accident of birth.*” Writing in 2000, McMahon and Binchy (*op cit*, [118]) commented that the conceptual scaffolding adopted by the Irish court was said to have gone further than the original English edifice, *Anns v Merton London Borough Council* [1978] AC 728, later rejected in *Murphy v Brentwood District Council* [1991] AC 398. The harm suffered by the claimant “*must flow from that part or aspect of the defendant’s conduct, which was wrongful, and from no other part or aspect of the defendant’s conduct, was confirmed by the Court of Appeal in South Australia Asset Management Corporation v York Montague Ltd [[1997] AC 191 (SAAMCO)]*”. See also Young, R, Faure, M, Fenn, P, *Defences in negligence: Implications for tortfeasor care* (2006) 26 International Review of Law and Economics 67, 69.

¹⁶⁴ *Glencar Explorations plc v Mayo County Council (No 2)* [2002] 1IR 84, 136, per Keane CJ, citing: *Donoghue v Stevenson* [1932] AC.562 and *Hedley Byrne & Co Ltd v Heller and Partners Ltd* [1964] AC 465.

¹⁶⁵ *Glencar Explorations plc v Mayo County Council (No 2)* [2002] 1IR 84, 138, per Keane CJ. See also Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 274 (n), citing: *W v Ireland (No 2)* [1997] 2 IR 141, 153 (HC), where Costello P observed the “*view of the Irish courts has been that Anns was a ‘confirmation’ of the long established principles of the law of tort contained in Donoghue v Stevenson and was not (as some commentators in England seem to coincide) a major innovation in the law of tort.*”

Ryan and Ryan have commented that: "... the Court in *Glencar* decisively rejected, by way of obiter comments, the proposition that Mr Justice McCarthy's celebrated judgment in *Ward v McMaster* was a correct statement on the test for inquiring into the existence of the duty of care."¹⁶⁶

It is submitted that judicial classification of those *dicta* of McCarthy J as *obiter* is unconvincing. For more than a decade, the analysis of McCarthy J was regarded in the Superior Courts as a correct statement of the law.¹⁶⁷ The retreat from *Anns*, in which there is a place for judicial incrementalism, has set about confining the application of the Atkinian neighbour principle.¹⁶⁸

The post-*Glencar* jurisprudence, as exemplified in *Fletcher v Commissioners of Public Works*, has been to confine the scope of *Ward v McMaster*.¹⁶⁹

3.2.1 Duty Principles and Policy

Quill states that "*the primary consequences of having a general conception of the duty of care concept is that the boundaries of the tort of negligence are somewhat fluid, allowing the court to extend its scope when faced with new situations or to contract its scope when it is seen to lead to injustice.*"¹⁷⁰ Acknowledging that the "*existence of a duty has been established for many of the*

¹⁶⁶ Ryan, R, Ryan, D, *Some Comments about Caution: Emerging Trends in Irish Negligence Law* (2004) 7 Trinity College Law Review 114, 115.

¹⁶⁷ For example, see *Hanahoe v Hussey* [1998] 3 IR 69, 105 (HC), Kinlen J (The respondents accepted in their submissions that disclosure emanating from some careless conduct on the part of one or more Gardaí would amount to negligence under the principle set out in *Ward v McMaster* [1988] IR 337).

¹⁶⁸ See, further, Ryan, R, Ryan, D, *loc cit*, 116.

¹⁶⁹ *Fletcher v Commissioners of Public Works* [2003] 1 IR 465, 482, per Keane CJ: "*As the decision of this court in Glencar Explorations plc v Mayo County Council (No 2)* [2002] 1 IR 84 made clear, the question as to whether economic loss is recoverable in cases other than those of negligent misstatement and within the categories laid down in *Siney v Corporation of Dublin* [1980] IR 400 and *Ward v McMaster* [1988] IR 337 still awaits authoritative resolution." See also Law Reform Commission, *Report on Privity of Contract and Third Party Rights* (LRC 88 – 2008) (2008) Law Reform Commission, Dublin, 15 (n): "*For example, an action in tort for pure economic loss is available (a) when the plaintiff suffers a financial loss as a result of a negligent misstatement by another, in circumstances where the provider of the information owes a duty of care to the plaintiff: Hedley Byrne & Co Ltd v Heller & Partners Ltd* [1964] AC 465; *Wildgust v Norwich Union Life Insurance Society* [[2006] 1 IR 570]; (b) when a solicitor's negligence in drafting a will causes financial loss to a third party who was to benefit from the will: *Wall v Hegarty* [1980] ILRM 124." The Canadian Supreme Court in *Cooper v Hobart* and *Edwards v Law Society of Upper Canada* altered its analysis, taking the opportunity "*highlight and hone the role of policy concerns in determining the scope of liability for negligence*": Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 173, referring to *Cooper v Hobart* [2001] 3 SCR 537; *Edwards v Law Society of Upper Canada* [2001] 3 SCR 562 (This author has substituted citations in the Supreme Court Reports Series).

¹⁷⁰ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 24. See also Vetri, D, Levine, LC, Vogel, JE, Finley, LM, *Tort Law and Practice*, Third Edition (2006) LexisNexis, Newark (NJ), 690-604: exceptions to the foresight rule (generally used as the test for scope of liability) are the Medical Malpractice Complications Rule (tortfeasor cannot foist on a plaintiff a second trial on complications arising from treatment of original injuries), the Eggshell (Thin Skull) Plaintiff Rule (tortfeasor must take a plaintiff as he finds him) and the Rescuer Rule.

more frequent situations that give rise to accidental injury”, Quill continues: “modern cases usually address the question of whether a duty exists in either problem areas (such as misstatement, pure economic loss and psychological injury) or in the review of existing authorities.”¹⁷¹

A distinction must be drawn between positive acts and failures to act. An affirmative duty involves the imposition of a duty in respect of omissions requiring the one to whom the duty is addressed to intervene to protect another.¹⁷² Quill has advanced the four categories of affirmative duty.¹⁷³

These are:

- i. Where the relationship between the plaintiff and the defendant is such that the defendant is to be treated as responsible for the plaintiff’s protection against the injury in question (e.g. parent and child).¹⁷⁴
- ii. Where the relationship between the plaintiff and the wrongdoer is such that the defendant should have interceded for the plaintiff’s protection (e.g. motorist’s duty to control passengers so that they do not cause injury to other road users).¹⁷⁵
- iii. Where the defendant has created the danger – the duty here would be to take precautionary measures to prevent foreseeable injuries (this would be appropriate where the actual creation of the initial risk was not negligent in itself).¹⁷⁶
- iv. Where the defendant has knowledge of a danger emanating from property under his control (e.g. an occupier’s duty in respect of the occupied property or a motorist’s duty in respect of the roadworthiness of a vehicle).¹⁷⁷

¹⁷¹ Quill, E, *loc cit.* See also: Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 165, for what Prof Klar terms ‘frontier areas’, namely, “the duty to assist others, liability for pure economic losses and the tort liability of public authorities”.

¹⁷² Quill, E, *op cit*, 39.

¹⁷³ Quill, E, *op cit*, 40-41, adapting the classification within the speech of Lord Goff of Chieveley in *Smith v Littlewoods* [1987] AC 241.

¹⁷⁴ See, for example, *McKenna v Best Travel and Chudleigh Ltd*, Unreported, Supreme Court, 29 June, 1998. (Failure to warn of civil unrest in an area which the travel agent knew that the plaintiff intended to visit, even though no booking arrangements could have been made by the defendant). The author doubts whether a similar result would arise today, in a climate of greater self-responsibility coupled with wider availability of information technology, as the customer could be urged to consult travel advisories on the Internet from the Irish Department of Foreign Affairs, or alternatively, the UK Foreign & Commonwealth Office or the US State Department. In *Dobson v Dobson* [1999] 2 SCR 753, the Supreme Court of Canada did not impose a duty upon an expectant mother for the benefit of her unborn child.

¹⁷⁵ For example, *Curley v Mannion* [1965] IR 543 (Sup Ct).

¹⁷⁶ For example, *Rivtow Marine Ltd v Washington Iron Works* (1973) 40 DLR (3d) 530.

¹⁷⁷ Quill, E, *op cit*, 45: buildings and land as a source of danger to neighbours and passers-by may give rise to liability in torts other than negligence.

Quill comments that the “*distinction between acts and omissions is perhaps overstated ... as most instances of pure omissions fail to give rise to liability, due to lack of causation.*”¹⁷⁸

3.2.1.1 Application to Pharmacists in Ireland

The pharmacist’s duty to the patient clearly belongs in the first category. Omissions in the course of providing a professional service are problematic for the pharmacist. Omission to clarify a prescription with the medical practitioner, who issued same, where such a course of action is warranted, may result in injury (causation being established without great difficulty). The omission here relates to one health professional’s intervention with another for the patient’s benefit (rather than the intercessional paradigm of the motorist, as outlined above).

3.2.2 Physical Damage to the Person or to Property

Murphy and Witting describe the hierarchy of protected interests: “[t]he law of negligence reflects protective priorities in wider tort law; a duty of care is more readily recognised with respect to physical integrity than with either mental or financial interests.”¹⁷⁹ These authors say that recognition of a duty to avoid physical damage to “*another’s property, as much as his person, raises no unique problem of principle,*”¹⁸⁰ This author draws the inference from the foregoing statements that jurists and scholars accept the imposition of a duty of care in relation to injuries to the person, with a lower requirement for analysis than will be applied to physical damage caused to property. Actionable injury (where a legally recognised form of damage has been inflicted) is a central ingredient in a negligence action. Quill’s statement that “*duties are delineated by the type of harm that is likely to result from the defendant’s conduct*”¹⁸¹ is a suitable alternative iteration of the hierarchy of protected interests. For instance, physiological change, without present adverse health effects, has been held by the House of Lords not to constitute an injury.¹⁸²

¹⁷⁸ Quill, E, *loc cit*.

¹⁷⁹ Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 71. See also McMahon, B, Binchy, W, *Irish Law of Torts*, Third Edition (2000) LexisNexis Butterworths, Dublin, 115: “*Failure to act and pure economic loss are the principal remaining areas where the courts are still hesitant to impose a wide-ranging duty of care*”.

¹⁸⁰ Murphy, J, Witting, C, *op cit*, 87.

¹⁸¹ Quill, E, *op cit*, 52.

¹⁸² *Rothwell v Chemical & Insulating Co Ltd* [2008] 1 AC 281.

Occasionally, the courts can find a remedy in a tort other than negligence; dust as physical damage to property was the issue in *Hunter v Canary Wharf Ltd*.¹⁸³ However; damages were awarded for nuisance, where there was personal discomfort to the owner, assessed on the basis of compensation for diminution of the amenity value of the land rather than damages for that personal discomfort.

It does not follow from the mere fact that injury has been caused to the person of the plaintiff that the defendant(s), whom he has joined in suit, must be liable in damages.

In *Keane v ESB*,¹⁸⁴ the child plaintiff, having evaded the outer and inner perimeter fences, climbed upon an electricity installation, coming in contact with the high tension cables of the transformer and received extensive injuries to an arm. Griffin J said in the Supreme Court that the duty of care may be discharged “*by warning notices and attempted physical exclusion*”.¹⁸⁵ The Supreme Court held¹⁸⁶ that the evidence at the trial established that the defendants had taken reasonable steps to avert such injury to the plaintiff and that a jury,¹⁸⁷ properly directed, could not have found otherwise reasonably.

An injured mineworker was the plaintiff/appellant in *Sweeney v Duggan*.¹⁸⁸ Because of the employer company’s liquidation and the non-existence of any policy of employer's liability insurance, the judgment that the plaintiff obtained against the company had remained unsatisfied; it appeared that the plaintiff as a preferential creditor of the company would receive only 15% of his award.

The plaintiff claimed, *inter alia*, that the defendant had a duty, in all the relevant circumstances, to arrange employers' liability insurance to meet any claim which the plaintiff might have for damages for personal injuries against the company or, failing that, to warn the plaintiff that no such policy was in existence. It was furthermore contended that, in the circumstances of the case,

¹⁸³ *Hunter v Canary Wharf Ltd* [1997] AC 655 (HL). See also Lee, M, *Hunter v Canary Wharf Ltd* (1997), Chapter in Mitchell, C, Mitchell, P (Editors), *Landmark Cases in the Law of Tort* (2010) Hart Publishing, Oxford, 318.

¹⁸⁴ *Keane v ESB* [1981] IR 44 (Sup Ct). See also Law Reform Commission, *Report on Occupiers’ Liability* (LRC 46 – 1994) (1994) Law Reform Commission, Dublin, 8: “... trespassers would not inevitably recover under the *McNamara* rule can clearly be seen from such cases as *O’Keeffe v Irish Motor Inns* [1978] IR 85 and *Keane v ESB* [1981] IR 44.”

¹⁸⁵ *Keane v ESB* [1981] IR 44, 56, per Griffin J.

¹⁸⁶ O’Higgins CJ dissented as to the trial judge’s undue regard to the Supreme Court decision in *McNamara v ESB* [1975] IR 1, a case with dissimilar facts. The learned Chief Justice favoured a retrial.

¹⁸⁷ Since the enactment of the Courts Act 1988, personal injuries cases are heard by a judge.

¹⁸⁸ *Sweeney v Duggan* [1997] 2 IR 531 (Sup Ct). See also Binchy, W, *Meskill, the Constitution and Tort Law* (2011) 18 Dublin University Law Journal 339.

the defendant should be personally liable to satisfy the judgment which the plaintiff had obtained against the company.

The defendant denied that he owed any such duty of care to the plaintiff and in particular denied that he had any duty, whether arising from a contract of employment or at common law, to insure the plaintiff in respect of accidents at work.

Barron J dismissed the plaintiff's claim, holding that the statutory duty imposed no general statutory duty of care of the type which the plaintiff sought to establish; that the common law could not devise or impose a duty to effect employers' liability insurance which the Oireachtas had not thought fit to impose; and that the terms, whether expressed or implied, of the plaintiff's contract of employment were not material as the contract was made with the company and not with the defendant.

In the High Court, the plaintiff deployed a constitutional argument that the State had been deficient in failing to afford him a protection under Article 40.3.2 of the Constitution, which provides: "*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.*"¹⁸⁹ Barron J was unreceptive to this argument. The learned trial judge proclaimed that the relevant Constitutional provision "*gives [the plaintiff] no more than a guarantee of a just law of negligence, which in the circumstances exists.*"¹⁹⁰ That constitutional argument was not raised before the Supreme Court.

The Supreme Court unanimously dismissed the plaintiff's appeal holding that the courts would imply a term into a contract when such a term could be inferred on the basis of the presumed intention of the parties. The relevance of the presumed intention of the parties differed in different cases. Contract law laid the canvas for the bulk of the analysis in the Supreme Court. The parties had not agreed that the employer would insure for the perils that formed the kernel of the litigation: the courts would not intervene in the circumstances.

The plaintiff in *Gaffey (a minor) v Dundalk Town Council*¹⁹¹ was playing football on a grassed open space close to his family home. While doing so he injured himself when accidentally he fell into a

¹⁸⁹ Bunreacht na hÉireann (Constitution of Ireland), Art 40.3.2.

¹⁹⁰ [1991] 2 IR 274, 285, per Barron J.

¹⁹¹ *Gaffey (a minor) v Dundalk Town Council* [2006] IEHC 436 (Peart J).

fire hydrant which is located on this grassed area, and he sustained a bad cut to his right shin and an avulsion fracture to his left ankle.

Peart J stated that it was “*certainly not clear*” that the defendant Town Council could be found to have been negligent. The learned judge said that “*the mere fact that the plaintiff sustained an injury when he accidentally fell into a hydrant the lid of which had been removed did not mean that the Council caused this to happen*”. It did not follow that the Council should be held liable in negligence to pay compensation to the plaintiff: “[n]egligence must be established.”

McMahon and Binchy note that it is difficult to find judicial reference in road accident litigation to the duty of care “*because all parties take it for granted that a road user has a duty of care not to injure other road users.*”¹⁹² Following the enactment of the Occupiers’ Liability Act 1995, the occupier of premises owes no duty to any trespasser in respect of damages due to the state of the premises.¹⁹³

In *Beatty v The Rent Tribunal*, Geoghegan J stated that the law on the issue of differentiating physical harm from economic loss has not been finally determined in Ireland.¹⁹⁴

3.2.2.1 Application to Pharmacists in Ireland

The popular conception of a pharmacist’s liability in negligence concerns physical injury, which will be apt for the great majority of possible situations. Damage to property is also a possibility for the pharmacist, as a professional person (as opposed to a seller of goods). For example, some medication may discolour permanently clothing or fabrics (in the absence of any risk of physical injury to the patient herself). The pharmacist must therefore warn against such an eventuality.

3.2.3 Psychological Damage

Psychological damage consequential to personal injury is recoverable under the common law. This term is more precise than the one it replaced, ‘nervous shock’. A genuine difficulty relates to “*situations where the psychological suffering is sustained by someone who was at no point subject to any likelihood of being physically injured by the defendant’s conduct.*”¹⁹⁵ This is a branch of the

¹⁹² McMahon, B and Binchy, W, *Irish Law of Torts* Third Edition (2000), LexisNexis Butterworths, Dublin, 128.

¹⁹³ McMahon, B and Binchy, W, *op cit*, 129.

¹⁹⁴ *Beatty v The Rent Tribunal* [2006] 1 ILRM 164, 173, per Geoghegan J.

¹⁹⁵ Quill, E, *op cit*, 63-64. See for example *Hornibrook v Stokes Bros* [1925] 1 KB 141 (mother perceiving accident with her own unaided senses) – a ‘near miss’ would also be valid: *Dooley v Cammell Laird & Co Ltd* [1951] 1 Lloyds Rep 271. (Quill distils the principle that “*bystanders, unrelated to the immediate victim,*

law in which there are many Irish authorities; the analysis in the thesis is supported by case law from other jurisdictions, which may be of persuasive authority.

The advice of the Privy Council in *Victorian Railways Commissioners v Coultas* was most hostile to recovery for non-physical injuries.¹⁹⁶ Two Irish courts declined to follow this decision: *Bell v Great Northern Railway Co*, following *Byrne v Southern and Western Railway Co*. In *Bell v Great Northern Railway Co*, an Irish Court permitted recovery for fear of immediate physical injury inducing physical damage or a medically recognised psychiatric disturbance.¹⁹⁷

Improvements in medical science and a more litigious society have brought about a significant number of modern cases on psychological damage. In the healthcare *milieu*, there may be liability arising from insensitively communicated test results, particularly if the communication is inaccurate.¹⁹⁸

In *McLoughlin v O'Brian* the nervous shock assumed to have been suffered by the plaintiff had been the reasonably foreseeable result of the injuries to her family caused by the defendants' negligence.¹⁹⁹ Although unanimously finding for the plaintiff, there was disagreement in the House of Lords on the principles to be applied in such claims. Ordinary negligence principles, factoring in the relationship of the plaintiff and the circumstances in which the accident was perceived, found favour with Lords Bridge and Scarman.²⁰⁰ Lords Wilberforce and Edmund-Davies suggested an additional policy overlay on the foregoing factors, which would be more rigorously applied. The plaintiff would be required to show, proximity, foreseeability and the presence of those special factors.²⁰¹

were owed a duty if they witnessed an accident, provided that the accident was sufficiently serious to shock a person of reasonable fortitude and the defendant's negligence caused them to believe that they had been instrumental in causing an injury").

¹⁹⁶ *Victorian Railways Commissioners v Coultas* (1888) 13 App Cas 222 (PC). See also Binchy, W, *Recent Developments in Tort Law* [2004] 1 Judicial Studies Institute Journal 8, 11.

¹⁹⁷ *Bell v Great Northern Railway Co* (1890) 26 LR (Ir) 428 (Ex Div) following *Byrne v Southern and Western Railway Co*, Court of Appeal, 1884 (Unreported), cited at 26 LR (Ir) 428. See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 63. See also McMahon, B and Binchy, W, *Irish Law of Torts* Third Edition (2000), LexisNexis Butterworths, Dublin, Chapter 17.

¹⁹⁸ Harpwood, V, *Modern Tort Law*, Seventh Edition (2009) Routledge-Cavendish, London, 48: "There have been conflicting views as to the scope of any duty to break bad news sensitively. The law does now lean in favour of such a duty, especially if the news that is communicated is inaccurate." Harpwood cites *inter alia*: *Allen v City & Hackney Health Authority* [1996] 7 Medical Law Review 167. (Tidings of a baby's death sensitively, though inaccurately, communicated to parents).

¹⁹⁹ *McLoughlin v O'Brian* [1983] 1 AC 410 (HL).

²⁰⁰ Quill, E, *op cit*, 65.

²⁰¹ Quill, E, *loc cit*. In *Jaensch v Coffey* (1984) 155 CLR 549 (HCA), there was a similar dichotomy: reasonable foreseeability (Brennan J) as opposed to proximity (Gibbs CJ and Deane J).

A toll of multiple deaths and injuries at a sporting event was the backdrop to *Alcock v Chief Constable of South Yorkshire*.²⁰² The House of Lords held that, in order to establish a claim in respect of psychiatric illness resulting from shock, it was necessary to show not only that such injury was reasonably foreseeable, but also that the relationship between the plaintiff and the defendant was sufficiently proximate.²⁰³ Their Lordships also held that the class of persons to whom a duty of care was owed as being sufficiently proximate was not limited by reference to particular relationships such as husband and wife or parent and child, but was based on ties of love and affection, the closeness of which would need to be proved in each case: remoter relationships would require careful scrutiny.²⁰⁴ A plaintiff also had to show propinquity in time and space to the accident or its immediate aftermath.²⁰⁵ Dismissing the appeal, that in the cases of the plaintiffs who had been present at the football match the mere fact of the relationship shown was insufficient to give rise to a duty of care; that the viewing of the disaster on television could not be said to be equivalent to being within sight and hearing of the event or its immediate aftermath; and that, accordingly, the plaintiffs' claims failed.²⁰⁶

²⁰² *Alcock v Chief Constable of South Yorkshire* [1992] 1 AC 310. See also Nolan, D, *Alcock v Chief Constable of South Yorkshire Police* (1991), Chapter in Mitchell, C, Mitchell, P (Editors), *Landmark Cases in the Law of Tort* (2010) Hart Publishing, Oxford, 291:

"The four-year period from 1985 to 1989 is often referred to as the UK's 'disaster era' because of the large number of man-made disasters which occurred during that time. ... Inevitably many of the disasters gave rise to large-scale litigation, some of which focused on psychiatric illness suffered by those involved. Most such litigation was dealt with by means of out-of-court settlements or arbitration, so that the full picture remains unclear, but there are enough reported cases and other sources of information to leave no doubt as to the very significant liabilities which those responsible for the disasters incurred."

²⁰³ *Alcock v Chief Constable of South Yorkshire* [1992] 1 AC 310. See also Nolan, D, *op cit*, 286-287: the House of Lords was aware that *Dillon v Legg* (1968) 441 P2d 912 (Cal Sup Ct), which was cited before their Lordships, had recently been abandoned by the California 'High Court'—that State's Supreme Court decision in *Thing v La Chusa* (1989) 771 P2d 814—without the latter authority's having been opened to the Appellate Committee. *Dillon v Legg* was the first case in which damages were awarded to a secondary victim who was not within the foreseeable range of physical injury "(or 'zone of danger') created by the defendant's negligence. In underlining the orthodoxy that communication by a third party would not suffice for recovery, the House of Lords doubted two English first instance decisions, reported one immediately before the other in the All England Reports: *Hevican v Ruane* [1991] 3 All ER 65 (QB) (Mantell J); *Ravenscroft v Rederiaktiebolaget Transatlantic* [1991] 3 All ER 73 (QB) (Ward J). It has been noted that *Thing v La Chusa* did not receive analysis from the Court in either of these (post-1989) cases, although *Dillon v Legg* is mentioned in both judgments.

²⁰⁴ *Alcock v Chief Constable of South Yorkshire* [1992] 1 AC 310, 397, per Lord Keith: "*The kinds of relationship which may involve close ties of love and affection are numerous, and it is the existence of such ties which leads to mental disturbance when the loved one suffers a catastrophe.*"

²⁰⁵ Quill, E, *op cit*, 66: identification of remains at a mortuary several hours later would not satisfy that criterion. See also Binchy, W, *Recent Developments in Tort Law* [2004] 1 Judicial Studies Institute Journal 8, 11-12. See Mullany, N, Handford, P, *Tort Liability for Psychiatric Damage*, Second Edition (2006) Lawbook Company, Pyrmont (NSW), 217, on the need for physical presence at the accident scene in psychiatric damage cases, which had been "*consigned to the lumber room of rejected legal fallacies*", citing *O'Dowd v Secretary of State for Northern Ireland* [1982] NI 210, 214, per Lord Lowry.

²⁰⁶ *Alcock v Chief Constable of South Yorkshire* [1992] 1 AC 310. See also Steele, J, *Scepticism and the Law of Negligence* (1993) 52 Cambridge Law Journal 437.

The House of Lords, in the author's view, created a policy matrix through which it would be exceedingly difficult for the thousands of potential claimants to wade in order to satisfy a test on nearness in familial ties. Close family members present at the ill fated football match may have perished together and recovery was denied to those who merely witnessed the event on television. Murphy and Witting criticise the 'primary-secondary' test in *Page v Smith*²⁰⁷ for conflating two kinds of damage, which are (typically) caused in different ways (original emphasis omitted): "*Personal injuries usually arise from external impact, whereas psychiatric illness always develops indirectly through a reaction to events.*"²⁰⁸ These authors mention how *Page v Smith* has been distinguished in the House of Lords.²⁰⁹

Quill notes the distinction in English law between primary and secondary victims, as in *Page v Smith*.²¹⁰ This statement probably implies that the point has not yet arisen for judicial decision in Ireland in a case where the *ratio decidendi* actually turned on that 'primary-secondary' distinction so as to deny recovery, which is the general sense that this author has taken from the Irish authorities.²¹¹ For example, in *Cuddy v Mays & Ors*,²¹² Kearns J stated: "*It is not disputed by the defendants that the plaintiff was a secondary or 'aftermath' victim of the accident and that he suffered nervous shock, as the same is understood in law, as a direct consequence of the events which he witnessed*".²¹³ The learned judge canvassed the types of relationships that should or should not be recognised for the purposes of psychological damage. The author posits that these

²⁰⁷ *Page v Smith* [1996] 1 AC 155.

²⁰⁸ Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 80.

²⁰⁹ Murphy and Witting, *loc cit*. See further *Grieves v FT Everard & Sons Ltd (sub nom Rothwell v Chemical & Insulating Co)* [2008] 1 AC 291 (HL), 301, per Lord Hope: "*The labels that were identified in Page v Smith should not be extended beyond what was in contemplation in that case. The category of primary victim should be confined to persons who suffer psychiatric injury caused by fear or distress resulting from involvement in an accident caused by the defendant's negligence or its immediate aftermath.*"

²¹⁰ [1996] 1 AC 155. See Quill, E, *loc cit*. In *Page v Smith*, Lords Ackner, Browne-Wilkinson and Lloyd made *dicta* to the effect that, in cases of nervous shock, it is essential to distinguish between the primary victim and secondary victims. In claims by secondary victims the law insists on certain control mechanisms, in order to limit the number of potential claimants. These control mechanisms have no place where the plaintiff is the primary victim. Candour on policy matters is evident in *White v Chief Constable of South Yorkshire* [1999] 2 AC 455, 511 (per Lord Hoffmann): "*No one can pretend that the existing law [on recovery in negligence for psychiatric damage] . . . is founded upon principle*". See also Mullany, N, Handford, P, *op cit*, 153-159; the general rule is that liability is limited to the primary victim. The House of Lords, in *Best v Samuel Fox & Co Ltd* [1952] AC 716, refused to extend to a wife the anachronistic action for loss of consortium.

²¹¹ In *Kelly v Hennessy* [1995] 3 IR 253 (Sup Ct), Hamilton CJ stated that the facts of the case were set out in the judgment of Denham J, who categorised the plaintiff as a secondary victim. However, this classification did not require much exploration. The Supreme Court held (Denham J *diss*) that in relation to future damages, the trial judge, in finding that the plaintiff would never fully recover, had anticipated that she would make a partial recovery. In the circumstances, the figure awarded was excessive and should be reduced by 50%. The plaintiff in *Mullally v Bus Eireann* [1992] ILRM 522 was also a secondary victim who brought a successful suit.

²¹² *Cuddy v Mays & Ors* [2003] IEHC 103.

²¹³ *Cuddy v Mays & Ors* [2003] IEHC 103, per Kearns J.

were *obiter dicta* by Kearns J, because the plaintiff came upon the aftermath of a deceased brother and two deceased cousins; at least the former familial nexus alone should have been sufficiently close, in the *Alcock* sense.

The Supreme Court in *Kelly v Hennessy* followed a *via media*, reflecting aspects of both approaches in *McLoughlin v O'Brian* and *Jaensch v Coffey*.²¹⁴ Those criteria are:

- i. The plaintiff must suffer a recognised psychiatric illness
- ii. The illness must arise by way of 'shock'
- iii. It must be foreseeable that the initial event could cause psychiatric injury; foreseeability of general personal injury is not enough
- iv. The illness must result from the perception of actual injury or a risk of injury to oneself or another person
- v. If harm results from perception of the aftermath, there must be a close personal relationship between primary victim and plaintiff
- vi. There are no public policy limits on recovery where the plaintiff establishes sufficient proximity and foreseeability by fulfilling the above conditions²¹⁵

Two members of the High Court of Australia (Gummow and Kirby JJ) rejected "reasonable fortitude" in the joined cases of *Tame v New South Wales* and *Annetts v Australian Stations Pty Ltd*.²¹⁶ The learned justices preferred an inquiry into foreseeable risk.²¹⁷

In the case of *Curran v Cadbury (Ireland) Ltd*²¹⁸ Unknown to the plaintiff, there was a fitter inside the machine that the plaintiff operated in the course of her employment. The fitter was repairing the machine when the plaintiff set it in motion. The plaintiff immediately became aware of commotion and screams close to her. She thought she had killed or seriously injured her fellow employee. As a result of the accident, the plaintiff suffered a serious psychiatric illness. She sought damages for nervous shock from the defendant. Judge McMahon (as he then was) remarked that:

²¹⁴ *Jaensch v Coffey* (1984) 155 CLR 549.

²¹⁵ Quill, E, *op cit*, 68-69, citing: *Kelly v Hennessy* [1995] 3 IR 253 (SC). See also *Curran v Cadbury (Ireland) Ltd* [2000] 2 ILRM 343 (Circ Ct) (Judge McMahon). (The plaintiff had a reasonable though unfounded belief of having caused injury to a co-worker through her employer's unsafe system of work that allowed a piece of equipment to be set in operation although someone was inside the apparatus).

²¹⁶ *Tame v New South Wales, Annetts v Australian Stations Pty Ltd* [2002] HCA 35.

²¹⁷ See Ryan, R, Ryan, D, *Some Comments about Caution: Emerging Trends in Irish Negligence Law* (2004) 7 Trinity College Law Review 114, 127.

²¹⁸ *Curran v Cadbury (Ireland) Ltd* [2000] 2 ILRM 343 (Circ Ct). See also Handford, P, *Psychiatric injury in breach of a relationship* (2007) 27 Legal Studies 26, 38 (n).

"... the English courts imposed liability where the plaintiff foreseeably suffered a nervous breakdown because of unreasonably stressful working conditions imposed on him by his employer. There is no reason to suspect that our courts would not allow this line of authority if it came before the courts in this jurisdiction."²¹⁹

McMahon J held that the plaintiff was a 'primary victim' in the sense that she was a participant in the accident and suffered injury as a direct consequence. She was not a 'secondary victim', that is a person who was not involved in the accident itself, but was removed from the direct action or came on the immediate aftermath of the accident. The learned judge opined that he was not convinced that the separation of victims into these two categories does anything to assist the development of legal principles that should guide the courts in this complex area of the law.

Alcock has been considered in the Irish Supreme Court in *Fletcher v Commissioners of Public Works* and *Devlin v National Maternity Hospital*²²⁰ The Supreme Court in *Fletcher v Commissioners of Public Works* allowed an appeal against an award of damages to the plaintiffs for psychiatric injury resulting from an irrational fear of contracting a disease because of their negligent exposure to health risks by their employers where the plaintiff's medical advisors assessed the risk to be remote.²²¹ It was unreasonable in the circumstances to impose a duty of care on employers to guard against mere fear of a disease even if such fear might have led to a psychiatric condition. Binchy states that the *Fletcher* case strikes a blow, not against malingering plaintiffs, but against "genuine victims of carelessness in the workplace."²²² Murphy and Witting note that, in *Grievs v FT Everard & Sons Ltd*,²²³ there was no relevant external event, "such as occurs in the

²¹⁹ [2000] 2 ILRM 343, 349, per Judge McMahon. The reasoning in *Curran v Cadbury* has been approved in *Fletcher v Commissioners of Public Works* [2003] 1 IR 465 (Sup Ct) and in *McGrath v Trintech Technologies Ltd* [2005] 4 IR 382 (HC) (Laffoy J). In *Quigley v Complex Tooling and Moulding Ltd* [2009] 1 IR 349, *Curran v Cadbury* was followed in the High Court (Lavan J) and considered in the Supreme Court. See also *Walker v Northumberland County Council* [1995] 1 All ER 737.

²²⁰ *Fletcher v Commissioners of Public Works* [2003] 1 IR 465 (SC); *Devlin v National Maternity Hospital* [2008] 2 IR 222 (Sup Ct).

²²¹ *Fletcher v Commissioners of Public Works* [2003] 1 IR 465 (SC). See also Binchy, W, *Recent Developments in Tort Law* [2004] 1 Judicial Studies Institute Journal 8, 10-17. See also Miller, C, *Environmental Rights: European Fact or English Fiction?* (1995) 22 Journal of Law and Society 374, 377, citing: *Gunn v Wallsend Slipway and Engineering Co Ltd*, *The Times*, 23 January, 1989, in which it was held that an employer's duty of care did not extend to the family of an employee (whose wife's fatal lung cancer was alleged to have been caused by asbestos fibres brought into the home on her husband's clothing).

²²² Binchy, W, *The Implications of the Act for Tort Law and Practice*, Chapter in Quigley, P, Binchy, W (Editors), *The Personal Injuries Assessment Board Act 2003: Implications for Legal Practice* (2004) First Law, Dublin, 117.

²²³ Reported *sub nom Rothwell v Chemical & Insulating Co* [2008] 1 AC 291 (HL).

more usual psychiatric illness case,”²²⁴ with respect to which it had been foreseeable that the claimant might suffer a psychiatric reaction. In *Devlin*, Denham J noted that the common law has evolved by reference to the occurrence of a specific event, a railway or car accident.²²⁵ The learned judge cited from *Alcock* Lord Ackner’s definition of ‘shock’, which had “yet to include psychiatric illness caused by the accumulation over a period of time of more gradual assaults on the nervous system.”²²⁶

Denham J adopted that statement as reflecting “the common law in Ireland where the ‘aftermath’ cases either relate to the event, or the situation in its immediate aftermath.”²²⁷

Negligently induce psychiatric injury was said to arise in “somewhat unusual circumstances” in *A and W v C and D*, where the defendant brothers, executors of their father’s will, demolished a disputed wall in a highly irresponsible manner.²²⁸ The plaintiff, W (who had two previous psychiatric hospital admissions) tried unsuccessfully to prevent the demolition with a motor vehicle.²²⁹

In Quill’s view, the position of rescuers in aftermath cases has been left unresolved: the Supreme Court has held in aftermath cases there must be a close personal relationship between the primary and secondary victims, if a duty is to be imposed in respect of the secondary victim.²³⁰ Quill adds that some support may be derived from the position that rescuer claims are well established in other jurisdictions.²³¹ From the Supreme Court decision in *Phillips v Durgan*, it is clear that a duty of care is owed to rescuers, if a reasonably foreseeable risk of inducing a rescue attempt has been created.²³²

²²⁴ Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 78.

²²⁵ *Devlin v National Maternity Hospital* [2008] 2 IR 222, 239, per Denham J.

²²⁶ *Alcock v Chief Constable of South Yorkshire* [1992] 1 AC 310, 401, per Lord Ackner.

²²⁷ *Devlin v National Maternity Hospital* [2008] 2 IR 222, 239, per Denham J.

²²⁸ Byrne, R, Binchy, W, *Annual Review of Irish Law 2007* (2008) Round Hall, Dublin, 536-540, citing: *A and W v C and D* [2007] IEHC 120 (Laffoy J).

²²⁹ Trespass was not available, as the defendants were executors of the estate and intentional infliction of emotional suffering [under the rule in *Wilkinson v Downton* [1897] 2 QB 57] had not been pleaded: Byrne, R, Binchy, W, *op cit*, 537. See also Watson, P, *Searching the Overfull and Cluttered Shelves: Wilkinson v Downton Rediscovered* (2004) 23 University of Tasmania Law Review 264.

²³⁰ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 73.

²³¹ Quill, E, *loc cit*, citing: *Chadwick v British Transport Commission* [1967] 1 WLR 912; *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383.

²³² *Phillips v Durgan* [1991] 1 IR 89 (Sup Ct). See also *Weir Rodgers v The SF Trust Ltd* [2005] 1 IR 147 (No duty to erect warning notices or barriers in relation to an obvious danger). Also see Townsend, R, *Public Health Policy and Personal Responsibility in Sport - Competitive or Collaborative?* [2007] Sports Law eJournal, Art 5, 4, (One footnote inserted):

“By the late 1990s, changes were afoot with a distinct move away from the values of community responsibility and paternalism and a shift towards ‘risk-choice’ and self-

The facts were these. The plaintiffs, husband and wife, were injured in an accidental fire which occurred in the defendant's premises whilst they were engaged in cleaning those premises at the defendant's request. The fire began in the kitchen as a result of the first plaintiff slipping against a defective gas cooker whilst holding a cloth which consequently caught fire. The fire spread rapidly due to the filthy and greasy state of the kitchen and a large number of old newspapers lying on the floor. The second plaintiff was injured in the process of dragging his wife out of the burning kitchen to safety.

Egan J, in an *ex tempore* judgment, applied the rescue principle on the basis that the plaintiffs were under an obligation to prevent the fire spreading and awarded damages to both plaintiffs. He found that the fire had not started due to any negligence on the part of the plaintiffs nor to the immediate negligence of the defendant, but that the dirty condition of the defendant's premises, for which the defendant was responsible, had contributed to the spreading of the fire. The defendant appealed to the Supreme Court on the grounds, *inter alia*, that the rescue principle did not apply in Irish law and that, as the plaintiffs could see the condition of the premises, they were guilty of contributory negligence. The Supreme Court unanimously dismissed the appeal except on the issue of contributory negligence against the first plaintiff. The first plaintiff was guilty of contributory negligence in failing to take special precautions about the area in which she was working. However, the second plaintiff sustained his injuries in attempting to put out the fire and to rescue the first plaintiff and was not guilty of contributory negligence.

In *O'Neill v Dunnes Stores*,²³³ a member of the public was attacked while assisting a supermarket security guard. As a 'rescuer', the plaintiff sought to have the defendant supermarket held liable for injuries suffered by him. Key issues in the case were whether liability for injury to rescuer extends to the wrongful act of a third party and where the precise nature of the attack had not been foreseen.

responsibility. In 2001, the High Court held that councils do not owe a duty of care to pedestrians who trip on an uneven footpath. There were a string of negligence actions that were linked with council play equipment and other recreational areas. This resulted in many local councils removing play equipment and restricting access to recreational areas in an attempt to limit litigation. In Agar v Hyde [(2000) 201 CLR 552] the High Court determined that no duty of care was owed to two men who sustained spinal injuries whilst playing rugby. The Court stated that the plaintiffs were freely consenting adults who chose to participate in a game which held an obvious element of danger. They could not reasonably expect to hold anyone other than themselves to blame for their injuries."

²³³ *O'Neill v Dunnes Stores* [2011] 1 IR 325 (Sup Ct).

O'Donnell J said that in the case "*there [was] a particularly close connection between the negligence established against the defendant and the injury caused to the plaintiff.*"²³⁴ He went onto to state that the Supreme Court's analysis:

*"... there is little doubt that the need for rescue by a member of the public was caused by the negligence of the defendant. If the defendant had not been negligent ... Mr. [X] and Ms. [Y] would not have had to ask the plaintiff or any other member of the public for help; if the plaintiff had not responded to the requests for help he would not have been injured."*²³⁵

The learned judge said that it "*would indeed be regrettable if the message delivered by the law of tort to a member of the public faced with a cry for help, is that if they intervene they do so at their own risk and that in all the circumstances it would be wiser to pass by on the other side.*"²³⁶

3.2.3.1 Application to Pharmacists in Ireland

Physical damage that may be caused by a pharmacist is readily conceptualised. The possibility for a pharmacist to occasion psychological damage to a patient also exists. A medical practitioner may have set about shielding a vulnerable patient from psychological damage by withholding information regarding the true nature and extent of his illness or the (possibly stigmatising) characteristics of the medication prescribed for him. This general area is one to which the Oireachtas has assigned considerable importance. For example, a request for the disclosure of personal data pursuant to section 7 of the Freedom of Information Act 1997 may, by virtue of section 28 (3) of that Act, be refused where such a request relates to "*a record of a medical or psychiatric nature relating to the requester concerned ... and, in the opinion of the head concerned, disclosure of the information concerned to the requester might be prejudicial to his or her physical or mental health, well-being or emotional condition*". Accepting that psychological damage can occur due to negligent disclosure to a vulnerable patient of the full nature of his illness or the sensitive nature of the medication that has been prescribed for him, such damage may also be caused in other ways outside the scope of this thesis. For example, there could be an intentional disclosure of confidential information to a third party in breach of duty.

²³⁴ [2011] 1 IR 325, 344 per O'Donnell J.

²³⁵ [2011] 1 IR 325, 344 per O'Donnell J.

²³⁶ [2011] 1 IR 325, 345 per O'Donnell J.

3.2.4 Economic Loss

This sub-section sets the context for the analysis of Negligent Misstatement, which is of relevance to pharmacists.

Consequential economic loss (loss consequent on physical damage to the claimant's property) is recoverable; relational loss is loss suffered 'in relation' to physical damage caused to the property of another.²³⁷ The latter is not recoverable in the English courts. A pithy statement of the law was given in *Spartan Steel & Alloys Ltd v Martin & Co (Contractors) Ltd*, where Lord Denning MR stated that "*the question of recovery of economic loss is one of policy*".²³⁸

The policy set by the Court of Appeal in *Spartan Steel* differed from the approach in *Caltex Oil Pty Ltd v The Dredge 'Willemstad'*, where the High Court of Australia held that in certain circumstances a plaintiff could recover damages for relational economic loss.²³⁹ Trindade, Cane and Lunney have rejected the notion that recovery is to be limited to expenses actually incurred as opposed to profits not realised, given that the distinction "*is apt to operate quite fortuitously*."²⁴⁰ The High Court of Australia in *Perre v Apand* confirmed its position in *Caltex Oil* and introduced the control mechanism in the requirement that the plaintiff be a member of a foreseeable, ascertainable class of persons to ward off indeterminate liability.²⁴¹

Klar states that *Canadian National Railroad v Norsk Pacific Steamship Co* and *Bow Valley Huskey (Bermuda) Ltd v Saint John Shipbuilding Ltd* are cases that show where a solution to the problem of indeterminacy in the absence of countervailing policy factors will lead to the imposition of a duty.²⁴² In *Bow Valley Huskey (Bermuda) Ltd*, the imposition of a duty to warn was negated by the spectre of indeterminate liability.

²³⁷ Beever, A, *Rediscovering the Law of Negligence* (2007) Hart, Oxford, 224.

²³⁸ *Spartan Steel & Alloys Ltd v Martin & Co (Contractors) Ltd* [1973] 1 QB 27, 36, Per Lord Denning MR. See also Perry, R, *The Deepwater Horizon Oil Spill and the Limits of Civil Liability* (2011) 86 Washington Law Review 1, 10-21 generally, and in particular, [12], (n 65), citing the *Restatement (Second) of Torts*, § 766C (1979) ("*One is not liable to another for pecuniary harm not deriving from physical harm to the other.*").

²³⁹ *Caltex Oil Pty Ltd v The Dredge 'Willemstad'* (1976) 136 CLR 529 (HCA).

²⁴⁰ Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 756.

²⁴¹ *Perre v Apand Pty Ltd* (1999) 198 CLR 180 (HCA). See also Coveney, G, *Who Said You Can't Have It All? The perils of ignoring risk allocate on in cases of relational economic loss* (2007) 19 Bond Law Review, Iss 1, Art 4, 5: "*Whether the reasons justifying recovery for economic loss caused by negligent misstatement could be attacked on the same basis as those concerning relational economic loss is now somewhat moot. In Australia at least, the provisions of Part V of the Trade Practices Act 1974 (Cth) provide a statutory basis for that relief.*"

²⁴² Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 273: *Canadian National Railroad v Norsk Pacific Steamship Co* (1992) 91 DLR (4th) 289; *Bow Valley Huskey (Bermuda) Ltd v Saint John Shipbuilding Ltd* [1997] 3 SCR 1210.

Pure Economic Loss

Relational loss arises from damage to something other than the plaintiff's own person or property: *Cattle v Stockton Waterworks Co.*²⁴³ Purely economic losses, not involving injuries to persons or their property, "may be distributed through other methods, such as insurance, and hence should not be the subject of expensive, litigious processes."²⁴⁴ There was an uncompromising stance taken by the House of Lords in *Murphy v Brentwood District Council* against imposing liability on a builder, absent a contractual duty or a *Hedley Byrne* style special relationship of proximity.²⁴⁵ The claimant in *Murphy* was not the first purchaser of the house. Beever treats *White v Jones*, a paradigm 'disappointed beneficiary case', as an exception to the rule that pure economic loss is irrecoverable.²⁴⁶ The author agrees that *White v Jones* may certainly be characterised thus, however the majority of commentators place it in the 'extended *Hedley Byrne*' category. In *Associated Consolidated Press v Uren*,²⁴⁷ the Privy Council acknowledged that there was scope for divergent development in the common law in the different jurisdictions that retained the right of appeal to the Privy Council.²⁴⁸ Clear divergence is evident in *Invercargill City Council v Hamlin*.²⁴⁹ Five socio-political factors, such as New Zealand's high proportion of owner-occupied housing and considerable Government support for private housing (not dissimilar to Ireland), coupled with the Building Act 1991 (NZ) and other relevant

²⁴³ *Cattle v Stockton Waterworks Co* (1875) 10 QB 453.

²⁴⁴ Klar, LN, *op cit*, 269. See also Benson, P, *The Problem with Pure Economic Loss* (2009) 60 South Carolina Law Review 823, 829. See also Carty, H, *An Analysis of the Economic Torts* (2001) Oxford University Press, Oxford, 239: the judicial policy was to redress "only the proximate and direct consequences of wrongful acts" (attributed originally to Coleridge J in *Lumley v Gye* (1853) 118 ER 749, 760).

²⁴⁵ *Murphy v Brentwood District Council* [1991] 1 AC 398, 480 (HL)

²⁴⁶ Beever, A, *Rediscovering the Law of Negligence* (2007) Hart, Oxford, 115, citing *White v Jones* [1995] 2 AC 207.

²⁴⁷ *Associated Consolidated Press v Uren* [1969] AC 590 (PC).

²⁴⁸ See Beckmam, RC, *Divergent Development of the Common Law in Jurisdictions Which Retain Appeals to the Privy Council* (1987) 29 Malaya Law Review 254, 254-256. In *Kirmani v Captain Cook Cruises Pty Ltd (No 2)* (1985) 159 CLR 461, 461, the High Court of Australia unanimously refused to grant a certificate under s.74 of the Constitution of Australia, describing "the vestigial remnant of the hierarchical connection which formerly existed between Australian courts exercising federal jurisdiction and the Privy Council" (i.e. jurisdiction affecting the Commonwealth of Australia and the States *inter se*). In passing, the New Zealand Attorney-General's Discussion Paper, *Reshaping New Zealand's Appeal Structure* (2000) Crown Law Office, Wellington. Available from <http://www.crownlaw.govt.nz/uploads/PCDiscuss.pdf> (Last accessed 12 January, 2012), stated ([2]): "In recent times the Privy Council itself has acknowledged that final decisions on matters of important legal policy are best made in New Zealand by referring cases back to the Court of Appeal", citing: *Invercargill City Council v Hamlin* [1996] 1 NZLR 513 and *Lange v Atkinson* [2000] 1 NZLR 257. See also McInnis, JA, *Commonwealth Courts and the Move Away from English Authority in Tort Law* (1997) 27 Hong Kong Law Journal 28. See also Stapleton, J, *Benefits of Comparative Tort Reasoning: Lost in Translation* (2007) Journal of Tort Law Vol 1, Iss 3, Art 6, 7.

²⁴⁹ *Invercargill City Council v Hamlin* [1996] 1 NZLR 513 (NZCA). See also Todd, S, *Negligence: Particular Categories of Duty*, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 270: it was fortuitous for the plaintiff that the New Zealand Court of Appeal found the Council to be responsible for its surveyor's negligence, as the builder had long since ceased trading.

issues “*meant that the defendant had assumed responsibility to the claimant.*”²⁵⁰ This view was endorsed by a majority of the High Court of Australia in *Bryan v Maloney*.²⁵¹

The High Court of Australia, in *Woolcock Street Investments Pty Ltd v CDG Pty Ltd*,²⁵² “*refined its position*” denying a duty towards a subsequent purchaser of a commercial property.²⁵³ Liability was to be imposed only in respect of a ‘vulnerable’ claimant (who could not protect himself from loss by other means).²⁵⁴ Sometimes, as in *Rolls Royce New Zealand Ltd v Carter Holt Harvey Ltd*, a plaintiff will be expected to pursue an available contractual remedy for economic loss, as opposed to tort, which “*provides only remedies of last resort.*”²⁵⁵

In *McShane Wholesale Fruit and Vegetables Ltd v Johnston Haulage Co*,²⁵⁶ Flood J did not apply the exclusionary rule: *McShane* has probably been overruled by *Glencar Explorations plc v Mayo County Council (No 2)*.²⁵⁷

3.2.5 Negligent Misstatement

Prior to the House of Lords decision in *Hedley Byrne & Co Ltd v Heller & Partners Ltd* liability for negligent misstatement was confined to a fiduciary relationship between the parties or a misstatement going to a contractual term between them.²⁵⁸ This was the view of the majority in *Candler v Crane Christmas & Co*.²⁵⁹ There can have been few dissenting judgments so frequently cited as the one from Denning LJ (as he then was) in *Candler v Crane Christmas & Co* set forth in what Witting appropriately calls an “*important dissent*”.²⁶⁰ The door to recognising a duty in

²⁵⁰ Beever, A, *op cit*, 115, citing *White v Jones* [1995] 2 AC 207. See also Stapleton, J, *op cit*, 17: “... *though Australia and New Zealand are extremely close in many socio-economic and cultural ways, aspects of their tort systems could not be in starker contrast ... even when a federal system such as Australia has a unified ‘common law’, the ‘law of torts’ will diverge where the states have legislative capacity in the field traditionally addressed by common law of torts.*”

²⁵¹ *Bryan v Maloney* (1995) 182 CLR 609.

²⁵² *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* (2004) 216 CLR 515.

²⁵³ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 128.

²⁵⁴ Beever, A, *Rediscovering the Law of Negligence* (2007) Hart, Oxford, 254. See also *Winnipeg Condominium Corporation No 36 v Bird Construction Co* [1995] 1 SCR 85 (Dangerous defects).

²⁵⁵ Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 464, citing: *Rolls Royce New Zealand Ltd v Carter Holt Harvey Ltd* [2005] 1 NZLR 324 (CA).

²⁵⁶ *McShane Wholesale Fruit and Vegetables Ltd v Johnston Haulage Co* [1997] 1 ILRM 86.

²⁵⁷ *Glencar Explorations plc v Mayo County Council (No 2)* [2002] 1 IR 84. See Quill, E, *op cit*, 65.

²⁵⁸ *Hedley Byrne & Co Ltd v Heller & Partners Ltd* [1964] AC 465 (HL).

²⁵⁹ *Candler v Crane, Christmas & Co* [1951] 1 All ER 426. See also Winfield, PH, *The History of Negligence in the Law of Torts* (1926) 42 Law Quarterly Review 184, 198: “*It is worth while noting here that deceit was disembarassed of negligence in 1889*” in *Derry v Peek* (1889) 14 App Cas 337.

²⁶⁰ *Candler v Crane, Christmas & Co* [1951] 1 All ER 426. See Witting, C, *The Law of Negligent Misstatement* (2004) Oxford University Press, Oxford, 158-159. Witting regarded that dissent (rightly in the author’s view) as sufficiently important to merit an entire Section within a Chapter for its exploration.

relation to negligent words opened with *Nocton v Lord Ashburton*: the courts may find other special relationships to exist, distinct from contractual or fiduciary ones.²⁶¹ Denning LJ noted that the defendant (accountant) was a professional person, of whom the law expects a high degree of skill in carrying out professional activities. Proximity was the key: persons who were (or at any rate who ought to have been) in the contemplation of the accountant were “*not restricted to those in contractual relations*”.²⁶² Foreseeability is not an effective control mechanism, as the range of foreseeable consequences is “*almost limitless*”.²⁶³ The concept of foreseeability has been scrutinised closely in *Grieves v FT Everard & Sons Ltd*, among the tetralogy of appeals in *Rothwell v Chemical & Insulating Co*,²⁶⁴ where Lord Hoffmann said: “*The answers to a test of foreseeability will vary according to, first, the precise description of what should have been foreseen and, secondly, the degree of probability which makes it foreseeable.*”²⁶⁵ In *Hedley Byrne* it was established in English law that a duty exists where there is a ‘special relationship’ between the parties and the statement’s maker can foresee that the recipient will rely upon the statement.²⁶⁶ On the facts, the defendants benefited from an express disclaimer incorporated in the statement.

McMahon and Binchy pose the question of whether *Macken v Munster & Leinster Bank Ltd and O’Grady* could be regarded as an Irish harbinger of *Hedley Byrne*. The author considers this Circuit Court decision to be an excellent candidate for that appellation. With only one exception, the cases cited in argument and within the judgment of Judge Deale arose well before 1950.²⁶⁷ In *Securities Trust Ltd v Hugh Moore & Alexander Ltd*, Davitt P held that the defendant company owed a duty to a member of the defendant company to ensure that the copy of the company’s

²⁶¹ *Nocton v Lord Ashburton* [1914] AC 932 (HL).

²⁶² Witting, C, *op cit*, 159.

²⁶³ Quill, E, *op cit*, 46.

²⁶⁴ *Rothwell v Chemical & Insulating Co* [2008] 1 AC 291 (HL).

²⁶⁵ [2008] 1 AC 291 (HL), 295, [29], per Lord Hoffmann.

²⁶⁶ Quill, E, *loc cit*.

²⁶⁷ McMahon, and Binchy, *Irish Law of Torts* Third Edition (2000) Butterworths, Dublin, 218, citing *Macken v Munster & Leinster Bank Ltd and O’Grady* (1960) 95 ILTR 17 (Circ Ct). The only quite contemporary authority to *Macken* cited in that judgment, is a decision of Salmon J, *Woods v Martin Bank Ltd & Anor* [1958] 3 All ER 166 (Leeds Assizes). The barrister who prepared the report made it plain (at 167) that the “*case is reported only on the responsibility of the defendant bank for financial advice honestly but negligently given.*” Salmon J said [[1958] 3 All ER 166, 172] that the cause of action in fraud failed, as he was not persuaded that the defendant, Mr. Johnson, “*did not honestly believe in the advice which he gave to the plaintiff.*” *Macken* may be contrasted with *Woods*, as the latter involved a customer of the defendant bank while the former did not. Neither case mentions *Candler v Crane, Christmas & Co* [1951] 1 All ER 426. Salmon J did review the *Candler* case (and other earlier authorities) in a later judgment, *Clayton v Woodman & Son (Builders) Ltd* [1962] 2 QB 533, 544-545. In *Clayton*, the learned judge queried the distinction between the duty of care in making a statement causing physical loss and one causing financial loss. Therefore, it is submitted, *Macken’s* case would appear to be the first reported judgment, in the British and Irish common law sphere, which imposed liability for negligent words on a similar basis to the one that the House of Lords would proclaim, around four years afterwards.

Memorandum and Articles of Association supplied to that member was accurate.²⁶⁸ Such a duty was not owed to the community at large, including the plaintiff company. *Hedley Byrne* received Supreme Court approval in *Bank of Ireland v Smith*.²⁶⁹ Kenny J held that a relationship ‘equivalent to contract’ (lacking only the *indicium* of contractual consideration) in circumstances where there was an assumption of liability was a prerequisite to imposition of liability.²⁷⁰

TE Potterton Ltd v Northern Bank Ltd is the illustration Quill sets forth for the following proposition of the law: “As a general rule, a bank owes no duty of care to the payee of a cheque, but where the bank voluntarily proceeds to offer an explanation of its conduct, it may owe a duty in relation to representations arising from that explanation.”²⁷¹

The House of Lords introduced “a more constrained [conceptual] approach” to the imposition of a duty in respect of negligent misstatements.²⁷² For a special relationship to exist, the defendant would be required to have knowledge of the plaintiff, either as an individual or as a member of an identifiable class of persons. The foreseeability requirement was “construed as requiring that the purpose of making the statement was connected with a specific transaction or type of transaction.”²⁷³

The Irish Supreme Court in *Wildgust and Carrickowen Ltd v Bank of Ireland and Norwich Union Life Assurance Society* refused to adopt the *Caparo* formulation on the facts, but reserved its view on

²⁶⁸ *Securities Trust Ltd v Hugh Moore & Alexander Ltd* [1964] IR 417 (HC).

²⁶⁹ *Bank of Ireland v Smith* [1966] IR 646 (Sup Ct).

²⁷⁰ McMahon, B and Binchy, W, *Irish Law of Torts*, Third Edition (2000), LexisNexis Butterworths, Dublin, 220.

²⁷¹ Quill, E, *loc cit*, citing: *TE Potterton Ltd v Northern Bank Ltd* [1993] 1 IR 414 (Misstatement that a mere technical difficulty existed in clearing a cheque rather than the true position of the drawer’s insufficiency of funds).

²⁷² Quill, E, *op cit*, 49. See also Mitchell, P, *Hedley Byrne & Co Ltd v Heller & Partners Ltd* (1963), Chapter in Mitchell, C, Mitchell, P (Editors), *Landmark Cases in the Law of Tort* (2010) Hart Publishing, Oxford, 177. See also Strong, AJ, “But he told me it was safe!”: *The Expanding Tort of Negligent Misrepresentation* (2009) 40 *University of Memphis Law Review* 105, 111 (n 14), citing *Derry v Peek* (1889) LR 14 App Cas 337 for its reporting that “no cause of action is maintainable for a mere statement, although untrue, and although acted upon to the damage of the person to whom the statement is made, unless the statement be false to the knowledge of the person making it” [quoting *Dickson v Reuter’s Telegraph Co Ltd* (1877) LR 3 Com Pl 1]. Mitchell (*op cit*, 178) underlines that at the time of *Hedley Byrne v Heller* the House of Lords had yet to free itself to depart from its own earlier decisions. That was to come about through the *Practice Statement (Judicial Precedent)* [1966] 1 WLR 1234. See also Oliphant, K, *Fairchild v Glenhaven Funeral Services Ltd* (2002), Chapter in Mitchell, C, Mitchell, P (Editors), *Landmark Cases in the Law of Tort* (2010) Hart Publishing, Oxford, 354, referring to occasions on which the House of Lords had been asked to review its own approach under the 1966 Practice Statement “in the light of the perception that it [was] out-of-line internationally”, e.g. *Hall (Arthur JS) & Co v Simons* [2002] 1 AC 615 (HL).

²⁷³ Quill, E, *op cit*, 49-50.

whether that might formulation might be applied in another case.²⁷⁴ There the court found that personal reliance (usually an ingredient in a successful claim) was not a *sine qua non* and third party reliance was sufficient.²⁷⁵ Quill emphasises that “*actual reliance* is a causal requirement; duty is only concerned with whether the reliance can be anticipated and is reasonable.”²⁷⁶ Witting clarifies that ‘extended *Hedley Byrne* cases’ are decided by analogy with *Hedley Byrne*, rather than directly on its authority, and such cases typically involve a third party: “*ordinarily there is no mutuality of relations between the parties.*”²⁷⁷ Witting has identified the most important proximity factors in such cases.²⁷⁸

Comparative skill or expertise

In *Spring v Guardian Assurance plc*, a duty to provide a reference was part of the background to a claim in negligent misstatement, when defamation was not an option.²⁷⁹

Actual knowledge

The ‘wills cases’, like *White v Jones*, show that there are good reasons for imposing liability when the person with the knowledge (e.g. a solicitor) is aware of the damage that can result (e.g. to disappointed beneficiaries).²⁸⁰

Conscious decision

Again, *White v Jones* is the paradigm, where the solicitor knew the implications of accepting the testator’s instructions.

Tight causal connections

Here again *White v Jones* is an example. Also *Hill v Van Erp*, in respect of which Witting commented that the case pointed to the “*almost-inevitable loss that will befall the beneficiary*”.²⁸¹

²⁷⁴ Quill, E, *op cit*, 50, citing: *Wildgust and Carrickowen Ltd v Bank of Ireland and Norwich Union Life Assurance Society* [2006] 1 IR 570.

²⁷⁵ Quill, E, *op cit*, 51.

²⁷⁶ Quill, E, *loc cit*.

²⁷⁷ Witting, C, *Duty of Care: An Analytical Approach* (2005) 25 Oxford Journal of Legal Studies 33, 58 and, generally, 58-61. The ‘extended’ label is derived from *White v Jones* [1995] 2 AC 207, 268 and 270, where Lords Goff and Browne-Wilkinson called for extension by analogy of the *Hedley Byrne* principle to the facts of the case.

²⁷⁸ Witting, C, *op cit*, 59-61. See also Carty, H, *An Analysis of the economic Torts* (2001) Oxford University Press, Oxford, 259: “*The malicious falsehood tort, unlike negligence, always protects in a three-party setting*”.

²⁷⁹ *Spring v Guardian Assurance plc* [1995] 2 AC 296 (HL). See also: *Midland Metals Overseas Pty Ltd v The Christchurch Press Co Ltd* [2001] NZLR 289 (CA), [51] (Blanchard J). See also: Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 505 (n), citing *Sullivan v Moody* (2001) 207 CLR 562 and making the point that tort law should not be used to outflank defamation law.

²⁸⁰ *White v Jones* [1995] 2 AC 207.

²⁸¹ Witting, C, *op cit*, 61, citing: *Hill v Van Erp* (1997) 188 CLR 159.

Few cases have imposed a duty despite an express disclaimer. One such case is *Walsh v Jones Lang Lasalle Ltd*: evidence of commercial practice that such disclaimers in an auctioneer's brochure were taken to cover merely minor inaccuracies was accepted by Quirke J.²⁸²

In *ACC Bank PLC v Fairlee Properties Ltd*, Counsel for the plaintiff sought to rely upon the speech of Lord Hoffmann in *South Australia Asset Management Corporation v York Montague Ltd* (SAAMCO).²⁸³ In SAAMCO, Lord Hoffmann stated: "A plaintiff who sues for breach of a duty ... (whether in contract or tort or under statute) must ... show that the duty was owed to him and that it was a duty in respect of the kind of loss which he has suffered."²⁸⁴

Later, Lord Hoffmann said: "A plaintiff has to prove both that he has suffered loss and that the loss fell within the scope of the duty."²⁸⁵ On the facts of the SAAMCO case, it was held that the lender was not entitled to recover a loss greater than the difference between the negligent valuation and the true valuation and not the loss resulting from the reduction in market value. Finlay Geoghegan J opined that SAAMCO was consistent with authorities binding on her, by implication *Glencar v Mayo County Council*, which she mentioned extensively earlier in her judgment.²⁸⁶

Quill makes a forceful point that "[t]he only truly voluntary aspect [in the voluntary assumption of responsibility conceptual model] is that the defendant chooses whether to make the statement."²⁸⁷ Quill states that 'voluntary assumption of responsibility' could be misleading, and this author agrees, in giving "the impression that the existence of a duty is a matter for the subjective choice of the defendant." This can be only one of several competing factors from which the Court may determine whether a duty is to be imposed.²⁸⁸

²⁸² *Walsh v Jones Lang Lasalle Ltd* [2007] IEHC 28. See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 52. Also see Byrne, G, *Negligent Misrepresentation: Recent Developments in English and Irish Law* (2008) 2(4) Quarterly Review of Tort Law 22, 27 (critical of the decision for not reducing the damages for contributory negligence).

²⁸³ *ACC Bank PLC v Fairlee Properties Ltd* [2009] IEHC 45, Finlay Geoghegan J, discussing *South Australia Asset Management Corporation v York Montague Ltd* [1997] AC 191 (HL).

²⁸⁴ *South Australia Asset Management Corporation v York Montague Ltd* [1997] AC 191, 211. See also Todd, S, *Negligence: The Duty of Care*, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 213: "In *Prime Commercial Ltd v Wool Board Disestablishment Co Ltd* [[2006] NZCA 295] the Court of Appeal held that an attempt to use the tort of negligence to make up for the lack of a process contract should be rebuffed on policy grounds. A vendor of property might, conceivably, commit itself to process obligations. But where such obligations had not been assumed, it was difficult to detect a principled basis upon which a vendor could be held to have a duty of care to protect the interests of prospective purchasers."

²⁸⁵ *South Australia Asset Management Corporation v York Montague Ltd* [1997] AC 191, 218.

²⁸⁶ *ACC Bank PLC v Fairlee Properties Ltd* [2009] IEHC 45, [81], Finlay Geoghegan J.

²⁸⁷ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 51.

²⁸⁸ Quill, E, *loc cit*.

The *Glencar (No 2)* decision is a major setback to those who would sue a public body for the negligent exercise of a statutory function. The position is different where the public body is sued as a private party.

There was a successful outcome for the plaintiffs in *Walsh v South Tipperary County Council*.²⁸⁹ It was agreed between the parties that a mistake had been made by the defendant Council in issuing a letter or certificate in respect of a public right of way. Its true extent was not properly recorded in a new digital database that the defendant created (since the year 2000). In the course of a subsequent conveyancing transaction, that error was discovered. As a result of that error, the sale ultimately closed but on significantly less advantageous terms. The defendant was sued in negligent misstatement. Apart from a failure to mitigate loss, the character or nature of losses “being concerned with concessions made to secure closure in a falling market and losses attributable to delay”²⁹⁰ had been foreseeable.

The recent case of *Bates v Minister for Agriculture, Fisheries and Food* is similarly noteworthy in this branch of the law.²⁹¹ There was a misstatement by an official of the defendant Department regarding the entitlement of the plaintiffs to fish for scallops in Area VIIIa within the Bay of Biscay. It was as a result of having received the (admitted) assurances that they fished in Area VIIIa in contravention of an EU Regulation (dating from 1995). The plaintiffs incurred expenditure and loss as a result of the arrest of two vessels, confiscation of the catch, and criminal and civil proceedings in France. It was agreed between the parties that the gross outlay incurred by the plaintiffs was €40,000. Laffoy J awarded an additional sum of €9,600 in relation to lost earnings arising from some days of fishing activity that would have been possible before that opportunity had been foreclosed by implementation of an EU Regulation (dating from 2003).

3.2.5.1 Application to Pharmacists in Ireland

It is submitted that a not insignificant obstacle to a judicial holding that a pharmacist is liable to a patient in negligent misstatement is the difficulty in proving the existence of a contractual or fiduciary relationship between the pharmacist and the patient.

²⁸⁹ *Walsh v South Tipperary County Council* [2011] IEHC 503, Clarke J.

²⁹⁰ [2011] IEHC 503, [6.1], per Clarke J.

²⁹¹ *Bates v Minister for Agriculture, Fisheries and Food* [2011] IEHC 429, Laffoy J.

The recent case of *Thompson v Potter*²⁹² required the New Mexico Court of Appeals to examine, as a matter of impression, the nature of the duty owed by a consulting pharmacist holding a contract with a nursing facility to provide pharmaceutical services to the patients therein. The plaintiff sued, asserting that his deceased wife's seizure was caused by the sudden and abrupt withdrawal of Ativan (a benzodiazepine drug). He did not sue the nurse who improperly transcribed the doctor's order, the nurse's employer, Casa Arena, or the doctor who changed the prescription. He sued NCS Healthcare of Albuquerque, which was under contract with Casa Arena to provide pharmacy consultant services and pharmacy services to Casa Arena, and its registered pharmacist, the defendant, Doyle Potter.

The plaintiff did not point to the extrinsic evidence that might establish intent to benefit a third party to the contract, nor did he point to any specific ambiguity in the contract (which excluded conferral of third party rights). The New Mexico Court of Appeals concluded that the plaintiff failed to submit admissible relevant evidence to demonstrate an issue of material fact.

Although the appellate bench held that the defendants had been properly granted summary judgment on all the plaintiff's claims, no doubt *Thompson v Potter* (as a persuasive authority) will focus attention on the consulting pharmacist's role, whether viewed in a contract or tort setting. As nursing home facilities become more numerous and larger in size in Ireland, depending on the intention of the parties entering into a pharmacy consultancy arrangement, the consulting pharmacist role may embrace patients as third parties.

3.3 Breach of Statutory Duty

Let us now consider whether a pharmacist may be liable to a civil claim in tort for damages for breach of statutory duty taken by, or in respect of, a patient. This section sets the context for the section on the Pharmacy Act 2007 and Associated Duties of the Pharmacist in Ireland.

²⁹² *Thompson v Potter* (2011) 268 P3d 57 (NM Ct App). See also Sawicki, NN, *Patient Protection and Decision-Aid Quality: Regulatory and Tort Law Approaches* (2012) 54 Arizona Law Review 621, 666: "... no privity is required for liability in pharmaceutical advertising and labeling cases, despite the fact that the patient and pharmaceutical manufacturer are separated by at least two intermediaries — the prescribing physician and the pharmacist."

The action for breach of statutory duty can arise where the criminal law (or regulatory law) imposes a duty on the defendant to act or avoid acting in a particular way, under pain of sanction and the statutory provision in question is enacted or made for the benefit of a particular class of people, rather than the public at large.²⁹³

Quill contrasts statutory provisions with negligence: “*unlike negligence, [statutory provisions] do not have a single behavioural standard for the discharge of the obligations created*”.²⁹⁴ The availability of an action can be determined in one of three ways:

- “(i) *There may be a statutory scheme of liability in which all the elements are contained in the statute, such as the Liability for Defective Products Act 1991 and the Occupiers’ Liability Act 1995.*

- “(ii) *There may be a specific section in the statute expressly governing actionability, such as section 21 of the Control of Dogs Act 1986.*

- “(iii) *Where there is no express provision in the statute governing the availability of a civil action to enforce the obligations contained therein, it is a matter of judicial interpretation of the statute to determine whether such an action is available.*”²⁹⁵

In the case of *Doe Dem Murray, Lord Bishop of Rochester v Bridges*, Lord Tenterden CJ canvassed two propositions:

“[A]s the Act has provided for its payment and recovery in [a particular] manner, it appears to us that there can be no other mode of enforcing the payment. ... And where an Act creates an obligation, and **enforces the performance in a specified manner**, we take it to be a general rule that performance cannot be enforced in

²⁹³ Proving the existence of a statutory duty in the first instance may not be possible: see, for example, *Delahunty v South Eastern Health Board, St Joseph's Industrial School, Kilkenny and The Minister for Education and Science* [2003] 4 IR 361. There was an allegation that the defendant Minister failed to make regulations under the Children Act 1941, s 3. However desirable the making of such regulations might have been, there was no statutory duty imposed on the Minister to make such regulations.

²⁹⁴ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 140.

²⁹⁵ Quill, *ibid*. The first of the three options is described as a statutory tort, while the second and third involve the common law action for breach of duty. The British and Irish approach is to be contrasted with the approach in the American courts (negligence *per se*) and in the Canadian courts—see *The Queen (Canada) v Saskatchewan Wheat Pool* [1983] 1 SCR 205. In those jurisdictions, the standard of care is contained in the statute.

*any other manner. If an obligation is created, but **no mode of enforcing its performance is ordained**, the common law may, in general, find a mode suited to the particular nature of the case.”*²⁹⁶

The first proposition precluded a civil remedy, when a criminal sanction had already been specified.²⁹⁷ The second is self-explanatory. A modern restatement of the gradually developed exceptions to the first proposition has been set out in *Lonrho Ltd v Shell Petroleum (No 2)*²⁹⁸:

“[T]here are two classes of exception to [the] general rule[:]

*The first is where upon the true construction of the Act it is apparent that the obligation or prohibition was imposed for the benefit or protection of a particular class of individuals, as in the case of the Factories Acts and similar legislation.*²⁹⁹ ...

*The second exception is where the statute creates a public right ... and a particular member of the public suffers what Brett J in *Benjamin v Storr*³⁰⁰ described as ‘particular, direct, and substantial’ damage ‘other and different from that which was common to all the rest of the public.’”³⁰¹*

The requirement for suffering additional harm above other members of the same class was discussed in *M'Daid v Milford Rural District Council*.³⁰² A rural district council made an improvement scheme under the Labourers Acts based upon a representation signed by, or on

²⁹⁶ *Doe Dem Murray, Lord Bishop of Rochester v Bridges* (1831) 109 ER 1001, 1005-1006, per Lord Tenterden CJ. (Emphasis added).

²⁹⁷ Quill, *op cit*, 143.

²⁹⁸ *Lonrho Ltd v Shell Petroleum (No 2)* [1982] 1 AC 173.

²⁹⁹ See also *Gallagher v Mogul of Ireland Ltd* [1975] IR 204 (Sup Ct). The Mines and Quarries Act 1965, s49(1) states that “it shall be the duty of every manager of every mine to take such steps by way of controlling movement of the strata in the mine and supporting the roof and sides of every road or working place as may be necessary for keeping the road or working place secure”. The Supreme Court held that the relevant duty is absolute in the sense that liability for a breach of that duty is not dependent upon what could or could not have been reasonably foreseen by the person alleged to have contravened the sub-section. See also *Daly v Greybridge Co-operative Creamery Ltd* [1965] IR 497; an invitee (or, post-1995, a lawful entrant) was not a member of a class covered by the Factories Act 1955. The Supreme Court held in *Sweeney v Duggan* [1997] 2 IR 531 (*affirming* Barron J, [1991] 2 IR 274) that the statutory duty imposed on the defendant by the Mines and Quarries Act 1965, s23, related only to safety and imposed no general statutory duty of care of the type which the plaintiff sought to establish; the Mines and Quarries Act 1965 does not include any obligation to insure.

³⁰⁰ *Benjamin v Storr* (1874) LR 9 CP 400, 407.

³⁰¹ [1982] 1 AC 173, 185, per Lord Diplock.

³⁰² *M'Daid v Milford Rural District Council* [1919] 2 IR 1 (CA).

behalf of agricultural labourers. Amongst those was the plaintiff, whose representation was in respect of a cottage and about an acre of land. Regulations in pursuance of section 29 of the Labourers (Ireland) Act 1906 were framed and adopted by the council. Pending the erection of the cottage, the council, acting under section 15 of the Labourers (Ireland) Act 1886 made a temporary letting of the plot to a farmer who had not signed a representation, whereupon the plaintiff claimed damages on the ground that they were bound to give him a preference.³⁰³

Ronan LJ said the following:

*“It appears to me that the application of the statutory preference only arises when they have arrived at the conclusion that they can properly give a cottage to any one of two or more labourers, and that there is no substantial ground for giving it to one more than to another. In such a case, the statutory preference would make it their duty to give it to the representators. ... The competitors consist of all agricultural labourers. Giving a plot to a farmer deprives all the competitors of the right to compete. It further deprives all the representators of their right to be preferred caeteris paribus to other agricultural labourers. In each case, the injury is to every member of the class. **There is no special injury to any particular member.** The King's Bench Division judgment shows that, in the case of the larger class, it would be absurd to hold that this would give a right of action to every competitor. The judgments in the House of Lords seem to me to apply the same principle to the smaller class.”³⁰⁴*

A statutory instrument will not normally create a contractual remedy for breach of its provisions. The possibility of suit in the tort of breach of statutory duty appears more promising. Where there is no express provision in a statute “*governing the availability of a civil action to enforce the obligations contained therein*”, it is a matter for the court to determine whether such an action is available.³⁰⁵ It is relatively simple to put forward conceptually that a patient or other pharmacy

³⁰³ Labourers (Ireland) Act 1886, 49 & 50 Vic, c 59 and Labourers (Ireland) Act 1906 6 Edw 7, c 37: these two enactments were repealed by the Housing Act 1966 (No 21 of 1966).

³⁰⁴ *M'Daid v Milford Rural District Council* [1919] 2 IR 1, 17, per Ronan LJ (Emphasis added). Ronan LJ went on to contrast the effect of the emergent common law doctrine known today as ‘loss of a chance’. See further [1919] 2 IR 1, 20, per Ronan LJ: “*The case of Chaplin v Hicks* [[1911] 2 KB 786] put side by side with this case makes it perfectly clear that the election of an unqualified person to an office does not give a right of damages to every person who would be a qualified candidate; but if a qualified person comes up to be examined and is excluded from the examination he has a good cause of action. In *Chaplin v Hicks* the plaintiff was a competitor in a group of fifty, from which twelve were to be selected for engagements; and in violation of the terms of the contract the defendant refused to examine the lady.”

³⁰⁵ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 140-145. Quill clarifies that *M'Daid* could be regarded as being in conflict with *dicta* of Lord Diplock in *Lonrho Ltd v Shell Petroleum Co Ltd (No 2)* [1982] 1 AC 173 (which regarded the two limbs, described by Quill as being in the *M'Daid* case separate

patron could suffer a particular kind of harm, which mischief the Regulations were designed to prevent, although that is a matter of construction of the statute for the court to decide. The requirement for the plaintiff to suffer damage over and above other members of the given class of persons does not seem an insurmountable hurdle: ingestion or application of a medicinal product is easier to prove than, for example, in an action for nuisance, that one person was more affected (by the defendant's breach) than other members of the same class.³⁰⁶ Lord du Parc suggested, in *Cutler v Wandsworth Stadium Ltd*,³⁰⁷ that matters would be greatly simplified if statutes made express provision in respect of civil liability for breach of the duties those statutes contained.

In Ireland, one should not ignore the constitutional dimension. In *Lovett v Gogan*,³⁰⁸ the Supreme Court approved the decision reached by O'Hanlon J in the case of *Parsons v Kavanagh*.³⁰⁹ The *Parsons* judgment reviewed the English decisions concerning the right of individuals to institute proceedings for injunctive relief in respect of a criminal offence committed by another in contravention of a statute not considered by the Court as intended to provide protection for the category of persons in which the plaintiff should be numbered. From these cases, it is difficult to postulate an immediate constitutional argument that could possibly avail a patron of a pharmacy: *Parsons* and *Lovett* concerned the right to earn a livelihood. The right to bodily integrity is a more likely litigation topic for patients and other pharmacy consumers. In *W v Ireland (No 2)*,³¹⁰ Costello P held that where the plaintiff's right to bodily integrity is effectively protected by the law of torts, albeit with limitations considered appropriate for the particular tort,³¹¹ the Constitution is not to be construed as conferring a new and discrete cause of action for damages.

We shall return to the application of the foregoing principles of statutory interpretation in the context of members of the public who avail themselves of services provided by pharmacies.

categories of exception). Quill contends that *M'Daid* may be seen as compatible with more modern English authorities, for example, *Hague v Deputy Governor of Parkhurst Prison, Weldon; Weldon v Home Office* [1992] 1 AC 58: see in particular *dicta* by Lord Jauncey of Tullichettle [170-171].

³⁰⁶ See Quill, E, *op cit*, 144-145: damages will not always be the available remedy for breach of statutory duty; alternatives are the grant of an injunction or a prerogative writ (*mandamus*, for instance).

³⁰⁷ *Cutler v Wandsworth Stadium Ltd* [1949] AC 398, 410 per Lord Parcq.

³⁰⁸ *Lovett v Gogan* [1995] 3 IR 195 (Sup Ct).

³⁰⁹ *Parsons v Kavanagh* [1990] ILRM 560.

³¹⁰ *W v Ireland (No 2)* [1997] 2 IR 141 (HC), Costello P.

³¹¹ In *W v Ireland (No 2)*, the plaintiffs, victims in Northern Ireland of the paedophile criminal conduct of Revd. Brendan Smyth, were held not to be in a sufficiently proximate relationship with the Attorney-General to impose on him a duty of care towards them when exercising his functions in relation to the extradition of the accused.

The interest of the legislators is to give to the victim of the breach, who must be intended to be so benefited, a civil right of action for damages. In rare cases, the legislature clarifies its intent, one way or the other, as to whether a civil right of action should arise for breach of the statutory duty. In the overwhelming majority of cases, however, the legislative provision is silent on the question and the court must engage in the, largely fictional, enquiry into discerning the legislative interest. As McMahon & Binchy observe:

“In truth, the legislature probably had no ‘intent’, one or way the other, on the matter; indeed, its failure to provide explicitly for a remedy might reasonably be considered to imply that it did not intend that any remedy should be available to persons injured by breach of the statute’s provisions. Nevertheless, there are good reasons why the courts should exercise themselves in the task of pursuing this ‘will o’ the wisp of a non-existing legislative intention’. To recognise a civil right of action in controlled circumstances arising from a breach of statute may be seen as strengthening the criminal sanction, as well as assisting the judiciary in controlling the jury. To describe the Court’s deliberation as strictly that of legislative interpretation would be naïve: a considerable element of judicial creativity is also involved.”³¹²

3.4 The Pharmacy Act 2007 and Associated Duties of the Pharmacist in Ireland

There is no statute imposing on Irish pharmacists particular duties the breach of which is expressly stated to entitle the victim to a civil action for compensation. The question thus becomes one of implied legislative intent. In this context, it is useful to examine the Regulation of Retail Pharmacy Businesses Regulations 2008.³¹³

The Pharmacy Act 2007³¹⁴ has a Long Title from which certain objectives are particularly relevant to this discussion: *“An Act to make New Provision for the Regulation of Pharmacy ... for the Creation of Certain Offences relating to Pharmacy and for the Setting up of New Procedures to ensure that Pharmacists are and continue to be fit to practise ... and to provide for Related Matters.”³¹⁵*

³¹² McMahon, B, Binchy, W, *Irish Law of Torts*, Third Edition (2000) Butterworths, Dublin, 592 (footnotes omitted).

³¹³ SI No 488 of 2008.

³¹⁴ Pharmacy Act 2007, 2007 No 20.

³¹⁵ Contrast with the Pharmacy Practice Act 2007 (SA), which provided for registration of ‘pharmacy depots’ meaning premises (other than a pharmacy and located in the vast rural expanses beyond Metropolitan

Section 18 (*Regulation of retail pharmacy businesses*) enables the Minister for Health and Children to make regulations (“for the purposes of the health, safety and convenience of the public”). Section 18(3) provides for criminal liability. Regulation 15 designates the relevant provisions for the purpose of offences. These are:

(a) Regulations 4(5), 5(1)(c), 5(3), 6, 8, 11, and 12(1)(b), and

(b) Regulation 5(1)(a), (b), (d) and (f) and Regulation 13, in so far as those Regulations relate to veterinary medicinal products.

Apart from those provisions, at the sub-section level or below, that are not specified as ‘relevant provisions’, it is clear that Regulation 7 (*Appropriate storage of medicinal products*), Regulation 9 (*Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription*) and Regulation 10 (*Counselling in the supply of medicinal products other than on foot of a prescription*)³¹⁶, in their entirety, do not bear criminal sanction.

In the Regulations, “‘patient’ means the person named on the prescription and in respect of whose treatment the prescription is issued”.³¹⁷ It is for this reason that duties owed to a person who enters into a consumer³¹⁸ contract with the pharmacist cannot be embraced under Regulation 9. Accordingly, those duties are the subject of Regulation 10.

In the overall legislative scheme, it could be contended that: “convenience” may give rise to duties for the benefit of the public as a whole; “safety” may concern the class of persons who avail of community pharmacy services, as well as individual patients or patrons, and the public at large; “health” may mean ‘public health’ in a general sense, although of the three rubrics, it is arguably the one most capable of evoking individual wellbeing and bodily integrity. It is submitted that statutory duties framed around ‘health’ could give rise to a cause of action to a particular member

Adelaide) at which prescriptions for drugs or medicines are left for dispensing by a pharmacist, or where such items, dispensed by a pharmacist on prescription, are left for collection by or on behalf of the person for whom the drugs or medicines are prescribed. The Pharmacy Practice Act 2007 (SA) was repealed by Sch 1 cl 28(f) of Health Practitioner Regulation National Law (South Australia) Act 2010, effective 01 July, 2010.

³¹⁶ The Pharmaceutical Society of Ireland provides professional guidance to pharmacists on occasion. See, for example, Pharmaceutical Society of Ireland, *Supply by Pharmacists of a Non-Prescription Medicinal Product Containing Levonorgestrel (Norlevo® 1.5mg Tablets) as Emergency Hormonal Contraception, Interim Guidance for Pharmacists on Safe Supply to Patients* (2011) Available from http://www.thepsi.ie/Libraries/Publications/Norlevo_1_5mg_Interim_Guidance.sflb.ashx. (Last accessed 22 February, 2011).

³¹⁷ SI No 488 of 2008, Regulation 3 (*Interpretation*).

³¹⁸ There is no definition of ‘consumer’ in the Regulations.

of the pharmacy-utilising class within the general public. In the pharmacy setting, particular damage to one member of a class is readily imagined.

The new statutory duties for *Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription*,³¹⁹ which affect all prescribed medicinal products, are not dependent on the existence of a provider contract like the Community Pharmacy Contractor Agreement (CPCA).³²⁰

A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist must ensure that, *“prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient.”*³²¹

The review provided for in Regulation 9 (1) includes screening for any potential therapy problems which may arise out of the use of any medicinal product that may have been prescribed and which the registered pharmacist is, or, in the course of his professional practice, ought reasonably to be, aware of. The potential problems to be screened for *“shall include those which may be due to therapeutic duplication, interactions with other medicinal products (including serious interactions with non-prescription medicinal products, herbal products or foods), incorrect dosage or duration of treatment, allergic reactions, and clinical abuse and/or misuse.”*³²²

Following completion of the review provided for in Regulation 9 (1), the registered pharmacist *“shall ensure that each patient has sufficient information and advice for the proper use and storage of the prescribed medicinal product and shall offer to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant.”*³²³

The statutory duty regarding *“all such matters”* is arguably more onerous than that imposed under the CPCA. The contractual duty refers to *“any other matters which may be included or*

³¹⁹ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 9.

³²⁰ See Department of Health and Children, *Community Pharmacy Contractor Agreement* (1996) Department of Health and Children, Dublin. Available from http://www.dohc.ie/publications/pdf/community_pharmacy_services.pdf. (Last accessed 12 January, 2012).

³²¹ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 9(1).

³²² Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 9(2).

³²³ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 9(3).

*referred to in the patient information leaflet supplied with the medicine.*³²⁴ A literal construction of the “*patient information leaflet supplied with the medicine*” is such printed matter as is physically included within the medicinal product’s outer packaging (a document obviously fixed in content from the time the medication enters pharmaceutical distribution). Updating of the patient leaflet is the manufacturer’s responsibility, at some juncture, in assembling future batches of finished medicinal product for distribution. On the other hand, a requirement focused on “*any other matters which may be included or referred to in the summary of product characteristics for the medicinal product concerned*” is arguably not static by reference to the point at which the medicinal product entered the pharmaceutical distribution chain or (later) came into the pharmacy’s possession.³²⁵ The Summary of Product Characteristics in its most recent revision should be available to pharmacists for (1) centrally (*i.e.* EU Commission) authorised medicinal products, (2) mutually recognised authorisations [authorised in one European Economic Area (EEA) ‘reference’ member state and recognised in another], or (3) nationally authorised medicinal products.³²⁶ In Ireland, the competent authority is the Irish Medicines Board (IMB).

The 2008 Regulations also impose a new statutory duty in relation to *Counselling in the supply of medicinal products other than on foot of a prescription.*³²⁷ In the absence of a prescription, it is most probable that the pharmacist, not the physician, is the gatekeeper. In some cases, a physician may advise a person under his care that a particular medication does not require a prescription. Theoretically, for a physician not to issue a prescription in respect of a given medicinal product (where he might otherwise have done) may deny the recipient the status of ‘patient’ under the Regulations in respect of that product. If, however, the medical consultation terminates with a prescription issued for one or more other items, then the theoretical point may have little practical significance.

There is no “*offer to discuss*” mandated here because “*a registered pharmacist [must be] satisfied*” on the matters specified in the Regulations, namely, “*the appropriate use of the medicinal product is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse.*” For that to be fulfilled, discussion is required. Criminal sanctions are not prescribed under Regulation 10. The pharmacist is already subject to other legislation (for example, the Misuse of Drugs Regulations), tortious liability and ethical responsibilities. Contrasted with Regulation 9, under Regulation 10 the range

³²⁴ Community Pharmacy Contractor Agreement, Clause 9 (5) (k).

³²⁵ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 9 (3) (h).

³²⁶ Various Summaries of Product Characteristics are available from the European Medicines Agency (EMA), Irish Medicines Board (IMB) and Irish Pharmaceutical Healthcare Association (IPHA) websites.

³²⁷ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 10.

of specified duties is narrower and the potential damage from non-prescription medication is lower. It could therefore be suggested that an argument for the imposition of liability in breach of statutory duty pursuant to Regulation 10 might be less favourably received than one made with regard to Regulation 9.

It is a matter for the courts to divine the legislative intent in order to ascertain whether a civil remedy concurrent with the criminal liability or a freestanding civil remedy cognisable in tortious breach of statutory duty has been created for a given statutory duty laid down in the 2008 Regulations.

Apart from the usual 'legislative housekeeping' in a statutory instrument (in this case, Regulations 1, 2 and 3) and the Regulations analysed above that do not bear criminal sanctions (Regulations 7, 8 and 10), some other topics in the Scheme of the Regulations are considered below. Although these provisions contain criminal sanctions in relation to breach of a particular Regulation or paragraph, the 2008 Regulations on the whole do not provide that breach of any particular provisions in the Regulations shall not be cognisable in civil proceedings.

3.4.1.1 Regulation 4: Staff, premises, equipment and procedures.

Most of what this Regulation specifies is obvious from its title. Of particular note is paragraph (3), which prescribes as follows:

“The pharmacy owner shall provide a separate and designated area conveniently located within the pharmacy premises so that a pharmacist may review and discuss in private with the person for whom a prescription has been issued, or with the carer of such a person, such matters relating to the medicine therapy as either of the said persons may request or as the pharmacist, in the exercise of his or her professional judgment, may deem necessary.”

Pharmacy premises constructed in the more recent years prior to 2008 already designed in this necessary feature to safeguard patient confidentiality.

3.4.1.2 Regulation 5: Management and supervision of a retail pharmacy business.

Some safeguards contained in this Regulation are noteworthy. Prescription only medication for human³²⁸ or veterinary use, and human or veterinary medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988, are not to be “*accessible to the public for self-selection*”. It is to be anticipated that a person injured as a result of a breach of this Regulation might bring civil proceedings based on such breach.

3.4.1.3 Regulation 6: Sourcing of medicinal products.

This provision imposes the obligation to source human or veterinary products from a licensed manufacturer or wholesaler. Regulation 6 “*shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient.*” The ‘occasional transaction’ route of supply would have to be well documented in order to escape the rigours of product liability law.

3.4.1.4 Regulation 8: Medicinal products that may be sold or supplied.

Apart from allopathic (or conventional) medicinal products, since 30 April, 2012, all traditional herbal medicinal products or homeopathic medicinal products,³²⁹ sold or supplied in retail pharmacy businesses, are required to be the subject of “*a marketing authorisation which is for the time being in force*”. This is a significant (additional) statutory protection to a patient or consumer, which supplements product liability law.

3.4.1.5 Regulation 11: Veterinary medicinal products which may be sold or supplied.

Protections similar to those laid down for allopathic human medicinal products (in Regulation 8) are specified in Regulation 11. Again, the protection afforded by product liability law is supplemented.

³²⁸ Human medicines subject to prescription control under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

³²⁹ Homeopathic products to which Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 applies.

3.4.1.6 Regulation 14: Publication of guidelines by the Council.

The Council of the Pharmaceutical Society of Ireland “*may, with the prior approval of the Minister, publish detailed guidelines for the purpose of facilitating compliance with these Regulations.*”³³⁰

The existence of such guidelines raises the possibility that their breach will expose the pharmacist to one or more sanctions of a disciplinary, criminal or civil nature.

3.5 Pharmacists’ Duties at Common Law

Apart from professionally mandated obligations, it is clear from the case law that a pharmacist will owe some legal duties to the patient. Much analysis of such duties has come from the US courts. There has been very little corresponding analysis in the British and Irish courts in the absence of relevant case law. It appears obvious that courts in any jurisdiction would impose duties on pharmacists to properly dispense lawful prescriptions³³¹ and to identify obvious errors in prescriptions.³³² The comparative materials from other jurisdictions have been included to illustrate the range of duties that may be owed by a pharmacist in Ireland.

In *Adkins v Mong* and *Stebbins v Concord Wrigley Drugs Inc*, there have been judicial pronouncements to the effect that pharmacists should not be placed in the position of having to second guess every prescription to escape tortious liability to the patient.³³³

Certainly, any professional person should aspire to and achieve greater things than the notion that “*a pharmacy is no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and unquestioningly obey the written orders of omniscient physicians*”, which argument the court in *Riff v Morgan Pharmacy* rightly rejected.³³⁴ As a net point, it may be noted that in the US, it has been held that the plaintiff’s own

³³⁰ Pharmaceutical Society of Ireland, *Guidance to facilitate compliance with Regulations* (2012) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/gns/pharmacy-practice/practice-guidance/regulations_section_18.aspx. (Last accessed 07 October, 2012).

³³¹ For example, *Adkins v Mong* (1988) 425 NW2d 151 (Mich App), 152.

³³² For example, *Stebbins v Concord Wrigley Drugs Inc* (1987) 416 NW2d 381 (Mich App), 388.

³³³ *Adkins v Mong* (1988) 425 NW2d 151, 153; *Stebbins v Concord Wrigley Drugs Inc* (1987) 416 NW2d 381, 387.

³³⁴ *Riff v Morgan Pharmacy* (1996) 508 A2d 1247 (Pa Sup Ct), cited in Vivian, JC, Brushwood, DB, *Legal Cases That Raise Ethical Issues*, Chapter in Haddad, AM (Editor), *Teaching and Learning Strategies in Pharmacy Ethics*, Second Edition (1997) Pharmaceutical Products Press, Binghamton (NY), 4. See also analysis of *Riff v Morgan* in *Joyce v Boulevard Physical Therapy & Rehabilitation Center* (1997) 694 A2d 648, 656-657 (Pa: Super Ct). The *Joyce* decision drew an analogy between physical therapists and pharmacists

illegal conduct, at common law, is a bar to recovery of damages, where the pharmacy has been negligent.³³⁵

3.5.1 Scope of the Duty

In the context of *financial advice* (here a convenient simplification) being litigated before the House of Lords, Lord Bridge of Harwich opined: "[i]t is never sufficient to ask simply whether A owes B a duty of care. It is always necessary to determine the scope of the duty by reference to the kind of damage from which A must take care to save B harmless".³³⁶ The upper limit of the pharmacist's duty of care can be set intuitively. A pharmaceutical product (or its use) inappropriate to the patient's clinical situation may cause injury on a broad spectrum with death as the most extreme kind of harm.

3.5.1.1 Duty to clarify Prescription with the Prescriber

In *Prendergast v Sam & Dee Ltd, Kozary and Miller*,³³⁷ a patient suffered irreversible brain damage as a result of overdosing of an anti-diabetic medication due to the third-named defendant's poor handwriting on a medical prescription. The prescription was for an antibiotic which was misinterpreted by the pharmacist (the second-named defendant) as an anti-diabetic tablet. Both the doctor and the pharmacist were found negligent. In this case, the pharmacist failed to check with the doctor the doubtful writing, "*the unusually high strength (25 times the normal dosage) for the misinterpreted anti-diabetic tablet, the unusual frequency of dose, the unusual quantity and the unusual combination of medications in the script to contain both diabetic and asthmatic medication.*"³³⁸

In the Court of Appeal, Dillon LJ confirmed the established law to be that a pharmacist has a duty to satisfy himself about any prescription that he dispenses and, in the case of doubt, to contact the doctor (or other prescriber). It was argued on behalf of Dr Miller that because the pharmacist's mistakes were so glaring, Dr Miller's bad handwriting could not be said to be a cause of the injury to the plaintiff. The trial judge and the Court of Appeal both rejected this view however. Cook, Doyle, and Jabbari noted that "[b]oth courts stated that the negligence of the

³³⁵ *Orzel by Orzel v Scott Drug Co* (1995) 537 NW2d 208, (Mich App), cited in *Kaminer v Eckerd Corp of Florida Inc* (2007) 966 So2d 452 (Fla Fourth Dist Ct App). In *Orzel v Scott Drug Co*, the plaintiff had obtained amphetamines, a controlled substance, through the negligence of a pharmacy and was attempting to hold the pharmacy liable for his injuries resulting from taking the amphetamines.

³³⁶ *Caparo Industries Plc v Dickman* [1990] 2 AC 605 (HL), 627, per Lord Bridge of Harwich.

³³⁷ *Prendergast v Sam & Dee Ltd* [1989] 1 Med LR 36 (CA).

³³⁸ See Ming, KLY, *A Duty to Care: Pharmacists' Negligence: Implications for Pharmacists and Lessons Arising* (2003) 5 *Allied Health Professions* 1, 4.

pharmacist was just the sort of thing a doctor should take into account when writing a prescription, since a pharmacist may be busy or tired. Dr Miller's handwriting was below the standard of legibility expected by the law."³³⁹

The applicability of the holding in this case to the position of pharmacists seems straightforward. Indeed, is considered a paradigm case by authors on the law relating to pharmacy in Ireland.³⁴⁰

3.5.1.2 Failure to detect Prescriber's wrong Directions

In *Dwyer v Roderick*,³⁴¹ a UK pharmacist dispensed an overdose of an anti-migraine medication by following the prescription directions literally. The overdosage resulted in the patient's developing gangrene and having toes amputated. The pharmacist was held to be negligent for failing to query the unusually high dose; liability was apportioned 40% to the pharmacist and 60% to the doctor.³⁴² Irish pharmacists become aware of this case also through their training.

3.5.1.3 Supply of Medicine Withdrawn from the Market

Downing v Hyland Pharmacy is a recent case in which a patient brought an action in negligence against pharmacy, alleging that pharmacy negligently filled his prescriptions for a drug that had been withdrawn from the market by the Food and Drug Administration (FDA) and the manufacturer.³⁴³ The Utah Supreme Court held that learned intermediary rule did not preclude a negligence claim against pharmacy for dispensing drug that had been withdrawn from market, finding (as a matter of law) that a pharmacist owes a duty of reasonable care in such a situation.³⁴⁴

It is submitted that an Irish court would have arrived at the same result, as a matter of impression, in a case with a similar factual basis. The topic is now dealt with by the Regulation of Retail Pharmacy Businesses Regulations 2008.

³³⁹ See Cook, T, Doyle, C, Jabbari, D, *Pharmaceuticals Biotechnology and The Law* (1991) Stockton Press, New York, 371-372, citing *Prendergast v Sam & Dee Ltd & Others* [1989] Med LR 36 (CA).

³⁴⁰ For example, see Crean, F, *Liability of Community Pharmacists in Negligence and for Defective Products*, Chapter in Weedle, P, Clarke, L (Editors), *Pharmacy and Medicines Law in Ireland* (2011) Pharmaceutical Press, London, 311.

³⁴¹ *Dwyer v Roderick*, The Times, 12 November, 1983.

³⁴² See Ming, KLY, *op cit*, 4-5.

³⁴³ *Downing v Hyland Pharmacy* (2008) 194 P3d 944 (Utah Sup Ct).

³⁴⁴ Presumably the manufacturer, acting in co-ordination with the FDA, would have arranged a product recall, if necessary.

3.5.2 Pharmacist's Duty to Warn

The case of *Ferguson v Williams*³⁴⁵ may still be regarded as authority for the proposition that a pharmacist has no generalised duty to warn,³⁴⁶ but once alerted to the specific facts and voluntarily undertakes to advise, he must advise correctly.³⁴⁷

Lasley v Shrake's Country Club Pharmacy was a case in which a customer sued a pharmacist for damages allegedly arising out of filling of prescriptions for addictive drugs.³⁴⁸ The Superior Court entered summary judgment for pharmacist and the plaintiff appealed. The Court of Appeals held that material issues of fact existed as to whether pharmacist breached applicable standard of care by filling prescriptions for drugs known to have addictive properties. The case was reversed and remanded. Material issues of fact, precluding summary judgment on behalf of pharmacist, existed as to whether pharmacist had breached standard of care owed to customer in filling prescriptions.³⁴⁹ There was evidence that pharmacist had filled prescriptions for Doriden (Glutethimide) and codeine, over ten-year period, without advising patient of highly addictive nature of drugs or advising prescribing doctor that patient was taking them in quantities inconsistent with manufacturer's recommended dosage guidelines.³⁵⁰

The appellate court noted Shrake's contention that the trial court correctly ruled that Shrake's had no duty to warn Lasley or his physician of the potentially addictive nature of drugs legitimately prescribed for Lasley. The court "*believes, however, that the trial court's ruling*

³⁴⁵ *Ferguson v Williams* (1988) 374 SE2d 438, appeal after remand, (1991) 399 SE2d 389 (NC Ct App).

³⁴⁶ By 2006, in the following 19 US states (some sparsely populated): Alaska; Colorado; Delaware; Hawaii; Idaho; Kentucky; Minnesota; Montana; Nebraska; New Hampshire; New Jersey; New Mexico; North Dakota; Oklahoma; Rhode Island; South Dakota; Virginia; Wisconsin; Wyoming, the issue of a pharmacist's duty to warn still had not been judicially decided under each respective state's own law. Author's empirical observation based on: Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf. (Last accessed 12 January, 2012).

³⁴⁷ Huang, SW, *The Omnibus Reconciliation of Act 1990: Redefining Pharmacists' Legal Responsibilities* (1998) 24 American Journal of Law & Medicine 417, 432 (n 214). The case of *Ferguson v Williams* has not been followed on the judicial question of granting a rehearing (Westlaw negative indirect history omitted).

³⁴⁸ *Lasley v Shrake's Country Club Pharm Inc* (1994) 880 P2d 1129 (Ariz App Ct). See also *Pittman v Upjohn Co* (1994) 890 SW2d 425, 435 (Tenn). (Recognising pharmacy's duty to warn of a drug's dangerous propensities when no warning had been given by the physician).

³⁴⁹ See also *Dooley v Everett* (1990) 805 SW2d 380 (Tenn Ct App) concerning a theophylline-erythromycin interaction. The minor patient suffered cerebral seizures as result of toxic blood levels of theophylline caused by that interaction. The pharmacy's motion for summary judgment was appealed successfully. The Tennessee Court of Appeals held *inter alia* that the matter of whether pharmacy had duty to warn customer of potential drug interaction was a question of fact which precluded summary judgment.

³⁵⁰ Glutethimide is a piperidinedione derivative hypnotic, developed during the 1950s, which was intended to be a safer alternative to barbiturates. In clinical use, the drug transpired to be problematic on its own account and especially in combination with codeine.

*confuses the concept of duty with that of standard of care.*³⁵¹ The *Shrake's* court cited the Arizona Supreme Court's decision in *Markowitz v Arizona Parks Board*.³⁵² In *Markowitz*, the Arizona Supreme Court cautioned against confusing the existence of a duty with details of the standard of conduct.³⁵³ Specific details of conduct do not determine whether a duty exists but instead bear on whether a defendant who owed a duty to the plaintiff breached the applicable standard of care.³⁵⁴ In explaining the concept, the court in *Coburn v City of Tucson*³⁵⁵ quoted from Prosser and Keeton:

*It is better to reserve "duty" for the problem of the relation between individuals which imposes upon one a legal obligation for the benefit of the other, and to deal with particular conduct in terms of a legal standard of what is required to meet the obligation. In other words, "duty" is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty [if it exists] is always the same-to conform to the legal standard of reasonable conduct in the light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty.*³⁵⁶

The court pointed out that, in its answer, *Shrake's* admitted that it owed a duty to *Lasley* to comply with the applicable standard of care. The concession was something with which the court agreed: *"Thus, the answer to the threshold question in this appeal is that Shrake's did owe a duty of reasonable care to Lasley. The trial court therefore erred in finding, as a matter of law, that Shrake's owed no duty to Lasley."*³⁵⁷

Regulations 9 and 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (dealing with prescription and non-prescription medication, respectively) impose duties on the pharmacist

³⁵¹ *Lasley v Shrake's Country Club Pharm Inc* (1994) 880 P2d 1129, 1131-1132.

³⁵² *Markowitz v Arizona Parks Board* (1985) 706 P2d 364 (Ariz Sup Ct).

³⁵³ *Markowitz v Arizona Parks Board* (1985) 706 P2d 364, 367. See also *Coburn v City of Tucson* (1984) 691 P2d 1078 (Ariz Sup Ct), 1079-80.

³⁵⁴ *Markowitz v Arizona Parks Board*, (1985) 706 P2d 364, 367.

³⁵⁵ *Coburn v City of Tucson* (1984) 691 P2d 1078.

³⁵⁶ *Coburn v City of Tucson* (1984) 691 P2d 1078, 1080, citing: Keeton, W, Dobbs, D, Keeton, R, Owen, D, *Prosser and Keeton on Torts*, Fifth Edition (1984) West Publishing Company, St Paul, § 53, [356].

³⁵⁷ *Lasley v Shrake's Country Club Pharm Inc* (1994) 880 P2d 1129, 1132. See also: Arizona (General duty of reasonable care, which may include duty to warn in certain circumstances.), citing: *Lasley v Shrake's Country Club Pharm Inc* (1994) 880 P2d 1129 (Ariz App Ct) (Duty to warn of drug's addictive nature and to advise physician that patient taking drugs in quantities inconsistent with recommended dosage). Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf. (Last accessed 12 January, 2012).

to address the possibilities of abuse and/or misuse. It is submitted that such duties were already owed by pharmacists at common law in Ireland.

3.5.2.1 Waiver of counselling,

Waiver of counselling under State of California Regulations facilitated by Omnibus Budget Reconciliation Act (OBRA 90) and at common law was considered in *Hooper v Thrifty Payless Inc.*³⁵⁸ A patient's refusal of offer to consult with pharmacist was effective, and thus pharmacist was not required under administrative code to provide oral consultation to patient about prescribed medication or its side effects, even though pharmacy was busy when the offer was made, the patient believed the medication to be benign, and the offer to consult was made by a pharmacy clerk, as opposed to the pharmacist.

The duties contained in the Omnibus Budget Reconciliation Act (OBRA 90) are broadly similar to those specified in Clause 9 of the Community Pharmacy Contractor Agreement held by pharmacies in Ireland. Clause 9 provides that, prior to the dispensing of each prescription, and prior to the supply of the medicine, a pharmaceutical contractor is obliged ensure that a pharmacist reviews the medicine therapy of the individual for whom the prescription is issued. Following completion of the review, the pharmacist is required to make an “*offer to discuss with the individual for whom the prescription is issued, or with the carer of such person,*” certain matters the ambit of which is specified in Clause 9. It may be prudent for a pharmacist to document that an “*offer to discuss*” had been declined by a patient or carer.

3.5.2.2 Warning about Side-Effects and Adverse Effects

In *Ingram v Hooks Drugs Inc*, the duty to warn was seen as “*part and parcel of the physician-patient relationship*”.³⁵⁹ The court said that pharmacists do not have access to patients’ medical records; therefore the duty to warn of side-effects should remain with the physician, unless the

³⁵⁸ *Hooper v Thrifty Payless Inc*, 2002 WL 31820207 (Cal App 3 Dist). The court was prepared to assume, for the purposes of the opinion in the case before it, that a pharmacist has a common law duty to warn, and held that there had been a valid waiver of such a duty at common law also. The California Court (at Page 10 of its opinion) analysed the United States Supreme Court's decision in *United States v Drayton* (2002) 536 US 194: “*If the Fourth Amendment right against unreasonable searches—a right of constitutional dimension—can be waived without an admonition of the right to refuse, surely, a statutory or common law right to a consultation can be waived without admonitions—at least as long as a reasonable person would understand that he or she had the right to a consultation and the nature of such a consultation.*” California Code of Regulations, Title 16, Section 1707.2 implements a federal statute, section 1396r-8(g) of Title 42 of the United States Code, which was adopted as part of the Omnibus Budget Reconciliation Act 1990 (“OBRA 90”).

³⁵⁹ *Ingram v Hooks Drugs Inc* (1985) 476 NE2d 881 (Ind: Ct App), 886.

pharmacist has been instructed by the physician to impart such information.³⁶⁰ Against the EU regime of Patient Information Leaflets, in particular, the reasoning in this Indiana decision appears unattractive.

Casey, a commentator in the US, notes that the courts traditionally have imposed no duty upon pharmacists to warn patients of the adverse effects of prescription drugs.³⁶¹ That author notes that “*professional progression and tort litigation have chipped away steadily at this no-duty rule, spurring a new trend where courts hold pharmacists liable for failing to warn patients on either a defective- or inadequate-warning theory.*”³⁶²

Although of persuasive authority only, it is submitted that this reasoning appears applicable to the situation of pharmacy in Ireland. The Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 have provided the edifice for formulating duties to warn about side-effects and adverse effects.

3.5.2.3 Sufficiency of warning

The sufficiency of the warning given came in for analysis in *Vollendorff v United States*.³⁶³ The US Court of Appeals accepted compelling testimony before the trial court that people do not respond to a warning as they would do towards a special warning.³⁶⁴ The *Vollendorff* case is remarkable for the involvement of the (government) employer’s vicarious liability for medication warnings. The *Vollendorff* case is based on a distinctive set of facts. Nevertheless, it is submitted that it may be of persuasive authority to an Irish court where sufficiency of warning is in issue.

³⁶⁰ (1985) 476 NE2d 881, 886-887.

³⁶¹ Casey, J, *Prescription for Compromise: Maintaining Adequate Pharmacist Care Contraindicates Imposition of a General Duty to Warn* (2005) 17 Journal of Law & Policy 287, [287], citing: Marchitelli, DJ, Annotation, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User* (2002) 44 ALR 5th 393.

³⁶² Casey, J, *loc cit*. Casey argues that this trend abrogates the Learned Intermediary Doctrine (the Doctrine) embodied in the *Restatement (Third) of Torts: Products Liability*, citing: § 6(d) & Comment b, Reporters’ Note to Comments b, d (1998). “*The Learned Intermediary Doctrine provides that the prescribing physician is the ‘learned intermediary’ between the drug manufacturer and the patient. As such, the prescribing physician is in the best position to assess the danger of a prescription drug to a patient because the physician knows the patient’s needs and can evaluate the drug’s effects and contraindications in light of those needs*”: *op cit* 287-288.

³⁶³ *Vollendorff v United States* (1991) 951 F2d 215 (USCA, 9th Ct).

³⁶⁴ *Vollendorff v United States* (1991) 951 F2d 215 (USCA, 9th Ct). A US serviceman was required (for reasons of combat preparedness) to take chloroquine as an anti-malarial prophylactic drug, which he stored at home (with objectively inadequate precautions): his daughter was severely injured through accidental chloroquine ingestion. The US Government stressed that the basis for much of the evidence adduced by the plaintiffs predated the advent of ‘child-proof’ (more realistically, child resistant) containers and warning labels. On the issue of *respondeat superior* (alternatively described as employer’s vicarious liability or the ‘Master-Servant Rule’), the court said that the record, which supported the government’s position, went to the weight, rather than the sufficiency of the evidence. The court could not conclude, on that record, that the finding of conduct within the scope of employment was clearly erroneous.

3.5.2.4 Other US Cases on the Duty to Warn – Prior to OBRA 90 Duties

Walker v Jack Eckerd Corp was a case arising before the offer-to-discuss requirement came into operation. The Georgia Court of Appeals ruled that a pharmacist has no duty to warn a patient of, or to refuse to dispense a medication in light of, a potentially severe side effect arising from excessive dosage. Summary judgment entered for the defendant pharmacy was upheld on appeal, but the court noted that this "would not be controlling precedent for cases involving pharmacists' duties arising after January 1, 1993".³⁶⁵ In a separate case, *Johnson v Walgreen Co*, arising also before 01 January, 1993, effective date of OBRA 90, the Florida Court of Appeals ruled that a pharmacist who accurately dispensed medication but failed to alert the patient or prescriber of potentially serious adverse drug interactions has no duty to warn.³⁶⁶

The comparative law value in cases such as *Walker* and *Johnson* (as persuasive authorities) is to contrast the situation prior to a relevant statute's coming into effect with the current situation; namely, in Ireland, the position following the enactment of the Pharmacy Act 2007 and the making of the Regulation of Retail Pharmacy Businesses Regulations 2008.

3.5.3 Pharmacist's Assumed Duties

The Illinois case of *Frye v Medicare-Glaser Corp* is a well-known example of an assumed duty of care at common law.³⁶⁷ The County Circuit Court granted the defendant's motion for summary judgment. On appeal however the Fifth District Court of Appeals reversed the inferior court's decision and remanded the cause of action. The issue on appeal was whether the pharmacist and

³⁶⁵ *Walker v Jack Eckerd Corp* (1993) 434 SE2d 63 (Ga App). Further information is available from Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf, (Last accessed 12 January, 2012). In Georgia, regarding the duty to warn about side effects, it remains an open question as to whether the duty embraces "common severe side or adverse effects of interactions and therapeutic contraindications": *Chamblin v K-Mart Corp* (2005) 612 SE2d 25, 27 (Ga App Ct).

³⁶⁶ *Johnson v Walgreen Co* (1996) 675 So2d 1036 (Fla App). In Florida, the appellate court districts have disagreed about what circumstances subject pharmacist to liability for failure to warn. Duty to warn may be voluntarily assumed: *Powers v Thobhani* (2005) 903 So2d 275 (Fla 4th DCA) (Duty to question excessive refills, disagreeing with *Johnson* and *Sharp*); *Sharp v Omnicare Inc* (2004) 879 So2d 34 (Fla 5th DCA) (Consulting pharmacist not liable for failure to review drug regimen, account for/reconsider drug usage, assess treatment); *Johnson v Walgreen Co* (1996) 675 So2d 1036 (Fla 1st DCA) (No duty to warn of adverse interactions); *Pysz v Henry's Drug Store* (1984) 457 So2d 561 (Fla 4th DCA) (No duty to warn customer about drug or physician about patient's addiction). See: Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf, (Last accessed 12 January, 2012).

³⁶⁷ *Frye v Medicare-Glaser Corp* (1991) 579 NE 2d 1255 (Ill App Ct), *appeal granted*, 143 Ill 2d 637 (1992). See Strobl, DB, *Prescription Drug Warnings Must Be Complete and Accurate* (1992) *Journal of Pharmacy & Law* 93.

pharmacy had a legal duty to warn consumers/patients of the dangers of mixing prescription drugs with alcohol, after voluntarily undertaking to provide other cautionary warnings.³⁶⁸ The appellate court reasoned that under the learned intermediary doctrine a pharmacist has no initial duty to provide warnings to the patient. However, if the pharmacy or pharmacist undertakes the duty to provide a warning, the warning must be given with reasonable care. In the *Frye* case, the court found that, although the warning about drowsiness was accurate, the warning was incomplete because it did not include a warning label about the hazard of consuming alcohol concomitantly. According to Strobl, the kernel of the judgment was: “*The court determined that the absence of an auxiliary label about alcohol could have been misleading to the decedent because the decedent may have assumed that the warnings were complete and that no other dangers existed.*”³⁶⁹ The court concluded that the defendant had assumed a duty to provide a complete and accurate warning about the dangers of taking Fiorinal with alcohol and that a label about the effects of alcohol was necessary to make the warning complete.³⁷⁰ The court held that a pharmacy or pharmacist who provides warnings about a prescription medication undertakes a duty to exercise reasonable care in giving an accurate and complete (*i.e.* not a misleading) warning.³⁷¹

3.5.3.1 Product Recall

Apart from patients who call in person to the pharmacy, who can be appropriately advised at the time, the responsibility to notify a patient of a recall³⁷² by letter should belong to medical practitioners. Even if a pharmacist or pharmacists were to assume a duty to write to every patient in relation to a recalled medicinal product, it could be disquieting and confusing to any patient who might receive a separate letter from each pharmacy (including pharmacies that operate within a rota system) that dispensed merely a single prescription for the recalled medication within, for argument’s sake, the previous five years.

³⁶⁸ In the factual matrix, the pharmacist, Evelyn Nightengale “attached the following warning labels to the [Fiorinal] bottle: ‘May cause drowsiness’ and ‘Caution Federal Law prohibits transfer of this drug to persons other than the patient to whom it was prescribed’. Nightengale did not attach an auxiliary label which warned that ‘Alcohol may intensify the effect of this drug’ because she believed that people might be offended by the implication that they imbibe in alcohol.” Strobl, DB, *op cit*, 93. Fiorinal is a combination product containing aspirin, butalbital and caffeine. Butalbital is a barbiturate hypnotic and sedative drug for which the serious interaction with alcohol has been described extensively in the scientific literature.

³⁶⁹ Strobl, DB, *loc cit*.

³⁷⁰ Strobl, DB, *op cit*, 94.

³⁷¹ See, however, *Kasin v Osco Drug Inc* (2000) 728 NE2d 77 (Ill App Second Dist) (By voluntarily undertaking to list some of a drug’s side effects, a pharmacy did not assume a duty to list all possible side effects, so as to remove it from the protection of the learned intermediary doctrine regarding side effects it did not list; the side effects listed by the pharmacy constituted the extent of its undertaking).

³⁷² Rothstein, MA, Siegal, G, *Health Information Technology and Physicians’ Duty to Notify Patients of New Medical Developments* (2012) 12(1) *Houston Journal of Health Law & Policy*, [4]-[5]. Forthcoming. Available at SSRN: <http://ssrn.com/abstract=2126126>. (Last accessed 01 October, 2012).

3.5.4 Scope of Assumed Duties

3.5.4.1 Pharmacist's Assumed Duties

The appeal in *Sanderson v Eckerd Corp*³⁷³ conditioned the court seized to remark that the voluntary undertaking doctrine may be applied to a dispensing pharmacist in a proper case, although not raised on the instant pleadings. Commenting, in 2006, on the *Sanderson* case, Gallagher said that a pharmacy that advertised a promise that its computer system would detect and warn customers of adverse drug reactions and interactions “voluntarily assumed a duty to warn the scope of which was measured by the level of care and skill which in light of all relevant circumstances is recognised as acceptable and appropriate by other reasonably prudent pharmacists.”³⁷⁴ This author agrees. Assumed duties in the financial services sector and their scope depend on the particular factual matrix; the scope of a pharmacist’s duty to warn is more easily placed in the context of what another reasonably prudent practitioner might have done.

The *Sanderson* case is a persuasive authority that may assist an Irish court in a relevant case. However, the facts put forward in support of an assumed duty may permit the court to hold, as a matter of impression, that such a duty had been undertaken.

3.5.4.2 Doctor's Assumed Duties to the Patient

A doctor will owe professional duties once he assumes responsibility for the care of another, undertaking expressly or by implication to provide medical care and exercise skill on the patient’s behalf.³⁷⁵ While an ordinary member of the public is under no common law duty to render emergency assistance to another, for medical practitioners the case is not so clear-cut. Public dependence on doctors for medical attention (together with the ethical obligation to render it) raises the possibility of liability in negligence for failure to act. There is a line of authority in which *Glencar Explorations plc v Mayo County Council (No 2)*³⁷⁶ is prominent.

³⁷³ *Sanderson v Eckerd Corp* (2001) 780 So2d 930 (Fla Dist Ct App).

³⁷⁴ Gallagher, RA, *Pennsylvania Pharmacists Should No Longer Assume That They Have No Duty to Warn* (2006-2007) 45 Duquesne Law Review 59, 79 (n 110).

³⁷⁵ Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 271.

³⁷⁶ *Glencar Explorations plc v Mayo County Council (No 2)* [2002] 1IR 84 (Sup Ct).

In *Capital and Counties plc v Hampshire County Council*,³⁷⁷ although the public service at issue was a fire brigade, the Court of Appeal clarified the legal liability of medical services. Stuart-Smith LJ said the following:

*"[A] doctor who happened to witness a road accident will very likely go to the assistance of anyone injured, but he is not under any legal obligation to do so, save in certain limited circumstances which are not relevant, and the relationship of doctor and patient does not arise. If he volunteers his assistance, his only duty as a matter of law is not to make the victim's condition worse. Moreover, it is clear that no such duty of care exists, even though there may be close physical proximity, simply because one party is a doctor and the other has a medical problem which may be of interest to both."*³⁷⁸

In *Lowns v Woods*,³⁷⁹ the New South Wales Court of Appeal noted that the Medical Practitioners Act 1938 (NSW), Section 27(2) provided that a failure to attend in an emergency situation constituted professional misconduct, although it is doubtful that the *Lowns* case would be followed, even in Australia.

The doctor's situation in such a situation is more complex and has been described for contrast with that of the pharmacist.

3.5.5 Duty to refuse to fill a valid Prescription

The case of *Hook's SuperX, Inc v McLaughlin* deals with circumstances when the pharmacist knows or ought to know that a patient's medication consumption is excessive and will cause

³⁷⁷ *Capital and Counties plc v Hampshire County Council* [1997] QB 1004 (CA).

³⁷⁸ [1997] QB 1004, 1035, per Stuart-Smith LJ (for the Court).

³⁷⁹ *Lowns v Woods* [1996] Australian Tort Reports 81 – 376 (NSWCA). See also Law Reform Commission, *Report on Civil Liability of Good Samaritans and Volunteers* (LRC 93 – 2009) (2009) Law Reform Commission, Dublin, 32-33 (internal footnote inserted): "In 1997, a year after the Australian decision, the English Court of Appeal, in *Capital and Counties plc v Hampshire County Council* [[1997] QB 1004, 1035] and without referring to *Lowns v Woods* reasserted the view that mere physical proximity between a doctor and a sick person, of itself, does not create a duty to treat." See also Australian Government, The Treasury, *Submission by the Law Council of Australia to the Negligence Review Panel on the Review of the Law of Negligence* (2002) Australian Government, The Treasury, Parkes (ACT), 21. Available from <http://revofneg.treasury.gov.au/content/subs/033LCA3.pdf> (Last accessed 12 January, 2012). The Submission suggested that it was unclear whether the case of *Lowns v Woods* would be followed in future because of "the High Court's change in direction in determining the duty of care."

foreseeable harm to the patient.³⁸⁰ On the facts, a pharmacy customer brought a negligence action against the pharmacy based on pharmacists' alleged refilling of prescription for dangerous and addictive drug at rate faster than prescribed. The Circuit Court recognised a duty on part of pharmacists under circumstances of case, and pharmacy appealed. The Court of Appeals reversed, and petition to transfer was filed. The Supreme Court held (there being one dissident who published no opinion) the following:

(1) Where a customer (patient) is having prescription for dangerous drug refilled at unreasonably faster rate than rate prescribed, pharmacist has duty to cease refilling prescription pending direct and explicit directions from prescribing physician.³⁸¹

(2) The standard of care governing such duty was that degree of care ordinarily prudent pharmacist would exercise under same or similar circumstances.³⁸²

(3) A factual issue existed as to whether customer's suicide attempt constituted intervening cause.³⁸³

The Missouri Court of Appeals, in *Horner v Spalitto*,³⁸⁴ reversed a summary judgment granted to the defendant pharmacist where the lower court had ruled that the pharmacist's "*only obligation was to fill the prescriptions accurately.*" The case involved a "*strong hypnotic drug prescribed at three times the normal dose.*" The court said, "*Pharmacists are trained to recognize proper dose and contraindications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer.*" Summary judgment was set aside and the case

³⁸⁰ *Hook's SuperX, Inc v McLaughlin* (1994) 642 NE2d 514 (Ind Sup Ct). See also Hotopp, B, *Hook's SuperX, Inc v McLaughlin: Pharmacists' Duty toward Their Patients* (1996) 6 Journal of Pharmacy & Law 35.

³⁸¹ *Hook's SuperX, Inc v McLaughlin* (1994) 642 NE2d 514, 517-518 (Where a pharmacy customer is having prescriptions for dangerous drug refilled at unreasonably faster rate than rate prescribed, the pharmacist has a duty to cease refilling prescription pending direct and explicit directions from prescribing physician; the relationship between pharmacist and customer is direct contractual one independent of relationship between physician and patient. The risk of possible addiction to dangerous drug is foreseeable, and there is strong public policy interest in preventing intentional and unintentional drug abuse).

³⁸² The author discusses "standard of care" elsewhere in this thesis.

³⁸³ *Hook's SuperX, Inc v McLaughlin* (1994) 642 NE2d 514, 520-521. The Westlaw negative indirect history to *Hook's SuperX, Inc v McLaughlin* (accessed 03 May, 2009) in *Estate of Heck ex rel Heck v Stoffer* (2001) 752 NE2d 192 (Ind App) is not really in point, since in *Heck*, the Estate specifically proposed, "*the owner or possessor of a gun owes a duty to the public to exercise at least ordinary care ... with respect to the storage and safekeeping of the gun.*" The *Heck* court said (at 199) that "[f]inding no Indiana cases to support its proposition, the Estate cited Indiana cases discussing the duty of reasonable care in other contexts" (including *Hooks*, regarding pharmacists' duty to warn). It is perhaps difficult to reconcile the aim of technological efficiency in an online case law database with the element of sophistication required to explain the precise circumstances in which a given judicial authority has been distinguished in another case.

³⁸⁴ *Horner v Spalitto* (1999) 1 SW3d 519 (Mo App).

remanded to the inferior court for adjudication on whether the pharmacist met his legal duty under the facts of the case.³⁸⁵

Konnor has commented in effect that, despite linguistic diversity in court opinions, the pharmacist's duties have gone beyond functional literalism in response to a physician's order.³⁸⁶

A passage from Osborne was cited with approval in the recent Canadian case of *Donaldson v John Doe*.³⁸⁷ The foreseeability requirement is analysed thus:

"The foreseeability requirement of a duty of care is more narrowly focused than the similar inquiry in respect of the standard of care. The essence of negligent conduct is foreseeability of some damage. The essence of a duty of care is foreseeability of damage to the plaintiff. Negligence in the common

³⁸⁵ *Horner v Spalitto* (1999) 1 SW3d 519 (Mo App). On Missouri law, see also Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf (Last accessed 12 January, 2012). The pharmacist's duty is to exercise "care and prudence which a reasonably careful and prudent pharmacist would exercise." The duty encompasses more than just filling prescriptions accurately. *Horner v Spalitto* (1999) 1 SW3d 519 (Mo App Ct) (abrogating *Kampe*); *Kampe v Howard Stark Professional Pharmacy Inc* (1992) 841 SW2d 223 (Mo App Ct) (The only duty is to inquire about irregularities on face of prescription).

³⁸⁶ Konnor, DD, *Pharmacy Law Desk Reference* (2006) Haworth Press, Philadelphia, 122. The Indiana Supreme Court, in *Hook's SuperX, Inc v McLaughlin* (1994) 642 NE2d 514 (Ind Sup Ct), revisited the appellate court's 1985 view of the duties of a pharmacist and, without overruling the *Ingram* case, held that a pharmacist's duty went beyond dispensing the prescription order correctly and could include a duty to monitor a patient's drug use and to warn the physician of abuse and the patient of potential harm. "Although the courts have not been uniform in their opinions" [*Horner v Spalitto* (1999) 1 SW3d 519 (Mo App); *Happel v Wal-Mart Stores Inc* (2002) 766 NE2d 1118 (Ill)]. {See also Rumore, MM, *Legal Aspects of Drug Information Practice*, Chapter in Malone, PM, Kier, KL, Stanovich, JE, (Editors) *Drug information: a guide for pharmacists*, Third Edition (2006) McGraw-Hill Professional, Columbus, 416: "The pharmacy's computer system was overridden, and the pharmacist failed to warn a patient allergic to aspirin and ibuprofen of the potential cross-allergenicity with ketorolac."}; *Cottam v CVS Pharmacy* (2002) 764 NE2d 814 (Mass)], "the clear tendency has been to recognize that pharmacists can be sued for professional duties above those involving dispensing prescription orders exactly as written by what one court referred to as 'the omniscient physician'": *Riff v Morgan Pharmacy* (1996) 508 A2d 1247 (Pa: Sup Ct.). See also: Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf, (Last accessed 12 January, 2012). *Indiana: No duty to warn of side effects unless requested by physician on prescription. Duty to refuse excessive refills absent physician approval. Hook's SuperX, Inc v McLaughlin* (1994) 642 NE2d 514 (Ind); *Allberry v Parkmor Drug Inc* (2005) 834 NE2d 199 (Ind App Ct). On *Happel v Wal-Mart Stores Inc* (2002) 766 NE2d 1118 (Ill), it is noteworthy that the US Court of Appeals, Seventh Circuit (Flaum, Williams, and Sykes, Circuit Judges) has allowed a retrial on damages so that Heidi Happel and Kent Happel may seek separate damage awards: *Happel v Wal-Mart Stores Inc* (2010) (USCA, 7th Cir) (Decided 19 April, 2010). The Happels' initial suit also asserted professional negligence claims against Heidi's primary care physician, Dr Z Ted Lorenc, for prescribing Toradol (generic name: ketorolac). In March 1999, Dr Lorenc settled out of court with Heidi and Kent for \$75,000 each, and Dr Lorenc was dismissed from the lawsuit.

³⁸⁷ *Donaldson v John Doe*, 2009 BCCA 38 (CanLII) [29]. As the appeal in *Donaldson* concerned the liability of commercial hosts who serve alcohol when someone is injured by an intoxicated patron, duty of care was naturally in issue. The *Donaldson* case itself does not warrant more extensive treatment here, since pharmacists are unlikely to deny that patients/consumers are owed a duty of care.

*law is a relational concept. A duty of care is not owed to the world. It is owed only to those whom the defendant might reasonably foresee as being adversely affected by his failure to take care. It is not, however, necessary that the particular individual be foreseen so long as he belongs to a **class** of persons who might foreseeably be harmed if care is not taken. ...”³⁸⁸*

The editors of Jackson & Powell state that “[p]roblems as to the extent of a doctor’s duty of care are more likely to arise in cases of advice than in treatment.”³⁸⁹ The pharmacist’s situation is arguably even more advice-based than treatment-centred than a doctor’s.³⁹⁰

The foregoing cases, it is submitted, are of persuasive value to an Irish court in benchmarking the pharmacist’s duty to refuse to dispense a valid prescription. The pharmacist may become alerted to facts of which an individual medical practitioner is unaware. For instance, the patient may be seeking prescriptions from several doctors none of whom is aware of the patient’s particular behaviour. In such circumstances, there is a duty to contact the prescriber(s) in order to convey the relevant information

3.5.6 Caution in Use and Contraindications

The Michigan Court of Appeal in *Kathleen Gay Hooper v Venita Prabhakar*³⁹¹ provided a clear distinction between the pharmacist’s duty of care in situations calling for caution and where there is an outright contraindication. That court referred to its own jurisprudence, as in *Baker v Arbor Drugs Inc*, the court found that “a pharmacy voluntarily assumed a duty of care to a customer where it had implemented a computer system and then advertised that this system would detect harmful drug interactions for its customers.”³⁹² Moreover, the court specifically reserved

³⁸⁸ Osborne, PH, *The Law of Torts*, Third Edition (2007) Irwin Law Inc, Toronto, 70-71. Bold type has been added to highlight original author’s Italics; underlining added by the British Columbia Court of Appeal. Osborne followed the Canadian court’s quoted text immediately with this observation: “*Nevertheless, it is an unusual fact situation where the defendant has been guilty of negligent conduct but the plaintiff was not within the scope of the risk created*”, citing one of the paradigm cases to which authors on negligence refer: *Palsgraf v Long Island Railroad Company* 162 NE 99 (NY 1928).

³⁸⁹ Jackson, R, Powell, JL, *Jackson & Powell on Professional Liability*, Sixth Edition (2007) Sweet & Maxwell, London, 902.

³⁹⁰ Pharmacists’ extended role activities may call for a revision in this assessment.

³⁹¹ *Kathleen Gay Hooper v Venita Prabhakar* (Michigan Court of Appeal, 20 September, 1996, *Per Curiam*, Unpublished, Docket Number 178665), 3-4. Available from <http://coa.courts.mi.gov/resources/asp/textsearchrtn.asp?querytext=pharmacist+negligence&inputsource=FinalAll&StartRecord=0&StartPage=0&includeunpublished=on>. (Last accessed 12 January, 2012).

³⁹² *Baker v Arbor Drugs Inc* (1996) 544 NW2d 727, (Mich App), 731. See also: Pozgar, GD, Santucci, N, Pinnella, JW, *Legal and Ethical Issues for Health Care Professionals*, Second Edition (2010) Jones & Bartlett Publishers, Sudbury (MA), 289; Rumore, MM, *Legal Aspects of Drug Information Practice*, Chapter in

consideration of the scope of a pharmacist's liability "where the pharmacist either knows of a particular patient's unique problems or where the pharmacist fills two incompatible prescriptions."³⁹³

These cases can only be of persuasive value to an Irish court. There is a potential danger for a pharmacist in assuming a duty of such nature to a patient, in that the pharmacist may not be in a position effectively to limit the scope of the assumed duty, against the background of existing professional responsibilities and published guidance.

3.5.7 No Duty to safeguard Caregiver Wellbeing

A child patient was injured; the case the pharmacist had to meet was whether the obligation to offer to counsel the parents, *qua* caregivers and the patient's agents, gives rise to a legal obligation related to the parents for their emotional well-being, as opposed to the actual patient's well-being. The Supreme Court of California decided in *Huggins v Longs Drug Stores California Inc*³⁹⁴ that to do so would be an unwarranted enlargement of potential liability. Although the *Huggins* case can only be of persuasive authority, there is a general counterpart in Ireland. A post-mortem examination on a deceased child carried out without consent, in which organs removed and retained, was the issue in *Devlin v National Maternity Hospital*.³⁹⁵ While deeply sympathetic to the parents, the Supreme Court declined to extend the law. Denham J said that "[a]ny such development would give rise to uncertainty in the law of liability generally and to potentially unforeseeable repercussions."³⁹⁶

Malone, PM, Kier, KL, Stanovich, JE, (Editors) *Drug information: a guide for pharmacists*, Third Edition (2006) McGraw-Hill Professional, Columbus, 415. In *Baker*, the pharmacy technician had overridden the drug interaction (that the system detected from the patient's medication profile) between two medicaments. The tranlycypromine in one product inhibited the enzymatic breakdown of the phenylpropanolamine in the other product, thereby increasing its circulating levels in the bloodstream. The patient committed suicide after suffering a stroke following the interaction between the offending drugs.

³⁹³ *Baker v Arbor Drugs Inc* (1996) 544 NW2d 727, 731; *Stebbins v Concord Wrigley Drugs Inc* (1987) 416 NW2d 381, 388.

³⁹⁴ *Huggins v Longs Drug Stores California Inc* (1993) 862 P2d 148 (Cal). Bystander and "direct victim" theories of negligence are often advanced in cases based on a family relationship. The California jurisprudence on no duty to warn of possible side effects was reiterated in *Russo v Safeway Inc* (2006) No VG05212054 (Cal Super Ct), cited in Clausen Miller PC, *Pharmacists' Duty to Warn: A Nationwide Survey* (2006) Chicago, Available from http://www.clausen.com/dir_docs/ind_pubs/ebbf590-ccc1-4d08-8a31-9bd1c521918a_pdfdocument.pdf, (Last accessed 12 January, 2012).

³⁹⁵ *Devlin v National Maternity Hospital* [2008] 2 IR 222 (Sup Ct). See also Byrne, R, Binchy, W, *Annual Review of Irish Law 2007* (2008) Thomson Round Hall, Dublin, 539-540.

³⁹⁶ *Devlin v National Maternity Hospital* [2008] 2 IR 222, 240, Denham J.

3.6 Drug Information Provision

We have seen that tortious liability may be imposed for negligent misstatements, irrespective of a contractual or fiduciary relationship.³⁹⁷ In that regard, the position of pharmacists merits closer examination.

Pharmacists will be held liable for their conduct relating to Drug Information (DI), which is a specialised discipline of pharmacy and held to a higher degree of care by the law.³⁹⁸ The recipients of DI, most often, are other health professionals, greatly raising the stakes when the information is indefensibly wrong.³⁹⁹ DI provision by pharmacists, however, is not confined to those ‘other health professional’ groups; members of the public also are the recipients of such a service. The thesis will present the situation of participants in sports. Such persons are a particularly ‘broad church’, because a pharmacist’s DI advice may be sought by a ‘team doctor’, a national association or a body tasked with ensuring probity in sport, apart from the amateur and professional sports competitors, and their lay mentors, who reside in the communities served by pharmacists.

3.6.1 Advice to Other Health Professionals

In a recent Alabama case, *Springhill Hospitals v Larrimore*, there was no evidence that the pharmacist knew anything specific about the patient’s renal insufficiency and, in the court’s holding, the pharmacist had no duty to make enquiry of the physician.⁴⁰⁰ The pharmacist lacked the “*special knowledge*” that would serve as an exception to the general “no duty” to warn.⁴⁰¹ Brushwood and Nanni also alluded to the other exception, namely, where a pharmacist undertakes a duty to the patient.⁴⁰²

³⁹⁷ See also Byrne, G, *Negligent Misrepresentation: Recent Developments in English and Irish Law* (2008) 2(4) Quarterly Review of Tort Law 22. (This article is cited in Banakas, S, *Voluntary Assumption of Tort Liability in English Law: a Paradox?* InDret 4/2009).

³⁹⁸ Although Medicines Information is the term in wider use in Ireland, the author adopts the abbreviation (DI). To do so will avoid any confusion with myocardial infarction for which MI is the recognised abbreviation in the medical and pharmaceutical literature.

³⁹⁹ Rumore, MM, *Legal Aspects of Drug Information Practice*, Chapter in Malone, PM, Kier, KL, Stanovich, JE, (Editors) *Drug information: a guide for pharmacists*, Third Edition (2006) McGraw-Hill Professional, Columbus, 412.

⁴⁰⁰ *Springhill Hospitals v Larrimore* (2008) 5 So3d 513, (Ala): discussed in Brushwood, DB, Nanni, KR, *Hospital liability for accuracy of pharmacist consultations* (2009) 66 American Journal of Health-System Pharmacy 680, 680-683.

⁴⁰¹ See Brushwood, DB, Nanni, KR, *op cit*, 682. See, however, *US v Smith* (2009) 573 F3d 639 [CA 8 (Minn)] (Pharmacist could provide expert testimony regarding type of information a doctor should have to prescribe a particular drug).

⁴⁰² Brushwood, DB, Nanni, KR, *loc cit*. The authors cited *Baker v Arbor Drugs Inc* (1996) 544 NW2d 727 (Mich App).

Although the physician was considered the learned intermediary, responsible for communicating the manufacturer's warnings to the patient, the Omnibus Budget Reconciliation Act (OBRA 90) may be shifting this responsibility to the pharmacist.⁴⁰³ Regarding DI, Rumore states (emphasis supplied) that:

*"Once the duty of care is established, the plaintiff would need a preponderance of evidence to prove that (1) the information provided was materially deficient (2) the deficient information was a proximate cause of injury suffered (or at least a substantial contributing factor), (3) the recipient reasonably relied on the information provided, (4) the information deficiency was due to failure to exercise reasonable care, and (5) the pharmacist knew or should have known that the safety or health of another may have depended on the accuracy of the information provided."*⁴⁰⁴

The author doubts that British and Irish law would receive so readily what is facially a departure from the "but for" causation test. The "material contribution" test is clearly exceptional.⁴⁰⁵

Contrasting information provision at its broadest with the duty to warn, to which we shall later return, let us consider some other US cases. Using nomenclature for a pharmacist that reads inelegantly in the Twenty-First Century, the North Carolina Court of Appeal, in *Batiste v American Home Products Corp*, did not "hold a retail druggist liable without fault because of injuries and damage resulting from the use of a drug compounded or sold in strict compliance with the physician's order, in the absence of any knowledge which would constitute negligence."⁴⁰⁶ The court held that pharmacists have a duty beyond accurately filling a prescription based on known contraindications that would alert a reasonably prudent pharmacist to a potential problem.⁴⁰⁷ However, the court in *Morgan v Wal-Mart Stores* did not find for the plaintiff, opining that pharmacists have no generalized duty to warn, as this would cut across the proper application of the learned intermediary doctrine.⁴⁰⁸ The pharmacist in *Heredia v Johnson*⁴⁰⁹ dispensed an Pediotic Otic Suspension (*i.e.* ear drops) without relaying the manufacturer's warning, contained in the package insert, directed against using the product in the presence of tympanic membrane

⁴⁰³ Rumore, MM, *op cit*, 413.

⁴⁰⁴ Rumore, MM, *loc cit*.

⁴⁰⁵ *E.g. Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32 (HL).

⁴⁰⁶ *Batiste v American Home Products Corp* (1977) 231 SE2d 269 (NC Ct App), 275.

⁴⁰⁷ *Morgan v Wal-Mart Stores Inc* (2000) 30 SW3d 455 (Tex App), 466.

⁴⁰⁸ (2000) 30 SW3d 455, 469, per Patterson JA.

⁴⁰⁹ *Heredia v Johnson* (1993) 827 FSupp 1522 (D Nev).

rupture (or eardrum perforation).⁴¹⁰ The patient did have a perforated eardrum and suffered permanent brain damage. The defendant's motion for summary judgment was denied under Nevada's strict liability law.⁴¹¹

Liability in negligent misrepresentation (misstatement) has not been out-ruled for pharmacists who provide false information to a person who relies thereon and suffers injury in consequence of such reliance.⁴¹² Let us consider a salutary tale from Victoria, Australia.⁴¹³ A doctor sought advice from a pharmacist on the appropriate dosage of a cocaine mouthwash for a patient with pain post-tonsillectomy. The pharmacist recommended a dose at least 10 times stronger than that used for cancer patients. The doctor adopted the pharmacist's advice, prescribing the medication, which was dispensed by the same pharmacist. A friend of the patient consumed the excessively-potent mouthwash with alcohol at a party, leading to her death from the combined drug toxicity. The coroner regarded the case as simply one of "*the blind leading the blind.*" Both the doctor and pharmacist argued that they did not owe a duty of care to the deceased. The matter was referred to the Pharmacy Board of Victoria and the Australian Medical Association for investigation of professional misconduct. On the given facts, it may be submitted that allegations of negligence and negligent misstatement could plausibly have been made in civil proceedings.

Drug information may be defective for a variety of reasons: it may be outdated, incomplete (therefore misleading), effectively none provided through an incomplete literature search or by

⁴¹⁰ Pediotic Suspension contains neomycin sulfate, polymyxin B sulfate and hydrocortisone acetate. The propensity of neomycin to induce permanent hearing loss due to cochlear damage has long been known and the risk is greater with prolonged use. See also Vivian, JC, Brushwood, DB, *Legal Cases That Raise Ethical Issues*, Chapter in Haddad, AM (Editor), *Teaching and Learning Strategies in Pharmacy Ethics*, Second Edition (1997) Pharmaceutical Products Press, Binghamton (NY), 5. See further Owen, DG, *Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate* (2010) 42 Connecticut Law Review 733,768, making the statement: "[b]ecause pharmacists are more in the nature of service providers, like doctors, than retail merchants, like hatters, they are subject to liability for selling prescription drugs only in negligence, not strict liability." Owen qualifies that statement in Footnote No 166: "...But see *Heredia v Johnson* [(1993) 827 F Supp 1522, 1525 (D Nev)] (denying the defendant's motion for summary judgment with regard to the claim of strict liability); *Griffith v Blatt* [(2002) 51 P3d 1256, 1262 (Or)] (finding that a pharmacist who sold prescription lotion was a 'seller' under section 402A [of the Restatement (Second) of Torts] and, hence, possibly subject to strict liability in tort for failing to warn)."

⁴¹¹ *Heredia v Johnson* (1993) 827 F Supp 1522, 1523. Under Nevada law, strict liability may be imposed on sellers or distributors for their role in placing a defective product into stream of commerce. The focus is not on the product's being a drug nor the negligent conduct of a pharmacist: "*failure to warn may constitute product defect*". See also Hedley, S, *Tort*, Seventh Edition (2011) Oxford University Press, Oxford, 90 (Distributors have no general duty to make a check of goods. However, there are special circumstances in which such a duty will be imposed: where the goods came from another supplier with a dubious reputation; where the manufacturer's instructions are that there should be a check).

⁴¹² Rumore, MM, *op cit*, 418.

⁴¹³ See Ming, KLY, *A Duty to Care: Pharmacists' Negligence: Implications for Pharmacists and Lessons Arising* (2003) 5 *Allied Health Professions* 1, 5, citing: Adams, D, *Mixture led to death, court told*, *The Age*, 21 February, 2001, Melbourne, 3; Gilchrist, I, *Chemist gave OK on cocaine; doctor prescribed killer mouthwash*, *Herald Sun*, 24 April, 2002, Melbourne, 15.

an incompetent searcher. Information negligence may occur by parameter negligence (failure to consult the correct source) or omission negligence (consulting the correct source, but failure to locate the information that would guide the correct conclusions).⁴¹⁴ The fault can lie anywhere in the information dissemination chain, publication, collection, storage, retrieval, dissemination or utilisation. Few cases have been brought before the courts concerning the liability of print or online information sources. Where the service rendered is deemed to be a professional service, the US courts have been reluctant to impose strict liability.

With exceptions, persons physically injured because of their reliance on defective and unreasonably dangerous information have only negligence as a cause of action, against the author however, not the publisher; only if the publisher is negligent or offers intentionally misleading information could it be held liable (*Winter v GP Putnam's Sons*).⁴¹⁵ The plaintiffs in *Winter v GP Putnam's Sons* were mushroom enthusiasts, became severely ill from picking and eating mushrooms after relying on information in *The Encyclopedia of Mushrooms*, a book published by the defendant. The plaintiffs sued the publisher and sought damages under various theories. The District Court granted summary judgment for the defendant, affirmed upon appeal.⁴¹⁶ The appellate court characterised *The Encyclopedia of Mushrooms* as like a book on how to use a compass or an aeronautical chart. The latter were likened to a physical 'product' while the "*How to Use' book is pure thought and expression.*"⁴¹⁷ The court declined "*to expand products liability law to embrace the ideas and expression in a book.*"⁴¹⁸ Members of the appellate panel declared that they knew of no court that has chosen the path to which the plaintiffs point. There was a finding of fact that *The Encyclopedia of Mushrooms* was a reference guide containing information on the habitat, collection, and cooking of mushrooms, written by two British authors and originally published by a British publishing company.⁴¹⁹ The defendant Putnam, an American book publisher, purchased copies of the book from the British publishing house and distributed the finished product in the United States. Putnam neither wrote nor edited the book.

⁴¹⁴ Rumore, MM, *loc cit*. Legal practitioners will be aware of the consequences at stake in failure or omission to present to the bench all the relevant legal authorities during certain types of applications to court.

⁴¹⁵ *Winter v GP Putnam's Sons* (1991) 938 F2d 1033 (9th Cir). The court said ([1034]) that products liability law "*is geared to the tangible world.*"

⁴¹⁶ Rumore, MM, *op cit*, 419.

⁴¹⁷ (1991) 938 F2d 1033, [12].

⁴¹⁸ (1991) 938 F2d 1033, [13].

⁴¹⁹ Dickinson, C, and Lucas, J (Editors), *The Encyclopedia of Mushrooms* (1979) GP Putnam's Sons, New York – originally published by Orbis Books, London (1978). It could not have been reasonably foreseeable to the authors in 1978, when they assigned the copyright to their British publishers, that their work would find its way onto the US market, given the general partition of UK publication rights from the corresponding rights for USA and Canada during the 1960s and 1970s. Another publisher, also named Orbis Books, is based at Maryknoll (NY): that US operation is associated with a missionary society and is unconnected with the London-based entity. For that reason also, it would have been somewhat improbable that a 'British' Orbis title would have been destined to enter 'stream of commerce'.

Strauch, Walker and Bebensee have remarked that, as medical library Web sites actively participate in electronic delivery, it is said that they have the potential to be drawn in as endorsers or actual publishers of erroneous data.⁴²⁰

The case of *Demuth Development Corp v Merck & Co Inc*, concerned the right of a publisher of the Merck Index, an encyclopedia of chemicals and drugs to publish free of fear of liability, which the court vindicated.⁴²¹ The Federal District Court described the action taken by *Demuth* as asserting (what was then) “*the novel claim that the publisher of an encyclopedia of chemicals and drugs is liable in damages for allegedly misrepresenting the toxicity of a chemical utilized in plaintiff's product, thereby causing a loss of plaintiff's customers and business.*”⁴²² Central to the litigated controversy was the Merck Index's treatment of triethylene glycol, “*a chemical indispensable to the operation of plaintiff's glycol vaporizer*”.⁴²³ Triethylene glycol, when vaporized in plaintiff's appliance, had been used as a germicidal agent to disinfect the air in hospitals, laboratories and other places where a germ-free environment was required. The plaintiff alleged that references in the Merck Index misrepresented the toxicity of triethylene glycol, which plaintiff asserted to be completely non-toxic when inhaled as a vapour and significantly less toxic than ethylene glycol when ingested orally. It was urged on the court that the Merck Index was widely used by plaintiff's customers as a reliable authority on the toxic effect of chemicals and drugs. It is claimed that the alleged untrue publication caused those customers and potential customers of plaintiff to fear a toxic effect from triethylene glycol and to discontinue or refuse to purchase the glycol vaporizer as unfit and unsafe for air sterilization purposes. Ultimately, the court said that “[g]eneralized claims of business loss caused by defendant's exercise of its right to publish cannot overcome the clear absence of liability as a matter of law.”⁴²⁴

The pharmacist's role includes information interpretation, evaluation and giving advice, functions that librarians are not equipped to discharge.⁴²⁵ In *Reben v Ely*, the drug information was not

⁴²⁰ See Strauch, AB, Walker, E, Bebensee, M, *Is There a Pending Change in Medical Publisher and Library Liability?* (2007) 4 Journal of Electronic Resources in Medical Libraries 101.

⁴²¹ See *Demuth Development Corp v Merck & Co Inc* (1977) 432 FSupp 990 (EDNY). (The right to publish is guaranteed by the First Amendment and the overriding societal interest in the untrammelled dissemination of knowledge). See also *Libertelli v Hoffman-La Roche* (1981) 7 Media Law Reporter (BNA) 1734, 1736 (SDNY) (The publisher of the Physician's Desk Reference was not liable for failure to include drug warning because the work was like a published advertisement of products rather than a reference work).

⁴²² (1977) 432 FSupp 990, 991, per Neaher DJ.

⁴²³ *Loc cit.*

⁴²⁴ (1977) 432 FSupp 990, 995, per Neaher DJ.

⁴²⁵ Rumore, MM, *op cit*, 420.

sufficiently thorough in that it failed to recommend emergency room attention.⁴²⁶ The Arizona Poison and Drug Information Center was found liable for greater than fifty per cent of the plaintiff's damages.

Professor Lars Noah notes that books were “*mass-produced and disseminated long before the industrial revolution but, apart from libel claims, are rarely the subject of tort litigation.*”⁴²⁷ To furnish one of those rare contrary examples, he cites Whittaker on a 1986 decision by a French court imposing liability on the author and publisher of a guide to edible fruits and plants, which included a photograph of wild carrot that was misleadingly similar to poisonous aquatic hemlock.⁴²⁸

One mentions parenthetically some recent decisions of the English Court of Appeal. *Scullion v Bank of Scotland plc (trading as Colleys)*⁴²⁹ involved valuation of property on behalf of a mortgagee for purpose of a buy-to-let mortgage, the Court of Appeal rejected an approach by the claimant/respondent that was close to treating a negligent misstatement as a warranty.⁴³⁰ Toulson LJ opined in *Parabola Investments Ltd v Browallia Cal Ltd*⁴³¹ that “[f]raudulent (or negligent) misstatement involves a claimant acting to his detriment under the inducement of a false belief. That influence ceases once the truth becomes known.”⁴³² The learned appellate judge had more to say (outwith the scope of this thesis) about inducement to change one's position that cannot be readily undone and chances irredeemably lost, in commercial settings. It is submitted that the consequences of negligent DI provision may have proceeded well beyond recall ‘before the truth is known’.

⁴²⁶ *Reben v Ely* (1985) 705 P2d 1360 (Ariz: Ct of App, 2nd Div). It is interesting to note the differing pharmaceutical and legal perspectives in *Reben v Ely*. The court said (at Page 1360): “*The facts of the case are of little significance to the legal question involved.*” The (unsuccessful) defendants/appellants' sole issue was that loss of filial consortium was not a cognisable cause of action in Arizona and that therefore the judge erred in permitting evidence and in instructing on that element of the parents' injury. See also Lashkajani, EL, *A Child's Right to a Cause of Action for Loss of Parental Consortium* (1994-1995) 15 Children's Legal Rights Journal 48.

⁴²⁷ Noah, L, *Authors, Publishers, and Products Liability: Remedies for Defective Information in Books* (1998) 77 Oregon Law Review 1195, 1196.

⁴²⁸ Noah, L, *op cit*, 1199 (n), citing: Whittaker, S, *European Product Liability and Intellectual Products* (1989) 105 Law Quarterly Review 125, 133

⁴²⁹ *Scullion v Bank of Scotland plc (trading as Colleys)* [2011] 1 WLR 3212 (CA).

⁴³⁰ [2011] 1 WLR 3212, 3228, per Lord Neuberger of Abbotsbury MR.

⁴³¹ *Parabola Investments Ltd v Browallia Cal Ltd* [2011] 1 QB 477 (CA).

⁴³² [2011] 1 QB 477, 488-489, per Toulson LJ.

3.6.1.1 Implications for Pharmacists

Much of the case law discussed above is based on information alleged to be inaccurate or erroneous that has been published in books. Books of a pharmaceutical nature have been traditionally in the custody of their intended readership, the pharmacists. Therefore physicians and others would rely on the pharmacist to provide information that the enquirers could not source for themselves. Modern online databases may provide independently some answers to physicians' enquiries that have been traditionally directed to a pharmacist. However, the US authorities may be persuasive to an Irish court in deciding whether a pharmacist owed a duty to another health professional in relation to advice sought and provided in return.

3.6.2 Pharmacists and Participants in Sports

Pharmacists may be called upon to advise in relation to medication (whether or not prescription controlled) and dietary supplements, all of which may be supplied or sold in a pharmacy. Those who seek such advice are likely to be (elite⁴³³ or recreational) athletes and other sports participants, whether amateur or professional, or possibly a mentor to a team or an individual competitor.

Pharmacists should be fully conversant with the pharmacological interface⁴³⁴ their profession has with the remit of the World Anti-Doping Agency (WADA) [in French, *l'Agence mondiale antidopage* (AMA)].⁴³⁵ WADA was established in 1999⁴³⁶ as "*an international independent agency composed and funded equally by the sport movement and governments of the world.*"⁴³⁷ A pharmacist will need to be aware of annual modifications to the WADA Prohibited List⁴³⁸ and

⁴³³ See McArdle, D, *Elite Athletes' Perceptions of the Use and Regulation of Performance Enhancing Drugs in the United Kingdom* (1999) 9 *Journal of Legal Aspects of Sport* 43, 48: "... they seemed to lack faith in the 'official' sources of information and preferred to seek another athlete's, doctor's or pharmacist's advice if necessary."

⁴³⁴ See Cox, N, Schuster, A, *Sport and the Law* (2004) First Law, Dublin, 86-99.

⁴³⁵ The WADA-AMA Website has the URL: <http://www.wada-ama.org/>.

⁴³⁶ See James, M, *Sports Law* (2010) Palgrave Macmillan, Basingstoke, 18-19, on the earlier major initiative in this area, the Council of Europe Anti-Doping Convention 1989. See further Council of Europe (CoE), *Anti-Doping Convention*, European Treaty Series - No 135 (1989). Available from http://www.coe.int/t/dg4/sport/Source/CONV_2009_135_EN.pdf. (Last accessed 04 April, 2012). See also Council of Europe (CoE), *Additional Protocol to the Anti-Doping Convention* (2002) Done at Warsaw, 12 IX 2002. Available from <http://conventions.coe.int/Treaty/en/Treaties/Html/188.htm>. (Last accessed 04 April, 2012).

⁴³⁷ World Anti-Doping Agency, *About WADA* (2011) World Anti-Doping Agency, Montreal. Available from <http://www.wada-ama.org/en/About-WADA/>. (Last accessed 03 April, 2012).

⁴³⁸ World Anti-Doping Agency, *Prohibited List* (2011) World Anti-Doping Agency, Montreal. Available from <http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/International-Standards/Prohibited-List/>. (Last accessed 03 April, 2012).

periodic amendments to the International Standard for Therapeutic Use Exemptions (ISTUE).⁴³⁹ One recommends that all relevant previous versions of such documents should be downloaded from the WADA Website and retained, since any litigation will hinge on the version in force at the material time.

Sports supplements are an area of particular concern. Increasingly, sportspersons will seek to obtain such items 'at home' rather than risk using a product sourced abroad with an unknown provenance. It is submitted that it is not enough for a pharmacist to prevent a sportsperson from going 'offside' with respect to the WADA regime. There is a duty also to warn, in appropriate cases, about the questionable or proven deleterious health effects of supplements, for example, cobalt (a heavy metal).⁴⁴⁰ The Irish Sports Council Website has a section on Supplements and Sports Food Policy for guidance.⁴⁴¹ Ultimately, the athlete is strictly liable for any substance detected within her corporeal system.⁴⁴²

While the WADA regime is one of strict liability, a 'modified' approach has emerged.⁴⁴³ Its origins lie in the Court of Arbitration for Sport (CAS) award in *USA Shooting & Quigley v UIT*.⁴⁴⁴ The CAS Panel held that if a strict liability standard is to be applied, "*it must be clearly articulated and, although the fight against doping is 'arduous' and requires strict rules.*"⁴⁴⁵ It should be the case that:

"[R]ule-makers and the rule-appliers must begin by being strict with themselves. Regulations ... must[:] be predictable ... emanate from authorised bodies ... be adopted in constitutionally proper ways ... Athletes and officials should not be confronted with a thicket of mutually qualifying or even contradictory rules that

⁴³⁹ World Anti-Doping Agency, *Therapeutic Use Exemptions* (2011) World Anti-Doping Agency, Montreal. Available from <http://www.wada-ama.org/en/Science-Medicine/TUE/>. (Last accessed 03 April, 2012).

⁴⁴⁰ Lippi, G, Franchini, M, Guidi, GC, *Blood doping by cobalt. Should we measure cobalt in athletes?* (2006) 1:18 *Journal of Occupational Medicine and Toxicology*.

⁴⁴¹ Irish Sports Council, *Supplements and Sports Food Policy* (Undated Web Resource) Irish Sports Council, Dublin, Available from http://www.irishsportsCouncil.ie/Anti-Doping/Medicines_TUEs/Supplements_Nutrition/ (Last accessed 03 April, 2012).

⁴⁴² See Gardiner, S, James, M, O'Leary, J, Welch, R, Blackshaw, I, Boyes, S, Caiger, A, *Sports Law*, Third Edition (2007) Routledge Cavendish, Abingdon, 275: "*Strict liability may appear to be a draconian provision. The reason for it is a fear that rules requiring proof of intent would be impossible to implement: it is feared that athletes would find little difficulty in producing someone prepared to take responsibility and vouch for the athlete's innocence.*"

⁴⁴³ See Anderson, J, *Modern Sports Law: A Textbook* (2010) Hart Publishing, Oxford, 126-127.

⁴⁴⁴ CAS 94/129 *USA Shooting & Quigley v UIT*.

⁴⁴⁵ Anderson, J, *op cit*, 126.

can be understood only on the basis of the de facto practice over the course of many years by a small group of insiders."⁴⁴⁶

These *dicta* represent an ornate (although fundamental) call for the application of fair procedures. Some supplements, whether or not positioned in the sports marketplace, have a Product Authorisation (PA) duly issued by the Irish Medicines Board (IMB). Others are not the subject of a PA. Pharmaceutical companies that market authorised medicinal products are required to follow Good Manufacturing Practice (GMP). Pharmacists should bear in mind that even those companies that produce authorised medicines (as part of their entire product portfolio) will not have to adhere to GMP when manufacturing unauthorised supplements⁴⁴⁷; the possibility cannot be excluded that contaminants may be present in such products.⁴⁴⁸

Pharmacists have a role in prevention of inadvertent doping. For example, pseudoephedrine (a decongestant contained in several cold remedies) is not allowed in competition⁴⁴⁹ on grounds of its stimulant properties. The Monthly Index of Medical Specialities for Ireland (MIMS Ireland) contains a guide on *Medicines and Sport*, which summarises the WADA regime.⁴⁵⁰

The spectre of reliance on statements made by the pharmacist looms large in the sporting 'arena', because of the grave consequences for the sportsperson arising from acting upon a negligent misstatement to his detriment. It is submitted that rural pharmacists would be particularly vulnerable to suit in negligence or negligent misstatement because a court could be persuaded that they should have known the 'sport stars' in their own community (or county). In view of the *BALCO* scandal,⁴⁵¹ it may not be too remote to suggest that pharmacists should be wary of any

⁴⁴⁶ CAS 94/129 *USA Shooting & Quigley v UIT*, [34].

⁴⁴⁷ See CAS 2011/A/2645 *Union Cycliste Internationale (UCI) v Alexander Kolobnev & Russian Cycling Federation* for a 'digest' of cases involving supplements.

⁴⁴⁸ The question of caffeine and contaminants arose in *FINA v CBDA & Ors* (2011) Joined Cases: CAS 2011/A/2495 *FINA v César Augusto Cielo Filho & CBDA*; CAS 2011/A/2496 *FINA v Nicholas Araujo Dias dos Santos & CBDA*; CAS 2011/A/2497 *FINA v Henrique Ribeiro Marques Barbosa & CBDA*; CAS 2011/A/2498 *FINA v Vinicius Rocha Barbosa Waked & CBDA*. The caffeine ingredient in ostensibly pure Caffeine Capsules, to be magisterially compounded in a Brazilian pharmacy, was inadvertently contaminated with the diuretic (and notorious masking agent) furosemide, which was being used in a heart disease medication prepared at the pharmacy immediately prior to the Caffeine Capsules batch.

⁴⁴⁹ Since January 2010.

⁴⁵⁰ The Irish Sports Council, *Medicines and Sport*, MIMS Ireland, April 2012, MPI Ireland, Dublin, xiii. The information is also accessible through the MIMS Ireland Website: www.mims.ie. The Medicines and Sport Section is prepared on behalf of the Irish Sports Council by the Website, www.eirpharm.com, which resource itself allows medication to be checked for conformity to the WADA regime.

⁴⁵¹ See Henne, K, *WADA, the Promises of Law and the Landscapes of Antidoping Regulation* (2010) 33 *PoLAR: Political and Legal Anthropology Review* 306. See also Grady, J, McKelvey, S, Clement, A, *A New "Twist" for the Home Run Guys: An Analysis of the Right of Publicity versus Parody* (2005) 15 *Journal of Legal*

entreaty to identify, compound or otherwise supply some material similar to, although not identical with, a substance already banned by WADA.

Pharmacy computer systems are programmed to alert the pharmacist to drug interactions. There is a case to be made for a modular refinement to cross-check routinely, prescribed and non-prescribed medication for sportspersons, against the WADA Prohibited List, if this is not already done.

Some pharmacists may specialise in sports pharmacology and nutrition. Others will not hold themselves out as possessing such expertise. It is an evergreen public policy objective to increase popular participation in exercise generally and in sports. Accordingly, pharmacists should keep abreast of developments through the aforementioned resources and the multidisciplinary literature.⁴⁵² In this manner, for example, pharmacists may become aware of contemporary trends in substances and techniques that may subsequently become restricted or banned by WADA. Apart from any autodidactic approach, it is noteworthy that, in March 2012, the Japanese Anti-Doping Agency (JADA) announced an update to its 'sports pharmacist' accreditation system (launched in 2009), which initiative could be emulated elsewhere.⁴⁵³

3.7 Patient Information Leaflets (Patient Package Inserts)

The provision of such patient-oriented information, to be placed within medication packaging, in Ireland is governed by EU Law. For the EU (and the wider EEA), the package leaflet must be based on the Summary of Product Characteristics (SPC).⁴⁵⁴ The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.⁴⁵⁵ The

Aspects of Sport 267. See also Nafziger, JAR, *Baseball's Doping Crisis and New Anti-Doping Program* (2006) 1 & 2 *International Sports Law Journal* 10.

⁴⁵² For example, Goldstein, ER, Ziegenfuss, T, Kalman, D, Kreider, R, Campbell, B, Wilborn, C, Taylor, L, Willoughby, D, Stout, J, Graves, BS, Wildman, R, Ivy, JL, Spano, M, Smith, AE, Antonio, J, *International society of sports nutrition position stand: caffeine and performance* (2010) 7:5 *Journal of the International Society of Sports Nutrition*.

⁴⁵³ World Anti-Doping Agency, *JADA progress with Sports Pharmacist System* (2012) World Anti-Doping Agency, Montreal. Available from <http://www.wada-ama.org/en/News-Center/Articles/JADA-progress-with-Sports-Pharmacist-System/>. (Last accessed 03 April, 2012). JADA's declared goal "by 2014 is to have in excess of 7,000 pharmacists either certified or attending seminars with a view to gaining certification."

⁴⁵⁴ Article 59 of EU Council Directive 2001/83/EC, as "replaced" by Article 44 of EU Council Directive 2004/27/EC.

⁴⁵⁵ Article 59(3) of EU Council Directive 2001/83/EC, as "replaced" by Article 44 of EU Council Directive 2004/27/EC.

PIL must also be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market.⁴⁵⁶

By contrast, the US judicial approach to package inserts is typified by the case of *McKee v American Home Products Corp.*⁴⁵⁷ The State of Washington's Supreme Court stated that pharmacists do not have a duty to provide customers with manufacturer's package insert for prescription drugs, where this document contains professional prescribing information for physicians.⁴⁵⁸ Patient Package Inserts (PPIs) are required to be supplied with, for example, oral contraceptives. The court added that the professional package inserts may "*confuse or frighten the patient*".⁴⁵⁹ Another judicial concern was that receipt by consumers of manufacturer's insert could "*abrogate learned intermediary doctrine and could impact not only pharmacists' liability, but that of manufacturers and physicians as well.*"⁴⁶⁰ Manufacturers who seek to influence prescriber behaviour, by going beyond disclosing the risks in using a medicinal product, may "*forfeit the protection of the learned intermediary doctrine*" in those jurisdictions where it applies.⁴⁶¹

3.8 Negligence with a Transatlantic Denouement

A British case with the involvement of US physician and pharmacist is *Horton v Evans*.⁴⁶² The High Court held that the British pharmacist had a duty, under the Royal Pharmaceutical Society of Great Britain's Code of Medicines, Ethics and Practice, to consider whether the medication was suitable for the patient. The same requirement appeared in a manual produced by the second defendant, a large chain of high street pharmacies. In the case of a patient for whom previous prescriptions for the same medication had been dispensed by the same pharmacy, such a large increase in the dose of the medication should at least have raised a possibility in the mind of the dispenser that the instructions on the prescription might be incorrect. The pharmacy chain's branch procedures manual covered this precise situation, and in failing to follow the procedure as

⁴⁵⁶ Article 63, Paragraphs (2) and (3), of EU Council Directive 2001/83/EC, as "*replaced*" by Article 48 of EU Council Directive 2004/27/EC.

⁴⁵⁷ *McKee v American Home Products Corp* (1989) 782 P 2d 1045 (Wash). See also Green, TC, *Licking, Sticking, Counting, and Pouring - Is That All Pharmacists Do? - McKee v American Home Products Corp* (1990-1991) 24 Creighton Law Review 1449, 1450.

⁴⁵⁸ *Laws v Johnson* (1990) 799 SW2d 249, 251 (Tenn Ct App). (Pharmacists who removed printed inserts, addressed to physicians, from packages before dispensing prescription drugs were not guilty of negligence).

⁴⁵⁹ *McKee v American Home Products Corp* 782 P 2d 1045, 1055.

⁴⁶⁰ *McKee v American Home Products Corp*, loc cit.

⁴⁶¹ See Wu, CS, *Distributive Justice in Pharmaceutical Torts: Justice where Justice is due?* (2006) 69 Law and Contemporary Problems 207, 221

⁴⁶² *Horton v Evans* [2006] EWHC 2808 (QB); 94 BMLR 60.

stated in the manual, and not questioning whether the prescription was correct, the dispensing was negligent.

The physician in the US had not been negligent, as he had merely been asked to provide a “repeat” prescription, and had no reason to suspect that it was not accurate. The judge concluded that the deterioration in the claimant's health could be attributed to the negligence of the defendants, and that the act of the pharmacist in the US did not break the chain of causation, because it was reasonable to suppose that a reasonably competent pharmacist would have foreseen that the label on the bottle might be used by a doctor to identify what the prescription had been.

The author's not unreasonably pedantic reaction is that, when initially approached by the claimant, the US physician did not 'repeat' anything. That medical practitioner was issuing a prescription to the patient for the first time whilst believing it to be entirely consistent with the medicinal product previously ordered by his British colleague. Whilst *Horton v Evans* is undoubtedly of persuasive value to an Irish court, it is submitted that certain questions would have to be asked if a case based on like facts were to come before our courts today. Would it not have been possible to make initial contact with the original pharmacy by telephone, fax or email to establish what had (or should have) been dispensed? Would it not have been advisable to limit the quantity of the medication supplied to the patient by the pharmacy in the second country until the accuracy of the prescription had been confirmed by the physician in the first country?

3.9 Pregnancy as Personal Injury

Nolan has discussed the role of the pharmacist in pregnancy that the patient had sought to avoid.⁴⁶³ Assumption of liability, the author contends, is unlikely in the case of a manufacturer of defective condoms or a pharmacist who mistakenly dispenses tranquillisers instead of contraceptives. Yet there was an assumption of liability in the pharmacist case to which Nolan refers.⁴⁶⁴

⁴⁶³ Nolan, D, *New Forms of Damage in Negligence* (2007) 70 *Modern Law Review* 59, 72.

⁴⁶⁴ *Troppi v Scarf* (1971) 187 NW2d 511 (Mich Ct App). See also: Ramsay, M, *The Religious Beliefs of Tort Victims: Religious Thin Skulls or Failures of Mitigation* (2007) 20 *Canadian Journal of Law & Jurisprudence* 399, 414. In that case, a couple with several children attempted to prevent further pregnancies, as they could not afford to raise additional children. Unfortunately, their pharmacist was negligent in filling a prescription for birth control pills with sleeping pills. “*The pharmacist accepted responsibility for the resulting pregnancy but argued that both abortion and adoption were open as paths of reasonable mitigation. The court however ruled that the couple's moral objections to abortion and adoption were reasonable and that they could not be expected to mitigate their losses through either of these paths.*” To

Vikingstad referred to *Troppi v Scarf* within the spectrum of wrongful parentage cases.⁴⁶⁵ Wrongful conception claims may also be brought against a pharmacist who negligently fills a birth control prescription (*Troppi v Scarf*⁴⁶⁶), a physician who improperly inserts or positions a contraceptive device (*Jackson v Baumgartner*⁴⁶⁷), a manufacturer or pharmaceutical company who manufactures a defective contraceptive (*JPM v Schmidt Labs Inc*⁴⁶⁸) or a physician who fails to inform parents of the likelihood their future children would be handicapped or impaired in a way that would cause the parents to avoid conception (*Lininger v Eisenbaum*⁴⁶⁹). The other claim brought under the umbrella of wrongful parentage is a claim for wrongful continuation of a pregnancy: not usually against a pharmacist.

Murtaugh has traced the judicial policy analysis that culminated in *Troppi's Case*.⁴⁷⁰ In *Sherlock v Stillwater Clinic*, the Minnesota court reasoned that an action for wrongful birth was “analytically indistinguishable from an ordinary medical malpractice action, and stated that, ‘[w]here the purpose of the physician’s actions is to prevent conception or birth, elementary justice requires that he be held legally responsible for the consequences which have in fact occurred’.”⁴⁷¹

The Minnesota court allowed damages for rearing the unplanned child, but offset the award by an amount equal to the benefits conferred upon the parents as a result of the child’s birth. The court concluded that this procedure should be coupled with “strict judicial scrutiny of verdicts” in order to prevent excessive awards.⁴⁷²

The Michigan court’s decision in *Troppi* has been “praised by other courts as the most logical means to achieve an equitable result when the parents seek the costs of rearing an unplanned

Ramsay, it “seems unfair to expect a woman to provide clear evidence of her pre commitment to a religion or philosophical code that precludes abortion or adoption.” Ramsay cited *inter alia*: Calabresi, G, *Ideals, beliefs, attitudes, and the law: private law perspectives on a public law problem* (1985) Syracuse University Press, New York, 52-56.

⁴⁶⁵ Vikingstad, KC, *The use and abuse of the tort benefit rule in wrongful parentage cases* (2007) 82 Chicago-Kent Law Review 1063, 1067-1068.

⁴⁶⁶ *Troppi v Scarf* (1971) 187 NW2d 511.

⁴⁶⁷ *Jackson v Baumgartner* (1986) 347 SE2d 743 (NC Sup Ct).

⁴⁶⁸ *JPM v Schmidt Labs Inc* (1981) 428 A2d 515 (NJ Super App Div).

⁴⁶⁹ *Lininger v Eisenbaum* (1988) 764 P2d 1202 (Colo Sup Ct).

⁴⁷⁰ See Murtaugh, MT, *Wrongful Birth: The Courts' Dilemma in Determining a Remedy for a Blessed Event* (2006-2007) 27 Pace Law Review 241, 255.

⁴⁷¹ *Sherlock v Stillwater Clinic* (1977) 260 NW2d 169 (Minn Sup Ct), 174, cited at [14].

⁴⁷² See Murtaugh, MT, *op cit*, 256: in a footnote, the author clarified that “[t]he court also mandated that all actions for wrongful birth be submitted to the jury with a special verdict form with explanatory instructions, to assist them in measuring the complex elements of damage.”

child.”⁴⁷³ However, ten years after *Troppi*, the United States District Court for the District of Columbia declined to employ that rationale in *Hartke v McKelway*.⁴⁷⁴ Rather, it maintained that a determination of the purpose itself should be the controlling factor in awarding damages commensurate with the injury suffered.⁴⁷⁵ The court found that it was not the plaintiff’s purpose to avoid the expenses of raising a child. The court held that the defendant’s “*wrong against the plaintiff consisted [only] in imposing the pain, suffering and mental anguish of pregnancy on her, not in imposing the [financial] costs of a healthy child,*” and thus denied the plaintiff’s claim for rearing costs.⁴⁷⁶

Here the author has intentionally gone beyond mere description of duty in *Troppi’s Case*. The legal strategy evinced in the defendant’s assumption of a duty, with the objective of making the plaintiff entirely responsible for mitigating or, somewhat indelicately, eliminating the damage, was to a large extent counterproductive. But for the reduction formula that the Michigan Appeal Court applied, the defendant would have been required to shoulder an even greater financial burden. There is no gainsaying that assumption of duty is a fraught activity: *Troppi* is a prime example of how a “confession and avoidance” strategy is itself best avoided.

3.9.1 Conscientious Objection to dispensing Contraceptives

There is a quite distinct question of pharmacist’s conscientious objection to filling prescriptions for contraceptives.⁴⁷⁷ Herbe has declared that pharmacy “*as a profession entails a duty to assure and promote the patient’s best interests and to prioritise those interests over their own personal interests*”.⁴⁷⁸ In 1988, the American Pharmaceutical Association (APhA) and subsequently various other pharmaceutical organisations

⁴⁷³ See Murtaugh, MT, *op cit*, 257, citing: *Betancourt v Gaylor* (1975) 344 A2d 336 (NJ Super Ct); *Anonymous v Hospital* (1976) 366 A2d 204 (Conn Super Ct).

⁴⁷⁴ *Hartke v McKelway* (1981) 526 FSupp 97 (DDC).

⁴⁷⁵ The plaintiff sought sterilization because she had previously suffered an ectopic (extra-uterine) pregnancy and “*feared for her life should she become pregnant again*”: *Hartke v McKelway* (1981) 526 FSupp 97, 99.

⁴⁷⁶ *Hartke v McKelway* (1981) 526 FSupp 97, 105.

⁴⁷⁷ Afif, MT, *Prescription Ethics: Can States Protect Pharmacists Who Refuse to Dispense Contraceptive Prescriptions?* (2005) 26 Pace Law Review 243, 265, section: *The Argument Against Providing Legal Protection to Pharmacists Who Refuse to Dispense Due to Moral Objections*: “*After evaluating many of the arguments for and against legal protection for pharmacists, Cantor and Baum came to the conclusion that it may be impossible, in all cases, to protect the rights of both the pharmacist and the patient*”; Cantor, J, Baum, K, *The Limits of Conscientious Objection—May Pharmacists Refuse to Fill Prescriptions for Emergency Contraception?* (2004) 351 New England Journal of Medicine 2008, 2011: “*In rural areas, objecting pharmacists should provide referrals within a reasonable radius.*”

⁴⁷⁸ Herbe, DW, *Right to Refuse: A Call for Adequate Protection of a Pharmacist’s Right to Refuse Facilitation of Abortion and Emergency Contraception* (2002-2003) 17 Journal of Law & Health 77, 87.

*“eased the conflict between personal and professional morals by adopting policies recognising a pharmacist’s right to refuse dispensing medications based on the pharmacist’s personal beliefs. However if the pharmacist exercises her right of conscience and refuses to fill the prescription the duty to the patient is not extinguished and could be fulfilled by referring the patient to another pharmacist or distributor.”*⁴⁷⁹

In *Frye v Medicare-Glaser Corp*, the court made clear that a voluntary undertaking is just that—voluntary—and as such, the scope of the duty that is assumed is limited to the extent of the undertaking.⁴⁸⁰

3.9.2 Pregnancy as Personal Injury - The Irish Dimension

In *Byrne v Ryan*, the High Court dismissed a plaintiff’s claim for the costs of rearing two children (from successive pregnancies) following a failed sterilisation: the plaintiff sought general damages arising out of the failed procedure and special damages for the costs of rearing the two children.⁴⁸¹ The defendant conceded that in the event of a finding of negligence the plaintiff would be entitled to damages for the pain suffering and inconvenience of pregnancy and childbirth and of course for having to have the sterilisation repeated. Special damages for extra medical expenses were also conceded. Those concessions were made having regard to the views expressed in *McFarlane v Tayside Health Authority*⁴⁸² by the majority in the House of Lords.⁴⁸³ Kelly J was therefore not required to consider whether as a matter of principle it was open to the plaintiff to recover damages arising from her pregnancy and the births of two children.

⁴⁷⁹ Herbe, DW, *op cit*, 88-89.

⁴⁸⁰ *Frye v Medicare-Glaser Corp* (1992) 605 NE2d 557, 561. See also: *Castro v Brown’s Chicken & Pasta Inc* (2000) 732 NE2d 37 (Ill: App Ct, 1st Dist, 4th Div), 42 (“Under the voluntary undertaking doctrine of liability, the duty of care to be imposed upon the defendant is limited to the extent of the undertaking”).

⁴⁸¹ *Byrne v Ryan* [2009] 4 IR 542 (HC), Kelly J. See also Ryan, D, *Making Connections: New Approaches to Vicarious Liability in Comparative Perspective* (2008) 15 Dublin University Law Journal 41. (Much of the earlier part of the judgment by Kelly J was given over to the question of the hospital’s vicarious liability for the breach of the duty of care owed to the plaintiff by the medical practitioner in carrying out the tubal ligation).

⁴⁸² *McFarlane v Tayside Health Authority* [2000] 2 AC 59 [HL(SC)].

⁴⁸³ Kelly J clarified that the decision in *McFarlane* was subsequently considered by a differently constituted judicial committee of the House of Lords in *Rees v Darlington Memorial Hospital NHS Trust* [2004] 1 AC 309 without adverse implications for the *McFarlane* jurisprudence. See also Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 417. Healy (*loc cit*) mentions *parenthetically* the following: “(It is worth observing *en passant* Kelly J queried the concession, though he did not review it.)” Lord Bingham’s “more robust dicta” in *Rees* - [2004] 1 AC 309, 316 - received the approval of Kelly J in *Byrne v Ryan*. Healy [418] states that *Rees* rests on policy disinclined “to equate the birth or life of a child, whether wanted or unwanted, with financial liability, and a belief that the imposition of liability for the costs of rearing an unplanned child runs counter to the principles of distributive justice *ad offends* community values on how public resources should be distributed.”

Kelly J quoted *Fletcher v Commissioners for Public Works* as authority for excluding an award of damages in certain circumstances on the grounds of policy.⁴⁸⁴ The value which the Constitution places upon the family, the dignity and protection which it affords to human life are matters which were, in the view of Kelly J, better served by a decision to deny rather than allow damages of the type claimed. The tactical concurrence of the parties in agreeing the quantum of damages (€381,678) for rearing the children went therefore without fruition.

Having adopted, without citing them *in extenso*, the conclusions reached by the House of Lords in both in the *McFarlane* and *Rees*, Kelly J said those were to be preferred to the majority view expressed in the Australian case of *Cattanach v Melchior*.⁴⁸⁵ It was the opinion of Kelly J that it would not be “*fair or reasonable*” to impose on a doctor who negligently performs a sterilisation procedure the cost of rearing a healthy child conceived and born subsequent to the failure of such procedure.⁴⁸⁶

Kelly J did find that there was a breach of duty of care owed to the plaintiff and awarded general damages in the total sum of €90,000, made up of €45,000 in respect of the first pregnancy, €35,000 in respect of the second pregnancy (which figures took into account the shock and emotional distress caused to the plaintiff) and €10,000 in respect of having to undergo a second tubal ligation.

The judgment in *Byrne v Ryan* has been appealed to the Supreme Court.⁴⁸⁷

⁴⁸⁴ *Fletcher v Commissioners of Public Works* [2003] 1 IR 465.

⁴⁸⁵ *Cattanach v Melchior* (2003) 215 CLR 1 (HCA). Further, see Stretton, D, *Wrongful Life and the Logic of Non-Existence: Harriton v Stephens; Waller v James* [2006] Melbourne University Law Review 31. Footnote [3]: “See *Cattanach v Melchior* ..., which allowed damages for wrongful birth, including the ordinary costs of raising the child to maturity, although those costs are now excluded by state legislation: see *Civil Liability Act 2002 (NSW) s 71; Civil Liability Act 2003 (Qld) s 49A; Civil Liability Act 1936 (SA) s 67.*” See also *Magill v Magill* [2006] HCA 51 [216], (Heydon J).

⁴⁸⁶ See Kancler, M, *To Be or Not to Be Born? Civil Liability for Damage Resulting from Birth in a Comparative Context: Recent Polish and Irish Caselaw Concerning Wrongful Birth and Wrongful Conception* (2009) 13.3 *Electronic Journal of Comparative Law*, [6]: “In order to justify such refusal, he invoked both the already mentioned *burden v benefit* rule (‘the benefits of a healthy child outweigh any loss incurred in rearing the child’), as well as the values protected by the Irish Constitution, such as: family, dignity and protection of all human beings, which are, in his view ‘(...) better served by a decision to deny rather than to allow damages of the type claimed’”.

⁴⁸⁷ See Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 419. Healy suggests it is likely that the Supreme Court would “not recognise a right to recover the financial costs of raising a healthy child in wrongful conception, pregnancy, or birth cases.” Healy also points out (*loc cit*) that recovery of the additional ‘extraordinary’ costs associated with raising a disabled child is yet a question for determination in the Irish courts.

3.10 Conclusions

It is submitted that healthcare professionals, through their ethical standards, will acknowledge legal duties of care in a manner simply unparalleled, say, in the financial services sector.⁴⁸⁸

The statutory duty expressed in the Regulation of Retail Pharmacy Businesses Regulations 2008, regarding “*any other matters which may be included or referred to in the summary of product characteristics for the medicinal product concerned*” is arguably not static by reference to the point at which the medicinal product entered the pharmaceutical distribution chain or (later) came into the pharmacy’s possession.⁴⁸⁹ That statutory duty appears more onerous than that imposed under the Community Pharmacy Contractor Agreement (CPCA). The contractual duty refers to “*any other matters which may be included or referred to in the patient information leaflet supplied with the medicine.*”⁴⁹⁰

The Regulation of Retail Pharmacy Businesses Regulations 2008 also impose a new statutory duty: *Counselling in the supply of medicinal products other than on foot of a prescription*. No “*offer to discuss*” is mandated here because the pharmacist, not the physician, is the gatekeeper: “*a registered pharmacist [must be] satisfied*” on the matters specified in the Regulations. For that to be fulfilled, discussion is required.⁴⁹¹

Although there is no current statutory underpinning for the CPCA, Clause 9 would appear to pay homage in some degree to the duties flowing from Omnibus Budget Reconciliation Act (OBRA 90).⁴⁹² Unlike OBRA-90, the CPCA does not require Irish community pharmacists to interrogate the “*peer-reviewed medical literature*”.

⁴⁸⁸ Young, R, Faure, M, Fenn, P, *Defences in negligence: Implications for tortfeasor care* (2006) 26 International Review of Law and Economics 67, 69: “*Although there has been legal commentary on the (absence of a) duty of care as well as on causation, in legal practice the emphasis has primarily been on the absence of breach. A defendant to an action in tort will, in most European legal systems, primarily argue that he did not breach the duty of care (or was not at fault), instead of focusing on, for example, causation issues.*”

⁴⁸⁹ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 9 (3) (h).

⁴⁹⁰ Community Pharmacy Contractor Agreement, Clause 9 (5) (k).

⁴⁹¹ Regulation of Retail Pharmacy Businesses Regulations 2008, Regulation 10.

⁴⁹² The Health (Community Pharmacy Contractor Agreement) Regulations 1996 (SI 152 of 1996) were revoked by the Health (Community Pharmacy Contractor Agreement) Regulations 1996 (Revocation) Regulations 2002 (SI No 28 of 2002) for policy reasons that do not touch on the Clause 9 duties. See also Gorecki, PK, *Providing Quality Pharmacy Services: Good Intentions Are Not Enough*, ESRI Research Bulletin 2010/03/05 (2010) ESRI, Dublin, 1 (n). Available from <http://hdl.handle.net/2262/57206>. (Last accessed 12 January, 2012). The author noted that “[t]hese regulations were unexpectedly revoked in January 2002 following legal action.” Nowhere in this Working Paper has the author suggested that the exercise of

A discrete duty expressed in a statute, when viewed as a principled statement in isolation from the statutory architecture itself (especially a penal statute), may be apt for inclusion in the ever-developing common law duty of care. Expert evidence could show that the professional duty has evolved to the extent that such an obligation has become subsumed into professional practice.

Liability in negligent misrepresentation (misstatement) has not been ruled out for pharmacists who provide false information to a person who relies thereon and suffers injury in consequence of such reliance. It is submitted that a not insignificant obstacle to a judicial holding that a pharmacist is liable to a patient directly or (indirectly to a third party⁴⁹³) in negligent misstatement is the difficulty in proving the existence of a contractual or fiduciary relationship between the pharmacist and the patient.

It remains to be seen how liability might attach to negligently disseminated information from a pharmacy Web site, notwithstanding any published disclaimer or territorial limitation sought to be imposed on potential users of the site.

Reliable medicines (or drug) information is vital to the proper functioning of a multidisciplinary healthcare team, whether in the nosocomial or ambulatory care setting. Some caution must be exercised relating to the degree of protection from liability afforded to US information sources, namely, under the commercial free speech provisions of the First Amendment to the US Constitution.

The Learned Intermediary Doctrine (LID) has circumscribed the US courts to some extent in the duties to be imposed on pharmacists. Medical and dental practitioners are no longer the only prescribers of human medicines. Pharmacist and nurse prescribers have emerged in recent years. The notion that there is only one class of learned intermediary no longer accords with reality. Apart from the general non-reception of foreign (mostly British) post-1776 common law decisions in the US courts, the withering of the LID would allow a further intellectual convergence in theories of pharmacist liability.⁴⁹⁴

Minister's discretion to revoke the Regulations had been improperly exercised. On the contrary, the author opposed the Regulations on theoretical and practical grounds.

⁴⁹³ *Sanchez ex rel Sanchez v Wal-Mart Stores Inc* (2009) 221 P3d 1276 (Nev: Sup Ct) (Pharmacies do not have a duty to act to prevent a pharmacy customer from injuring an unidentified third party).

⁴⁹⁴ *Butterfield v Forrester* (1809) 103 ER 926 (KB) (on contributory negligence) and *Byrne v Boadle* (1863) 159 ER 299 (on *res ipsa loquitur*) are notable exceptions to the US judicial non-reception policy directed generally towards decisions from other common law systems.

It is entirely plausible that the massive retrenchment in the law of negligence that was wrought in *Caparo v Dickman* may have been influenced to some extent by common knowledge of the Hillsborough disaster. That calamity occurred approximately six months before *Caparo's* first hearing day in the House of Lords. It was almost inevitable that the events of a particular spring day in 1989 would come before an appellate court, if not their Lordship's House itself. Eventually the *Alcock* case materialised. In the House of Lords, the speeches in *Alcock* focused in part on scrutiny of relationships and timing of events, while the conceptual structure for denying recovery in negligence had already been erected in *Caparo*.

Chapter 4 Professional Negligence and the Standard of Care

Introduction

The purpose of this chapter is to examine professional negligence in the settings of medical practitioners and pharmacists. With particular regard to medical practitioners, the position in England & Wales, Ireland, Scotland, Australia and Canada is considered. *Blyth v Birmingham Waterworks Co*⁴⁹⁵ has provided an oft-quoted definition of 'negligence':

*"Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do."*⁴⁹⁶

The reasonable man became known in England as the man on the Clapham omnibus.⁴⁹⁷ The 'public transport user' metaphor has been used elsewhere.⁴⁹⁸ The 'reasonable man' test is applied to many situations of ordinary negligence, e.g. driving a motor vehicle. Placed before 'man', the epithets 'reasonable' or 'average' or 'ordinary' were introduced "at a time when judges had to give juries guidance as to the appropriate standard to apply in deciding whether conduct was negligent".⁴⁹⁹

In professional negligence generally, the objective comparator is the practitioner of ordinary skill and competence. However, the position of medical practitioners has been acknowledged as being more complex. An early example of judicial recognition of that complexity came in *Hunter v*

⁴⁹⁵ *Blyth v Birmingham Waterworks Co* (1856) 156 ER 1047.

⁴⁹⁶ (1856) 156 ER 1047, 1049. See also Fleming Jr, J, *Nature of Negligence* (1952-1953) 3 Utah Law Review 275, 279-280, citing: *Osborne v Montgomery* (1931) 234 NW 372 (Wis Sup Ct), 379, per Rosenberry, CJ: "Every person is negligent when, without intending to do any wrong, he does such an act or omits to take such a precaution that under the circumstances present [, which] he, as an ordinarily prudent person, ought reasonably to foresee that he will thereby expose the interests of another to an unreasonable risk of harm."

⁴⁹⁷ The first recorded judicial reference to this personification of reasonableness was to a comment attributed to Lord Bowen, which was rehearsed in a libel case, *McQuire v Western Morning News Company* [1903] 2 KB 100, 109, per Collins MR: "the ordinary reasonable man, 'the man on the Clapham omnibus,' as Lord Bowen phrased it". Lord Bowen had died some nine years earlier. In the negligence arena, "the man on the Clapham omnibus" was first mentioned by Greer LJ in *Hall v Brooklands Auto-Racing Club* (1933) 1 KB 205, 224.

⁴⁹⁸ See Forell, C, *Reasonable Woman Standard of Care* (1992) 11 University of Tasmania Law Review 1, 4. See also Asprey, MM, *Plain Language for Lawyers*, Third Edition (2003) Federation Press, Sydney, 119, for the Hong Kong version, namely, the man who rides the Shau Ki Whan tram. In the Foreword to McMahon, B, Binchy, W, *Irish Law of Torts* (1981) Professional Books, Abingdon, Walsh J remarked that it had not been recognised hitherto in Irish legal practice, within the system (as opposed to the body) of law that is torts, that the man on the Crumlin omnibus was not the same as the man on the Clapham omnibus.

⁴⁹⁹ Jones, M, *Medical Negligence*, Fourth Edition (2008) Sweet & Maxwell, London, 228.

Hanley⁵⁰⁰: “[t]he true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care.”⁵⁰¹ This is also clear from *Bolam v Friern Hospital Management Committee*,⁵⁰² in which McNair J explained the legal principles to the jury with which he was sitting (emphasis added): “[W]here you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is **not the test of the man on the top of a Clapham omnibus, because he has not got this special skill.**”⁵⁰³ The test is the standard of the ordinary skilled person exercising and professing to have that special skill, which need not be the highest expert level; ordinary skill of an ordinary competent medical practitioner.⁵⁰⁴

This chapter examines the professional standards applied to pharmacists and to medical practitioners. The scholarly texts understandably focus more attention on the medical profession due to the varied and complex situations that have shaped the case law affecting the many branches of that profession. The legal principles that affect both the medical and pharmaceutical professions are generally explored in greater depth in the academic literature in the context of the medical profession. In order to avoid unnecessary repetition, in this thesis, some analysis of the black letter law affecting pharmacists, as professional persons, is covered in the section on the medical profession.

4.1 Medical Practitioners

4.1.1 Professional Standard Principles and Rules

For a variety of reasons, the legal and medical professions were “*considered to expound and exercise difficult skills of fundamental importance to society and public affairs*” the cultivation of which “*required more elaborate specialist education and training*” and the practice of which “*was guided by ethical imperatives*”.⁵⁰⁵

⁵⁰⁰ *Hunter v Hanley* 1955 SLT 213.

⁵⁰¹ 1955 SLT 213, 217 per Clyde LPJ.

⁵⁰² *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

⁵⁰³ [1957] 1 WLR 582, 586, per McNair J.

⁵⁰⁴ [1957] 1 WLR 582, 586, per McNair J. See also *F v R* (1983) 33 SASR 189, 190, per King CJ: “*The standard of care that is to be expected of an ordinarily careful and competent practitioner of the class to which the practitioner belongs*”.

⁵⁰⁵ Healy, *op cit*, 277-278.

4.1.1.1 Scope of the Professional Standard Model

The requirement for expert evidence in determining the scope of the professional standard model was stated succinctly in *Block v McVay*.⁵⁰⁶ Parker J clarified that “... in cases of medical malpractice where the physician's or surgeon's want of skill or lack of care is such that it is within the comprehension of laymen and requires only common knowledge and experience to judge it, expert evidence is not required.”⁵⁰⁷

It must be remembered that a medical practitioner is neither a general insurer⁵⁰⁸ nor a warrantor of a particular outcome.⁵⁰⁹ Healy suggests that there is “often an unspoken benchmark between the application of the professional standard of care and the generic tests of negligence”, suggested by the number of decisions “finding hospitals or doctors liable for failings of a more administrative nature”.⁵¹⁰ One may venture that the relevant ‘conflicting theories’ may in some situations be reduced to the perennial pair: ‘professional negligence’ and ‘ordinary negligence’. In *Canterbury v Spence*,⁵¹¹ a seminal case on informed consent, Robinson J declared that there was “no basis for operation of the special medical standard where the physician’s activity [did] not bring his medical knowledge and skills peculiarly into play”.⁵¹²

4.1.2 Legal Developments in Ireland

The Supreme Court in Ireland first addressed the professional standard in *Daniels v Heskin*,⁵¹³ where the rules, as they then stood, were endorsed.⁵¹⁴ The majority in the Supreme Court in

⁵⁰⁶ *Block v McVay* (1964) 126 NW2d 808 (SD Sup Ct).

⁵⁰⁷ (1964) 126 NW2d 808, 810, per Parker J. See also *Corn v French* (1955) 289 P2d 173, 179 (Nev: Sup Ct) per Badt J, citing *Burriss v Titzell* (1920) 177 NW 557 (Iowa): “[C]ases do arise where common knowledge of physical facts and of the natural laws that govern physical life are so well known that a jury, from the facts before it, is able to determine, and correctly, whether the treatment was proper or not.” For a poignant, yet understated dictum, see *Stickleman v Synhorst* (1952) 52 NW2d 504, 508 (Iowa: Sup Ct), per Garfield J: “Also, where a physician injures a part of the body not under treatment expert evidence is not always required.”

⁵⁰⁸ See *Hancke v Hooper* (1835) 173 ER 37, 38, per Tindal CJ. See also *Mahon v Osborne* [1939] 2 KB 14, 31, per Scott LJ.

⁵⁰⁹ See *Lanphier v Phipos* (1839) 173 ER 581, 583, per Tindal CJ. See also *Block v McVay* (1964) 126 NW2d 808, 811, per Parker J (SD, Sup Ct): “Physicians and surgeons are not to be held responsible for results, but only for the kind of service rendered by them”, citing *inter alia*: *Dean v Seeman* (1920) 176 NW 649 (SD); *Warwick v Bliss* (1923) 195 NW 501 (SD).

⁵¹⁰ Healy, J, *op cit*, 284-285. Three of these cases, *Kelly v Board of Governors of St Laurence’s Hospital*, *Armstrong v Eastern Health Board & St Patrick’s Hospital* and *Healy v North Western Health Board* are considered in the psychiatric medicine context elsewhere in this thesis. A fourth case, *Fanning v South Eastern Health Board & Ors* [2005] IEHC 25 was one in which liability was imposed for a hospital’s negligent continued use of a corroded instrument that later broke, leaving a piece in the patient’s abdomen during surgery.

⁵¹¹ *Canterbury v Spence* (1972) 464 F2d 772 (Ct App, DC).

⁵¹² (1972) 464 F2d 772, 785, per Robinson J.

⁵¹³ *Daniels v Heskin* [1954] IR 73 (Sup Ct).

Daniels v Heskin affirmed the trial Judge, who found that there was no evidence to support a finding that the breaking of a surgical needle in the course of an operation was caused by negligence. The defendant surgeon decided to close the surgical incision and to defer the operation for removal of the broken portion of the needle: he was found to have acted reasonably and without negligence. A further finding was that non-disclosure to the patient (or her husband) of the fact that the broken portion of the needle remained in the patient's perineum did not cause damage, was reasonable in the circumstances and did not amount to negligence.

The Supreme Court revisited medical negligence in *O'Donovan v Cork County Council*.⁵¹⁵ Healy⁵¹⁶ remarks that what divided Lavery J (now a dissident, while he had been in the majority in *Daniels v Heskin*) from the majority in *O'Donovan* was the effect of the honest difference principle, becoming liable only for acting “*otherwise than in a manner approved by a responsible body of opinion*.”⁵¹⁷ Although the approach outlined by Lavery J subsequently found favour in England, particularly since *Bolitho*, Healy states that this development was for the different purpose.⁵¹⁸ The English courts have consistently refused to qualify the defence of customary practice, as done by Walsh J in *O'Donovan*.⁵¹⁹ That qualification finds expression in the Inherent Defects Rule,⁵²⁰ which is analysed below.

4.1.3 The *Dunne* Test

Healy points to the sources of precedent “*in the previous rulings in Daniels v Heskin, O'Donovan v Cork County Council, Reeves v Carthy & O'Kelly*,⁵²¹ and *Roche v Peilow*”,⁵²² from which, in *Dunne v National Maternity Hospital*,⁵²³ Finlay CJ consolidated the principles and rules for medical negligence:

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

⁵¹⁴ See Healy, *op cit*, 291-293.

⁵¹⁵ *O'Donovan v Cork County Council* [1967] IR 173 (Sup Ct).

⁵¹⁶ Healy, *op cit*, 296-297.

⁵¹⁷ [1967] IR 173, 186, per Lavery J.

⁵¹⁸ Healy, *op cit*, 297.

⁵¹⁹ See McMahon, B, *The Irish Contribution to Tort Law* (1982) 4 Dublin University Law Journal 1, 1 (citation inserted): “*McNamara v ESB* [[1975] IR 1] shows that the Irish Judiciary are willing to depart from English precedents.” In regard to the *O'Donovan* qualification of the defence of customary practice, it would appear that the English Judiciary are willing to reciprocate.

⁵²⁰ See [1967] IR 173, 193, *dicta* of Walsh J.

⁵²¹ [1984] IR 348 (Sup Ct).

⁵²² Healy, *op cit*, 299, citing [1989] IR 91, 109, per Finlay CJ.

⁵²³ *Dunne v National Maternity Hospital* [1989] IR 91 (Sup Ct).

as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care.⁵²⁴

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 skill⁵²⁵ 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.

6. If there is **an issue of fact**, the determination of which is necessary for the decision as to whether a particular medical practice is or is not general and

⁵²⁴ Redolent of *Hunter v Hanley* 1955 SLT 213, 217, per Lord President Clyde. See also *Byrne v Ryan* [2009] 4 IR 542, 554, per Kelly J:

"The thrust of the evidence from the two experts leads me to the conclusion that that failure [to apply the clip to the plaintiff's left fallopian tube] on the part of Dr. Murray was one which no medical practitioner of equal specialist status and skill would have been guilty of if acting with ordinary care. To put it in the words of Dr. McKenna:

'If you put the clip on the wrong place and there are no extenuating circumstances, the operator has got to face the music for that'.

"The presence of adhesions in the present case did not in my view constitute an extenuating circumstance such as would excuse what occurred. There was a breach of the duty of care owed to the plaintiff."

⁵²⁵ Healy, *op cit*, 301, on the reasonable doctor test.

*approved within the meaning of these principles, that issue must in a trial held with a jury be left to the determination of the jury.*⁵²⁶

(Emphasis added)

In order to make “*these general principles readily applicable to the facts of this case*”,⁵²⁷ Finlay CJ found it necessary to state further conclusions not expressly derived from the cited authorities.

4.1.3.1 How many ‘Reputable Practitioners’ are required?

*“(a) ‘General and approved practice’ need not be universal but must be approved of and adhered to by a substantial number of reputable practitioners holding the relevant specialist or general qualifications.”*⁵²⁸

It is possible for a physician or surgeon to be part of a substantial number of reputable practitioners and yet to be in a minority. Healy has commented that excluding reputable but minority practices leaves the door open for a *res ipsa loquitur* approach in a deviation from customary practice.⁵²⁹ The phrase “*substantial number of reputable practitioners*” does not appear in any of the three Irish cases cited by the Supreme Court in *Dunne* or in any subsequent Irish decision.⁵³⁰ The Court of Appeal for England & Wales said in *De Freitas v O’Brien* that the trial judge in that case was correct in not following *Dunne* to the extent of not insisting upon a “*substantial number*” of such practitioners.⁵³¹ *De Freitas* was a case in which the plaintiff,

⁵²⁶ Healy, *op cit*, 302: there is here a suggestion that this was already obsolescent in 1989.

⁵²⁷ [1989] IR 91, 109, per Finlay CJ.

⁵²⁸ [1989] IR 91, 109, per Finlay CJ. See also Healy, *op cit*, 299: “*This would appear therefore to preclude reputable but minority practices from formal application of the defence of general and approved practice identified in the second and third premises.*”

⁵²⁹ Healy, *op cit*, 302. See also von Bar, C, *The Common European Law of Torts: Damage and damages, liability for and without personal misconduct, causality, and defences* (2000) Oxford University Press, Oxford, 299, citing *inter alia*: *Dunne v National Maternity Hospital* [1989] IR 91, 109: “*European courts are still extremely cautious about concluding that a negative outcome automatically means malpractice. With the exception of the general rules on prima facie evidence (res ipsa loquitur) the rule that the patient has to prove the surgeon’s negligence still prevails.*”

⁵³⁰ A body of opinion underpinning a professional practice needs to be substantially estimable as opposed to having a substantial number of proponents. See also De Cruz, P, *Comparative Healthcare Law* (2001) Routledge Cavendish, London, 540: “*There are problems in using the word ‘substantial’, for instance, in a case like Dunne, where it is necessary for the court to decide which expert opinion was better, which is never an easy task.*”

⁵³¹ *De Freitas v O’Brien* [1995] 2 Med LR 155. This contention is not without parallel: see also *Jones v Chichester* (1992) 610 A2d 964 (Pa: Sup Ct), 968, per Papadakos J:

“Other jurisdictions also appear to waffle between the two standards. In McHugh v Audet [(1947) 72 FSupp 394 (Pa: MD)], the ‘considerable number’ test was held to be the test. Some years later, however, another federal court in Pennsylvania cited Remley [v Plummer

defendant and all the experts who gave evidence in the case were *ad idem* on the standard of care.⁵³² A specialty may have so few exponents that their number may not appear substantial.

4.1.3.2 *Diagnosis versus Treatment*

*“(b) Though treatment only is referred to in some of these statements of principle, they must apply in identical fashion to questions of diagnosis.”*⁵³³

It is noted by Healy that the *Dunne* principles have to be read against the subsequent jurisprudence of the Supreme Court, particularly on disclosure of risks (further analysed below).

4.1.3.3 *What is meant by ‘Medical Administrator’?*

*“(c) In an action against a hospital, where allegations are made of negligence against the **medical administrators** on the basis of a claim that practices and procedures laid down by them for the carrying out of treatment or diagnosis by medical or nursing staff were defective, their conduct is to be tested in accordance with the legal principles which would apply if they had personally carried out such treatment or diagnosis in accordance with such practice or procedure.”*⁵³⁴

The learned Chief Justice did not clarify the term “*medical administrator*”.⁵³⁵ The National Maternity Hospital had and certain other hospitals have a prestigious office titled ‘The Master’, filled from the hospital’s own Consultant Obstetrician/Gynaecologist community. That post is held

(1922) 79 Pa Super 117] for the proposition that the two schools of thought doctrine is applicable where one is advocated by ‘reputable, respectable and reasonable’ experts. Harrigan v United States [(1976) 408 FSupp 177 (Pa: ED)]. This result should be contrasted with the holding in O’Neill v Kiledjian [(1975) 511 F2d 511 (6th Cir), 513] that the defense is available ‘when both alternatives have the support of a considerable body of competent medical opinion in the community.’ O’Neill followed Gresham v Ford [(1951) 241 SW2d 408 (Tenn)], which construed Duckworth [v Bennett (1935) 181 A 558 (Pa)] and concluded in a quantitative fashion that an accepted alternative treatment is ‘one advocated by many of the doctors in good standing’.”

(Emphasis added)

⁵³² See Herring, J, *Medical Law and Ethics*, Second Edition (2008) Oxford University Press, Oxford, 97, touching on *De Freitas v O’Brien*; a responsible body may consist merely of four or five practitioners.

⁵³³ [1989] IR 91, 109, per Finlay CJ.

⁵³⁴ [1989] IR 91, 110, per Finlay CJ (Emphasis added).

⁵³⁵ There are two cases: *O’Neill v Beaumont Hospital Board* [1990] ILRM 419 (Sup Ct); *Georgopoulos v Beaumont Hospital Board* [1998] 3 IR 132 (HC and Sup Ct), in which the term refers to an office holder having a disciplinary function within Beaumont Hospital, which opened its doors to the public on 29 November, 1987. Apart from these two cases, in the course of this research, no Irish judge appeared to have used the term ‘medical administrator’ outside a context that had already been described by Finlay CJ.

for a fixed term and embraces managerial functions within the hospital. It is submitted that it is perhaps this culture, which Finlay CJ had in mind.

The Chief Justice emphasised how it is consistent “*with the common good that doctors should be obliged to carry out their professional duties under frequent threat of unsustainable legal claims.*”⁵³⁶

4.1.3.4 General, Conventional and Minority Practices

Byrne and Binchy have pondered the “*contours of the concept of a customary practice*”.⁵³⁷ Such a practice may be an ordinary repetitive process or an “*individuated exercise of particularised medical judgment as to how to proceed, based on the unique circumstances of the patient*”⁵³⁸ and often involves the latter kind.⁵³⁹

Healy points out that the general and approved practices by which to measure a doctor’s conduct “*in principle those practices and standards that existed in his medical community at the time of the act or omission alleged to constitute a breach of duty on his part. This is sometimes called the locality rule...*”⁵⁴⁰ Healy notes that practices in Ireland are frequently contrasted with those in the

⁵³⁶ [1989] IR 91, 110, per Finlay CJ. There was considerable reluctance among patients in the late nineteenth century and early twentieth century to sue a doctor: such a suit was seen at the time as being quite presumptuous. See Teff, H, *Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship* (1994) Oxford University Press, Oxford, 17, citing *Farquhar v Murray* 1901 3 F 89, 92, per Lord Young: “[T]his action is certainly one of a particularly unusual character. It is an action of damages by a patient against a medical man. In my somewhat long experience, I cannot remember having seen a similar case before.” Teff added (*loc cit*) that only the most wealthy could afford to bring such an action. An early opponent of defensive medicine, according to Jones (*op cit*, 295) was the ever plain-speaking Denning LJ. See *Roe v Minister of Health*, *Woolley v Minister of Health (sub nom Roe v Minister of Health)* [1954] 2 QB 66, 86-87, per Denning LJ. See also Jones, MA, *Medical Malpractice in England and Wales – A Postcard from the Edge* (1996) 3 *European Journal of Health Law* 109, 112 (Endnote 17, Endnote text: [123]-[124]).

⁵³⁷ Byrne, R, Binchy, W, *Annual Review of Irish Law 2006* (2007) Thomson Round Hall, Dublin, 561.

⁵³⁸ Byrne & Binchy, *loc cit*.

⁵³⁹ See Byrne & Binchy, *loc cit*, where it is urged on the reader that individuated judgments “*are no more exempt from the first rule in Dunne than they are from the third*”.

⁵⁴⁰ See Healy, *op cit*, 306. For some reasons why there is a different standard between rural and urban practice, see Wilson, G, Kelly, A, Thommasen, HV, *Training Physicians for Rural and Northern British Columbia* (2005) 47 *British Columbia Medical Journal* 373, 373. This urban-rural divide has existed for generations: see Billings, F, *Modern Medicine and the General Practitioner* (1921) 11 *Canadian Medical Association Journal* 634, 637 (proposing incentives to attract and to retain rural practitioners in the United States). Justice Williams noted in *Siirila v Barrrios* (1976) 248 NW2d 171 (Mich: Sup Ct) that the locality rule is a doctrine peculiar to American law, originating in the vast distances characteristic of the US and the apparent differences between urban and rural practice in the nineteenth century. Justice Williams, joined by Justice Levin, advocated less rigidity in the application of the locality rule because of advances in technology and consolidation of medical information throughout the country.

United Kingdom because of the similarity in public healthcare structures and medical information.⁵⁴¹

The Supreme Court of Canada in *ter Neuzen v Korn*⁵⁴² reversed a verdict against an obstetrician for failing to guard against the risk of HIV transmission by artificial insemination in a procedure carried out months before that possibility first appeared in the medical literature in 1985.⁵⁴³ The locality rule was given short shrift: Canadian obstetricians would be “*expected to have familiarised themselves with developments in the US*”.⁵⁴⁴ It is submitted that, in confronting a global pandemic with high morbidity/mortality, keeping tabs on one’s immediate neighbours may not be enough.⁵⁴⁵ Recently in Ireland, the High Court was receptive to a surgeon’s locality as a factor in denying recovery to the plaintiff. In *English v North Eastern Health Board & Anor*,⁵⁴⁶ Charleton J held: “... *I might add, that I am not convinced by the evidence that it is probable that the plaintiff would have had a better result ... had he been referred to, and obtained, specialist care from a hand surgeon in a dedicated unit.*”⁵⁴⁷

No general or approved practice supported the defendant’s failure to identify future permanent adverse *sequelae* in a medical report in *Butler v Regan*.⁵⁴⁸ The court therefore did not have to consider the issue of any conflicting schools of thought.⁵⁴⁹ Experimental procedures may be particularly problematic.⁵⁵⁰

⁵⁴¹ Healy, *op cit*, 306.

⁵⁴² *ter Neuzen v Korn* (1993) 103 DLR (4th) 473 (SCC).

⁵⁴³ See Healy, *op cit*, 306-307.

⁵⁴⁴ See Healy, *op cit*, 307.

⁵⁴⁵ A ‘regional’ or ‘global’ medical strategy, informed by the relevant peer-reviewed literature, may be required.

⁵⁴⁶ *English v North Eastern Health Board & Anor* [2009] IEHC 189.

⁵⁴⁷ [2009] IEHC 189, [17], per Charleton J. The test applied here would appear to be a categorical one relative to a sub-category of expertise.

⁵⁴⁸ *Butler v Regan* [2004] IEHC 326, Abbott J.

⁵⁴⁹ See Healy, *op cit*, 307. Healy remarks that cases where the defendant’s inability or failure to demonstrate some reputable professional support for the course of action taken rarely progress to trial: the court has a much freer hand when inferring negligence from the evidence.

⁵⁵⁰ See *Coughlin v Kuntz* (1987) 42 CCLT 142 (BCSC), *affirmed* [1990] 2 WWR 737 (BCCA). See also Jones, M, *Medical Negligence*, Fourth Edition (2008) Sweet & Maxwell, London, 249. See Feldthusen, B, *Punitive Damages: Hard Choices and High Stakes* [1998] New Zealand Law Review 741, 754, citing, *inter alia*, *Coughlin v Kuntz*: “*The importance of advertence is illustrated in the few negligence actions ever to have supported a claim for punitive damages.*” Two further Canadian cases are instructive: *Cryderman v Ringrose* [1978] 3 WWR 481 (Alta Sup Ct) [alternatively cited as (1978) 89 DLR (3d) 646] was echoed to some extent in *Zimmer v Ringrose* (1981) 124 DLR (3d) 215. The (one-page) judgment of the court was delivered by McGillivray CJA (orally). See also Jones, M, *op cit*, 258 (n), citing *Waters v West Sussex Area Health Authority* [1995] 6 Med LR 362, as an example of an innovative neurosurgical technique that complied with standards of responsible medical opinion. On the requirement for a clear warning, see Giesen, D, *International medical malpractice law: a comparative law study of civil liability arising from medical care* (1988) Martinus Nijhoff Publishers, Dordrecht, Boston, London, 552.

The personal conduct of the medical practitioner may also constitute a departure from professional practice.⁵⁵¹ A detailed excursion into ethical dilemmas, such as how a single-handed rural GP ought to lead one's social life, is beyond the scope of this thesis.

4.1.3.5 *Honest Differences in Medical Opinion*

It is clear from *Hunter v Hanley*,⁵⁵² in diagnosis and treatment, there is “*ample scope for genuine differences of opinion*”.⁵⁵³ Merely arriving at a different conclusion or displaying a lower level of skill or knowledge than colleagues is not negligent: “[t]he true test for establishing negligence in diagnosis or treatment ...”⁵⁵⁴ has been ventilated elsewhere in this thesis.⁵⁵⁵ *Hunter v Hanley* was one of only two cases cited in *Bolam v Friern Hospital Management Committee*.⁵⁵⁶ McNair J stated that a doctor was not negligent when acting in accordance with an approved practice “*merely because there is a body of opinion that would take a contrary view.*”⁵⁵⁷

As a decision that preceded *Hunter v Hanley*, it is submitted that the case of *Daniels v Heskin*,⁵⁵⁸ covered the same territory, although with greater attention paid to the role of the jury.⁵⁵⁹ Lavery J and Kingsmill Moore J gave judgments emphasising that it was not open to the jury⁵⁶⁰ to infer negligence, where there was an honest difference of opinion between medical practitioners and one course rather than the other was followed. The honest difference of opinion principle received Supreme Court approval in *O'Donovan v Cork County Council*⁵⁶¹: that jurisprudence was further endorsed in “*the fourth and fifth premises of the consolidating test*” in Dunne.⁵⁶²

⁵⁵¹ See, for example, *Landau v Werner* (1961) 105 SJ 1008 (CA). (A psychiatrist's social contact with patient was rightly condemned by all the medical evidence adduced).

⁵⁵² 1955 SLT 213.

⁵⁵³ 1955 SLT 213, 217 per Clyde LPJ.

⁵⁵⁴ 1955 SLT 213, 217 per Clyde LPJ.

⁵⁵⁵ See also Stewart, A, *New Wine in Old Barrels: Medical Negligence and Reasonable Care* (2007) 11 Edinburgh Law Review 251, 251: “*Lord President Clyde chose not to use the words ‘reasonable care’ - eloquent silence on the part of someone briefed at an earlier stage of his career in Donoghue v Stevenson. He talked about ‘ordinary care’*”. Diplomatically, Stewart does not mention that Mr JL Clyde, Advocate, appeared for the losing side in that leading case.

⁵⁵⁶ [1957] 1 WLR 582.

⁵⁵⁷ [1957] 1 WLR 582, 587.

⁵⁵⁸ [1954] IR 73 (Sup Ct).

⁵⁵⁹ See Healy, *op cit*, 309.

⁵⁶⁰ For reasons already stated, the jury trial in personal injuries cases had to be a greater preoccupation of the judiciary in Ireland than in England & Wales (until the 1980s).

⁵⁶¹ [1967] IR 173.

⁵⁶² See Healy, *op cit*, 309.

The Supreme Court in *Griffin v Patton & Tyndale*⁵⁶³ clarified that “a bare division of opinion on whether a doctor exercised sufficient care or skill when treating a patient in accordance with customary practice does not of itself divest the court of its ability to infer the doctor’s negligence.”⁵⁶⁴

The House of Lords endorsed the honest difference of opinion principle in *Maynard v West Midlands Regional Health Authority*.⁵⁶⁵ Dismissing the appeal, their Lordships held that, in view of errors made by the trial judge, the Court of Appeal had been entitled to treat the issue of negligence as being at large; and that, on the evidence, the Court of Appeal had been right to reverse his finding. Lord Scarman expressed the feeling that the celebrated *dictum* of Clyde LPJ in *Hunter v Hanley*⁵⁶⁶ could not be bettered.⁵⁶⁷

In medical negligence cases, Healy has concluded, that a defendant “who is able to adduce expert testimonial support for his course of conduct is, relative to defendants in cases of negligence simpliciter, significantly protected against a finding of negligence.”⁵⁶⁸

4.1.3.6 Failings in Judgement and Skill

The courts have distinguished medical misadventure (professional error) from medical negligence on the ground that the former does not prove the latter.⁵⁶⁹ In *Whitehouse v Jordan*,⁵⁷⁰ Lord Denning commented simplistically that “in a professional man, an error of judgment is not negligent.”⁵⁷¹ The House of Lords corrected this impression.⁵⁷² The courts should not rely on hindsight to consider whether a doctor was guilty of negligence.⁵⁷³

⁵⁶³ *Griffin v Patton & Tyndale* [2004] IESC 46. See also Quill, E, *Ireland*, Chapter in Koziol, H, Steininger, BC, (Editors), *European Tort Law 2004* (2005) Springer, Vienna, 369-370.

⁵⁶⁴ See Healy, *op cit*, 312. Healy comments that the fourth and fifth *Dunne* premises act more as a principle designed to assist the court in making a fair decision, although not in the manner of a rule of law that binds the hands of a court otherwise minded to infer negligence from the evidence adduced.

⁵⁶⁵ *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634 (HL).

⁵⁶⁶ 1955 SLT 213, 217, per Clyde LPJ *supra*.

⁵⁶⁷ [1984] 1 WLR 634, 638-639, per Lord Scarman.

⁵⁶⁸ See Healy, *op cit*, 315.

⁵⁶⁹ See Healy, *op cit*, 317

⁵⁷⁰ *Whitehouse v Jordan* [1980] 1 All ER 650 (CA).

⁵⁷¹ [1980] 1 All ER 650, 658, per Lord Denning MR. See also Robertson, GB, *Whitehouse v Jordan: Medical Negligence Retried* (1981) 44 *Modern Law Review* 457, 458: “A similar, albeit less unequivocal, statement can be found in *Hatcher v Black* [*The Times*, 02 July, 1954]”. Sitting as a judge of first instance, Denning LJ charged the jury that ‘you must not, therefore, find him [the doctor] negligent-simply because something goes wrong; if, for instance, one of the risks inherent in an operation actually takes place . . . or if in a matter of opinion he makes an error of judgment.’ See also *Mordaunt v Gallagher & McParland* [1997] IEHC 123, [21], per Laffoy J: “An error of judgment is not necessarily negligence.”

⁵⁷² See *Whitehouse v Jordan* [1981] 1 WLR 246, 257-258 (HL), per Lord Edmund-Davies.

⁵⁷³ See Grant, SM, De Marco, J, Hamilton, A, *Defences to Professional Liability Claims* (1998-1999) 21 *Advocates’ Quarterly* 242, 250-251, citing *Lapointe v Hôpital Le Gardeur* [1992] 1 SCR 351 (SCC).

Statistics should not be accorded undue weight in a case where the doctor's applied skill or factual causation are in issue because those statistics are not personal to the doctor's situation.⁵⁷⁴

Geoghegan J, in *Griffin v Patton & Tyndale*,⁵⁷⁵ said that the trial judge had paid particular attention to the appellant surgeon's own evidence and he then found that as a matter of probability, she did not carry out the necessary assessment of the foetal material that had been taken out correctly in the surgical procedure.⁵⁷⁶

4.1.3.7 Keeping up-to-date

Staying abreast of developments is complicated enough for authors of textbooks.⁵⁷⁷ However difficult it may be to keep up-to-date, it is nevertheless required of medical practitioners. It is not an answer to an allegation of negligence to rely on techniques that the practitioner has not refined or replaced since one's undergraduate days.⁵⁷⁸ The practitioner "*must not obstinately and pig-headedly carry on with the same old technique if it has been proved to contrary to what is really substantially the whole of informed medical opinion...*"⁵⁷⁹ Practices adopted in other countries are not necessarily evidence of the appropriate standard in Britain and Ireland⁵⁸⁰: in *Whiteford v Hunter*⁵⁸¹ the defendant's failure to employ a diagnostic instrument commonly used in the United States was held not to be negligent.

There is a duty to be reasonably aware of developments in the core journals of one's field.⁵⁸² In the 1950s the bar was not set too high.⁵⁸³ It is submitted that the bar is now higher, due to the

⁵⁷⁴ Healy, *op cit*, 320.

⁵⁷⁵ [2004] IESC 46.

⁵⁷⁶ See also Healy, *op cit*, 320.

⁵⁷⁷ See Veitch, K, *The Jurisdiction of Medical Law* (2007) Ashgate, Aldershot, 1: "*Like painting Scotland's Forth Bridge, no sooner has the ink dried on the latest textbooks that the pace of events, and the arrival of new topics, compel their authors to embark on the next, invariably longer, editions*".

⁵⁷⁸ See McMahon and Binchy, *op cit* 368.

⁵⁷⁹ See Harrington, JA, '*Red in Tooth and Claw: The Idea of Progress in Medicine and the Common Law*' (2002) 11 Social & Legal Studies 211, 220, citing: *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582, 587 (McNair J).

⁵⁸⁰ Jones, *op cit*, 267.

⁵⁸¹ *Whiteford v Hunter* [1950] WN 553. See also Jackson & Powell on Professional Liability, Sixth Edition (2007) Sweet & Maxwell, London, 920.

⁵⁸² McMahon and Binchy, *loc cit*. See also Jones, *op cit*, 266, citing *Gascoigne v Ian Sheridan & Co* (1994) 5 Med LR 437, on the responsibility of the 'shop floor gynaecologist' to keep himself "*generally informed on mainstream changes in diagnosis, treatment and practice through the mainstream literature*." See also The City Law School, *Professional Negligence Litigation in Practice* (Fourth Edition) (2008) Oxford University Press, Oxford, 10-11, citing *Gascoigne v Ian Sheridan & Co* to clarify that a doctor is not expected to read every publication. See also Gagan, M, *Legal Aspects of Independent and Supplementary Prescribing*, Chapter in Courtenay, M, Griffiths, M (Editors), *Independent and Supplementary Prescribing: An Essential Guide*,

wider availability of (institutional and individual) paper-based and Internet subscriptions, also open access databases, which professional persons may consult.⁵⁸⁴

4.1.3.8 Junior Doctors

A hospital may be found liable for having adopted a negligent protocol – either in the division of labour between its staff or in the extent of assistance provided to junior doctors.⁵⁸⁵ Vicarious liability will be imposed for a senior doctor’s negligent delegation of a task to a junior doctor who was not yet ready to perform it or the junior doctor’s negligent performance.⁵⁸⁶

Denning LJ said in *Jones v Manchester Corporation*⁵⁸⁷: “Errors due to inexperience or lack of supervision are no defence as against the injured person, but they are available to reduce the amount of contribution which the hospital board can demand.”⁵⁸⁸

In *Wilsher v Essex Area Health Authority*,⁵⁸⁹ the majority (Mustill and Glidewell LJ) adhered to the objective standard. A subjective test was proposed by Browne-Wilkinson V-C by reference to post-holders.⁵⁹⁰ The majority view was clearly stated by Glidewell LJ: “In my view, the law requires the trainee or learner to be judged by the same standard as his more experienced colleagues. If it did not, inexperience would frequently be urged as a defence to an action for professional negligence”.⁵⁹¹ It is submitted that perhaps tacitly in these *dicta* are these perspectives: health care provision does not demand regimentation of the medical profession by reference to ‘post’ or

Second Edition (2010) Cambridge University Press, Cambridge, 35 (Employers and members of the public alike will expect a medical practitioner to refresh one’s knowledge and practice regularly).

⁵⁸³ See *Crawford v Board of Governors of Charing Cross Hospital*. The Times, 08 December, 1953 (CA), per Somervell LJ: “... Mr Justice Gerrard had clearly based his judgment on Dr Clausen’s failure to read the article in *The Lancet*. ... it was quite impossible to support the judgment,” Denning LJ opined: “... it would be putting much too high a burden on a medical man to say that he must read every article in the medical Press.”

⁵⁸⁴ See Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 357. Healy mentions also the possibility of gleaning updated knowledge from conferences; many conference proceedings are subsequently available through the Internet.

⁵⁸⁵ See Healy, *op cit*, 321.

⁵⁸⁶ See Healy, *op cit*, 321.

⁵⁸⁷ *Jones v Manchester Corporation* [1952] 2 QB 852.

⁵⁸⁸ [1952] 2 QB 852, 871, per Denning LJ.

⁵⁸⁹ [1987] QB 730 (CA). The House of Lords in *Wilsher v Essex Area Health Authority* [1988] 1 AC 1074 (HL) directed a retrial on causation before a different judge.

⁵⁹⁰ [1987] QB 730, 776-777, per Browne-Wilkinson V-C. See also *Jackson & Powell on Professional Liability*, Sixth Edition (2007) Sweet & Maxwell, London, 921.

⁵⁹¹ [1987] QB 730, 774, per Glidewell LJ.

'office'; in a medical negligence case, the courts will not entertain disputes over the organisational standing of a post or the status (permanent, temporary or otherwise) of a post holder.⁵⁹²

An experienced doctor "*should recognise and exercise caution against the inexperience of colleagues.*"⁵⁹³ In *Drake v Pontefract Health Authority*,⁵⁹⁴ a consultant psychiatrist was found to have been negligent in allowing an inexperienced Senior House Officer to interview and treat the claimant without immediate supervision from a more experienced psychiatrist.

Factors other than inexperience are to be weighed against the objective standard of care in negligence: stress, overwork or ill-health, are not a defence.⁵⁹⁵

It may be submitted that medical training is a theoretically-logical incrementalism, although in quotidian practice its course is totally unpredictable. The medical trainee can only address the clinical picture of the individual patients who present for treatment. The law recognises this reality and will impose liability in a consistent manner. It is not permissible for a doctor in training to seek to gain wider experience by investigating for any obscure condition (that one can find in a medical text) when the patient simply does not exhibit the signs or symptoms (or his corporeal system is not associated with the actual laboratory test results) that would justify such a course of action.

4.1.3.9 Medical and Non-Medical Co-Defendants

At the High Court hearing of *Shuit v Mylotte*,⁵⁹⁶ White J acquitted the first-named defendant, a consultant obstetrician/gynaecologist of negligence.⁵⁹⁷ The Supreme Court allowed an appeal against the dismissal of the claim against the third- and fourth-named defendants, the plaintiff's GP and the health board responsible for the laboratory responsible for in all three smear tests

⁵⁹² Other possibilities include 'acting up' (functioning with the responsibility of a higher grade post) and service as a *locum tenens*. It may also be noted in passing that, unlike the Bar, the Solicitor's profession has no rank of seniority.

⁵⁹³ Jones, *op cit*, 286, citing: *Comeau v Saint John Regional Hospital* [2001] NBCA 113. See, in particular, Para [20]: "...Dr. Dornan had failed to exercise caution against Dr. MacDonald's inexperience compared to the referring emergentologist's extensive experience with patients presenting with chest pain."

⁵⁹⁴ *Drake v Pontefract Health Authority* [1998] Lloyd's Rep Med 425. See also Bartlett, P, *Psychiatric Treatment: In the Absence of Law?* (2006) 14 Medical Law Review, 124, 128: it was stated that database searches of WestLaw UK and Lawtel using 'negligence' and 'psychiatry/psychiatrist' as search terms had yielded very few cases in England and Wales in the 40 years prior to July 2005. *Drake v Pontefract Health Authority* [1998] Lloyd's Rep Med 425 is "*remarkable as the only case on such a search where a psychiatric patient successfully sues for negligence related to inappropriate prescription of medication.*"

⁵⁹⁵ See *Barnett v Chelsea and Kensington Hospital Management Committee* [1968] 1 All ER 1068.

⁵⁹⁶ *Shuit v Mylotte* [2006] IEHC 89; *appeal allowed and remitted* [2010] IESC 56.

⁵⁹⁷ See also Byrne, R, Binchy, W, *Annual Review of Irish Law 2010* (2011) Thomson Round Hall, Dublin, 611-612.

carried out on the plaintiff. This case is illustrative of the complexity to be found in some modern cases involving both medical professional services and laboratory diagnostic tests and their interpretation.

4.1.4 The Inherent Defects Rule

The third premise in *Dunne* is a qualification to the customary practice defence, which was first propounded in Ireland when it arose in *O'Donovan v Cork County Council*.⁵⁹⁸ The case is well-known for the principle: “[n]eglect of duty does not cease by repetition to be neglect of duty.”⁵⁹⁹ The reason for the qualification to the defence was explained in *Roche v Peilow*: automatically and mindlessly to follow the practice of others cannot be described as acting reasonably.⁶⁰⁰

O’Hanlon J in *Edwards v Southern Health Board*⁶⁰¹ rejected the testimony of an English expert witness. The trial judge reasoned that the method applied by the defendant was decried as “inappropriate...because it did not conform [to the expert’s] own best judgment”⁶⁰² In the Supreme Court, Finlay CJ found that there had been ample evidence before the trial court of “the acceptability and common usage”⁶⁰³ of the practice followed by the defendants’ staff.

In *Sidaway v Governors of the Bethlem Royal Hospital*,⁶⁰⁴ Lord Bridge said: “[T]he issue whether non-disclosure in a particular case should be condemned as a breach of the doctor’s duty of care is an issue to be decided primarily on the basis of expert medical evidence, applying the *Bolam* test. But I do not see that this approach involves the necessity ‘to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has

⁵⁹⁸ [1967] IR 173 (Sup Ct). See Healy, *op cit*, 325.

⁵⁹⁹ [1967] IR 173, 193, per Walsh J. Some commentators, without drawing much by way of conclusions on legal principle, have remarked on the similarity between the relevant *dictum* and one in the Privy Council Advice handed down in the Canadian Appeal, *Bank of Montreal v Dominion Gresham Guarantee & Casualty Co* [1930] 1 AC 659, 666 (PC), per Lord Tomlin: “Neglect of duty does not cease by repetition to be neglect of duty.” Although it is submitted, by way of general observation, that in a legal system based on *stare decisis* repetition is not unexpected, it should be clarified here that a Privy Council Advice is in no sense binding on the Irish Supreme Court.

⁶⁰⁰ [1985] IR 232, 254-255 (Sup Ct), per Henchy J.

⁶⁰¹ *Edwards v Southern Health Board* [1989] WJSC-HC 238 (HC); [1994] WJSC-SC 2764 (Sup Ct).

⁶⁰² [1989] WJSC-HC 238, 258, per O’Hanlon J. Healy, *op cit*, 327, comments that O’Hanlon J appears to have applied a stricter test than was necessarily envisaged in the earlier Supreme Court authorities, by assuming that the inherent defects qualification required proof that either one, but not both, of the practices advocated respectively by the plaintiff and defendant constituted the general or universal practice for such cases. This is at variance with the reality that most medical situations accommodate a number of approved practices for which the level of support may fluctuate with advances in medical science.

⁶⁰³ [1994] WJSC-SC 2764, 2772, per Finlay CJ.

⁶⁰⁴ *Sidaway v Governors of the Bethlem Royal Hospital* [1985] 1 AC 871 (HL).

been a breach of that duty.”⁶⁰⁵ In *Bolitho v City and Hackney Health Authority*,⁶⁰⁶ the House of Lords refused to sanction any fundamental qualification to the customary practice defence as it applies to cases of medical diagnosis and treatment; the basic position since *Bolam*. Lord Browne-Wilkinson also cited⁶⁰⁷ with approval a *dictum* of Sachs LJ in *Hucks v Cole*⁶⁰⁸ (“a case from 1968”⁶⁰⁹) His Lordship continued: “[i]f, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.”⁶¹⁰

The Supreme Court in *Collins v Mid-Western Health Board & O’Connor*⁶¹¹ held that the admissions system operated by the first defendant was not a ‘medical practice’ as such, and therefore the allegation of negligence could not be refuted by showing that it was a universally approved professional practice. The system was plainly defective in that it had failed to segregate a case which clearly required expert investigation from other routine or trivial cases. In that the admissions system allowed a junior hospital doctor to disregard the opinion of an experienced general practitioner, such a system clearly suffered from an inherent defect.⁶¹²

The Australian courts (for example, in *F v R*⁶¹³) have been particularly critical of the professional standard model that prevails in England. The High Court of Australia in *Rogers v Whitaker*⁶¹⁴ refused to follow English law (the *Bolam* and *Sidaway* line of authority) when assessing the standard of disclosure required in an informed consent case.⁶¹⁵ That raised questions of “*simple common sense*” that ought to be determined by the court rather than medical experts.⁶¹⁶ More recently in *Lowns v Woods*⁶¹⁷ the Court of Appeal for New South Wales interpreted *Rogers v*

⁶⁰⁵ [1985] 1 AC 871, 900, per Lord Bridge.

⁶⁰⁶ [1998] AC 232 (HL).

⁶⁰⁷ [1998] AC 232, 242, Lord Browne-Wilkinson.

⁶⁰⁸ *Hucks v Cole* [1993] 4 Med LR 393, 397, (Sachs LJ).

⁶⁰⁹ [1998] AC 232, 242.

⁶¹⁰ [1998] AC 232, 243, per Lord Browne-Wilkinson. Lord Browne-Wilkinson also cited [242] with approval Sachs LJ in *Hucks v Cole* [1993] 4 Med LR 393, 397.

⁶¹¹ *Collins v Mid-Western Health Board & O’Connor* [2000] 2 IR 154 (Sup Ct).

⁶¹² See Healy, *op cit*, 329-330.

⁶¹³ *F v R* (1983) 33 SASR 189 (SA Sup Ct). See also Cooke, JR, *Architects, Engineers and the Law*, Third Edition (2001) Federation Press, Sydney, 46, for a wider quotation from *F v R*. Healy, *op cit*, 331-332, states that *F v R* was applied subsequently in *E v The Australian Red Cross Society* [1991] 27 FCR 310.

⁶¹⁴ *Rogers v Whitaker* (1992) 175 CLR 479.

⁶¹⁵ Healy, *op cit*, 332.

⁶¹⁶ Healy, *op cit*, 332.

⁶¹⁷ Healy, *op cit*, 332, citing *Lowns v Woods* [1996] Australian Tort Reports 81 – 376 (NSWCA). See also Law Reform Commission, *Report on Civil Liability of Good Samaritans and Volunteers* (LRC 93 – 2009) (2009) Law Reform Commission, Dublin, 32-33 (internal footnote inserted): “In 1997, a year after the Australian decision, the English Court of Appeal, in *Capital and Counties plc v Hampshire County Council* [[1997] QB 1004, 1035] and without referring to *Lowns v Woods* reasserted the view that mere physical proximity between a doctor and a sick person, of itself, does not create a duty to treat.” See also Australian

Whitaker to have rejected the *Bolam* test in its application not just to disclosure but also diagnosis and treatment.⁶¹⁸ The court was prepared to recognise that where there is conformity to ordinary medical practice in the relevant specialty the patient bears a heavy forensic burden to negate reasonable care in the circumstances.⁶¹⁹

The position chosen by the Irish Supreme Court has more in common with the approach favoured in Canada, which is to modify the professional standard rules in response to new variants of claim and legal policy as and when desirable.⁶²⁰ In its avoidance of absolutes, a modified retention of the professional standard model is able to accommodate contemporary social concerns whilst remaining sensitive to the concerns traditionally expressed in medical negligence doctrine.⁶²¹ It affirms and articulates a power in the court to adjudge a medical practice defective and itself negligent, notwithstanding evidence of approval of the practice or its application in the plaintiff's case.⁶²² Whilst there is no doubt that the qualification articulated by Walsh J in *O'Donovan* represented a breakthrough in medical negligence jurisprudence in Ireland, the Irish courts in recent years have tended to apply it in the manner of a *rule* where it was all the time open to subsequent courts to view it as an illustrative description of a principle.⁶²³ When articulating its general qualification to the professional standard model, the Canadian courts have not been so reductionist and have expressed it in a number of different ways, subject to a caveat that the qualification is very much an exception to the general rule.⁶²⁴

It is submitted that the approach to 'inherent defects' (taken in *O'Donovan*) presents difficulties when viewed by courts in jurisdictions that have not adopted the same 'reductionist' approach as Ireland.⁶²⁵ Deploying *O'Donovan*, combined with any other judicial decision that is reasonably applicable to the facts, plaintiffs and their advisors may become emboldened in their quest to

Government, The Treasury, *Submission by the Law Council of Australia to the Negligence Review Panel on the Review of the Law of Negligence* (2002) Australian Government, The Treasury, Parkes (ACT), 21. Available from <http://revofneg.treasury.gov.au/content/subs/033LCA3.pdf> (Last accessed 12 January, 2012). The Submission suggested that it was unclear whether the case of *Lowns v Woods* would be followed in future because of "the High Court's change in direction in determining the duty of care."

⁶¹⁸ Healy, *op cit*, 332.

⁶¹⁹ Healy, *op cit*, 332. See also Teff, H, *The Standard of Care in Medical Negligence—Moving on from Bolam?* (1998) 18 *Oxford Journal of Legal Studies* 473, 484.

⁶²⁰ Healy, *op cit*, 332.

⁶²¹ Healy, *loc cit*.

⁶²² Healy, *loc cit*.

⁶²³ Healy, *loc cit*.

⁶²⁴ Healy, *loc cit*.

⁶²⁵ The *dictum*, "Neglect of duty does not cease by repetition to be neglect of duty" has its origin in a Privy Council Advice in the case of *Bank of Montreal v Dominion Gresham Guarantee & Casualty Co* [1930] 1 AC 659, 666 (PC), per Lord Tomlin, which in any event did not touch upon medical negligence. Given the *dictum's* terseness, at first blush, it might be difficult to pin down the *dictum's* basic philosophy; it could be said to outline either 'irrationality' or 'inherent defect', although it has been associated with the latter in Ireland.

identify and to prove a substantially a similar inherent defect in an analogous medical procedure or patient management technique. The *O'Donovan* 'inherent defects' approach allows less room for nuance in drafting and promulgating the opinion of the court.⁶²⁶ Focusing, '*Bolitho*-style', on the illogical, a court's holding may be distinguishable on the basis that the defendant's actions or omissions were irrational, rather than challenging the underlying procedure or technique that he purported to implement.

A qualification to the professional standard is also plain in *Roberge v Bolduc*⁶²⁷:

*"The fact that a professional has followed the practice of his or her peers may be strong evidence of reasonable and diligent conduct, but it is not determinative. If the practice is not in accordance with the general standards of liability, i.e., that one must act in a reasonable manner, then the professional who adheres to such a practice can be found liable, depending on the facts of each case."*⁶²⁸

The tendency in Ireland to assume that formulation of this qualification has frozen since *O'Donovan* is regrettable not least because the words 'inherently defective' are more extreme and semantically constricted than they need to be.⁶²⁹ It may plausibly be inferred from the earlier formulations of the qualification—in *O'Donovan* and *Roche v Peilow*—that recourse to such pejorative words as 'inherently defective' and 'fraught with risk' was prompted more by the court's views of the particular lapses in those cases than by concern to circumscribe the outer-limits of this qualification.

O'Donovan remains one of the weightier expressions of a principle that might be expressed in any number of ways compatibly with medical negligence doctrine.⁶³⁰ It might, for instance, have chosen to say that a doctor is negligent notwithstanding his adherence to a general or approved practice where the practice he followed exposed the plaintiff unreasonably to the risk of his injury; or where the practice he followed was itself unsafe to an extent that was or ought to have

⁶²⁶ See Healy, *op cit*, 333: "[T]he words 'inherently defective' are more extreme and semantically constricted than they needed to be".

⁶²⁷ *Roberge v Bolduc* [1991] 1 SCR 374. See also Healy, *op cit*, 333.

⁶²⁸ [1991] 1 SCR 374, 437, per L'Heureux-Dubé (Original emphasis). These *dicta* were approved by the Supreme Court of Canada in *Waldick v Malcolm* [1991] 2 SCR 456 and *Lapointe v Hôpital Le Gardeur* [1992] 1 SCR 351.

⁶²⁹ Healy, *op cit*, 333.

⁶³⁰ Healy, *op cit*, 333.

been obvious to a reasonable doctor exercising the ordinary care to be expected of his profession.⁶³¹

4.1.5 Principle of *Res ipsa loquitur*

The doctrine of *res ipsa loquitur* is intended to assist a claimant who, through no fault of his own, is unable to adduce evidence as to how the accident occurred.⁶³² If all the facts about the cause of the accident are known the maxim does not apply. Rather, the question then is “*whether, on the known facts, negligence by the defendant can be inferred.*”⁶³³ In Canada, *res ipsa loquitur* has been abolished as “*a distinct maxim for establishing the defendant’s breach of duty.*”⁶³⁴

In order for the maxim to apply, the defendant must be in control.⁶³⁵ In publicly-provided healthcare, the control of the defendant is easier to establish than in private medicine, as the hospital may not be vicariously liable for all the staff involved.⁶³⁶ For a ‘pre-NHS’ view of control, one can look at *Mahon v Osborne*.⁶³⁷ Goddard LJ said: “*The surgeon is in command of the operation, it is for him to decide what instruments, swabs and the like are to be used, and it is he who uses them. The patient, or, if he dies, his representatives, can know nothing about this matter.*”⁶³⁸ It is doubtful that the ‘command’ vision of surgical procedure(s), as portrayed by the future Lord Chief Justice of England, would be widely shared today. It is not to be assumed that ‘the surgeon’ is solely responsible for an operation’s performance; another consultant or a surgeon in training may also be involved. The Supreme Court of California controversially ruled in *Ybarra v Spangard*⁶³⁹ that *res ipsa loquitur* should apply in general to a case of unusual injury while the patient is unconscious, undergoing surgery.⁶⁴⁰

⁶³¹ Healy, *op cit*, 333.

⁶³² A patient who receives a general anaesthetic is unable to adduce such evidence. *Lindsay v Mid-Western Health Board* [1993] 2 IR 147 (Sup Ct) was a leading case in which the maxim’s application on the facts was upheld. However, the defendant rebutted the inference successfully. See Healy, *op cit*, 67.

⁶³³ See Jones, *op cit*, 307. See also Healy, *op cit*, 657: once the inference is rebutted, the defendant is not strictly required to go further and establish what instead caused the plaintiff’s injuries. In the United States, the doctrine of *res ipsa loquitur* is frequently aligned, in the jury-trial context, with common knowledge and experience. For example, see *dicta* of Torbert CJ (*per curiam*) in *Bell v Hart* (1987) 516 So2d 562, 566 (Ala: Sup Ct).

⁶³⁴ Jones, *op cit*, 306-307, citing: *Fontaine v British Columbia (Official Administrator)* (1997) 156 DLR (4th) 577 (SCC). See also Seavey, WA, *Res Ipsa Loquitur: Tabula in Naufragio* (1950) 63 Harvard Law Review 643, 644, commenting on *Byrne v Boadle* (1863) 159 ER 299.

⁶³⁵ See Hogan, TB, *Cook v Lewis Re-Examined* (1961) 24 Modern Law Review 331, 334. See also Jones, *op cit*, 306 and Healy, *op cit*, 656.

⁶³⁶ See Jones, *op cit*, 307-308. It has to be said that the possibility of outside interference in an operating theatre seems slight.

⁶³⁷ *Mahon v Osborne* [1939] 2 KB 14.

⁶³⁸ [1939] 2 KB 14, 50, per Goddard LJ.

⁶³⁹ *Ybarra v Spangard* (1944) 154 P2d 687 (Cal: Sup Ct).

⁶⁴⁰ See Healy, *op cit*, 661.

The circumstances must be such that in the ordinary course of things accidents do not happen unless someone has been negligent: *this is "largely a 'common sense' judgment based on common experience of life."*⁶⁴¹ In *Hucks v Cole*,⁶⁴² Lord Denning MR said it was not right to invoke *res ipsa loquitur* against a doctor "save in an extreme case".

4.1.5.1 Application of Res Ipsa Loquitur in a Medical Context

In *Ratcliffe v Plymouth and Torbay Health Authority*⁶⁴³ the Court of Appeal summarised the relevance of the maxim *res ipsa loquitur* to medical negligence cases⁶⁴⁴:

"(1) In its purest form the maxim applies where the plaintiff relies on the 'res' (the thing itself) to raise the inference of negligence, which is supported by ordinary human experience, with no need for expert evidence.

(2) In principle, the maxim can be applied in that form in simple situations in the medical negligence field (surgeon cuts off right foot instead of left; swab left in operation site; patient wakes up in the course of surgical operation despite general anaesthetic).

(3) In practice, in contested medical negligence cases the evidence of the plaintiff, which establishes the 'res', is likely to be buttressed by expert evidence to the effect that the matter complained does not ordinarily occur in the absence of negligence.

(4) The position may then be reached at the close of the plaintiff's case that the judge would be entitled to infer negligence on the defendant's part unless the defendant adduces evidence which discharges this inference.

⁶⁴¹ See Jones, *op cit*, 308. Jones contrasts the following two scenarios. Barrels of flour do not fall from warehouse windows in the ordinary course of events in the absence of negligence [*Byrne v Boadle* (1863) 159 ER 299]. Financial losses on the commodity market are not, without more, evidence of negligence by brokers [*Stafford v Conti Financial Services Ltd* [1981] 1 All ER 691].

⁶⁴² (1968), [1993] 4 Medical Law Reports 393, 396.

⁶⁴³ [1998] EWCA Civ 2000; [1998] Lloyds Rep Med 162. See also *Greenhorn v South Glasgow University Hospitals NHS Trust* [2008] CSOH 128 [110], per Lord Uist: "Cases such as *Ratcliffe v Plymouth and Torbay Health Authority* 1998 LI L R (Med) 162, *Bovenzi v Kettering Health Authority* [1991] 2 Med LR 293 and *Hendy v Milton Keynes Health Authority (No 2)* [1992] 3 Med LR 119 supported the proposition that if an occurrence was not a known complication of a medical procedure or was so rare, that itself could support an inference of negligence."

⁶⁴⁴ See Jones, *op cit*, 312-313.

(5) *This evidence may be to the effect that there is a plausible explanation of what may have happened which does not connote any negligence on the defendant's part. The explanation must be a plausible one and not a theoretically or remotely possible one, but the defendant certainly does not have to prove that his explanation is more likely to be correct than any other. If the plaintiff has no other evidence of negligence to rely on, his claim will then fail.*

(6) *Alternatively, the defendant's evidence may satisfy the judge on the balance of probabilities that he did exercise proper care. If the untoward outcome is extremely rare, or is impossible to explain in the light of the current state of medical knowledge, the judge will be bound to exercise great care in evaluating the evidence before making such a finding, but if he does so, the prima facie inference of negligence is rebutted and the plaintiff's claim will fail. The reason why the courts are willing to adopt this approach, particularly in very complex cases, is to be found in the judgments of Stuart-Smith and Dillon LJ in Delaney⁶⁴⁵*

(7) *It follows from all this that although in very simple situations the 'res' may speak for itself at the end of the lay evidence adduced on behalf of the plaintiff, in practice the inference is then buttressed by expert evidence adduced on his behalf, and if the defendant were to call no evidence, the judge would be deciding the case on inferences he was entitled to draw from the whole of the evidence (including the expert evidence), and not on the application of the maxim in its purest form."⁶⁴⁶*

To operate on the wrong patient, or the right patient in the wrong place on the body, will almost invariably raise an inference of negligence.⁶⁴⁷

⁶⁴⁵ *Delaney v Southmead Health Authority* [1995] 6 Med LR 355.

⁶⁴⁶ [1998] EWCA Civ 2000, [49], per Brookes LJ.

⁶⁴⁷ See Jones, *op cit*, 313. For instances where the maxim has been held to apply, and where it has not been so held, see Jones *op cit*, 314-317. See also the *dictum* of Hobhouse LJ in *Ratcliffe v Plymouth and Torbay Health Authority* [1998] Lloyd's Rep Med 162, 177: "*Res ipsa loquitur* is not a principle of law and it does not relate to or raise any presumption. It is merely a guide to help identify when a *prima facie* case is being made out. Where expert and factual evidence is being called on both sides at trial its usefulness will normally have been long since exhausted."

In some cases, even though *res ipsa loquitur* does not, strictly speaking, apply to the circumstances, the evidence is such that the defendant will have to come up with a credible explanation for the events or risk a finding of negligence.⁶⁴⁸

4.1.5.2 The effect of invoking *res ipsa loquitur*

There are two possible views as to the consequences in law of a successful plea of *res ipsa loquitur*.⁶⁴⁹ The first is that it raises a prima facie inference of negligence which requires the defendant to offer some reasonable explanation as to how the accident could have occurred without negligence by him.⁶⁵⁰ In the absence of such evidence the prima facie case is established, and he will be found liable. If the defendant does adduce evidence that is consistent with the absence of negligence on his part, then the inference of negligence is rebutted, and the claimant has to produce positive evidence that the defendant has acted without reasonable care.⁶⁵¹

The alternative view is that when *res ipsa loquitur* applies it has the effect of reversing the burden of proof, so requiring the defendant to show that the harm was not the product of his carelessness. Jones has stated⁶⁵² that the case which provides the strongest support for this proposition is the decision of the House of Lords in *Henderson v Henry E Jenkins & Sons*.⁶⁵³ It is submitted that *Henderson's case* is less momentous than might first appear. Lord Pearson said "the decision in this appeal turns on what is sometimes called 'the evidential burden of proof,' which is to be distinguished from the formal (or legal or technical) burden of proof."⁶⁵⁴

The court's first port of call will be the medical or surgical notes; however, in *Howard v Wessex Regional Health Authority*,⁶⁵⁵ the defence relied successfully on a largely theoretical explanation for what went wrong with the operation.⁶⁵⁶ In any event, an explanation of how the events could

⁶⁴⁸ See Jones, *op cit*, 319, and, for example, *Lillywhite & Anor v University College London Hospitals NHS Trust* [2005] EWCA Civ 1466, [32]-[34], per Latham LJ.

⁶⁴⁹ Jones, *op cit*, 320.

⁶⁵⁰ Jones, *op cit*, 320.

⁶⁵¹ Jones, *op cit*, 320-321, citing *Ballard v North British Railway Co* 1923 SC (HL) 43, 54, per Lord Dunedin. Jones (*op cit*, 321) remarks that, in practice, the claimant would not rely on the maxim if he had positive evidence of the defendant's carelessness.

⁶⁵² Jones, *op cit*, 321.

⁶⁵³ *Henderson v Henry E Jenkins & Sons* [1970] AC 282. A similar result was achieved in *Ward v Tesco Stores Ltd* [1976] 1 WLR 810.

⁶⁵⁴ [1970] AC 282, 301, per Lord Pearson.

⁶⁵⁵ *Howard v Wessex Regional Health Authority* [1994] 5 Med LR 91.

⁶⁵⁶ See *Jackson & Powell on Professional Liability*, Sixth Edition (2007) Sweet & Maxwell, London, 934 (A fibro-cartilaginous embolism, an extremely rare event, was advanced as the explanation). See also Leigh, MAMS, *Legal Commentary*, Section within Earl, CJ, *Iatrogenic Lesions of Peripheral Nerves*, Chapter in Garfield, J, Earl, CJ, *Medical Negligence: The Cranium, Spine and Nervous System*, Second Edition (1999) Wiley-Blackwell, Oxford, 197. See also Jones, *op cit*, 323.

have occurred without negligence will not *necessarily* rebut the inference of negligence, particularly where the explanation is a remote or unusual eventuality.⁶⁵⁷

Lamenting the current unhealthy status of *res ipsa loquitur*, as doctrine, Binchy has entertained the suspicion (“*impossible to verify*”) that the doctrine has “*probably resulted in a greater number of justified outcomes for patients than unjustified outcomes for the medical profession. But, even if this is so, it will have been on a hit-and-miss basis*”.⁶⁵⁸

4.1.6 Standard of Proof in Medical Negligence

The standard of proof in medical negligence is, in theory, the same as for any other case of negligence, *i.e.* the general standard applicable in civil cases, namely ‘on the balance of probabilities’.⁶⁵⁹ Jones⁶⁶⁰ cites May LJ in *Dwyer v Roderick*⁶⁶¹ :

*“Professional men ... are entitled to no special preference before the law, to no rule requiring a higher standard of proof on the balance of probabilities than any other. But it is to shut one’s eyes to the obvious if one denies that the burden of achieving something more than the mere balance of probabilities is greater when one is investigating the complicated and sophisticated actions of a qualified and experienced lawyer, doctor, accountant, builder or motor engineer than when one is enquiring into the momentary inattention of the driver of a motor car in a simple running-down action.”*⁶⁶²

⁶⁵⁷ Jones, *op cit*, 323, citing: *Glass v Cambridge Health Authority* [1995] 6 Med LR 91, which described the proffered explanation as “*at best a highly unlikely possibility*”.

⁶⁵⁸ See Binchy, W, *Issues of Proof in Medical Negligence Litigation: New Questions Posed in the Irish Courts*, Chapter in Craven, C, Binchy, W (Editors), *Medical Negligence Litigation: Emerging Issues* (2008) First Law, Dublin, 81-82. See also Healy, *op cit*,

⁶⁵⁹ Jones, *op cit*, 324. See also *Ashcroft v Mersey Regional Health Authority* [1986] 2 All ER 245, 247 (Kilner Brown J). See further Jones, *op cit*, 326: in *Bull v Devon Area Health Authority* [1993] 4 Med LR 117 (a 1989 case), within the context of the Limitation Act 1980, the Court of Appeal did not accept that allegations of ‘ancient negligence’ should be more strictly proved than allegation of negligence a few years ago.

⁶⁶⁰ Jones, *op cit*, 324.

⁶⁶¹ *Dwyer v Roderick*, The Times, 12 November, 1983.

⁶⁶² *Dwyer v Roderick*, The Times, 12 November, 1983, per May LJ. A noticeable omission from this list was “*pharmacist*”. The third defendant, Cross Chemists (Banbury) Ltd, was held 40% liable in negligence: two defendant medical practitioners were held 45% and 15% liable, respectively. It was reported that May LJ pinpointed *dicta* of Denning LJ in the case of *Bater v Bater* [1951] P 35, 37 (to the page only). See also Mullan, K, *Writing a wrong* (1988) 297 British Medical Journal 470.

The proviso that professionals are entitled to no special treatment clearly belies what followed in the passage above. There is, however, a suspicion that such judicial pragmatism is largely confined to the medical profession.⁶⁶³

4.1.6.1 Negligence in and around Diagnosis

The Supreme Court in *Philp v Ryan*⁶⁶⁴ affirmed the right to recover damages for loss to life expectancy in cases of negligently delayed diagnosis.⁶⁶⁵ General practitioners, being the gatekeepers, are a 'primary' target for 'loss of chance' litigation.⁶⁶⁶ GPs are expected to identify (if not altogether to recognise) symptoms that would merit a more specialised investigation.⁶⁶⁷

4.1.6.2 Examining the Patient and Eliciting History

In the case of *Collins v Mid-Western Health Board & O'Connor*,⁶⁶⁸ the plaintiff's claim was for damages for negligence and she alleged that the first defendant was negligent in failing to admit the plaintiff's husband in the first instance, and in particular, in operating an admissions system which allowed a junior hospital doctor substitute his judgment as to whether the plaintiff's husband required urgent admission for the judgment of an experienced general practitioner. As against the second defendant, the plaintiff alleged that he was negligent in his diagnosis of the plaintiff's husband in his first consultation, and further that he was negligent in having failed subsequently to refer the plaintiff's husband to a specialist. The plaintiff's claim was dismissed by the High Court (Johnson J) and the plaintiff appealed to the Supreme Court on the finding that there was no breach of any duty of care by the defendants.

The Supreme Court allowed the plaintiff's appeal and remitted the claim to the High Court for determination as to whether the plaintiff had suffered any loss from the breaches of the duty of care to the plaintiff.

The Supreme Court pointed to the evident concern of the plaintiff and the history given to the second defendant by the plaintiff's husband, the second defendant had failed to make proper

⁶⁶³ Jones, *op cit*, 324 (internal citation omitted).

⁶⁶⁴ *Philp v Ryan* [2004] 4 IR 241 (Sup Ct).

⁶⁶⁵ See Healy, *op cit*, 335.

⁶⁶⁶ See Healy, *op cit*, 335-336.

⁶⁶⁷ See Healy, *op cit*, 336, citing: *Reeves v Carthy & O'Kelly* [1984] IR 348 (Sup Ct); *Maitland v Swan & Ors* [1992] WJHC-SC 4291 (HC), *O'Doherty v Whelan*, Unreported Judgments (1993 5 1180) (HC, 18 January, 1993); *Collins v Mid-Western Health Board & O'Connor* [2000] 2 IR 154 (Sup Ct).

⁶⁶⁸ [2000] 2 IR 154 (Sup Ct). See also Healy, *op cit*, 337-340.

inquiries of the plaintiff's husband⁶⁶⁹ and had not done all that could be reasonably expected of a reasonably prudent general practitioner.

*O'Doherty v Whelan*⁶⁷⁰ was a case in which O'Hanlon J held that a GP has a duty to make a visit to the home of a person who was already the doctor's patient. In his testimony in court, the plaintiff's husband denied that the Defendant at any time had told him to bring his wife to hospital.⁶⁷¹

4.1.6.3 Misdiagnosis and the Effects of Delay

In *Philp v Ryan*,⁶⁷² the plaintiff was diagnosed with prostate cancer: a diagnosis missed by the defendant eight months earlier. The defendants sought to appeal the High Court's award of damages. The plaintiff cross-appealed on the ground that the trial judge had erred in failing to award damages for possible loss of life expectancy: an additional ground was that aggravated damages should have been awarded as a result of the conduct of the defence to the claim. The Supreme Court sustained both grounds of cross-appeal. In addressing the 'loss of chance' issue, the Supreme Court did not draw on the more recent English jurisprudence, notably, *Hotson v East Berkshire Area Health Authority*⁶⁷³ and *Fairchild v Glenhaven Funeral Services Ltd.*⁶⁷⁴

⁶⁶⁹ [2000] 2 IR 154, 165, per Barron J. The learned judge referred to the Canadian case, *Dale v Munthali* (1977) 78 DLR (3d) 588, in which a general practitioner was found negligent in failing to realise that his patient's illness - subsequently diagnosed to be meningitis - was something more than flu. One of the grounds for such finding was that the doctor should have questioned both the patient and his wife more thoroughly concerning the high fever that had existed prior to his visit. Also Barron J referred to *Langley v Campbell*, The Times, 05 November, 1975, in which a general practitioner was found negligent because he failed to consider the possibility that his patient, an Englishman who had recently returned from Uganda, could be suffering from a tropical disease; malaria. The trial judge in reaching his decision accepted evidence from members of the patient's family that the doctor had been told that the patient had just returned from Uganda and that he had suffered from malaria previously.

⁶⁷⁰ *O'Doherty v Whelan*, Unreported Judgments (1993 5 1180) (HC, 18 January, 1993). See also Healy, *op cit*, 343. See also *Chapman v Rix* [1994] 5 Med LR 238 (CA, HL). This was a case (in which judgment was handed down on 21 December, 1960) that was ultimately reported in 1994. See also Healy, *op cit*, 340. See also Ming, KLY, *A Duty to Care: Pharmacists' Negligence: Implications for Pharmacists and Lessons Arising* (2003) 5 Allied Health Professions 1, 7. Kelvin Ming suggests (*loc cit*) that this is a paradigm case for pharmacists too, as it concerns communication between health professionals. See also Giesen, D, *International medical malpractice law: a comparative law study of civil liability arising from medical care* (1988) Martinus Nijhoff Publishers, Dordrecht, Boston, London, 151 (Giesen stresses the failure to communicate with 'others' responsible for continuing a patient's treatment).

⁶⁷¹ *O'Doherty v Whelan*, Unreported Judgments (1993 5 1180) (HC, 18 January, 1993), per O'Hanlon J at p7 of the judgment (1993 5 1180, 1186). At pp23-24 (1993 5 1180, 1202-1203), the learned judge took into account the GP's personal difficulties with which she had to contend at the material time ("*ameliorating factors which should not be minimised*"), although her professional response "*to the patient's plea for help was neither adequate no appropriate.*" See also Law Reform Commission, *Report on Civil Liability of Good Samaritans and Volunteers* (LRC 93 – 2009) (2009) Law Reform Commission, Dublin, 31 (n). Available from http://www.lawreform.ie/_fileupload/Reports/rGoodSamaritan.pdf (Last accessed 12 January, 2012).

⁶⁷² [2004] 4 IR 241 (Sup Ct). See also Healy, *op cit*, 345-346.

⁶⁷³ [1987] AC 750 (HL).

The trial judge had erred in holding that damages depended on proof that life would probably, not possibly, have been prolonged. Such damages could also be described as an increased risk of shorter life expectancy. The Supreme Court was able to leave to another day analysis of the wider 'loss of a chance' jurisprudence.

In *Fitzpatrick v Midland Health Board*,⁶⁷⁵ a delay in prescribing antibiotics was found, on the balance of the probabilities, to have precipitated the amputation of a finger, which might have been avoided if antibiotics had been given to the plaintiff in a timely manner. "[A]ll the doctors indicate[d]" that measure ought to have been taken four days earlier than actually done.⁶⁷⁶

4.1.6.4 Further Investigation and Review

The cause of death in *Wolfe v St James' Hospital*⁶⁷⁷ was an extremely rare condition. The deceased had a tumour called a phaeochromocytoma⁶⁷⁸ (commonly called a 'phaeo'). It was not diagnosed in the hospital when the deceased attended there either in 1989 or 1991. It was only

⁶⁷⁴ [2003] 1 AC 32 (HL). For a contemporary article, see also Peel, E, 'Loss of a Chance' Revisited: *Gregg v Scott* (2003) 66 Modern Law Review 623.

⁶⁷⁵ *Fitzpatrick v Midland Health Board*, Unreported, High Court, 01 June, 1997, Johnson J. See also Healy, *op cit*, 351.

⁶⁷⁶ *Fitzpatrick v Midland Health Board*, per Johnson J, [7]. See also *Colwill v Oxford Radcliffe Hospitals NHS Trust* [2007] EWHC 2881 (QB). See *Coughlan v Whelton*, Unreported, High Court, 22 January, 1993, Lavan J, at p19. See also von Bar, C, *The Common European Law of Torts: Damage and Damages, Liability for and without Personal Misconduct, Causality, and Defences* (2000) Oxford University Press, Oxford, 302: "The inability of the defendant physicians to make a diagnosis did not constitute negligence on their part." The learned commentator has understandably glossed over the reality that one doctor had a case to answer, although no ground of negligence was established against him. See also *Caffrey v North Eastern Health Board*, Unreported, High Court, 10 February, 1995, Johnson J. See also *Goonan v Dooley*, Unreported, High Court, 23 March, 1994 (Lynch J). In clearly-acknowledged *obiter dicta*, (per Lynch J, at [9]) the learned judge ventured to speculate that a missed Child Development Clinic appointment, for which no fault attached to the plaintiff's parents or the defendants, might have revealed the early onset of the condition. See also von Bar, C, *The Common European Law of Torts: Damage and Damages, Liability for and without Personal Misconduct, Causality, and Defences* (2000) Oxford University Press, Oxford, 302, on the upshot of the tests that the medical practitioners had performed in *Goonan v Dooley*: "Nobody could reasonably ask for more."

⁶⁷⁷ *Wolfe v St James' Hospital* [2002] IESC 10. See also Quill, E, *Ireland*, Chapter in Koziol, H, Steininger, BC (Editors), *European Tort Law 2002* (2003) Springer, Vienna, 265-267. Quill comments that there were some inconsistencies in the judgment at first instance. The trial judge made a specific finding that searching for a phaeo was not required, although some further testing was necessary. The medical evidence presented had indicated that testing for a phaeo was the only testing that was required. See also *H v St Vincent's Hospital Trustees Ltd* [2006] IEHC 443 (*ex tempore*), Hanna J. See Byrne, R, Binchy, W, *Annual Review of Irish Law 2006* (2007) Thomson Round Hall, Dublin, 561- 562.

⁶⁷⁸ Although phaeochromocytoma (a neuroendocrine tumour of the adrenal medulla) is an acknowledged clinical rarity, pharmacy students are instructed in the pharmacological aspects of phaeochromocytoma. Particularly in its untreated state, phaeochromocytoma represents a contraindication to, or requires special precautions for, administration of *inter alia* commonly prescribed beta-blocker drugs. It is also recognised that the drug prazosin may cause false positive results in laboratory screening tests for phaeochromocytoma.

discovered on post-mortem. If it had been diagnosed, it could have been treated: undiagnosed, it was fatal.

4.1.6.5 Failure to refer to a specialist

In the event that a doctor proceeds to treat a patient though he lacks the requisite experience or skill, the standard of care he will be adjudged to owe is the standard ordinarily to be expected of a doctor who possessed that relevant specialty at the material time.⁶⁷⁹

4.1.6.6 Negligence in Choice of Medical Treatment

The treating doctor must be familiar with the side effects of any medication prescribed.⁶⁸⁰

Certain procedures are too difficult to delegate, for example, the administration of anaesthetics.⁶⁸¹ Doctors have been held liable for injecting medication into a vein instead of an artery.⁶⁸² In *Collins v Hertfordshire County Council*⁶⁸³ while undergoing an operation, a patient in a

⁶⁷⁹ See Healy, J, *op cit*, 357-359. See also *Gottstein v Maguire & Walsh* [2007] 4 IR 435 (HC). See *Maitland v Swan & Ors* [1992] WJHC-SC 4291 (HC). See also Quill, E, *Ireland*, Chapter in Koziol, H, Steininger, BC, (Editors), *European Tort Law 2003* (2004) Springer, Vienna, 257: “[T]here is a significant difference between an unavoidable side effect of a beneficial procedure, which a patient might not regard as an injury inflicted on her, and the same consequence flowing from an entirely unnecessary procedure.” See also *Conley v Strain* [1988] 1 IR 628 (HC).

⁶⁸⁰ See Healy, *op cit*, 362. See also *Reynard v Carr* (1983) 30 CCLT 42, 1983 CanLII 643 (BCSC). The trial judge in *Reynard v Carr* viewed the ceiling on non-pecuniary loss set as applicable only in relation to completely disabled plaintiffs and on this basis awarded a partially disabled plaintiff \$425,000 for non-pecuniary loss. On appeal [(1986) 38 CCLT 217], the British Columbia Court of Appeal ruled that this award was inconsistent with higher authority (*i.e.* the Canadian ‘trilogy’ cases) and reduced it to \$135,000. See Mullany, N, *A New Approach to Compensation for Non-Pecuniary Loss in Australia* (1989-1990) 17 Melbourne University Law Review 714, 719 (n). See also Ming, KLY, *A Duty to Care: Pharmacists’ Negligence: Implications for Pharmacists and Lessons Arising* (2003) 5 Allied Health Professions 1, 6: “To minimise negligence, pharmacists should familiarise themselves with all medications, and continue keeping themselves up to date with the latest advances in pharmaceutical healthcare”, citing Healy, J, *Medical negligence: Common law perspectives* (1999) Sweet & Maxwell, London, 54, wherein is mentioned *Reynard v Carr*.

⁶⁸¹ See *Williams v St Claire Medical Center* (1983) 657 SW2d 590 (Ky: CA). (Using the Kentucky court’s terminology, the appellant suffered permanent brain damage while being administered anesthetics prior to undergoing an arthroscopy at the appellee hospital: at that time, the hospital had no anesthesiologist on staff and thus all anesthetics were administered by nurse anesthetists.)

⁶⁸² See Healy, *op cit*, 362. For further examples of inappropriate routes of administration, see Giesen, D, *International Medical Malpractice Law: a Comparative Law Study of Civil Liability Arising from Medical Care* (1988) Martinus Nijhoff Publishers, Dordrecht, Boston, London, 138.

⁶⁸³ *Collins v Hertfordshire County Council* [1947] 1 All ER 633 (KBD), Hilbery J. [The operating surgeon had ordered procaine on the telephone, but the resident house surgeon (who was then unqualified) had misheard ‘procaine’ as ‘cocaine’, and had told the pharmacist to dispense a mixture which was, in fact, lethal. The pharmacist dispensed the mixture without making further inquiry and without requiring the written instruction of a qualified person, and the operating surgeon had given the injection without checking that it was what he had ordered.]

county council hospital was killed by an injection of cocaine which was given by the operating surgeon in the mistaken belief that it was procaine.⁶⁸⁴

In *Quinn v South Eastern Health Board*⁶⁸⁵ the defendant was held to be liable for a consultant's recommending remedial surgery before existing conservative treatment options had been exhausted. Following an irreversible complication of surgery (neurectomy), future conservative treatment options were potentially curtailed.⁶⁸⁶

4.1.6.7 Negligence in Performance of Treatment

Healy notes that in the Irish cases "*that particular difficulty may be encountered in the attempt*" to prove a lack of technical *skill* in the doctor (unless the plaintiff is given the benefit of the inferential reasoning facilitated by the *res ipsa loquitur* maxim).⁶⁸⁷ It is submitted that the lack at issue here is generally in the *exercise* rather than the *acquisition* (through appropriate training) of the skill.⁶⁸⁸

4.1.6.8 Failure to Prevent Harm or Suicide amongst Patients

A very significant number of personal injury actions have been brought in common law jurisdictions in recent decades grounded in the defendant's failure to prevent suicide or an attempted suicide in circumstances where the defendant owed such a duty.⁶⁸⁹ The maxim, *ex turpi causa non oritur jus*, has been for a long time deployed as a bar to recovery arising from suicide.⁶⁹⁰ The courts in these islands have been sympathetic to the plight of suicidal patients.⁶⁹¹

⁶⁸⁴ See Sweetman, S (Editor), *Martindale: The Complete Drug Reference*, Thirty-Sixth Edition (2009) Pharmaceutical Press, London, 1869: procaine has been replaced in general by lidocaine and other local anaesthetics.

⁶⁸⁵ *Quinn v South Eastern Health Board* [2002] IEHC 43.

⁶⁸⁶ See Healy, *op cit*, 363.

⁶⁸⁷ See Healy, *op cit*, 365.

⁶⁸⁸ See also *Barrett v Southern Health Board* [1988] IEHC 12. See *Lynskey v Governors and Guardians of the Charitable Infirmary of Jervis Street*, Unreported, 23 April, 1993, High Court, Hamilton P. See also *Mordaunt v Gallagher & McParland* [1997] IEHC 123, Laffoy J. See *Dunne v Eastern Regional Health Authority* [2008] IEHC 315, Peart J. See also Byrne, R, Binchy, W, *Annual Review of Irish Law 2008* (2009) Thomson Round Hall, Dublin, 595. See *O'Connor v Murphy* [2008] IEHC 248, de Valera J.

⁶⁸⁹ Healy, *op cit*, 369.

⁶⁹⁰ See *McMahon v Binchy*, *op cit*, 176.

⁶⁹¹ Healy, *op cit*, 370. See also Hart, HLA, Honoré, T, *Causation in the Law*, Second Edition (1985) Oxford University Press, Oxford, 155 (internal citations omitted): "*Cases of suicide by insane persons raise some difficult problems. An act intended to exploit the situation created by the defendant, by treating it as providing the occasion for doing what the actor independently wants to do, usually negatives causal connection. On the other hand, an act done without a full appreciation of the circumstances does not. Courts have some rope to play with here...*" The metaphor is unfortunate.

Allegations of contributory negligence are rarely well received.⁶⁹² The House of Lords rejected *novus actus interveniens* quite recently in the case of *Corr v IBC Vehicles*.⁶⁹³ Courts in the United States have more readily accepted a plea of *novus actus interveniens* in suicide cases.⁶⁹⁴

In *Reeves v Commissioner of Police of the Metropolis*,⁶⁹⁵ the deceased's deliberate and informed act intended to exploit a situation created by a defendant did not negative causation where the defendant was in breach of a specific duty imposed by law to guard against that very act. Those entrusted with the custody of prisoners had a duty to take reasonable care for their safety while in custody whether they were of sound or unsound mind. Since the defendant was admittedly in breach of duty, the deceased's act in taking his own life did not entitle the defendant to rely on the defences of *novus actus interveniens* or *volenti non fit injuria*. However, a plea of contributory negligence was sustained.⁶⁹⁶

In *Clunis v Camden and Islington Health Authority*,⁶⁹⁷ the plaintiff, who had a history of mental disorder, was discharged from hospital after having been detained under section 3 of the Mental Health Act 1983. He was subject to after-care by the defendant health authority under section 117 of the Act⁶⁹⁸ but failed to attend appointments arranged by the responsible medical officer. Some weeks later, in a sudden and unprovoked attack, he killed a man by stabbing him. The

⁶⁹² Healy, *op cit*, 370, citing: *Armstrong v Eastern Health Board & St. Patrick's Hospital* [1990] WJSC-HC 2473 (HC).

⁶⁹³ *Corr v IBC Vehicles* [2008] 1 AC 884 (HL).

⁶⁹⁴ See Kok, A, *Delictual Liability in Case of Suicide* (2001) 12 Stellenbosch Law Review 155, 162, citing: *Runyon v Reid* (1973) 510 P2d 943 (Okla Sup Ct) on *novus actus interveniens*; "[A] mental patient committed suicide by taking an overdose of pills. The patient's psychiatrist prescribed sleeping pills to the patient. The court found that the psychiatrist was not negligent as there was no indication that the patient was suicidal. The claim also failed because the court found that the voluntary act of suicide broke the causative chain." See also MacLeod, AJ, *A Gift Worth Dying For?: Debating the Volitional Nature of Suicide in the Law of Personal Property* (2008-2009) 45 Idaho Law Review 123 and 123 (n): "As a general rule, one cannot be held liable for the suicide of another, even where one has committed a negligent act but for which the suicide would not have occurred ... This rule does not relieve a tortfeasor from liability for a suicide resulting from the tortfeasor's intentional conduct, whether the suicide is voluntary or involuntary," citing *inter alia*: *Kimberlin v DeLong* (1994) 637 NE2d 121 (Ind).

⁶⁹⁵ *Reeves v Commissioner of Police of the Metropolis* [2000] 1 AC 360 (HL).

⁶⁹⁶ Their Lordships held that "fault" within the meaning of section 4 of the Law Reform (Contributory Negligence) Act 1945 could include intentional acts as well as negligence. Liability was apportioned equally in consequence of the deceased's act. See, in particular, [2000] 1 AC 360, 369-370, per Lord Hoffmann: "The late Professor Glanville Williams, in his book, *Joint Torts and Contributory Negligence* (1951), p199, expressed the view that '[a]lthough contributory **negligence** is ruled out of court in an action for original intention on the part of the defendant,] contributory **intention** should be a defence.'" (Original emphasis amplified). See Williams, G, *Joint Torts and Contributory Negligence* (1951) Stevens & Sons, London, 199.

⁶⁹⁷ *Clunis v Camden and Islington Health Authority* [1998] 2 WLR 902 (CA); [1998] 1 WLR 1093 (Petition Dismissed) (HL).

⁶⁹⁸ The Court of Appeal held that the primary method of enforcing the after-care obligations under section 117 of the Mental Health Act 1983 was by complaint to the Secretary of State; the wording of section 117 was not apposite to create a private law cause of action for failure to carry out duties imposed by the statute.

plaintiff pleaded guilty to manslaughter on the grounds of diminished responsibility and was ordered to be detained in a secure hospital. He brought an action against the defendant claiming that he had suffered injury, loss and damage and that the defendant was in breach of a common law duty to treat him with reasonable professional care and skill, that on the known information the responsible medical officer should have realised that he was in urgent need of treatment and was dangerous, and that, had he been given treatment, he would not have committed manslaughter and would not have been subject to the prolonged detention which he faced. The trial judge refused to strike out the action, holding that the plaintiff was not precluded from recovering damages consequent on his own criminal act. The Court of Appeal held in effect that, diminished responsibility notwithstanding, the claimant appreciated what he had done was wrong. The court was precluded from entertaining his claim.

In *Kelly v Board of Governors of St Laurence's Hospital*,⁶⁹⁹ Walsh J found the hospital's supervision of the plaintiff "...unquestionably negligent".⁷⁰⁰ He continued: "*The fact ... that a similar practice occurs in other hospitals does not alter the situation.*"⁷⁰¹ Walsh J⁷⁰² agreed with Finlay CJ that the judge's charge to the jury should not have been limited to probable, as opposed to possible, injury.⁷⁰³

A decision to discharge a psychiatric patient was held in *Armstrong v Eastern Health Board & St. Patrick's Hospital*⁷⁰⁴ to have been negligently based on insufficient information. The decision had been based on a first examination and an oral summary of the records.⁷⁰⁵ Prior to the computerisation age, the plaintiff's records were kept in another hospital unit, 10-15 minutes distant on foot, and no attempt had been made to retrieve the file.

In *Healy v North Western Health Board*⁷⁰⁶ a psychiatric patient committed suicide four days after his discharge from the defendant's psychiatric hospital. The key issue was reasonable foreseeability.⁷⁰⁷ Flood J, having set out the rules in *Dunne*, described the comparatively informal assessment procedure followed by the Board and its staff as undoubtedly common practice in many psychiatric institutions: it was not for him to choose which "*the better course of action*"

⁶⁹⁹ Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 371, citing *Kelly v Board of Governors of St Laurence's Hospital* [1988] 1 IR 402 (Sup Ct).

⁷⁰⁰ [1988] 1 IR 402, 412, per Walsh J.

⁷⁰¹ [1988] 1 IR 402, 410, per Walsh J.

⁷⁰² [1988] 1 IR 402, 408, per Finlay CJ.

⁷⁰³ Healy, *op cit*, 371.

⁷⁰⁴ *Armstrong v Eastern Health Board & St. Patrick's Hospital* [1990] WJSC-HC 2473 (HC).

⁷⁰⁵ Healy, *op cit*, 372-373.

⁷⁰⁶ *Healy v North Western Health Board* [1996] WJSC-HC 1339 (HC) (Flood J).

⁷⁰⁷ Healy, *op cit*, 373.

was.⁷⁰⁸ Flood J also avoided the inherent defects proviso: any “*system of assessment, however universal, is only as good as the manner in which it is carried out*”.⁷⁰⁹ Instead, Flood J found that the Board’s staff had made no pre-discharge mental assessment of the patient, or an inadequate one; “*they had not reached the clinical view that the patient was in firm remission prior to discharge*”.⁷¹⁰

The plaintiff was unsuccessful in *Madigan v Governor of St Patrick’s Hospital, Dublin*.⁷¹¹ The court’s decision was formally based on the plaintiff’s failure to establish negligence on the *Dunne* principles. It was “*predominantly influenced by the relative unforeseeability of the patient’s disappearance ... and on the variable nature of supervision regimes recommended for each individual psychiatric patient*”.⁷¹²

A recent case on psychiatric negligence is *Orpen v Health Service Executive*.⁷¹³ O’Neill J was satisfied that an appropriate medical risk assessment had been made, he said:

*“With all attempted suicides, or potential suicides, there is a well established menu of risk factors: some or all may be present in any individual case. Critically, however, the weight to be attached to any individual risk factor will vary depending upon the circumstances of each individual. Thus, the doctor assessing suicide risk cannot merely add up the relevant risk factors in a formulaic way, but must instead assess the real weight to be attached to each relevant factor when assessed in the context of the overall circumstances of the patient.”*⁷¹⁴

Amongst those factors was the deceased’s family history of suicide, which his sister could have given to the psychiatric Senior House Officer (SHO) “*had a collateral history been sought*”.⁷¹⁵ The SHO accepted that she should have sought this collateral history. The court heard evidence that very few depressions are treated in a hospital context and that of those who attempt suicide by overdose, only two percent commit suicide within the following year, “*meaning that 98% do not*

⁷⁰⁸ [1996] WJSC-HC 1339, 1357.

⁷⁰⁹ [1996] WJSC-HC 1339, 1358.

⁷¹⁰ Healy, *op cit*, 374. Healy suggests that Flood J did not avail of the option to impugn the hospital’s general practice in pre-discharge assessment of psychiatric patients—“*perhaps to avoid dictating alternatives*”.

⁷¹¹ *Madigan v Governor of St Patrick’s Hospital, Dublin* [2006] IEHC 259 (Johnson J).

⁷¹² Healy, *op cit*, 375. See also Healy, *op cit*, 375-376 on the implications of art 2 (right to life) and art 3 (prevention of inhuman and degrading treatment) of the European Convention on Human Rights.

⁷¹³ *Orpen v Health Service Executive* [2010] IEHC 410 (O’Neill J). See also Byrne, R, Binchy, W, *Annual Review of Irish Law 2010* (2011) Thomson Round Hall, Dublin, 614-616.

⁷¹⁴ [2010] IEHC 410, [59], per O’Neill J.

⁷¹⁵ Byrne, R, Binchy, W, *op cit*, 615.

*commit suicide.*⁷¹⁶ O’Neill J suggested that if expert evidence adduced by the plaintiff were correct, it would mean that statements by a person with depression who had made a suicide attempt, “*to the effect that they no longer had any intention of self-harming and did not have suicidal ideation, would have to be given little weight in the assessment of suicide risks and the selection of treatment options.*”⁷¹⁷ The inevitable consequence of such an approach, he said, was “*that there would be far more admissions to hospitals in those circumstances than occurs under present prevailing psychiatric practice.*”⁷¹⁸

Byrne and Binchy note that O’Neill J, in his conclusions on liability, did not regard the failure to take the collateral history as decisive.⁷¹⁹

4.2 Pharmacists

4.2.1 Traditional View of the Pharmacist’s Standard of Care

Pharmacists were “[l]ong thought of as mere technicians responsible only for accuracy and efficiency in dispensing drugs”.⁷²⁰ These words were written just 11 years ago by two American-based librarians, who “[i]n the absence of any actual library negligence cases, [considered] it [to be] worth examining how pharmacists have fared under ordinary negligence rules.”⁷²¹ The modern pharmacist’s practice is “no longer confined to pill counting”.⁷²² In former times, the pharmacist’s exercising of professional judgment was “discouraged as intruding on the physician-patient relationship”.⁷²³ Some US courts continued to set the standard of care under an outdated view that pharmacists are accountable for clerical accuracy only.⁷²⁴ The few British decisions on pharmacist’s liability over the last three decades have gone beyond that ergonomic literalism in the standard of care. Liability has been apportioned between pharmacists and doctors for injuries

⁷¹⁶ [2010] IEHC 410, [61], per O’Neill J.

⁷¹⁷ [2010] IEHC 410, [62], per O’Neill J.

⁷¹⁸ [2010] IEHC 410, [62], per O’Neill J.

⁷¹⁹ Byrne, R, Binchy, W, *op cit*, 616.

⁷²⁰ Diamond, R, Dragich, M, *Professionalism in Librarianship: Shifting the Focus from Malpractice to Good Practice* (2001) 49(3) *Library Trends* 391, 400.

⁷²¹ Diamond, R, Dragich, M, *loc cit*.

⁷²² Fleischer, L, *From Pill-Counting to Patient Care: Pharmacists’ Standard of Care in Negligence Law* (1999-2000) 68 *Fordham Law Review* 165, 169.

⁷²³ Fleischer, L, *op cit*.

⁷²⁴ Fleischer, L, *op cit*.

caused.⁷²⁵ Those British cases are widely thought to be of persuasive authority to the Irish courts where the pharmacist's compliance with the standard of care has been put in issue.

4.2.2 Regulation of the current Pharmacist's Standard of Care in Ireland

4.2.2.1 Introduction

Since the enactment of the Pharmacy Act 2007, the Pharmaceutical Society of Ireland is empowered to formulate practice standards and issue guidance to pharmacists. One must be mindful that the profession may put forward its conception of the standard of care. However, the courts will have the last word in either a disciplinary matter, where there has been a finding of "poor professional performance" or "professional misconduct",⁷²⁶ or, in civil proceedings for professional negligence.

4.2.2.2 What constitutes a similarly qualified Pharmacist?

According to Crean, the standard of care of professionals "is assessed by comparison with the conduct of a similarly qualified professional exercising reasonable care in the circumstances".⁷²⁷ In the case of Irish pharmacists, the absence of a divisional register for pharmacists (on the model applicable to registered medical practitioners) facilitates the comparison of their qualifications and experience. The 'new' Pharmaceutical Society of Ireland (PSI) is no longer empowered by statute to confer the honorific, 'Fellow', on pharmacists who have been of distinguished service to the profession. This unitary-pattern register therefore places all registered pharmacists on an outwardly equal footing with one another; a generalisation, however, that admits of one important reservation. The PSI is required by the Pharmacy Act 2007 to make the Register of Pharmacists accessible to the public⁷²⁸ and, in respect of each registrant, the bare fact of whether he or she has conditions attached to the continued registration as a pharmacist is indicated.

⁷²⁵ For example, *Prendergast v Sam & Dee Ltd & Others* [1989] Med LR 36 (CA).

⁷²⁶ Section 51 (*High Court's power to cancel, etc., disciplinary sanction*) and section 52 (*Confirmation by High Court of disciplinary sanction*) of the Pharmacy Act 2007 are the relevant provisions for bringing applications to court. Section 53 (*Expert evidence on poor professional performance and professional misconduct*) provides as follows: "On an application under section 51 or 52, the High Court may hear evidence from any person of good standing within the profession of pharmacy as to what constitutes poor professional performance or professional misconduct in that profession."

⁷²⁷ Crean, F, *Liability of Community Pharmacists in Negligence and for Defective Products*, Chapter in Weedle, P, Clarke, L (Editors), *Pharmacy and Medicines Law in Ireland* (2011) Pharmaceutical Press, London, 310.

⁷²⁸ The Register of Pharmacists is available openly on a Web Site maintained by the Pharmaceutical Society of Ireland.

4.2.2.3 The Pharmacy Act 2007 and regulating the Standard of Care.

The Pharmacy Act 2007 provides a mixed regulatory regime for pharmacists. Subject to oversight by the legislature, the Pharmaceutical Society of Ireland is empowered to take a range of actions, which will be effective to set the standard of care for pharmacists.

Section 76(1) of the Pharmacy Act 2007 provides that a code of conduct having effect under sections 7(2)(a)(iii) and 12,⁷²⁹ rules made under section 11, 30 or 74 and regulations made under section 18(4) “shall be laid before each House of the Oireachtas as soon as practicable after it has effect or, as the case may be, they are made.” Section 76(2) provides for annulment of regulations within the next 21 sitting days of the House of the Oireachtas that may pass such a resolution, “without prejudice to the validity of anything previously done under the regulations”. Section 76(3) provides that a draft of every proposed order under section 8 (through which the Minister for Health would confer additional functions on the Society) “shall be laid before each House of the Oireachtas and the order shall not be made unless a resolution approving of the draft has been passed by each such House”.

4.2.2.4 Pharmacist Training and Experience

Pharmacy pre-registration training does not proceed along the same lines as the medical ‘on-the-job’ professional training model. Supervision by a tutor pharmacist is required throughout and there is no limited form of professional registration akin to that accorded to the medical intern. It is expected that a pharmacy graduate will become a fully-formed professional, capable of independent decision making, after one year’s traineeship (internship),⁷³⁰ or, through the even more recent intercalated degree model, which will integrate periods of supervised practice into the academic learning programme.

The Community Pharmacy Contractor Agreement (1996) requires that a “**supervising pharmacist** has at least three years experience in the practice of community pharmacy including up-to-date professional knowledge and experience in the counselling of patients in their use of medicinal products and, is not acting in a similar capacity in respect of any other pharmacy.”⁷³¹ (Emphasis added).

⁷²⁹ Section 12 provides in relation to codes of conduct for reference to the Competition Authority and Ministerial consent.

⁷³⁰ In 2009-2010, the Royal College of Surgeons in Ireland, School of Pharmacy, introduced the Republic of Ireland’s first Masters in Pharmacy (M Pharm) Internship Programme. Hitherto, all the Republic’s pharmacy pre-registration trainees were graduates, who had been awarded a bachelor’s degree.

⁷³¹ Community Pharmacy Contractor Agreement, Clause 6(2). See Department of Health and Children, *Community Pharmacy Contractor Agreement* (1996) Department of Health and Children, Dublin. Available

4.2.2.5 Keeping Up-to-Date

It is submitted that professional bodies (including the pharmacy regulator, the Pharmaceutical Society of Ireland) will apply an objective standard to keeping oneself abreast of developments. As in the case of medical practitioners, the standard was not pitched at a very high level in the past. The availability of Internet resources both raises the professional standard for pharmacists and facilitates more than minimal attainment of such a standard. The Pharmaceutical Society of Ireland requires an annual declaration from members that they are undertaking Continuing Professional Development (CPD) and a statement of the relevant activities in which the member has been involved during the calendar year. So far, pharmacists' CPD in Ireland has not been organised in a formal credit accumulation system, which is the model for medical practitioners and legal professionals.

4.2.2.6 Practice Guidance from the Pharmaceutical Society of Ireland

The term 'practice guidance'⁷³² is not subject to the same strictures as 'code of conduct', 'rules' or 'regulations'. Indeed, the word 'guidance' does not appear in the Pharmacy Act 2007. It is therefore submitted that the philosophy of 'practice guidance' allows the PSI sufficient flexibility to communicate with pharmacists on topical matters affecting the standard of care, while considering whether an approach contemplated in section 76 of the Pharmacy Act may be ultimately required.

In its own words, the PSI "*issues guidance to facilitate compliance with pharmacy and medicines legislation as well as best practice in relation to dispensing and the operation of a pharmacy, in order to ensure the safety of patients and the public. All pharmacists and pharmacies are expected to comply with the guidance issued by the PSI.*"⁷³³ This guidance "*is issued in a number of ways:*

"Guidelines to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008, or 'Section 18' Regulations.

from http://www.dohc.ie/publications/pdf/community_pharmacy_services.pdf. (Last accessed 12 January, 2012).

⁷³² See Pharmaceutical Society of Ireland, Practice Guidance (2012) Pharmaceutical Society of Ireland, Dublin. Available from <http://www.thepsi.ie/gns/pharmacy-practice/practice-guidance.aspx>. (Last accessed 08 October, 2012).

⁷³³ Pharmaceutical Society of Ireland, *loc cit.*

Guidance on the safe supply to patients of both prescription and non-prescription medicinal products.

Guidance for superintendent pharmacists.

Through meetings with pharmacists, including educational meetings organised through a joint PSI/ICCPE Taskforce, addressing the provision of safe and appropriate patient care by pharmacists, for example in relation to services for Nursing Home and Residential care settings.

The PSI regularly issues practice updates to pharmacists on specific issues relating to pharmacy practice in order to facilitate on-going improvements in patient safety and compliance with pharmacy legislation.”⁷³⁴

The PSI also issues a “monthly e-newsletter to all registered pharmacists, to help pharmacists to keep informed and up to date with professional topics and developments.”⁷³⁵

4.2.2.7 Public Consultation in determining the Standard of Care

In 2007, the PSI became the first professional regulator in the world to have a governing body (the Council) structured with a majority of members not drawn from the ranks of the profession over which the Council’s governance functions are exercised.⁷³⁶

The ‘new’ Society has conducted a public consultation on draft guidelines to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Business Regulations 2008. The consultation process was to take place before final approval by the PSI Council.⁷³⁷

⁷³⁴ Pharmaceutical Society of Ireland, *loc cit.*

⁷³⁵ Pharmaceutical Society of Ireland, *loc cit.*

⁷³⁶ A similar regulatory model was subsequently applied to the medical profession by the Oireachtas in the Medical Practitioners Act 2007.

⁷³⁷ See Pharmaceutical Society of Ireland, *Guidance to facilitate compliance with Regulations* (2012) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/gns/pharmacy-practice/practice-guidance/regulations_section_18.aspx. (Last accessed 07 October, 2012).

4.2.2.8 Guidelines to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008

In 2010 to 2011, the PSI published formal guidance in respect of: Sourcing, Storage and Disposal of Medicinal Products; Patient Consultation Areas; Safe Supply of Non-Prescription Medicines containing Codeine. In May 2012, the PSI issued draft guidelines for public consultation on the Premises and Equipment Requirements of a retail pharmacy business. The draft guidelines “are intended to assist pharmacy owners as well as superintendent, supervising and other pharmacists, in ensuring that their premises meet required standards, and that all equipment used for the delivery of pharmacy services is fit for purpose and well maintained.”⁷³⁸

In the future,⁷³⁹ the PSI has stated that it will issue further guidelines to facilitate compliance with the remaining requirements of the regulations, such as: Supply/Patient Counselling for Prescription Medicines (Regulation 9); Supply/Patient Counselling for Non-Prescription Medicines (Regulation 10); Record-keeping Requirements; Management and Supervision of a Pharmacy.

4.2.2.9 Guidance on the safe supply to patients of both prescription and non-prescription medicinal products.

Some drugs are potentially toxic or associated with the potential for errors in the pharmacy and/or by the patient who is to consume the medication. Guidance would therefore be beneficial to members of the pharmaceutical profession and the public served by them.

A recent example of a PSI guidance document (June 2012) is the *Guidance for Pharmacists on Safe Supply of Oral Methotrexate*.⁷⁴⁰ Methotrexate is a “potent immunosuppressant used in the treatment of active rheumatoid arthritis in adults, severe recalcitrant psoriasis and some oncological indications.”⁷⁴¹ Oral methotrexate for rheumatological and dermatological indications is administered on a once-weekly basis. Incorrect dispensing, prescribing and use of methotrexate can result in significant patient morbidity and mortality, due to severe adverse

⁷³⁸ Pharmaceutical Society of Ireland, *Guidance to facilitate compliance with Regulations* (2012) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/gns/pharmacy-practice/practice-guidance/regulations_section_18.aspx. (Last accessed 07 October, 2012).

⁷³⁹ Pharmaceutical Society of Ireland, *loc cit*.

⁷⁴⁰ Pharmaceutical Society of Ireland, *Guidance for Pharmacists on Safe Supply of Oral Methotrexate* (2012) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/Libraries/Practice_Guidance/Methotrexate_Guidance_-_published_version.sflb.ashx. (Last accessed 08 October, 2012).

⁷⁴¹ Pharmaceutical Society of Ireland, *loc cit*.

effects which can occur abruptly. The PSI has stated that such cases “*have been reported in Ireland and elsewhere and are of concern to all individuals involved in the supply of methotrexate.*”⁷⁴²

The *Guidance for Pharmacists on Safe Supply of Oral Methotrexate* is most explicit on the standard of care to be met by pharmacists, specifying many essential activities. For example, the supervising pharmacist or other designated pharmacist is responsible for the management, supply and patient/carer counselling for methotrexate. Another example is the requirement that the pharmacist must personally deliver the appropriately labelled medicine to the patient/carer, and must verbally confirm the dosage requirements with the patient, reinforcing the labelled instructions in a clear manner. “*This understanding must be confirmed demonstrably by the patient/carer.*”⁷⁴³

4.2.2.10 Guidance for Superintendent Pharmacists

Superintendent pharmacists have an overall managerial role in relation to the pharmacies in their area of responsibility. The PSI has clarified in a guidance document that a key legal and professional responsibility of the superintendent pharmacist is “*to ensure compliance therewith and with any Regulations, Code of Conduct, Statutory Rules and professional guidelines as may be in force.*”⁷⁴⁴ It is not proposed to go into the role of the superintendent pharmacist in any great depth. In passing, one might mention that there is no pharmaceutical parallel to the ‘medical administrator’ posited by Finlay CJ in *Dunne v National Maternity Hospital*.⁷⁴⁵

4.2.2.11 Irish Centre for Continuing Pharmaceutical Education (ICCPE)

The Irish Centre for Continuing Pharmaceutical Education (ICCPE) has the declared mission “[t]o provide and promote quality lifelong education for pharmacists by updating knowledge and skills to improve integrated professional practice and pharmaceutical care of the community”.⁷⁴⁶ The ICCPE was established in 1998 following agreement on the Community Pharmacy Contractor Agreement (CPCA), between the Department of Health and Children and the Irish Pharmacy Union, to support delivery of high quality community pharmacy services to the public. Clause 9 of

⁷⁴² Pharmaceutical Society of Ireland, *loc cit.*

⁷⁴³ Pharmaceutical Society of Ireland, *loc cit.*

⁷⁴⁴ O’Brien, L, *Superintendent Pharmacists – Responsibilities and Accountabilities* (2010) Irish Pharmacy Journal, April-August 2010, 218, 218.

⁷⁴⁵ *Dunne v National Maternity Hospital* [1989] IR 91 (Sup Ct), 110, per Finlay CJ.

⁷⁴⁶ Irish Centre for Continuing Pharmaceutical Education, *About ICCPE* (2012) Irish Centre for Continuing Pharmaceutical Education, Dublin. Available from <http://www.iccpe.ie/iccpe.html>. (Last accessed 09 October 2012).

CPCA, “stipulating that pharmacists must ensure that medicines are appropriately indicated, effective, safe and acceptable to patients provided the catalyst for the foundation of the ICCPE. It was agreed that ‘A programme of continuing education for pharmacists (and pharmaceutical assistants) engaged in the delivery of community pharmacy services under the Health Act (1970) will be initiated’.”⁷⁴⁷

The activities of the ICCPE embrace the latest modern training techniques. Pharmacists are also encouraged “to share good practice with others implementing innovative schemes in practice sites around the country. Ultimately, good pharmacy practice enhances the role of the community pharmacy for pharmacist and patient alike.”⁷⁴⁸ The ICCPE has therefore a complementary role to the PSI in promoting pharmacists’ understanding of and adherence to the standard of care for their profession.

4.2.2.12 Practice Updates to Pharmacists issued by the PSI

The PSI regularly issues practice updates to pharmacists “in specific issues of pharmacy practice or patient safety, and to facilitate compliance with pharmacy and medicines legislation and the Code of Conduct for pharmacists.”⁷⁴⁹

A recent example is *PSI Guidance to pharmacists in relation to the advertising, promotion and sale of medicinal products, and related matters*.⁷⁵⁰ The PSI stated authoritatively that it was “exercising its function under Section 7(2)(b)(vii) of the Pharmacy Act 2007 in issuing this guidance”.

Specific issues of pharmacy practice or patient safety arising from time to time and not requiring a more formal, structured, response from the PSI are eminently suited to the medium of practice update.

⁷⁴⁷ Irish Centre for Continuing Pharmaceutical Education (ICCPE), *loc cit*.

⁷⁴⁸ Irish Centre for Continuing Pharmaceutical Education, *Pharmacy Practice* (2012) Irish Centre for Continuing Pharmaceutical Education, Dublin. Available from <http://www.iccpe.ie/pharmacy-practice.html>. (Last accessed 09 October 2012).

⁷⁴⁹ Pharmaceutical Society of Ireland, *Practice Updates* (2012) Pharmaceutical Society of Ireland, Dublin. Available from <http://www.thepsi.ie/gns/pharmacy-practice/practice-guidance/practice-updates.aspx>. (Last accessed 09 October, 2012).

⁷⁵⁰ Pharmaceutical Society of Ireland, *PSI Guidance to pharmacists in relation to the advertising, promotion and sale of medicinal products, and related matters* (2011) Pharmaceutical Society of Ireland, Dublin. Available from http://www.thepsi.ie/Libraries/Practice_Guidance/Final_Advertising_Guidance_2011_November.sflb.ashx. (Last accessed 09 October, 2012).

4.2.2.13 The Inherent Defects Rule

The Inherent Defects Rule, as expressed by Finlay CJ in the *Dunne v National Maternity Hospital* case has been examined in the context of medical practitioners. The performance of any professional, financial or other service may contain inherent defects. It is unsurprising therefore that the Irish courts will show no deference to inherently defective practices when a professional person is involved.

The Pharmaceutical Society of Ireland has produced 'checklists' for a variety of pharmacists' professional activities. Adherence to 'best practice' in this regard should facilitate the pharmacist to avoid inherently defective practices and liability for same.

4.2.3 Differing Schools of Thought in Pharmacy

On the possibility of differing schools of thought, it is difficult to envisage how ordinarily more than one could exist in pharmacy practice, from which a pharmacist would have to choose. This is certainly the impression one has formed of community practice. Clinical pharmacy in a hospital-based, multidisciplinary, location may be different, especially in a manufacturing facility⁷⁵¹ licensed by the national competent authority.⁷⁵² Medical practitioners are typically required to make rapid, even instant, decisions about treatment and in so doing to follow a reputable school of thought. The patient's episode of care from a hospital physician/surgeon may be an acute one, which will be followed up by other colleagues or the patient's GP. The same considerations do not apply to pharmaceutical services. In the community setting, the pharmacist will monitor the patient's medication longitudinally. A patient in hospital cannot expect the individual attention of one clinical pharmacist for the hospitalisation episode's entire duration. A hospital pharmacy department is therefore justified in formulating policies that permit seamless healthcare and by implication eliminate the scope for any alternative school of thought.

4.2.4 Application of Res Ipsa Loquitur to Pharmacists

The maxim, *res ipsa loquitur* is analysed in greater depth elsewhere in this thesis. The doctrine permits a rebuttable inference of negligence from the occurrence of an incident that does not ordinarily happen without negligence on the part of the person in whose exclusive control the *res* (thing) is to be found.

⁷⁵¹ The manufacturing process alluded to here is something different from a centralised or decentralised intravenous additive service.

⁷⁵² In the Republic of Ireland, the national competent authority is the Irish Medicines Board.

The following are illustrations from the United States, which may be of some persuasive authority in an appropriate case. The doctrine has not been a usual feature of British and Irish case law in the pharmacy context. Addressing the question of compounding ingredients under a (defendant) pharmacist's (exclusive) control, in *Ball Memorial Hospital v Freeman*⁷⁵³ Landis CJ held that doctrine of *res ipsa loquitur* was applicable to case where injuries were result of solution which was prepared, stored, and dispensed by hospital and delivered by it to patient who was injected with it. In *Allmon v Walgreen Company*,⁷⁵⁴ the *pro se* plaintiff alleged that the pharmacy switched her medication with that of another customer. Opposing the defendant's motion to strike the proceedings, Allmon argued that no expert testimony is needed to prove that the defendant was negligent. The plaintiff argued that the record already contains clear evidence of the defendant's negligence, and that this negligence would be obvious to any layperson, invoking the doctrine of *res ipsa loquitur*: the motion before a United States Magistrate Judge⁷⁵⁵ was not dispositive of the issue.⁷⁵⁶

4.2.5 Pharmacists and Psychiatric Medication

The legal position of medical practitioners in relation to psychiatric patients has already been considered in this thesis.

4.2.5.1 Phased Dispensing

In the context of psychiatric medication, it is necessary to consider pharmacists' phased dispensing of medication. While most routine medication may be prescribed on a monthly basis, common in the GMS Scheme, some may be dispensed at more frequent (usually weekly) intervals. For the award of a specific fee (additional to the Standard Fee), in the GMS Scheme only,⁷⁵⁷ the dispensing of a GMS reimbursable item may be phased for one of the reasons approved by the

⁷⁵³ *Ball Memorial Hospital v Freeman* (1964) 196 NE2d 274 (Ind: Sup Ct), 274-278, per Landis CJ.

⁷⁵⁴ *Allmon v Walgreen Company* (2010) (Dist Ct, ED Mo, E Div).

⁷⁵⁵ The parties consented to the exercise of plenary authority by a United States Magistrate Judge pursuant to 28 USC § 636(c). The matter was adjourned to determine whether Allmon had satisfied the requirements of diversity of citizenship subject matter jurisdiction under 28 USC § 1332(a).

⁷⁵⁶ Recent research (10 March, 2012) on the *Allmon* case has not revealed any record of a further step in the proceedings.

⁷⁵⁷ The Phased Dispensing Fee is covered by the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2011 (SI No 300 of 2011), which specifies the amount of each type of fee payable to such contractors: "*Phased dispensing — payable per drug item for each dispensing phase other than the first dispensing phase (for which the standard dispensing fee ... is payable)*".

Department of Health in 1996. Those reasons [conveniently labelled Reason (1) to Reason (4), inclusive] are the following⁷⁵⁸:

Reason (1)

At the request of a patient's physician (GP);

Reason (2)

Due to the inherent nature of a medicinal product, *i.e.* product stability and shelf life;

Reason (3)

Where a patient is commencing new drug therapy with a view to establishing patient tolerance and acceptability before continuing on a full treatment regime;

Reason (4)

In exceptional circumstances, where the patient is incapable of safely and effectively managing the medication regimen.

Phased dispensing fees do not apply to provision of a filled Multi-compartment Compliance Aid (MCA) - also commonly known as Monitored Dosage System (MDS).⁷⁵⁹

It is submitted that, in a Reason (1) scenario, reasonably foreseeable risk to a psychiatric patient will have been assessed by the GP, who will limit the amount of medication to be supplied to the patient on any single occasion.⁷⁶⁰ Reasons (2) and (3) describe less frequent, somewhat technical, situations that are not especially relevant here.⁷⁶¹ Reason (4), however, merits closer analysis.

For Reason (4), what may comprise "*exceptional circumstances*" has not been defined. In a Reason (4) scenario, it is to be implied that the GP has not made a request for phased dispensing

⁷⁵⁸ See Health Service Executive - National Shared Services - Primary Care Reimbursement Service, *Information and Administrative Arrangements for Pharmacists* (2006) Health Service Executive, Dublin, 64-65. Available from http://www.hse.ie/eng/Staff/PCRS/Contractor_Handbooks/PCRS_Handbook_for_Pharmacists.pdf. (Last accessed 12 January, 2012).

⁷⁵⁹ A Monitored Dosage System may sometimes be called a Controlled Dosage System, which is perhaps more accurate, particularly if the system is not being monitored by anyone – lay or professional.

⁷⁶⁰ Where the physician has not made a request for phased dispensing, and a pharmacist falsely represents that a medical practitioner has in fact made such a request, it is submitted that the pharmaceutical contractor may be estopped from denying a duty of care in negligence towards the patient.

⁷⁶¹ Examples of each are: Reason (2) - an antibiotic suspension reconstituted from powder through the addition of water; Reason (3) - an antihypertensive therapy not presented in a 'starter pack' from which the dosage could have been titrated in a standard manner.

on the particular occasion. It scarcely seems reasonable that Reason (4) should be deployed as a conduit to an additional fee because the GP supposedly 'forgot' to call for phased dispensing. To claim *via* Reason (4) on a broad, systematic, basis would strain the concept of 'exceptional circumstances'. Obviously, Reason (4) cannot apply when another (responsible) person manages the patient's medication, such as a member of one's family or the nursing home professional staff. If a *psychiatric patient* is, in the pharmacist's opinion, incapable of safely and effectively managing the medication regimen, where the GP has not requested phased dispensing, it is submitted that such a belief should be brought to the GP's attention. The pharmacist may have a greater insight than the GP into the patient's actual compliance with the prescribed medication: the patient could well have nobody but the pharmacist routinely monitoring this aspect of pharmacotherapy.

In general, it may be argued that a pharmacist, who takes a Reason (4) approach to a psychiatric patient, will have assumed a duty of care in negligence towards the patient to prevent the reasonably foreseeable risk from the prescribed medication that has been supplied.

4.3 Standards of Care and other Healthcare Workers

Healy has stated that the scope of the *Dunne* test beyond doctors and lawyers has not yet been authoritatively decided in Ireland, although in *Kelly v Board of Governors of St Laurence's Hospital*, the Supreme Court expressed the view that nurses did not constitute members of a profession for the purposes of the rule in *Dunne*.⁷⁶² It is submitted that the learned author of *Medical Malpractice Law* has summarised the current position of the law relating to the limits to the medical professional rule essentially correctly, although the route does not take account of the actual chronology and matters downstream of that timeline. *Kelly v Board of Governors of St Laurence's Hospital* was decided in 1988, the year prior to the *Dunne* principles' promulgation. It is further submitted Finlay CJ differentiated the occupational state of being a nurse (without expressly or impliedly denying that nursing was a profession) from membership of the medical profession.⁷⁶³ The *Kelly* case was held in the Supreme Court to concern the question of a nurse's exercise of due care, since the alleged breaches of duty were supervisory in nature.⁷⁶⁴

⁷⁶² Healy, J, *op cit*, 288-289, citing *Kelly v Board of Governors of St Laurence's Hospital* [1988] 1 IR 402 (Sup Ct).

⁷⁶³ See *Kelly v Board of Governors of St Laurence's Hospital* [1988] 1 IR 402, 406-407, per Finlay CJ. The Supreme Court in 1988 would have been aware that the nursing profession had been placed on its modern footing by the Nursing Act 1985, which provided *inter alia* in s39 for *Erasure or suspension of registration from register for professional misconduct, unfitness to practise or failure to pay retention fee* (emphasis added). See also *K v An Bord Altranais* [1990] 2 IR 396, 403 (Sup Ct) per Finlay CJ: *[T]he statutory provisions*

The *Bolam* test was analysed by the House of Lords in *Bolitho v City and Hackney Health Authority*.⁷⁶⁵ Lord Browne-Wilkinson opined that “*the court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis*”, further, the judge must ascertain whether “*the experts have directed their mind to the question of comparative risks and benefits and have reached a defensible conclusion on the matter.*”⁷⁶⁶

Healy⁷⁶⁷ mentions the unexpected nature of the recourse to the administrative law principle of *Wednesbury*⁷⁶⁸ irrationality by Dillon LJ in *Bolitho*. Irrationality, it is submitted, is not synonymous with unreasonableness. To be irrational, something will not have been elaborated completely through a proper deliberative process; such a defect may adversely affect the interests of the flawed thinker, much as it may impinge negatively on any potential litigious opponent. Practical expressions of ‘unreasonableness’ are directed at others and the concept is not understood to be reflexive; one does not hear of a person’s unreasonableness towards himself. However, Lord Browne-Wilkinson in *Bolitho* probably neutralised any *Wednesbury*-type controversy in medical negligence by pointing out the following: in the vast majority of cases the reasonableness of distinguished expert opinion will be upheld and seldom will it be right for a judge to arrive at a contrary conclusion. John Keown (writing in 1998) said the following: “*Bolitho is good as far as it goes, but it does not go as far as it should. For one thing, it is not clear whether medical opinion may be disregarded only if it is illogical. What if the logic is flawless but the premise unsound or unpersuasive?*”⁷⁶⁹

4.4 Patients’ Contributory Negligence

In any civil proceedings brought by a patient for professional negligence against a medical practitioner or pharmacist, the question of the patient’s contributory negligence may arise. On

which I was attempting to interpret in the cases concerning the Medical Practitioners Act, 1978, in their machinery and in the interpretation which should be placed upon them, are indistinguishable from the provisions of this Act of 1985. See also Perionowsky v Freeman (1866) 176 ER 873, 875, per Cockburn CJ: “The defendants [(surgeons)] would not be liable for the negligence of the nurses [in bathing the plaintiff], unless near enough to be aware of it and to prevent it.”

⁷⁶⁴ Healy, J, *Medical Malpractice Law* (2009) Round Hall, Dublin, 289.

⁷⁶⁵ *Bolitho v City and Hackney Health Authority* [1998] AC 232 (HL).

⁷⁶⁶ [1998] AC 232, 242, per Lord Browne-Wilkinson.

⁷⁶⁷ Healy, *op cit*, 316.

⁷⁶⁸ *Associated Provincial Picture Theatre Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223 (HL).

⁷⁶⁹ Keown, J, *Reining in the Bolam Test* (1998) 57 Cambridge Law Journal 248, 249.

contributory negligence generally, in *Nance v British Columbia Electric Railway Co Ltd*,⁷⁷⁰ Viscount Simon stated that:

“... when contributory negligence is set up as a defence, its existence does not depend on any duty owed by the injured party to the party sued, and all that is necessary to establish such a defence is to prove to the satisfaction of the jury that the injured party did not in his own interest take reasonable care of himself and contributed, by his want of care, to his own injury.”⁷⁷¹

Binchy and Komolafe have presented an instructive thematic approach⁷⁷² to patient contributory negligence, which has been followed below.

4.4.1.1 Failure by the patient to disclose pertinent information

If the patient cannot or will not provide a reliable medical history and a clear account of symptoms, “the doctor’s conduct, based on insufficient or misleading information, simply may not fall below the professional standard of care.”⁷⁷³ It is sometimes necessary for the medical practitioner to be proactive in eliciting from the patient information required for a sound diagnosis and treatment. The Supreme Court, in *Collins v Mid-Western Health Board & O’Connor*,⁷⁷⁴ held that the second defendant (a GP) had failed to make proper inquiries of the plaintiff’s husband and had not done all that could be reasonably expected of a reasonably prudent general practitioner.⁷⁷⁵

The failure to disclose, for more than a day after admission to hospital, an injury to the larynx (sustained in a road traffic accident) was central in *Caffrey v North Eastern Health Board*.⁷⁷⁶ Although specialist treatment had been delayed, the plaintiff could not prove “compensable damage”.⁷⁷⁷

⁷⁷⁰ *Nance v British Columbia Electric Railway Co Ltd* [1951] AC 601.

⁷⁷¹ [1951] AC 601, 611, per Viscount Simon.

⁷⁷² Binchy, W, Komolafe, RA, *Patients, Contributory Negligence and Medical Negligence Litigation* (2010-2011) 4(2) Quarterly Review of Tort Law 21. See also Radford, C, *Patient responsibility and contributory negligence* (2010) Bevan Brittan LLP, London. Available from

http://www.bevanbrittan.com/_layouts/E3BevanBrittanTemplates/DownloadPDF.aspx?url=http%3a%2f%2fwww.bevanbrittan.com%2farticles%2fPages%2fPatientResponsibilityandContributoryNegligence.aspx&title=Bevan+Brittan+LLP+-+Patient+responsibility+and+contributory+negligence. (Last accessed 01 April, 2011).

⁷⁷³ Binchy and Komolafe, *op cit*, 21.

⁷⁷⁴ *Collins v Mid-Western Health Board & O’Connor* [2000] 2 IR 154 (Sup Ct).

⁷⁷⁵ On this holding, the Supreme Court reversed Johnson J at first instance.

⁷⁷⁶ *Caffrey v North Eastern Health Board*, Unreported, High Court, 10 February, 1995, Johnson J.

⁷⁷⁷ See Ward, P, *Tort Law in Ireland* (2010) Kluwer Law International, Aalphen aan den Rijn (NL), 62.

*Rose v Dujon*⁷⁷⁸ was a case in which the plaintiff had been involved in a road traffic accident. Over a treatment period of several months, he failed to disclose several episodes of headache, blurred vision and dizziness. He developed a condition resulting in his blindness. Fraser J expressed himself to be satisfied on all the evidence that the symptoms the plaintiff, Rose, disclosed to Polack (the second defendant, a doctor whom Rose had consulted at a Hospital Emergency Department) were as related by Polack and not as alleged by Rose.⁷⁷⁹ The learned judge stated that “*the clear impression was that Rose was endeavouring to tailor his evidence*” in order to conform to “*what he now understood to be the essential symptoms demonstrated by a person suffering from subdural hematomas.*”⁷⁸⁰ Fraser J rejected also Rose's evidence as to what he disclosed on the alleged visits he supposedly made to Dujon (the defendant GP):

*“Further, if Rose is now to be believed as to the symptoms he allegedly disclosed to Dujon and Polack, it would necessarily follow that four doctors were wrong or inaccurate in the history which each took from Rose, namely Sunohara, Dujon, Polack and the physician who first saw Rose on his admission to hospital, Dr. Colin Fennell ... I can see no justifiable reason for reaching any such conclusion.”*⁷⁸¹

4.4.1.2 Failure to comply with medical instructions

On patient's contributory negligence, *Pidgeon v Doncaster Health Authority*⁷⁸² is notable. The claimant was incorrectly informed and negligently so that the results of her cervical smear test were negative. She developed cervical cancer. In spite of frequent reminders, the claimant failed to have further smear tests. Such investigations should have identified the cancer and facilitated treatment to commence much sooner than it actually did. Although not accepting that there had been a new intervening cause, the court held the claimant to be contributory negligence to the extent of two-thirds of the assessed damages.⁷⁸³

⁷⁷⁸ *Rose v Dujon*, 1990 CanLII 5950 (AB QB).

⁷⁷⁹ 1990 CanLII 5950, [66], per Fraser J.

⁷⁸⁰ *Loc cit.*

⁷⁸¹ *Loc cit.*

⁷⁸² *Pidgeon v Doncaster Health Authority* [2002] Lloyd's Rep Med 130 (Sheffield County Court, 23 November, 2001, Judge Bullimore). According to Jones, since the *Pidgeon* case was a County Court decision, it was therefore of no authority: Jones, MA, *Claimants' contributory fault, policy, and public authority "impecuniosity"*, Obligations Discussion Group Posting, 09 November, 2006 (2006) Obligations Discussion Group, University College Cork. Available from <http://www.ucc.ie/law/odg/messages/061109k.htm>. (Last accessed 12 January, 2012).

⁷⁸³ See Radford, C, *Patient responsibility and contributory negligence* (2010) Bevan Brittan LLP, London.

Available from

http://www.bevanbrittan.com/_layouts/E3BevanBrittanTemplates/DownloadPDF.aspx?url=http%3a%2f%2fwww.bevanbrittan.com%2farticles%2fPages%2fPatientResponsibilityandContributoryNegligence.aspx&title=Bevan+Brittan+LLP+-+Patient+responsibility+and+contributory+negligence. (Last accessed 01 April, 2011).

The pursuer, in *Sabri-Tabrizi v Lothian Health Board*,⁷⁸⁴ underwent a laparoscopic sterilisation procedure but fell pregnant some months later (the first pregnancy). She had an abortion in June 1992. In July 1992 the pursuer again became pregnant (the second pregnancy). Complications developed during the second pregnancy and the pursuer was delivered of a stillborn child and required to undergo an operation to remove the afterbirth. The pursuer brought an action of damages against the health board for the negligent sterilisation resulting in, *inter alia*, the second pregnancy and its consequences. Lord Nimmo Smith held that the pursuer's decision to have intercourse in the knowledge that she was not sterile constituted a *novus actus interveniens*, breaking the chain of causation with the result that the health board could not be held liable for the second pregnancy and the consequences thereof. To the author, it appears reasonable to conclude that the patient would have received appropriate contraceptive advice (on at least two occasions).

Herring and Foster suggest a case in which a doctor sets out the range of possible treatments. If the patient selects one of these, “*then the patient bears some responsibility for the choice.*”⁷⁸⁵ These authors suggest that the doctor may not be “*negligent, or there is joint responsibility and contributory negligence is relevant.*”⁷⁸⁶ A patient, who fails to follow the treatment recommended by a doctor, cannot sue in negligence the doctor for harm suffered as a result of the failure to take that treatment.⁷⁸⁷ In an unusual medical malpractice case, *Jackson v Axelrad*,⁷⁸⁸ both physician and patient were doctors. The court opined that “[*since*] jurors ... must consider a physician's special knowledge when a doctor is the defendant, it is hard to see why they should not do so when a doctor is the plaintiff.”⁷⁸⁹

4.4.1.3 Failure to undergo necessary medical treatment

The case of *Bohan v Finn*⁷⁹⁰ centred on a patient's refusal to undergo treatment, in a psychiatric hospital, for a psychosomatic illness; a successful outcome carried a probability of 85-90%. Although Murphy J appreciated the patient's perceived stigma in undergoing psychiatric

⁷⁸⁴ *Sabri-Tabrizi v Lothian Health Board* 1998 SC 373 (CSOH).

⁷⁸⁵ See Herring, J, Foster, C, *Blaming the patient: contributory negligence in medical malpractice litigation* (2009) 25 *Journal of Professional Negligence* 76, 87.

⁷⁸⁶ Herring, J, Foster, C, *loc cit.*

⁷⁸⁷ Herring, J, Foster, C, *op cit.*, 88.

⁷⁸⁸ *Jackson v Axelrad* (2007) 221 SW3d 650 (Tex: Sup Ct).

⁷⁸⁹ (2007) 221 SW3d 650, 657, per Brister J.

⁷⁹⁰ *Bohan v Finn*, *Doyle's Personal Injury Journal*, Trinity and Michelmas Terms 1994, 61. See also Ward, P, *Tort Law in Ireland* (2010) Kluwer Law International, Aalphen aan den Rijn (NL), 219.

treatment, he held that it was unreasonable for her to forego such a favourable prognosis.⁷⁹¹ At the other end of the spectrum is the case of *Yun v MIBI and Tao*.⁷⁹² The plaintiff was advised of the risks associated with an operation, including a risk of paraplegia in the range 1- 5%. The plaintiff had also been advised that if the surgery were successful, it may not necessarily have relieved her pain. Her surgical advisers recommended that she should undergo the surgery, which she was unwilling to do. She feared physical disability (and in particular paraplegia), which carried with it a special stigma in her home region in China. Quirke J rejected suggestions that it was 'irrational' for the plaintiff to refuse the surgical procedure. On a broader view of the cases, Binchy and Komolafe suggest that plaintiffs will not have their choices discounted, if they act unreasonably, although their damages will be reduced for that reason.⁷⁹³

In the recent Australian case *Young v Central Australian Aboriginal Congress Inc & Ors*,⁷⁹⁴ the deceased patient, Mr Clive Impu, was 26 years of age at the time of his death. The cause of death was coronary thrombosis. His family brought suit against Central Australian Aboriginal Congress Inc (CAACI), a publicly funded non-government organisation providing health care services, a medical practitioner, in respect of whom the CAACI was alleged to have been vicariously liable, and the insurance company of the first defendant.

The patient attended the CAACI. The deceased "*failed in his own interests*"⁷⁹⁵ to attend either an arranged appointment or to ever raise the issue of laboratory tests when he subsequently attended Congress for other unrelated conditions. The court distinguished⁷⁹⁶ previous decisions in which doctors have been found to be negligent in cases where they did not have any system in place to ensure follow ups.⁷⁹⁷ Thomas J (*Coram*) found that the contributory negligence of the

⁷⁹¹ Binchy, W, Komolafe, RA, *Patients, Contributory Negligence and Medical Negligence Litigation* (2010-2011) 4(2) Quarterly Review of Tort Law 21, 25.

⁷⁹² *Yun v MIBI and Tao* [2009] IEHC 318 (Quirke J).

⁷⁹³ Binchy and Komolafe, *loc cit*.

⁷⁹⁴ *Young v Central Australian Aboriginal Congress Inc & Ors* [2008] NTSC 47. See also Donovan, G, *Case Note: Young v Central Australian Aboriginal Congress Inc [2008] NTSC 47* (2009) First published in Australian Health Law Bulletin, February 2009, LexisNexis Australia. Reprinted by the author's Law Firm, Redlich Lawyers, Melbourne. Available from <http://www.holdingredlich.com.au/assets/docs/hrin-casenote-young-v-central-australian-aboriginal-congress-inc.pdf>. (Last accessed 27 February, 2012). See also Bird, S, *A Patient's Duty to Follow Up* (2009) 38 Australian Family Physician 333.

⁷⁹⁵ See Bird, *op cit*, 334.

⁷⁹⁶ [2008] NTSC 47, at [217] to [220].

⁷⁹⁷ See *Tai v Hatzistavrou* [1999] NSWCA 306 and *Kite v Malycha* (1998) 71 SASR 321.

deceased amounted to 50 percent.⁷⁹⁸ The appropriate discount for contributory negligence was to be determined in accordance with the Law Reform (Miscellaneous Provisions) Act (NT),⁷⁹⁹ Part V. The finding of the Northern Territory Supreme Court placed “*a significant amount of personal responsibility*” upon Mr Impu to take care for his own health.⁸⁰⁰ In doing so, the court gave weight to Mr Impu’s ability to understand the advice given to him. Thus, in assessing the culpability of an injured party, the court will consider the level of education and sophistication of the particular patient.⁸⁰¹

On causation, it was argued by the Defendants that Mr Impu had “*solely caused his death by exercising a right to allow his ischaemic heart condition to take its course.*”⁸⁰² However, the court found that “*the deceased's various presentations to medical practitioners following his appointment with Dr Boffa indicated a concern for his own health. Had the doctors mentioned the possibility of ischaemic heart disease or queried why he had not completed the follow up tests he would have undertaken the tests and his condition would have been treated.*”⁸⁰³

The Supreme Court of North Carolina concluded in *McGill v French*⁸⁰⁴ that expert medical testimony is not required to show the causal connection between a patient’s alleged contributory negligence and his injuries. The court held that there was sufficient evidence to support a finding of a causal connection between missing appointments and the spread or increased rate of spread of cancer.

4.4.1.4 Dangerous lifestyle choices

The courts have given “*varying answers*”⁸⁰⁵ to the question of how to view alcohol, other drugs (licit or not) and excessive food consumption or lack of exercise.

In *St George v Home Office*,⁸⁰⁶ the claimant, as a result of his own lifestyle decisions had become addicted to alcohol and drugs, was sentenced to four months in prison. On reception at the prison

⁷⁹⁸ *Young v Central Australian Aboriginal Congress Inc & Ors* [2008] NTSC 47, [262], per Thomas J.

⁷⁹⁹ The Law Reform (Miscellaneous Provisions) Act (NT) is a Consolidated Statute and, according to the practice of the Northern Territories Legislature, such a statute has no titular date, although it is identifiable by the version in force at any given time.

⁸⁰⁰ Donovan, G, *op cit*, [4].

⁸⁰¹ Donovan, G, *loc cit*.

⁸⁰² Donovan, G, *loc cit*.

⁸⁰³ Donovan, G, *loc cit*.

⁸⁰⁴ *McGill v French* (1993) 424 SE2d 108 (NC: Sup Ct). At [114], per Lake J: “[T]he standard of care by which the usual plaintiff is to be judged in medical malpractice cases is simply that of a person of ordinary prudence acting under the same or similar circumstances”.

⁸⁰⁵ Binchy, W, Komolafe, RA, *Patients, Contributory Negligence and Medical Negligence Litigation* (2010-2011) 4(2) Quarterly Review of Tort Law 21, 25.

he informed staff of his alcohol and drug abuse and that he had previously had epileptic seizures when in withdrawal. He was assigned to an ordinary open dormitory where he was allocated a top bunk. On his sixth day in prison he suffered an epileptic seizure which resulted from his withdrawal from alcohol and drugs and which caused him to fall from his top bunk, wounding his head, progressing to *status epilepticus*, which persisted for in excess of 180 minutes. As a result he sustained severe brain damage which left him very severely and permanently disabled. The claimant sued in negligence against the Home Office, seeking damages for personal injury. There was a preliminary issue as to liability. The Home Office appealed from the finding of liability in negligence and the claimant cross-appealed from the finding of (lifestyle-influenced) contributory negligence (15%). The Court of Appeal dismissed the appeal and allowed the cross-appeal. The claimant's fault in becoming so addicted was "*too remote in time, place and circumstance*"⁸⁰⁷ and was not sufficiently connected with the negligence of the prison staff to be properly regarded as a "*potent cause of the injury*".⁸⁰⁸

The cigarette smoking habit of a deceased worker was in issue in *Badger v Ministry of Defence*.⁸⁰⁹ The defendant's barrister accepted that significantly greater blame had to be attributed to the Ministry of Defence than to Mr Badger. The Ministry accepted that it was "*guilty of breaches of statutory duty at a time when the dangers of asbestos were known*."⁸¹⁰ The learned judge said that even if the entire period of Mr Badger's smoking had been blameworthy, and it was equally responsible for his lung cancer, "*his contributory negligence would be less than 50 per cent*".⁸¹¹ However, not all of the period of his smoking was held to be blameworthy: the contribution to his combined risk of his continuing to smoke after he should have stopped was "*in the region of a half of his ultimate risk*."⁸¹² The judge held that there had been contributory negligence to the extent of 20%.

By contrast, the claimant was not deceased in *Horsley v Cascade Insulation Services*.⁸¹³ Eady J stated the need for a discount in respect of any sum ultimately awarded in respect of contributory negligence, as was given, for example, in the case of *Badger v Ministry of Defence*.⁸¹⁴

⁸⁰⁶ *St George v Home Office* [2009] 1 WLR 1670 (CA).

⁸⁰⁷ [2009] 1 WLR 1670, 1684, per Dyson LJ.

⁸⁰⁸ [2009] 1 WLR 1670, 1685, per Dyson LJ.

⁸⁰⁹ *Badger v Ministry of Defence* [2006] 3 All ER 173.

⁸¹⁰ [2006] 3 All ER 173, 188, per Stanley Burnton J.

⁸¹¹ *Loc cit.*

⁸¹² *Loc cit.*

⁸¹³ *Horsley v Cascade Insulation Services* [2009] EWHC 2945 (QB).

⁸¹⁴ Eady J referred additionally to *Shortell v Bical Construction Ltd*, Unreported, 16 May, 2008, High Court (Mackay J).

*"I take account of the fact that the Claimant must have known throughout his smoking career of the health risks, as a matter of general knowledge, quite apart from the regular warnings he has received from medical practitioners. Furthermore, it is reasonably apparent from the answers he gave in cross-examination that he fully intends to carry on smoking for the indefinite future."*⁸¹⁵

The holding was likewise contributory negligence to the extent of 20%.

4.4.1.5 Pharmacists and Patients' Contributory Negligence

Given community pharmacy's ready accessibility, a pharmacist will not usually be able to suggest that 'missed appointments' manifest a patient's contributory negligence. Assessing compliance with prescribed therapy may not be straightforward. Monitored or controlled dosage systems exist. Some drugs (e.g. warfarin) may be monitored from sampled blood (in this regard, community pharmacists may be at a disadvantage compared with hospital colleagues). When a case comes on for hearing, the pharmacist's legal team may cross-examine the patient's carer (if there is a carer, whose conduct has been put in issue).

4.5 Unregistered Practitioners of Medicine

In the case of *Philips v Whitely (William) Ltd*,⁸¹⁶ a woman suffered infection allegedly as a consequence of having her ear pierced by a jeweller. The jeweller had not attained the standard of sterility in his instruments that a surgeon would have achieved, but it was nevertheless held that the defendant had taken all reasonable precautions in the preparation of his instruments.⁸¹⁷ Goddard J dismissed the plaintiff's claim with a penetrating comment about where to seek a higher standard.⁸¹⁸

In *Brogan v Bennett*,⁸¹⁹ the defendant, a charlatan, held himself out as being able to cure tuberculosis. The appeal to the Supreme Court was by way of case stated by Kingsmill Moore J sitting as a Judge of the High Court on Circuit. The action was one by the plaintiff who sued under

⁸¹⁵ [2009] EWHC 2945 (QB), [55], per Eady J.

⁸¹⁶ *Philips v Whitely (William) Ltd* [1938] 1 All ER 566.

⁸¹⁷ See Norrie, KM, *Reasonable: the keystone of negligence* (1987) 13 Journal of Medical Ethics 92, 93.

⁸¹⁸ [1938] 1 All ER 566, 569, per Goddard J: "If a person wants to ensure that the operation of piercing her ears is going to be carried out with that proportion of skill and so forth that a Fellow of the Royal College of Surgeons would use, she must go to a surgeon."

⁸¹⁹ *Brogan v Bennett* [1955] IR 119 (Sup Ct).

Lord Campbell's Act⁸²⁰ on behalf of himself and his wife for the death of their son, Christopher Brogan. It was alleged that he had died as a result of negligence by the defendant.

Around five months after being admitted, in 1950, to the County Longford Tuberculosis Hospital, suffering from tuberculosis of both lungs, Christopher Brogan had already made considerable progress under conventional medical, anti-tubercular, and nutritional treatment of his disease. About this time, he received a pamphlet published by the defendant, which contained copies of testimonials supposed to have been received by the defendant from persons who had been cured of tuberculosis by the defendant's treatment. It said that after treatment, certain patients had completely recovered. Some relatives when visiting Christopher Brogan were shown a pamphlet and at his request got in touch with the defendant who undertook to cure Christopher Brogan and make him fit for work within three months. Payment was subsequently made and treatment prescribed. The defendant constituted as a condition of treating him that Christopher Brogan should leave hospital immediately and return home and that the medicine which he provided should not be attended by any medical doctor. Christopher Brogan underwent the treatment by the defendant for approximately five weeks, after which he died.

The Supreme Court held that the defendant should be judged by the standard of care that attached to those with the expertise that he asserted he had—that of doctors. Maguire CJ observed that:

“...if a person is induced to become a patient of an unqualified person on the recommendation that that person is skilled, the latter owes a duty to use care in using the skill and administering the treatment which he has offered. He is not expected to employ the degree of skill which would be expected from a qualified man. He is only liable for failure to employ such skill as he said he had.”⁸²¹

It must be remembered that *Brogan v Bennett* was decided almost a decade before the House of Lords decision in *Hedley Byrne*. It is not surprising therefore that the judgments of the Supreme Court speak in terms of negligence rather than negligent misstatement. Moreover, the major loss occasioned by the defendant's negligent assertions was starkly physical—the death of the

⁸²⁰ Fatal Accidents Act 1846, 9 & 10 Vic, c 93. See also Spiller, P, Finn, J, Boast, R, *A New Zealand Legal History*, Second Edition (2001) Brookers, Wellington, 40. One of the most striking (and “compact”) reforming statutes of the Nineteenth Century was the Fatal Accidents Act 1846 (Lord Campbell's Act). For many years, the negligence of fellow employees remained a bar to recovery, as did contributory negligence until well into the Twentieth Century.

⁸²¹ *Ibid*, at 126.

patient—rather than merely economic in character. It therefore seems entirely reasonable to regard *Brogan v Bennett* as supporting the maxim that one who asserts an expertise of a particular kind, which he or she does not actually possess, should be judged by the standard appropriate to the acts of those who do possess that expertise. It is one thing to muse on an occupation, for example, mediation, that is arguably a nascent profession and on how its unregistered practitioners might fare in future.⁸²² To accept quackery and other questionable practices is an entirely different matter.

4.6 Conclusions

Medical treatment is not necessarily associated with definite, predictable, outcomes (that can be sensibly promised or reasonably expected). Apart from similarities with the legal profession, this is in contrast with other professional services.

The leading Irish cases (*Daniels, O'Donovan* and *Dunne*) were concerned with the role of the jury to a great extent. Once the jury had been removed from the equation, it is submitted that a less deferential approach to the medical profession could have been adopted. That has been the judicial thinking in *Rogers v Whitaker*.

Where a pharmacist's professional activities can be viewed through the lens of ordinary negligence, expert evidence is not required. Therefore, there is an incentive to settle proceedings. Cases involving pharmacist that reach the law reports usually involve shared (or at least contested) liability with medical practitioners: almost certainly expert medical evidence will be required.

It is usually obvious what the patient requires by way of professional services from a doctor or a pharmacist: in the United Kingdom and Republic of Ireland, negligence is of greater practical relevance than contract. However, it is important for any professional to know when it is appropriate to refer the patient/client for specialist advice (and treatment, where appropriate). In medicine, this will usually be within the same profession, whilst in pharmacy it will not be so.

Training of Professionals

Most of the literature focuses on the 'on the job' nature of medical training. Pharmacists, have a more sheltered existence in the immediate postgraduate phase of their career. It is submitted

⁸²² See Ardagh, D, *Is mediation now a profession?* ADR Bulletin, Vol 10, No 8 [2009], Art 3, 6-7.

that health authorities may not be doing enough, particularly in the out-of-hours context, to ensure that hospital consultants shoulder a realistic burden for supervision of medical practitioners in training. In a typical workplace (e.g. factory or warehouse), allegations of failure to provide adequate managerial support usually have one target. It mostly appears from medical negligence cases where a health authority is a defendant that argument focuses on the authority's management procedures rather than critically analysing any possible tortious liability arising from the hospital consultant's mentoring role (bearing in mind that lay managerial support is irrelevant to health professional formation). In Ireland's mixed health system, hospital consultants, in public and private practice, can be readily available to doctors in training during 'office hours' and yet consultant support may be relatively inaccessible during junior doctors' rostered overtime periods.

By virtue of Personal Injuries Assessment Board Act 2003, s 3,⁸²³ a civil action in relation to "the provision of any health⁸²⁴ service to a person" is excluded from the remit of the Act. It is submitted that this provision is broad enough to exclude a medical (or paramedical) service; a structured pharmaceutical service (like the GMS Scheme) and perhaps other pharmaceutical services also. The legislative intent is plain: a plaintiff should not be forced to pursue different healthcare providers in different *fora*.

Res ipsa loquitur

While much of the literature is concerned with medical practitioners, there is some scope for relevance to pharmacists. The United States jurisdictions use the applicability of *res ipsa loquitur* to determine whether expert evidence is required. Most pharmaceutical products are not compounded in the pharmacy nowadays; a product liability theory may obviate discussion around 'the exclusive management of the defendant'.

On the possibility of differing schools of thought, it is difficult to envisage how ordinarily more than one could exist in pharmacy practice, from which a pharmacist would have to choose. This is

⁸²³ Personal Injuries Assessment Board Act 2003, s 3: "This Act applies to the following civil actions—
(a) a civil action by an employee against his or her employer for negligence or breach of duty arising in the course of the employee's employment with that employer,
(b) a civil action by a person against another arising out of that other's ownership, driving or use of a mechanically propelled vehicle,
(c) a civil action by a person against another arising out of that other's use or occupation of land or any structure or building,
(d) a civil action not falling within any of the preceding paragraphs (other than one arising out of the provision of any health service to a person, the carrying out of a medical or surgical procedure in relation to a person or the provision of any medical advice or treatment to a person)."

⁸²⁴ The Act does not define 'health service'.

certainly the impression one has formed of community practice. Clinical pharmacy in a hospital-based, multidisciplinary, location may be different, especially in a manufacturing facility⁸²⁵ licensed by the national competent authority.⁸²⁶ Medical practitioners are typically required to make rapid, even instant, decisions about treatment and in so doing to follow a reputable school of thought. The patient's episode of care from a hospital physician/surgeon may be an acute one, which will be followed up by other colleagues or the patient's GP. The same considerations do not apply to pharmaceutical services. In the community setting, the pharmacist will monitor the patient's medication longitudinally. A patient in hospital cannot expect the individual attention of one clinical pharmacist for the hospitalisation episode's entire duration. A hospital pharmacy department is therefore justified in formulating policies that permit seamless healthcare and by implication eliminate the scope for any alternative school of thought.

Essentially, a pharmacist is faced with a decision whether or not to dispense a particular prescribed medicinal product, albeit in consultation with the prescriber. This would militate against equating the pharmacist's standard of care with that of medical practitioners, as adumbrated in the *Dunne Principles*.

⁸²⁵ The manufacturing process alluded to here is something different from a centralised or decentralised intravenous additive service.

⁸²⁶ In the Republic of Ireland, the national competent authority is the Irish Medicines Board.

Chapter 5 Causation

5.1 Introduction

Usually, in a suit for damages in tort, three separate questions arise under the heading of damages: causation; remoteness; quantum (measure).⁸²⁷ Causation is essential to any claim in negligence, “*as it links the defendant with the claimant’s harm.*”⁸²⁸ To succeed the plaintiff must show, through direct or circumstantial evidence,⁸²⁹ that the defendant caused the damage, which must be (not too remote).⁸³⁰ The defendant’s conduct must be the effective cause of the harm.⁸³¹ The defendant’s act or omission need not be the sole cause, except to counter a defence of contributory negligence at common law.⁸³² In exceptional cases, an injunction may be sought to prevent “*damage that is imminent, but has not yet occurred*”.⁸³³ If recovery is to be allowed, the court must decide the measure of damages to which the plaintiff is “*entitled in respect of his injuries.*”⁸³⁴ Where a tort is actionable *per se*, a certain level of damage is presumed without proof of causation.⁸³⁵

5.2 Factual Causation

The defendant must be linked in a factual or scientific⁸³⁶ way to the plaintiff’s injury if the defendant is to be considered as potentially liable.⁸³⁷ A factual link, however, is not sufficient: the courts must be satisfied, on policy grounds, that the defendant legally caused the damage to the

⁸²⁷ See McMahon, B, Binchy, W, *Irish Law of Torts*, Third Edition (2000) Butterworths, Dublin, 59.

⁸²⁸ See Horsey, K, Rackley, E, *Tort Law*, Second Edition (2011) Oxford University Press, Oxford, 222.

⁸²⁹ See also Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 410. See further, *op cit*, 413: whether the evidence allows a reasonable finding of causation is a question of law; whether any particular head of damage has been caused by the defendant’s negligence or breach of statutory duty is a question of fact.

⁸³⁰ McMahon, B, Binchy, W, *loc cit*. See also *Ward v Weeks* (1830) 131 ER 81, 83 (CP), per Tindal CJ: “*Every man must be taken to be answerable for the necessary consequences of his own wrongful acts*” Tindal CJ continued: “[*But*] a spontaneous and unauthorized communication cannot be considered as the necessary consequence of the original uttering of the words.”

⁸³¹ See Todd, S, *Causation and Remoteness of Damage*, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 942.

⁸³² See *Wakelin v London and South Western Railway Co* [1896] 1 QB 189, 190, per Brett MR. See also Bailey, SH, ‘*Causation in negligence: what is a material contribution?*’ (2010) 30 *Legal Studies* 167, 168.

⁸³³ See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 429.

⁸³⁴ McMahon, B, Binchy, W, *loc cit*.

⁸³⁵ See Quill, E, *loc cit*. See also Quill, *op cit*, 429-430: recovery for other specific losses over and above those presumed by law will have to be proved through establishing a causal connection to the defendant’s breach. See also Mullany, NJ, *Common Sense Causation--An Australian View* (1992) 12 *Oxford Journal of Legal Studies* 431, 431 (n) (Evidence that the defendant caused the plaintiffs loss is crucial even in relation to torts actionable *per se* to the extent that its absence results in the recovery of nominal damages only).

⁸³⁶ See Powers, M, Harris, NH, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 787-789.

⁸³⁷ See McMahon, B, Binchy, W, *loc cit*.

plaintiff.⁸³⁸ Causation is a legal conclusion.⁸³⁹ Remoteness of damage (legal causation) is concerned with the limit, which the court is to apply to the defendant's liability for the consequences of his actions.⁸⁴⁰ The American concept, 'truncation of responsibility' (known outside the United States as 'remoteness') has been said to rest "*entirely on the normative analysis of the facts.*"⁸⁴¹ Apart from vicarious liability, a defendant cannot be held liable for conduct that has no factual causal link to the plaintiff's injury.⁸⁴² Although the question of causation is primarily one of fact, "*some policy element is also inevitably present here too.*"⁸⁴³ The process of determining factual causation "*comes down to one of elimination rather than inclusion.*"⁸⁴⁴

5.2.1 The 'But-for' Test

The 'but-for' test may be placed in the following context.⁸⁴⁵ Strict liability systems operate simply by showing that the defendant's actions caused the harm.⁸⁴⁶ In fault-based systems like negligence, however, that is not enough.⁸⁴⁷ The harm suffered by the claimant must be caused by the defendant's actions having fallen below the standard of care (*i.e.* in breach of the duty of care).⁸⁴⁸ The normal rule of causation, which applies in almost all situations, has two aspects: "*the*

⁸³⁸ See McMahon, B, Binchy, W, *op cit*, 59-60.

⁸³⁹ See Kohanzad, R, *The Burden of Proof in Whistleblowing: Fecitt and Others v NHS Manchester* [2011] IRLR 111 (2011) 40 Industrial Law Journal 214, 216. See also Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 414, citing *Yorkshire Dale Steamship Co v Minister of War Transport* [1942] AC 691, 706, per Lord Wright: "*Causation is to be understood as the man in the street and not as either the scientist or the metaphysician would understand it.*"

⁸⁴⁰ See McMahon, B, Binchy, W, *op cit*, 60: "*There is no legal system which is so strict that it saddles the person liable for all the consequences of his actions.*" (Original emphasis removed). See also *Kuwait Airways Corp v Iraq Airways Corp (Nos 4 and 5)* [2002] 2 AC 883, 1105, [128] (*Dicta* of Lord Hoffmann). In *Iraq Airways*, as the tort of conversion is one of strict liability, liability could not have been avoided by showing but for the defendants' acts the plaintiffs would not have avoided loss of their aircraft because the Iraqi government might have retained such property (seized during the invasion of Kuwait) or disposed thereof in another manner. See Todd, S, *op cit*, 943: the causal question "*was answered by reference to the nature of the liability.*"

⁸⁴¹ See Stapleton, J, *Reflections on Common Sense Causation in Australia*, Chapter in Degeling, S, Edelman, J, Goudkamp, J (Editors), *Torts in Commercial Law* (2011) Thomson Reuters, Sydney, 307.

⁸⁴² See McMahon, B, Binchy, W, *op cit*, 60-61. See also Laski, HJ, *The Basis of Vicarious Liability* (1916) 26 Yale Law Journal 105. See also Peck, CJ, *Negligence and Liability without Fault in Tort Law* (1970-1971) 46 Washington Law Review 225.

⁸⁴³ See McMahon, B, Binchy, W, *op cit*, 61 (n), citing, *inter alia*, Malone, WS, *Ruminations on Cause-in-Fact* (1956) 9 Stanford Law Review 60, 72-79. Malone gives two examples of policy applications in this regard: rescue of seamen and escape from fire.

⁸⁴⁴ See Horsey, K, Rackley, E, *Tort Law*, Second Edition (2011) Oxford University Press, Oxford, 224.

⁸⁴⁵ The 'but for' test is also sometimes called the 'necessary condition' test; see Moore, M, *Causation and Responsibility: An Essay in Law, Morals, and Metaphysics* (2009) Oxford University Press, Oxford, 84.

⁸⁴⁶ Horsey, K, Rackley, E, *op cit*, 225.

⁸⁴⁷ Horsey, K, Rackley, E, *loc cit*.

⁸⁴⁸ Horsey, K, Rackley, E, *loc cit*.

*evidential and the conceptual.*⁸⁴⁹ One can apply these characteristics to the elucidation provided by Justice McLachlin (writing extra-judicially in 1998), describing the test as a simple inquiry as to “*whether the plaintiff would have escaped loss [(the evidential aspect)] but for the defendant’s conduct [(the conceptual aspect)].*”⁸⁵⁰

A prominent example in medical negligence litigation is *Barnett v Chelsea and Kensington Hospital Management Committee*,⁸⁵¹ where the plaintiff’s husband would have died from arsenic poisoning anyway, even if the defendant hospital had not negligently turned him away. The doctor admitted that he had been negligent (in breach of duty), although it could not be said that ‘but for’ the doctor’s negligence the man would not have died. A painter testified that he lent over too far and fell from a ladder in *Kenny v O’Rourke*.⁸⁵² The ladder’s defectiveness was therefore held not to be a ‘but for’ cause of the plaintiff’s injury.⁸⁵³

Cane and Atiyah have criticised the but-for test for being very indiscriminate “*in that it will identify as causes many factors that are of little interest because they are merely necessary conditions of the harm suffered.*”⁸⁵⁴ The court’s function is to seek the ‘proximate’ cause⁸⁵⁵ (*causa causans*) and not just a *causa sine qua non* (indispensible condition).⁸⁵⁶ McMahon and Binchy⁸⁵⁷

⁸⁴⁹ See Steel, S, Ibbetson, D, *More Grief on Uncertain Causation in Tort* (2011) 70 Cambridge Law Journal 451, 452.

⁸⁵⁰ McLachlin, BM, *Negligence Law—Proving the Connection*, Chapter in Mullany, NJ, Linden, AM, *Torts Tomorrow: A Tribute to John Fleming* (1998) LBC Information Services, Sydney, 18. See also Powers, Harris, Barton, *op cit*, 789: “[t]his test is also known as the ‘what if’ test and the ‘counterfactual conditional’. This test of causation entails two inquiries: (1) a question of historical fact (what actually happened); and (2) a question of hypothetical fact (what would have happened but for the matter complained of).”

⁸⁵¹ *Barnett v Chelsea and Kensington Hospital Management Committee* [1969] QB 428. See also *Conley v Strain* [1988] 1 IR 628 (HC). Lynch J gave judgment for the plaintiff against the first defendant, dismissing the action against the second and third defendants, holding *inter alia* that the plaintiff had been guilty of contributory negligence (14%) in not wearing a seat belt. It was also held that the second defendant had been negligent in prescribing hypotensive drugs, although their administration had wrought no adverse effects upon the plaintiff.

⁸⁵² *Kenny v O’Rourke* [1972] IR 339 (Sup Ct).

⁸⁵³ There was a similar result in *McWilliams v Sir William Arrol & Co Ltd* [1962] 1 WLR 295 [HL(SC)]. The trial judge found *inter alia* that, even if a safety belt had been provided, the deceased (steel erector) would not have worn it. That finding was upheld on appeal.

⁸⁵⁴ See Cane, P, Atiyah, PS, *Atiyah’s Accidents, Compensation and the Law*, Seventh Edition (2006) Cambridge University Press, Cambridge, 118-119. On necessary conditions, see Hart, HLA, Honoré, T, *Causation in the Law*, Second Edition (1985) Oxford University Press, Oxford, 110.

⁸⁵⁵ See Murray, M, *The Law of Describing Accidents: A New Proposal for Determining the Number of Occurrences in Insurance* (2009) 118 Yale Law Journal 1484, 1505 (Internal citations omitted): “*The building of a house, for example, is strictly speaking a but-for cause of the arson of the house. But, for obvious reasons, it is the arsonist, not the builder, who is liable for the arson.*”

⁸⁵⁶ See Lee, J, *Fidelity in interpretation: Lord Hoffmann and The Adventure of the Empty House* (2008) 28 Legal Studies 1, 11. See also *Reeves v Commissioner of Police for the Metropolis* [2000] 1 AC 360, 391, per Lord Hobhouse: “*The ordinary use of language makes a distinction, independent of any legal concept, between the normal and the abnormal in describing something as a cause.*”

⁸⁵⁷ McMahon, B, Binchy, W, *op cit*, 63-64.

mention the attractiveness of an alternative to the 'but for' test formulated by Prosser & Keeton,⁸⁵⁸ the material contribution test, although perceptibly lacking philosophical depth and definitional certainty.⁸⁵⁹ The 'but for' test is helpful in attempting to understand most of the cases.⁸⁶⁰ The court's application of the 'but for' test is "*strictly deterministic*⁸⁶¹ *and is all or nothing in effect*".⁸⁶² It may be mentioned in passing that the 'but for' causation is an essential of market deterrence, "*since it is only those who can avoid costs by taking precautions who can be deterred from incurring the costs that could be avoided.*"⁸⁶³

The 'but for' is at its greatest usefulness when it can be said that the event in question had only one cause.⁸⁶⁴ It is "*less helpful, and must be modified*" in its application where there are multiple causes in operation.⁸⁶⁵ McLachlin has described three situations for which the 'but for' test is "*troublesome*".⁸⁶⁶ The categories of case (which may overlap) are discussed below.

5.2.1.1 Indeterminate defendant

The classic example is the case of two hunters, *Cook v Lewis*,⁸⁶⁷ where it was held that both were responsible in circumstances where both had negligently placed the plaintiff at risk but it was

⁸⁵⁸ Keeton, W, Dobbs, D, Keeton, R, Owen, D, *Prosser and Keeton on Torts*, Fifth Edition (1984) West Publishing Company, St Paul, 267. See also Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 431-432. See also *Superquinn Ltd v Bray UDC* [1998] 3 IR 542, 564, per Laffoy J: "*It follows that the blockage of the culvert was not a material element or a substantial factor in bringing about the dam failure.*" (Emphasis supplied).

⁸⁵⁹ McMahan, B, Binchy, W, *op cit*, 64.

⁸⁶⁰ See McMahan, B, Binchy, W, *loc cit*. See also Thomson, JM, *Principle or Policy? The Judicial Development of the Law of Delict* (2003) 56 *Current Legal Problems* 123, 142-150.

⁸⁶¹ See Todd, S, *Causation and Remoteness of Damage*, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 955: "*Phenomena are deterministic when their past uniquely determines their future. They are indeterministic when they have a random component.*" See also Reece, J, *Losses of Chances in the Law* (1996) 59 *Modern Law Review* 188, 206.

⁸⁶² See Powers, M, Harris, NH, Barton, A, *op cit*, 789. See also Botterell, A, Essert, C, *Normativity, Fairness, and the Problem of Factual Uncertainty* (2009) 47 *Osgoode Hall Law Journal* 663, 667 (n), citing *Corey v Havener* (1902) 65 NE 69 (Mass Sup Jud Ct) as an example of an overdetermined case. See also Wright, R, *Causation in Tort Law* (1985) 73 *California Law Review* 1735, 1775. See also Bailey, SH, '*Causation in negligence: what is a material contribution?*' (2010) 30 *Legal Studies* 167, 169 (n). *Corey v Havener* has also been cited by the US Supreme Court in *Bigelow v Old Dominion Copper Mining & Smelting Co* (1912) 225 US 111, 131, per Lurton J, as authority for the proposition: "*There is no privity between joint wrongdoers, because all are jointly and severally liable.*"

⁸⁶³ See Hart, HLA, Honoré, T, *Causation in the Law*, Second Edition (1985) Oxford University Press, Oxford, lxxiii.

⁸⁶⁴ McMahan, B, Binchy, W, *op cit*, 63.

⁸⁶⁵ McMahan, B, Binchy, W, *loc cit*.

⁸⁶⁶ McLachlin, BM, *op cit*, 18-19.

⁸⁶⁷ *Cook v Lewis* [1951] SCR 830 (SCC). See also Veitch, E, *The Many Facets of Cook v Lewis* (2010) 34 *Manitoba Law Journal* 287. See also Schaffer, J, *Contrastive Causation in the Law* (2010) 16 *Legal Theory* 259, 282 (n).

unclear which one shot the plaintiff.⁸⁶⁸ In pharmaceutical products liability, there may be several manufacturers of a drug and the plaintiff cannot prove which one manufactured the drug actually ingested.⁸⁶⁹ The leading case is *Sindell v Abbott Laboratories*.⁸⁷⁰ Market-share liability relaxes the cause-in-fact requirement in certain products liability actions.⁸⁷¹ The plaintiff in a market-share liability action need not identify the particular company whose product injured him. Instead, the plaintiff must prove, “among other things, that each of the defendants manufactured a chemically identical product and that a product made by one or more of the defendants caused the plaintiff’s injury.”⁸⁷² Each manufacturer is then liable in proportion to its market share.⁸⁷³ Abraham describes market-share liability as “[t]he most prominent example of a developmental dead end in recent memory”.⁸⁷⁴ The market-share liability doctrine, which was originally applied to injuries resulting from exposure to diethylstilbestrol (“DES”) *in utero*, was adopted by a number of states other than California: the doctrine was extended to a few other products by the courts of some other states, in an overall unspectacular fashion.⁸⁷⁵ Market-share liability has been rejected in Canada.⁸⁷⁶ Within a more open ‘pharmaceutical economy’ than the US market, such as that of the European Economic Area,⁸⁷⁷ it is submitted that there are difficulties in assessing market share liability taking into account parallel importation (although perhaps not parallel distribution). The market-share doctrine has not so far been applied in a situation affecting Irish pharmacists and their patients.

⁸⁶⁸ See also Maag, KB, *Climate Change Litigation: Drawing Lines to Avoid Strict, Joint, and Several Liability* (2009) 98 Georgetown Law Journal 195, 210, citing the *Restatement (Second) of Torts* (1965), § 433A, cmt d. See also Vandall, FJ, *A Critique of the Restatement (Third), Apportionment as it affects Joint and Several Liability* (2000) 49 Emory Law Journal 565 (n): “The Reporters [for the Restatement (Third), Apportionment] prefer the word ‘responsibility’ to ‘fault’. This allows them to suggest that strict liability and intent on the part of the defendant can be weighed against plaintiffs’ negligence.” See, in particular, *Restatement (Third), Apportionment*, § 8, cmt a. See also Moore, M, *Causation and Responsibility: An Essay in Law, Morals, and Metaphysics* (2009) Oxford University Press, Oxford, 118-120.

⁸⁶⁹ McLachlin, BM, *op cit*, 19.

⁸⁷⁰ *Sindell v Abbott Laboratories* (1980) 607 P2d 924 (Cal Sup Ct). See Goldberg, JCP, Zipursky, BC, *The Oxford Introductions to US Law: Torts* (2010) Oxford University Press, Oxford, 169. The Diethylstilbestrol (DES) litigation was almost unique for the similarity of the defendants’ tortious behaviour and for the “completely passive, utterly blameless victims” who were *in utero* at the time of exposure. See also Delgado, R, *Beyond Sindell: Relaxation of Cause-in-Fact Rules for Indeterminate Plaintiffs* (1982) 70 California Law Review 881.

⁸⁷¹ See Geistfeld, MA, *The Doctrinal Unity of Alternative Liability and Market-Share Liability* (2006) 155 University of Pennsylvania Law Review 101, 101.

⁸⁷² See Abraham, KS, *Stable Divisions of Authority* (2009) 44 Wake Forest Law Review 963, 964-965.

⁸⁷³ See Abraham, *op cit*, 965, citing *Restatement (Third) of Torts: Liability for Physical Harm, (Proposed Final Draft No 1* (2005), § 28, cmt o.

⁸⁷⁴ See Abraham, *op cit*, 964-965.

⁸⁷⁵ See Abraham, *op cit*, 965.

⁸⁷⁶ *Snell v Farrell* [1990] 2 SCR 311 (SCC). See also Kutlesa, NJ, *Creating a Sustainable Immunization System in Canada — The Case for a Vaccine-Related Injury Compensation Scheme* (2004) 12 Health Law Journal 202, 228 (n).

⁸⁷⁷ Iceland, Liechtenstein and Norway are fully integrated into the EU pharmaceuticals policy.

5.2.1.2 Indeterminate plaintiff

An example is where a company discharges a toxic compound into the environment, which statistically increases the incidence of cancer. The plaintiff suffers from cancer but is unable to prove that he or she was not merely a member of the background group that, in any event, would have developed cancer.⁸⁷⁸ This term from the 'indeterminacy glossary' does not appear to be of practical application to the pharmacist's situation.

5.2.1.3 Indeterminate harm

The defendant's tortious conduct may not have demonstrably actually caused damage to the plaintiff, although it may be said that such conduct increased the risk of harm in that the plaintiff lost a chance of avoiding harm or of achieving a better result.⁸⁷⁹

5.2.1.4 Judicial Departures from Strict Application of the 'But-For' Test

There are several means by which the courts have departed from strict application of the 'but for' rule in medical negligence cases.⁸⁸⁰ These include: (1) the 'prudent patient' test and 'actual patient' test (objective and subjective tests, respectively) in disclosure of risks associated with treatment; (2) the doctrine of loss of a chance; (3) causation linked to occurrence of the very injury/damage it was the defendant's duty to prevent (*Chester v Afshar*⁸⁸¹).

5.2.2 Multiple Potential Causes

Where there is more than one potential cause of harm, it becomes factually difficult to establish "*in the absence of any clear evidence or proof*"⁸⁸² that any of the potential causes is more likely (greater than 50 per cent) "*than any other to be the cause*".⁸⁸³ Retroental fibroplasia (RLF), alleged to have been caused by medical negligence, was one of five factors in *Wilsher v Essex Area*

⁸⁷⁸ See McLachlin, BM, *op cit*, 19. The threshold of proof for statistical evidence is illustrated by the following *dicta* of Posner J in *Allen v Seidman* (1989) 881 F2d 375, 380 (Ct App, 7th Circ), per Posner, Ct J: "*The Corporation's attack on the plaintiffs' statistical case amounts to a contention that unless a plaintiff eliminates all alternative hypotheses he must lose. That would raise the threshold of proof too high.*" See also Dominici, F, Kramer, S, Zambelli-Weiner, A, *The role of epidemiology in the law: a toxic tort litigation case* (2008) 7 Law, Probability and Risk 15, 31.

⁸⁷⁹ McLachlin, BM, *loc cit*.

⁸⁸⁰ Fulham-McQuillan, S, *Case without a cause?: The Relevance of the "But For" Test in Medical Negligence Litigation* (2012) Law Student Colloquium 2012, Trinity College Dublin, 04 February, 2012. See further a subsequent publication: Fulham-McQuillan, S, *Hypothesising a Hypothetical on a Probable Basis: Can this be Factual Cause in Medical Negligence?* (2012) 15 Trinity College Law Review 1, 27-31.

⁸⁸¹ *Chester v Afshar* [2005] 1 AC 134 (HL).

⁸⁸² Horsey, K, Rackley, E, *Tort Law*, Second Edition (2011) Oxford University Press, Oxford, 226.

⁸⁸³ Horsey, K, Rackley, E, *loc cit*.

Health Authority.⁸⁸⁴ The House of Lords reversed the majority decision of the Court of Appeal, not being persuaded that on the balance of probabilities the doctor's negligence had caused the baby's harm.

5.2.2.1 Successive Accident Cases

Fischer clarifies that, in multiple sufficient cause cases, where both forces are tortious, all courts impose liability on both tortfeasors without requiring 'but for' causation.⁸⁸⁵ Early British Commonwealth cases relied on a conceptual rationale that the second harm-producing event "should not cut off the liability of the first tortfeasor because the disability caused by the first tortfeasor persisted even after the second accident."⁸⁸⁶ The court in *Stene v Evans*⁸⁸⁷ reasoned that because the first tortfeasor caused a twenty percent disability, the second accident, which was totally disabling, could only cause an eighty percent disability.⁸⁸⁸ The disability "caused by the first tortfeasor continued beyond the second accident."⁸⁸⁹ If the second accident had shortened the plaintiff's life, the liability of the first tortfeasor would terminate at the point of death "because the original disability would not persist beyond death."⁸⁹⁰ Except in nuisance, fresh damage is required to support any successive action.⁸⁹¹

5.2.3 Disclosure of Risks associated with Treatment

McMahon and Binchy⁸⁹² describe the three principal solutions that have been proposed to test a breach of the duty in negligence to disclose material risks. The first relates the issue to the generally accepted practice of the medical profession, the *Bolam* test (discussed elsewhere in this thesis). The second ("at the other end of the spectrum"⁸⁹³) focuses on the patient's right to self-

⁸⁸⁴ *Wilsher v Essex Area Health Authority* [1988] AC 1074 (HL).

⁸⁸⁵ See Fischer, DA, *Successive Cases and the Enigma of Duplicated Harm* (1998-1999) 66 *Tennessee Law Review* 1127, 1129.

⁸⁸⁶ See Fischer, *op cit*, 1157 (Internal citations omitted).

⁸⁸⁷ *Stene v Evans* (1958) 14 DLR (2d) 73 (Alta).

⁸⁸⁸ See further (1958) 14 DLR (2d) 73, [20], per McBride JA: "... it was quite correct for the trial judge to take the position in his judgment that whoever injured Stene in the second accident 'did not injure a 100 per cent man,' but injured an 80 per cent man, and that was a matter for the tribunal trying the second accident."

⁸⁸⁹ See Fischer, *loc cit*.

⁸⁹⁰ See Fischer, *loc cit*. See also McGregor, H, Strachan, DMA, *Variations on an Enigma* (1970) 33 *Modern Law Review* 378, 381 (n), citing *Stene v Evans* (1958) 14 DLR (2d) 73 (Alberta Sup Ct, App Div). See further (1958) 14 DLR (2d) 73, [20], per McBride JA: "... it was quite correct for the trial judge to take the position in his judgment that whoever injured Stene in the second accident 'did not injure a 100 per cent man,' but injured an 80 per cent man, and that was a matter for the tribunal trying the second accident."

⁸⁹¹ See generally Mullany, NJ, *Limitation of Actions and Latent Damage: An Australian Perspective* (1991) 54 *Modern Law Review* 216, 236-238, and particularly [236], (n 161): *dicta* of Brennan J in *Sutherland Shire Council v Heyman* (1985) 157 CLR 424, 491.

⁸⁹² See McMahon, B, Binchy, W, *Irish Law of Torts*, Third Edition (2000) Butterworths, Dublin, 380-381.

⁸⁹³ McMahon & Binchy, *op cit*, 380.

determination and the requirement for full disclosure of all material risks. The third (a *via media*) applies the *Bolam* test except where disclosure of a particular risk “was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical doctor would fail to make it.”⁸⁹⁴ Each of these approaches found favour with at least one judge in *Sidaway v Governors of the Bethlem Royal Hospital*.⁸⁹⁵ The *Bolam* approach was rejected in *Bolitho v City and Hackney Health Authority*.⁸⁹⁶ There are “indications”⁸⁹⁷ that a disclosure-of-material-risks test may ultimately prevail in England. In *Pearce v United Bristol Healthcare NHS Trust*,⁸⁹⁸ Lord Woolf MR observed:

*"In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, as indicated in the cases to which I have just referred, that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt."*⁸⁹⁹

This passage was endorsed in the House of Lords in *Chester v Afshar*⁹⁰⁰ and considered in *Fitzpatrick v White*.⁹⁰¹ A similarly “liberal”⁹⁰² approach has been favoured by the Supreme Court of Canada (*Reibl v Hughes*⁹⁰³) and the High Court of Australia (*Rogers v Whitaker*⁹⁰⁴). The first substantive examination of the subject in Ireland came in the case of *Walsh v Family Planning*

⁸⁹⁴ *Sidaway v Governors of the Bethlem Royal Hospital* [1985] 1 AC 871 (HL), 900, per Lord Bridge of Harwich.

⁸⁹⁵ *Sidaway v Governors of the Bethlem Royal Hospital* [1985] 1 AC 871. Lord Diplock favoured the first approach; Lord Scarman aligned himself with the second; Lords Bridge and Keith chose the third.

⁸⁹⁶ *Bolitho v City and Hackney Health Authority* [1998] AC 232 (HL).

⁸⁹⁷ *McMahon & Binchy*, *op cit*, 381.

⁸⁹⁸ *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P53 (CA). See *Fitzpatrick v White* [2008] 3 IR 551 (Sup Ct), 560-561 (Kearns J). See also *Kohli v Manchanda* [2008] INSC 42 (Sup Ct of India), [33], per Raveendran J: “Lord Scarman’s minority view in *Sidaway* favouring *Canterbury [v Spence]*, in course of time, may ultimately become the law in England. A beginning has been made in *Bolitho ... and Pearce*”.

⁸⁹⁹ [1999] PIQR P53, 59, per Lord Woolf MR.

⁹⁰⁰ *Chester v Afshar* [2005] 1 AC 134, 143, per Lord Steyn.

⁹⁰¹ *Fitzpatrick v White* [2008] 3 IR 551 (Sup Ct), 561, per Kearns J.

⁹⁰² *McMahon & Binchy*, *loc cit*.

⁹⁰³ *Reibl v Hughes* (1980) 114 DLR (3d) 1.

⁹⁰⁴ *Rogers v Whitaker* (1992) 175 CLR 479. See also Kirby, M, *Patients’ rights – Why Australian Courts have Rejected Bolam* (1995) 21 *Journal of Medical Ethics* 5.

*Services Ltd.*⁹⁰⁵ McMahon and Binchy have stated that it “cannot be said” the *Walsh* case “left the law in a clear or satisfactory state”.⁹⁰⁶

In *Walsh*, at first instance, MacKenzie J held that a vasectomy operation was properly performed on the plaintiff and without negligence. He found that the first doctor (Dr. S) had given the plaintiff a warning and this warning had been sufficient. He also found that a technical assault and battery was committed by the third defendant upon the plaintiff, who was unaware that the third defendant was undergoing training: the plaintiff did not consent to his participation in the operation. On appeal, this technicality was a mistaken view of the factual circumstances, according to four judges on the five-member Supreme Court panel. The barrister who prepared the report on the *Walsh* case for the Irish Reports series summarised that the Supreme Court held, where the gist of the plaintiff's plea is lack of informed consent to a surgical procedure, his action should be determined on “ordinary negligence” principles rather than assault and battery purporting to rest upon some vitiated consent.⁹⁰⁷ It is submitted that a more prosaic consideration might have been that medical negligence causes should not adopt the mantle of an assault plea, when the Oireachtas had abolished jury trials in personal injuries actions under the Courts Act 1988. None of the judgments actually used the term ‘ordinary negligence’, as opposed to ‘professional negligence’. Notwithstanding, this author submits that the correct standard on which to assess the disclosure or otherwise of information essential to a lay patient's deliberations is indeed ‘ordinary negligence’ (based on matters coming within the knowledge and experience of ordinary persons).

The *Walsh* Supreme Court (redolent of the eclecticism in *Sidaway*) took a variety of approaches to the issue of informed consent. Perhaps the Supreme Court judges were conditioned to explore different philosophies of informed consent by unanimity in their core holding that there was no evidence to warrant disturbing the finding of the trial judge that the operation had been performed without negligence. Finlay CJ opined that the test should be the same as the one he had propounded in *Dunne v National Maternity Hospital* (of which the author writes more below).⁹⁰⁸ O'Flaherty J effectively endorsed the position adopted by Lord Scarman in *Sidaway* and he cited *Reibl v Hughes*: he was particularly insistent on full disclosure in elective surgery.⁹⁰⁹ McCarthy and Egan JJ were dissentients on the test for disclosure of material risks. McCarthy J

⁹⁰⁵ *Walsh v Family Planning Services Ltd* [1992] 1 IR 496 (Sup Ct, reversing HC).

⁹⁰⁶ McMahon & Binchy, *op cit*, 382.

⁹⁰⁷ In related *dicta*, McCarthy J opined that defamation, assault or trespass actions should not be dressed up in a constitutional guise.

⁹⁰⁸ [1989] IR 91 (Sup Ct).

⁹⁰⁹ [1992] IR 496, 535, per O'Flaherty J. Hederman J concurred with the judgment of O'Flaherty J.

was “essentially a proponent of the Bridge/Keith test, which is consistent with that favoured in Dunne.”⁹¹⁰ McMahon and Binchy point to difficulty in discerning “precisely where Egan J stood on this issue”.⁹¹¹ These authors suggest that it is perhaps best to read Egan J’s judgment “as affording no real support for Dunne”.⁹¹²

In 2000, *Geoghegan v Harris*⁹¹³ was described as “the most sophisticated and closely-reasoned discussion” of the duty of disclosure by an Irish court.⁹¹⁴ In *Geoghegan v Harris*,⁹¹⁵ Kearns J (applying *Walsh v Family Planning Services Ltd*) held that the defendant was obliged to give a warning to the plaintiff of any material risk which was a known⁹¹⁶ or foreseeable complication of an operation. This was so notwithstanding the fact that the nature of the risk in the case was extremely remote. The risk was a known complication and a warning of the risk was required. The test to be adopted by the court, as to what risks ought to be disclosed to a patient before an operation, was the test of the reasonable patient. Kearns J expressed “considerable diffidence”⁹¹⁷ in disagreeing with *dicta* of Finlay CJ in *Walsh v Family Planning Services Ltd*⁹¹⁸:

“... it may be, certainly in relation to very clearly elective surgery, that the court might more readily reach a conclusion that the extent of warning given or omitted contained inherent defects which ought to have been obvious to any person giving the matter due consideration than it could do in a case of complicated medical or surgical procedures,”⁹¹⁹

The learned Chief Justice was invoking (in *Walsh*) an exception to the Third *Dunne* Principle. To Kearns J, it appeared that the foregoing “statement really only highlights the unreality of relating or contrasting the duty of disclosure to or with complicated medical treatment which is a separate and quite different function.”⁹²⁰ By adopting that test it was to be the patient, properly informed, rather than the medical attendant, who made the real choice as to whether the treatment was to be carried out.

⁹¹⁰ McMahon & Binchy, *op cit*, 385.

⁹¹¹ McMahon & Binchy, *loc cit*.

⁹¹² McMahon & Binchy, *op cit*, 386. There are no cases cited in the judgment of Egan J.

⁹¹³ *Geoghegan v Harris* [2000] 3 IR 536 (HC) Kearns J.

⁹¹⁴ McMahon & Binchy, *op cit*, 390.

⁹¹⁵ [2000] 3 IR 536.

⁹¹⁶ At [542], Kearns J gave this clarification: “clearly the duty must be confined to such consequences or to consequences which may be described as foreseeable or predictable consequences arising from such complications. Mere coincidental and unrelated risks, for example, could not properly fall within the compass of any duty, any more than consequences which might flow from the practitioner’s negligence.”

⁹¹⁷ [2000] 3 IR 536, 546, per Kearns J.

⁹¹⁸ *Walsh v Family Planning Services Ltd* [1992] 1 IR 496 (Sup Ct).

⁹¹⁹ [1992] 1 IR 496, 511, per Finlay CJ.

⁹²⁰ [2000] 3 IR 536, 546, per Kearns J.

Kearns J set forth the rationale for the ‘reasonable patient’ test:

“The application of the reasonable patient test seems more logical in respect of disclosure. This would establish the proposition that, as a general principle, the patient has the right to know and the practitioner a duty to advise of all material risks associated with a proposed form of treatment. The court must ultimately decide what is material. ‘Materiality’ includes consideration of both (a) the severity of the consequences and (b) the statistical frequency of the risk. That both are critical is obvious because a risk may have serious consequences and yet historically or predictably be so rare as not to be regarded as significant by many people.”⁹²¹

Kearns J has not adopted the ‘prudent patient’ test. He used the word ‘prudent’ only twice in his written judgment. On both occasions, this was done merely to recite the context in which ‘prudent’ had been used hypothetically by another jurist; in formulaic tests, applied in one instance to the doctor and in the other to the patient. It is submitted that the ‘prudent patient’ test is the incorrect approach for a judge to follow. McMahon and Binchy say the following:

“[The prudent patient] approach can perhaps be criticised on the basis that it suspends the general requirements of proof of causation on the basis of a concern that may have no application in particular cases. It raises an interesting question as to whether, in conjunction with the Scarman test, which requires disclosure of material risks, it completely dispenses with the causal enquiry. The answer to the question depends on whether there are some risks which ought to be disclosed under the Scarman test but which nevertheless are not such that a reasonable patient, on learning of them, would inevitably decline to go through with the proposed treatment.”⁹²²

At the outset in *Geoghegan v Harris*, Kearns J recounted two major North American authorities on ‘informed consent’. He clarified that *Canterbury v Spence*,⁹²³ which was followed in *Reibl v Hughes*,⁹²⁴ adopted the proposition that, “as a general principle, the patient has a right to know of

⁹²¹ [2000] 3 IR 536, 549, per Kearns J.

⁹²² McMahon & Binchy, *op cit*, 394.

⁹²³ *Canterbury v Spence* (1972) 464 F2d 772 (Ct App, DC).

⁹²⁴ *Reibl v Hughes* (1980) 114 DLR (3d) 1.

all material risks associated with a proposed form of treatment in exercise of the individual's right to self-determination."⁹²⁵

Kearns J stated that a subjective approach has been adopted in Australia in *Ellis v Wallsend District Hospital*⁹²⁶ and in two other Australian cases that he mentioned briefly.⁹²⁷

Concentrating on *Ellis v Wallsend District Hospital*, Kearns J agreed with Samuels JA in the *Ellis* case who opted for the subjective test, setting out the rationale as follows at [118]:

"The subjective test was regarded in Reibl (in which Canterbury was applied) as 'hypothetical and thus unreliable' and, as Laskin CJC observed (at [16]) calculated to 'put a premium on hindsight, even more of a premium than would be put on medical evidence is assessing causation by an objective standard'.

*I do not myself find these objections to the subjective test persuasive. I respectfully agree with Cox J in Gover v South Australia*⁹²⁸ ... *when he said at [566:] '... At any rate the basic causation principle governing actions in negligence plainly supports, in my opinion, the subjective test'.*"⁹²⁹

It was also clarified by Kearns J that *"the subjective test caters for the idiosyncratic patient who does not conveniently fit into the box which contains 'the reasonable patient' for reasons peculiar or particular to that individual patient."*⁹³⁰ When deciding whether or not a warning would cause a patient to forego an operation, Kearns J stated that the court was to adopt firstly an objective test. That objective test was to yield to a subjective test where there was clear evidence in existence from which a court could reliably infer what a particular patient would have decided. Although Kearns J did not use the expression himself, McMahon & Binchy have designated as a

⁹²⁵ [2000] 3 IR 536, 540.

⁹²⁶ *Ellis v Wallsend District Hospital* [1990] 2 Med LR 103.

⁹²⁷ On those two cases, see Madden, B, Cockburn, T, *What the plaintiff would have done: s 5D(3) of the Civil Liability Act 2002 (NSW)* (2006) 14(10) Australian Health Law Bulletin 1, 2, 4. Available from http://www.slatergordon.com.au/files/editor_upload/File/MedicalNegligence/HealthLawBulletin/HLB%2014%2010_pp116_119.pdf (Last accessed 18 March, 2012). These authors cite: *O'Brien v Wheeler*, Unreported, NSWCA, 23 May, 1997; *Bustos v Hair Transplant Pty Ltd*, Unreported, NSWCA, 15 April 1997. *Bustos* concerned the patient's desire for treatment: here the example was of a patient enthusiastic for cosmetic surgery). See also Forrester, K, Griffiths, D, *Essentials of Law for Health Professionals*, Third Edition (2010) Elsevier Australia, Chatswood (NSW), 4. (A material risk in the circumstances of the *Bustos* case meant anything associated with the procedure, which was both elective and cosmetic in nature).

⁹²⁸ *Gover v South Australia* (1985) 39 SASR 543.

⁹²⁹ [2000] 3 IR 536, 554, per Kearns J.

⁹³⁰ [2000] 3 IR 536, 555-556, per Kearns J.

'hybrid test'⁹³¹ the sequential process that Kearns J described. The objective test is concerned with (ordinary) negligence in relation to the duty to disclose risks. The subjective test is a test of causation with respect to the particular patient (plaintiff). In the subjective-based assessment, the court can take into account evidence of conversations with medical attendants, any admissions,⁹³² and the conduct of the patient prior to the surgical procedure.⁹³³

Kearns J held in *Geoghegan v Harris*⁹³⁴ that, despite the views of the medical experts, all to the effect that no warning was necessary of the remote risk of neuropathic pain, the decision in *Walsh* was nonetheless binding: accordingly, there was an obligation to warn.⁹³⁵ The learned judge declared that no category of inquisitive patient existed in Irish law because of the onerous obligations imposed on the medical profession to warn patients of all risks with severe consequences, regardless of their infrequency. The court found that the patient had not asked a question which could be reasonably construed as relating to ongoing pain or any question which required disclosure to him of the risk of chronic neuropathic pain.⁹³⁶ Overall, the court was satisfied that the plaintiff's conduct clearly suggested that he was not going to be deflected from having his operation because of some very remote risk when balanced against what he saw or perceived as the benefits the procedure would bring.⁹³⁷ Accordingly, the learned trial judge found against the plaintiff on the issue of causation. In the Irish Reports, there is a Reporter's Note on *Geoghegan v Harris* to the effect that following further submissions and certain findings of fact contained in a judgment delivered by the High Court,⁹³⁸ the parties compromised the proceedings.

Geoghegan v Harris has been followed by the Supreme Court in *Fitzpatrick v White*.⁹³⁹ As a member of the Supreme Court panel adjudicating that case, Kearns J (with whom Macken J and Finnegan J agreed) expressed himself to be fortified in his view that the patient centred test is

⁹³¹ McMahon & Binchy, *op cit*, 395-397.

⁹³² That is to say 'admissions' of an evidentiary nature, not the nosocomial kind.

⁹³³ See also *Arndt v Smith* [1997] 2 SCR 539, [44], per McLachlin J: "*The approach suggested by the fundamental principles of tort law is subjective, in that it requires consideration of what the plaintiff at bar would have done. However, it incorporates elements of objectivity; the plaintiff's subjective belief at trial that she would have followed a certain course stands to be tested by her circumstances and attitudes at the time the decision would have been made as well as the medical advice she would have received at the time.*"

⁹³⁴ [2000] 3 IR 536 (HC), Kearns J.

⁹³⁵ Per Kearns J, at [545]. At [549], Kearns J favoured the reasonable patient test. From a perusal of the authorities, it appeared to the court (at [561]) that "*the 'inquisitive patient' doctrine, if such it can be called, arose in England because of the limited duties of disclosure imposed on medical practitioners by Bolam*".

⁹³⁶ At [564].

⁹³⁷ [2000] 3 IR 536, 560.

⁹³⁸ (Kearns J) on 14 September, 2000.

⁹³⁹ *Fitzpatrick v White* [2008] 3 IR 551 (Sup Ct).

preferable.⁹⁴⁰ Kearns J opined that such a test is ultimately more satisfactory from the point of view of both doctor and patient alike, than any ‘doctor centred’ approach favoured by part of this court in *Walsh v Family Planning Services Ltd*.

The dominance of the ‘but for’ test was underlined in *Quinn v Mid-Western Health Board*⁹⁴¹:

*“Any approach which had the effect of reversing the onus of proof, or transferring the onus of proof to the defendant, would be one of such importance, even in the few exceptional cases where it might be appropriate, that it would require a full court - or perhaps even legislation - before a change of such magnitude to existing law could take place.”*⁹⁴²

It is worth noting, said Kearns J, that in Ireland this difficulty of joint tortfeasors and uncertain causation has been addressed by s. 11(3) of the Civil Liability Act 1961, which provides that:-

*“Where two or more persons are at fault and one or more of them is or are responsible for damage while the other or others is or are free from causal responsibility, but it is not possible to establish which is the case, such two or more persons shall be deemed to be concurrent wrongdoers in respect of the damage.”*⁹⁴³

Kearns J mentioned⁹⁴⁴ that the House of Lords took an exceptional course in *Fairchild v Glenhaven Funeral Services Ltd*,⁹⁴⁵ which was expressly acknowledged by Lord Hoffman in the course of his judgment in *Gregg v Scott*. Lord Hoffmann noted that “[a]cademic writers have suggested that in cases of clinical negligence, the need to prove causation is too restrictive of liability. This argument has appealed to judges in some jurisdictions ... most recently in ... Ireland ... *Philp v Ryan*”.⁹⁴⁶ For an Irish case to be cited in the United Kingdom Senior Courts is significant. It remains to be seen what direction the UK Supreme Court might take in this branch of the law, reflecting Lord Hoffmann’s comparative law orientation.

⁹⁴⁰ [2008] 3 IR 551, 563, per Kearns J.

⁹⁴¹ *Quinn v Mid-Western Health Board* [2005] 4 IR 1.

⁹⁴² *Quinn v Mid-Western Health Board* [2005] 4 IR 1, 19, per Kearns J. The learned judge added (*loc cit*) that the case was not one where there were multiple defendants or where a single agency was clearly established as the cause of the plaintiff’s condition.

⁹⁴³ [2005] 4 IR 1, 17-18, per Kearns J.

⁹⁴⁴ [2005] 4 IR 1, 18, per Kearns J.

⁹⁴⁵ [2003] 1 AC 32.

⁹⁴⁶ *Gregg v Scott* [2005] 2 AC 176, 197, per Lord Hoffmann.

5.2.3.1 Pharmacists and Disclosure of Risks (Warnings to the Patient)

The sort of medical/surgical decisions discussed above will not arise in the pharmacy. Medication available for non-prescription supply is limited both in terms of product range and in pharmacological potency. Of course, all medication has some degree of risk associated with its use. For example, a patient who is injured through the inappropriate, protracted, consumption of a pharmacy-only medicine may challenge the pharmacist's failure to warn her of the risks associated with such medication. It is submitted that a pharmacist's failings in this regard would be viewed with particular disdain where the initial ailment that prompted the patient to consult the pharmacist was either self-limiting or could have been controlled by fluid replacement or other straightforward dietary measures.

5.3 The Doctrine of Loss of a Chance

The law has different approaches to past events and future events. Past events, whether historical or hypothetical, are treated deterministically. Future events are treated probabilistically.⁹⁴⁷ The doctrine of lost chances⁹⁴⁸ stems from an English Court of Appeal decision on the plaintiff's loss of an opportunity to progress in an Edwardian 'talent show' (twelve women were each to be offered theatrical engagements for a period of three years upon winning).⁹⁴⁹ Waddams has stated that it is "*well established in English and Commonwealth law (though not so clear in American law) ... that a loss may be compensated even though its value cannot be established with any degree of certainty.*"⁹⁵⁰

⁹⁴⁷ See Powers, M, Harris, NH, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 790. See further, *loc cit*: "*The probability of the occurrence of an event may have application in terms of the probability of cause if it has occurred in the past or quantification of damage if it is in the future. These distinctions between past events and future events, causation and damage are thus crucial in negligence.*"

⁹⁴⁸ See however Frasca, R, *Loss of Chance Rules and the Valuation of Loss of Chance Damages* (2009) 15 Journal of Legal Economics 91, 93 (n 2), criticizing the elevation of a 'rule' to theoretical or doctrinal status.

⁹⁴⁹ *Chaplin v Hicks* [1911] 2 KB 786 (CA), discussed in van den Heever, P, *The Application of the Doctrine of Loss of Chance to Recover in Medical Law* (2007) Pretoria University Law Press, Pretoria, 5-6. The doctrine exists also in other European legal systems. In *Joseph v National Magazine Co Ltd* [1959] Ch 14, it was held that the plaintiff was entitled to damages for breach of contract, as through the defendants' failure to publish the article he had lost an opportunity of enhancing his reputation as an expert on jade; *Chaplin v Hicks* was neither cited in argument nor referred to in the judgment. The theory underlying 'loss of a chance' has been succinctly explained by a court in a jurisdiction that does not recognize the doctrine: see Duncan, MJ, *Personal Tort Law* (2010) 63 SMU Law Review 717, (*II Medical Malpractice-Still no Loss of Chance in Texas*) 717-720, discussing *Columbia Rio Grande Healthcare LP v Hawley* (2009) 284 SW3d 851 (Tex Sup Ct).

⁹⁵⁰ See Waddams, S, *Damages: Assessment of Uncertainties* (1998) 13 Journal of Contract Law 55, 68, cited in Cutler, P, *The Computation of Damages on a Reliance Loss Basis* (Undated Web Resource) Publication on Author's Personal Web Site, [17]. Available from <http://www.cutler.com.au/attachments/article/70/Reliance%20Damages.pdf>. (Last accessed 12 January, 2012). See van den Heever, P, *op cit*, 6-7, referring to Luntz, H, *Loss of Chance*, Chapter in Freckelton, I, Mendelson, D (Editors), *Causation in Law and Medicine* (2002) Ashgate/Dartmouth, Aldershot, 159, wherein

The court's application of the 'but for' test is strictly deterministic and is all or nothing in effect: "In determining what did happen in the past a court decides on the balance of probabilities. Anything that is more probable than not it treats as certain."⁹⁵¹ The loss of chance system does not apply in the event of certainty, since that would lead to situations where damages are less than the harm even though it is certain that the negligence of the defendant is the cause of the harm. In order to determine the amount of damages with the loss of chance system, the harm must be multiplied not by the probability that the defendant's negligence was the cause of the harm but instead by the increased probability of harm attributable to his negligence.⁹⁵²

In *Hotson v East Berkshire Area Health Authority*,⁹⁵³ resulting from the health authority's admitted negligence, the infant plaintiff was not treated for an injury to his left hip for five days, during which time he experienced considerable pain. Despite the treatment the plaintiff suffered avascular necrosis, with the inevitability of osteoarthritis developing. He claimed that the health authority's delay in diagnosing and treating his injury increased considerably the likelihood of long term disability. The health authority, although admitting liability in respect of the plaintiff's pain and suffering for five days, denied that their negligence had affected his future prospects of recovery since his injury was so severe that avascular necrosis would have occurred in any event.

At first instance, Simon Brown J found that even if the defendant health authority had diagnosed the injury correctly and treated the plaintiff promptly there had been a high probability which he assessed as a 75 per cent risk, that avascular necrosis would still have developed. He held that the plaintiff was entitled to damages for the loss of the 25 per cent chance that he would have made a nearly full recovery.

The Court of Appeal dismissed an appeal by the health authority. Sir John Donaldson MR opined:

Luntz suggested that *Fink v Fink* (1946) 74 CLR 127 (HCA) should not be seen as standing in the way for awarding damages for the loss of a chance in the medical context. See further Luntz, H, *Loss of Chance in Medical Negligence* [2010] University of Melbourne Law School Research Series 14.

⁹⁵¹ See Powers, M, Harris, NH, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 789, citing *Mallett v McMonagle* [1970] AC 166, 176, per Lord Diplock. See also Miller, C, *Gregg v Scott - loss of chance revisited* (2005) 4 Law, Probability & Risk 227, 230, on the "asymmetry, in law no less than in everyday experience, between past facts and future prospects". See also: *Mallett v McMonagle* [1970] AC 166 (HL); *Gregg v Scott* [2005] 2 AC 176 (HL).

⁹⁵² See Bieri, L, Marty, P, *The Discontinuous Nature of the Loss of Chance System* (2011) 2 Journal of European Tort Law 23, 27-28.

⁹⁵³ *Hotson v East Berkshire Area Health Authority* [1987] AC 750 (CA; HL). At first instance, *sub nom Hotson v Fitzgerald and Others* [1985] 1 WLR 1036 (QBD).

“As a matter of common sense, it is unjust that there should be no liability for failure to treat a patient, simply because the chances of a successful cure by that treatment were less than fifty per cent, nor by the same token can it be just that if the chances of a successful cure only marginally exceed fifty per cent, the doctor or his employer should be liable to the same extent as if the treatment could be guaranteed to cure.”⁹⁵⁴

Croom-Johnson LJ was similarly sympathetic to the claimant’s case:

“If the plaintiff succeeds in proving that he was one of the 25 per cent [of the population have a chance of recovery from a certain injury] and that the defendants took away that chance, the logical result would be to award him 100 per cent of his damages and not only a quarter, but that might be left for consideration if and when it arises. In this case the plaintiff was only asking for a quarter.”⁹⁵⁵

The House of Lords applied the ‘but for’ test; it could not be shown on the balance of the probabilities that the plaintiff would have avoided vascular necrosis if there had been no negligence on the part of the defendant’s medical staff.⁹⁵⁶ Accordingly, the claim failed. Lord Ackner opined in *Hotson* that the debate on the loss of a chance cannot arise where there has been a positive finding that before the duty arose the damage complained of had already been sustained or had become inevitable.⁹⁵⁷ His Lordship continued by clarifying that once liability is established on the balance of probabilities, the loss which the plaintiff has sustained is payable in full; not discounted by reducing his claim by the extent to which he has failed to prove his case with 100 per cent certainty.

In some professional negligence claims the claimant is able *“to recover damages for loss of the chance that a third party would have acted in a particular way, had the negligence not occurred.”*⁹⁵⁸ The Court of Appeal in *Allied Maples Group v Simmons & Simmons*⁹⁵⁹ accepted a

⁹⁵⁴ *Hotson v East Berkshire Area Health Authority* [1987] AC 750, 759-760, per Sir John Donaldson MR.

⁹⁵⁵ *Hotson v East Berkshire Area Health Authority* [1987] AC 750, 769, per Croom-Johnson LJ.

⁹⁵⁶ See also reference to *Hotson* in *Mugweni v NHS London* [2011] EWCA Civ 20, [44], per Davis LJ (26 January, 2012).

⁹⁵⁷ *Hotson v East Berkshire Area Health Authority* [1987] AC 750, 792, per Lord Ackner.

⁹⁵⁸ See Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 427. See also Tettenborn, A, *What It's Worth to Do Your Best* (2008) 28 Pace Law Review 297, 309 (n 35) (Priority citation substituted for original): “[S]ince the 1950s English courts have steadfastly refused to set up a ‘trial within a trial’ where lawyers negligently bungle a lawsuit. Instead they simply

claimant company's contention that it had been negligently not been advised by the defendant firm of solicitors to seek the vendors' protection against certain potential liabilities had lost a substantial chance compared with a speculative one.⁹⁶⁰ In several cases, the House of Lords declined to overrule the authorities so as to permit a claimant, "*who could prove that a doctor had acted negligently, to damages on the basis that the chance of a better outcome for his condition had been reduced, even though proof on a balance of probability that the outcome would be worse, was not available to him.*"⁹⁶¹ In *Gregg v Scott*,⁹⁶² the House of Lords by a majority held that an exception would not be made so as to allow a percentage reduction in the prospects of a favourable outcome as a recoverable head of damage.⁹⁶³

Mr. Gregg argued that he should be able to recover for being deprived of a chance of a cure using two alternative bases: the conventional damage "*hook*" argument, that is to say, damage consequential on a physical injury; the radical pure loss of a chance argument. The House of Lords in *Gregg*, by a majority, rejected physical damage as a "*hook*" on which to hang an orthodox claim for consequential reduced life expectancy.⁹⁶⁴ Overall, Gregg's claim failed for two reasons: review of the statistical evidence in light of disease remission; attributability to the tort (as opposed to the cancer) was less than 50%. The "*hook*" argument was available in *Hotson v East Berkshire Area Health Authority*,⁹⁶⁵ although not argued before their Lordships. However, the majority in *Gregg's Case* in the House of Lords did not invoke *Hotson*.

Martin Hogg has criticised the assessment of Lord Phillips in *Gregg v Scott*⁹⁶⁶ that loss of chance analysis is too difficult for medical negligence cases: "*Mr Gregg was not claiming in respect of the different possible outcomes listed ... but merely for the reduced chance of avoiding an earlier death. Given this, it would have been necessary for the court only to calculate a single loss of a*

award the now plaintiff the amount she would have obtained multiplied by her would-be chances of recovering it. See Kitchen v Royal Air Forces Association [[1958] 1 WLR 563 (CA)]".

⁹⁵⁹ *Allied Maples Group v Simmons & Simmons* [1995] 1 WLR 1602.

⁹⁶⁰ See, in particular, *dicta* of Stuart-Smith LJ, [1995] 1 WLR 1602, 1611. See also Rogers, WVH (Editor), *Winfield and Jolowicz on Tort*, Eighteenth Edition (2010) Sweet & Maxwell, London, 332-333.

⁹⁶¹ *Charlesworth and Percy*, *loc cit*.

⁹⁶² [2005] 2 AC 176.

⁹⁶³ See further *Gregg v Scott* [2005] 2 AC 176, 196 (Lord Hoffmann).

⁹⁶⁴ See Stapleton, J, *Cause in fact and the scope of liability for consequences* (2003) 119 Law Quarterly Review 388, 423, positing "*the 'hook' on to which to hang a lost chance as consequential on the actionable injury which is then recoverable under orthodox rules.*" See further Stapleton, J, *Loss of the Chance of Cure from Cancer* (2005) 68 Modern Law Review 996, 997-999. See also Stiggelbout, M, *The case of 'losses in any event': a question of duty, cause or damages?* (2010) 30 Legal Studies 558, 566 (n): wherein the 'hook' argument is attributed to Prof. Stapleton.

⁹⁶⁵ [1987] AC 750.

⁹⁶⁶ [2005] 2 AC 176, 220-221, per Lord Phillips.

chance figure.”⁹⁶⁷ Hogg suggests that where multiple possible chances are at issue, the courts have struggled to determine what the proper damages in a lost chance case should be.⁹⁶⁸

Murphy and Witting state that, at the very least, *Gregg v Scott* leaves “unanswered” (that is to say, in a clear line of judicial authority) the question of why loss of a chance is recoverable in professional negligence cases resulting in economic loss “but not where the professional negligence is that of a doctor.”⁹⁶⁹ It is submitted that the multifactorial nature of human physiology and human pathology give rise to more imponderables than an economic relationship between parties (possibly an ongoing nexus and of which there may be documentary evidence) and where the occurrence of losses in any event may be discerned by the court.

The New Zealand Court of Appeal held in *Benton v Miller & Poulgrain*⁹⁷⁰ held that the loss of chance analysis is available “whenever the issue relevant for determining the value of the loss suffered by the plaintiff involves the Court asking and answering a hypothetical question as to what a third party would have done.”⁹⁷¹ Fischer has stated that “[r]estricting loss of a chance to third party behavior effectively limits the use of probabilistic causation, but it is not clear that this distinction is sound. What the plaintiff would have done if presented with the opportunity is just as easily characterized as involving a loss of a chance that has value.”⁹⁷² It is submitted that Fischer could have gone further: decisions on medical treatment are so personalised that regard to what a third party might choose to do, presented with the same options, may be inappropriate.

In *Philp v Ryan*,⁹⁷³ the Supreme Court held that damages should have been awarded for possible loss of life expectancy due to the loss of the opportunity to avail of treatment.⁹⁷⁴ The balance of

⁹⁶⁷ Hogg, MA, *Re-establishing Orthodoxy in the Realm of Causation* (2007) 11 *Edinburgh Law Review* 8, 23.

⁹⁶⁸ See further the multiple lost chance case of *Paul v Ogilvy* 2001 SLT 171 [solicitor’s negligence leading to lost opportunities around selling land to developers] in Hogg, MA, *Paul v Ogilvy: a lost opportunity for lost chance recovery* (2003) 7 *Edinburgh Law Review* 86. See also Turton, G, *Defining Damage in the House of Lords* (2008) 71 *Modern Law Review* 987, 1011.

⁹⁶⁹ Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 155 (n). These writers suggest (in light of the general hierarchy of protected interests in tort law) that it is objectionable to permit claims in respect of the loss of a chance of financial gain but not the loss of a chance of physical cure, citing *Gouldsmith v Mid-Staffordshire General Hospitals NHS Trust* [2007] EWCA Civ 397.

⁹⁷⁰ *Benton v Miller & Poulgrain* [2005] 1 NZLR 66 (CA), analysed in Hegan, N, *SAAMCO, the Scope of the Duty and Liability for Consequences* (2007) 38 *Victoria University of Wellington Law Review* 465, 485-486.

⁹⁷¹ See Barker, A, *Damages for loss of chance in negligence: the availability of an alternative remedy* (Undated Web Resource) Shortland Chambers, Auckland, [2]. Available from <http://www.shortlandchambers.co.nz/pub/users/andrew-baker/files/NZLJartonlossofchance.pdf>. (Last accessed 12 January, 2012). Author Pre-Publication Draft of Barker, A, *Damages for loss of chance* [2007] *New Zealand Law Journal* 151: citation verified through Washington & Lee Law School, Current Law Journal Content (CLJC). (Note: updating of CLJC ceased on 13 May, 2011).

⁹⁷² See Fischer, DA, *Tort Recovery for Loss of a Chance* (2001) 36 *Wake Forest Law Review* 605, 645-646.

⁹⁷³ *Philp v Ryan* [2004] 4 IR 241 (SC).

probability test did not apply to the assessment of damages for future uncertain events. The trial judge had erred in holding that damages depended on proof that life would probably, not possibly, have been prolonged if the doctor had acted with due care. The head of such damages could also be described as an increased risk of shorter life expectancy. Fennelly J opined: “*It seems to me as illogical to award damages for a probable future injury as if it were a certainty, as to withhold them where the risk is low on the basis that it will not happen at all.*”⁹⁷⁵ The same matter had been dealt with by the Supreme Court in *Dunlop v Kenny*.⁹⁷⁶ Ó Dálaigh CJ (*per curiam*), having held that the trial judge had ‘overstated’ the risk, indicated the correct approach:

*"In cases such as this, where there is an issue of possibility or probability of some disability or illness arising or developing in the future, the damages to be awarded should be commensurate with, and proportionate to, the degree of that possibility or probability as the case may be. If the degree of probability is so high as to satisfy a jury that it remains only barely possible that the condition will not occur, a jury would be justified in acting upon the assumption that it will occur, and should measure the damages accordingly. On the other hand, if the probability that no such event will occur is so great that it is only barely possible that it would occur, damages should nevertheless be awarded, but should be proportionate the degree of risk, small though it might be."*⁹⁷⁷

Healy justifiably characterises *Philp* as “*a highly important decision — the more for its potential application in other cases*”.⁹⁷⁸ Healy continues “*no less because [Philp] omits to flag its reasoning or posit it within the grander scheme of common law negligence.*”⁹⁷⁹ ‘Lost chances’ have not been frequently litigated in Ireland. As Kearns J observed in *Quinn v Mid-Western Health Board*: “*[i]t must be said that there is a dearth of Irish authority on the topic of ‘loss of a chance’ which perhaps explains why the plaintiff’s advisers steered clear of it at trial.*”⁹⁸⁰

⁹⁷⁴ The Supreme Court approved of the *rationes decidendi* in *Dunlop v Kenny*, Unreported, Supreme Court, 29 July, 1969 and *Davies v Taylor* [1974] AC 207.

⁹⁷⁵ [2004] 4 IR 241, 249-250, per Fennelly J.

⁹⁷⁶ *Dunlop v Kenny*, Unreported, Supreme Court, 29 July, 1969. See also von Bar, C, *Non-Contractual Liability arising out of Damage caused to Another* (2009) Sellier de Gruyter, Berlin, New York, 379.

⁹⁷⁷ *Dunlop v Kenny*, Unreported, Supreme Court, 29 July, 1969, [11]-[12], per Ó Dálaigh CJ. See also Healy, J, *Causation in Tort Law: The Loss of Chance Doctrine* (2007) 3(1) Independent Law Review 8, 12. See also Ward, P, *Tort Law in Ireland* (2010) Kluwer Law International, Aalphen aan den Rijn (NL), 238.

⁹⁷⁸ Healy, *op cit*, 12.

⁹⁷⁹ Healy, *loc cit*.

⁹⁸⁰ *Quinn v Mid-Western Health Board* [2005] 4 IR 1, 14, per Kearns J.

The High Court of Australia has rejected the doctrine of loss of a chance in *Tabet v Gett*.⁹⁸¹ Kiefel J, with whom Hayne, Crennan and Bell JJ agreed, said:

*“The ‘but for’ test is regarded as having an important role in the resolution of the issue of causation, although more as a negative criterion than as a comprehensive test. ... Once causation is proved to the general standard, the common law treats what is shown to have occurred as certain. ... The result of this approach is that when loss or damage is proved to have been caused by a defendant’s act or omission, a plaintiff recovers the entire loss (the ‘all or nothing’ rule).”*⁹⁸²

Recently, Luntz has criticised the Australian Court’s distinguishing cases in which that forum “has allowed damages for loss of a commercial opportunity and ignored the analogy of the liability of solicitors”.⁹⁸³ Luntz continues: “Its policy consideration was extremely limited. It left open a tiny window for cases based on contractual reasoning, and possibly some other unspecified cases, but litigants would be wise not to embark on such a course because of the high cost of failure, which appears almost inevitable.”⁹⁸⁴ Faunce has stated that “[l]oss of a chance claims ... should not be allowed to distort informed consent actions by establishing professional practice standards requiring best possible rather than reasonably appropriate care.”⁹⁸⁵ Bearing in mind the New Zealand no-fault system, Faunce continued:

“Until such a no-fault compensation system is introduced, courts should be responsive to the injustice implicit in the artificialities forced on plaintiffs by the current restrictive medical negligence system. It is not fair that medical indemnity insurers being paid large amounts by both practitioners and governments and being protected for claims by that system should be insulated both by State legislation and the High Court from making a reasonable contribution to the

⁹⁸¹ *Tabet v Gett* (2010) 240 CLR 537.

⁹⁸² *Tabet v Gett* (2010) 240 CLR 537, [112]-[113], per Kiefel J. (Footnotes omitted).

⁹⁸³ See Luntz, H, *Loss of Chance in Medical Negligence* [2010] University of Melbourne Law School Research Series 14, [25]. See further [25 (n)]: “The question arises whether *Tabet v Gett* will influence Australian courts to re-evaluate the cases in which solicitors have been held liable for loss of chance. It has already been cited in such a case for the proposition that the plaintiff was ‘not entitled to damages merely because of the loss of an opportunity to consider what she might have done’: *Firth v Sutton* [2010] NSWCA 90, [103]. Of course, this has always been so in solicitors’ cases where what the plaintiff would have done has been at issue.”

⁹⁸⁴ See Luntz, H, *loc cit*. See also Birch, D, *Tabet v Gett: The High Court's own lost chance of a better outcome* (2011) 19 Tort Law Review 76.

⁹⁸⁵ See Faunce, T, *The High Court’s Lost Chance in Medical Negligence: Tabet v Gett* (2010) 240 CLR 537 (2010) 18 Journal of Law & Medicine 275, 283.

considerable needs of patients such as the appellant in this marginally defensible case.”⁹⁸⁶

5.3.1.1 Application to Pharmacists in Ireland

In a recent publication from the American Society for Pharmacy Law, Fassett stated: “It does not appear that a loss of chance cause of action has been asserted against a pharmacy defendant, but one can imagine situations in which a pharmacy’s failure to detect a drug-therapy-related problem could become a cause of a loss-of-chance injury.”⁹⁸⁷ It is submitted that an Irish court, drawing on the *Philp v Ryan* jurisprudence, could apply the same reasoning in an appropriate case. A pharmacist may supply a non-prescription medicine for an ailment for longer than advisable, depriving the patient of the opportunity to seek medical attention that may offer better outcomes than the pharmacy-supplied medicine.

5.4 Causation linked to Breach of Duty

Stated more expansively, this is a judicial approach to causation linked to injury/damage that was the defendant’s duty to prevent. The trial judge in *Chester v Afshar*⁹⁸⁸ had not found that, if properly informed, the claimant would never have undergone the operation and since the risk which eventuated was liable to occur at random irrespective of the skill and care with which the operation might be performed.⁹⁸⁹ The defendant’s failure to warn therefore neither affected the risk nor was the effective cause of the injury she sustained, so that, applying conventional principles, she could not satisfy the (but for) test of causation. Street on Torts describes helpfully *Chester v Afshar* as a case involving hypothetical conduct by the claimant against a background of evidential uncertainty.⁹⁹⁰

With two dissentients (Lords Bingham and Hoffmann), the House of Lords held that the issue of causation was to be addressed by reference to the scope of the doctor’s duty, namely, to advise

⁹⁸⁶ Faunce, T, *loc cit*.

⁹⁸⁷ Fassett, WE, *Emerging Trend in Torts: “Loss of Chance” as a New Cause of Action* (2012) 39(2) *Rx Ipsa Loquitur* 3. On *Philp v Ryan*, see Hayden, E, ‘Loss of chance’ actions are already among us (2012) *Irish Medical Times*, 02 October, 2012. Available from <http://www.imt.ie/opinion/2012/10/loss-of-chance-actions-are-already-among-us.html>. (Last accessed 10 October, 2012).

⁹⁸⁸ *Chester v Afshar* [2005] 1 AC 134. See also Khoury, L, *Chester v Afshar: Stepping further away from Causation?* [2005] *Singapore Journal of Legal Studies* 246.

⁹⁸⁹ See *Chester v Afshar* [2005] 1 AC 134, 142, *dicta* of Lord Steyn.

⁹⁹⁰ Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 157-159.

his patient of the disadvantages or dangers of the treatment he proposed.⁹⁹¹ Such a duty was closely connected with the need for the patient's consent and pivotal to her right to exercise an informed choice as to whether and, if so, when and from whom to receive treatment. Since the injury she sustained was within the scope of the defendant's duty to warn and was the result of the risk of which she was entitled to be warned when he obtained her consent to the operation in which it occurred, the injury was to be regarded as having been caused by the defendant's breach of that duty. Accordingly, justice required a narrow modification of traditional causation principles to vindicate the claimant's right of choice and to provide a remedy for the breach.⁹⁹²

5.5 Material Contribution Test

The 'material contribution' test is reserved only for those instances where proving 'but for' causation "*results in some logical impossibility that is obviously incorrect or unjust in a fault-based tort system.*"⁹⁹³ Particularly in the context of exposure claims it has been held sufficient that a claimant prove, on the balance of probability, that "*the defendant's breach of duty was a material, rather than exclusive, cause of any injury sustained.*"⁹⁹⁴

The facts in the celebrated case of *Bonnington Castings Ltd v Wardlaw*⁹⁹⁵ are the following. The pursuer was, in the course of his employment, exposed to silica dust stemming from the pneumatic hammer at which he worked and also from swing grinders. There was no technically possible dust extraction solution for the hammer's operational area. Although the swing grinders were fitted with dust extraction equipment, these were not kept free from obstruction: in consequence, the factory owners were in breach of statutory duty. Having contracted pneumoconiosis in the course of his employment, the pursuer sued his employers for damages. These *dicta* of Lord Reid in *Bonnington Castings Ltd v Wardlaw* capture the essence of material contribution:

⁹⁹¹ See *Chester v Afshar* [2005] 1 AC 134, 153, *dicta* of Lord Hope.

⁹⁹² See *Chester v Afshar* [2005] 1 AC 134, 146, per Lord Steyn: "*At the very least the Fairchild case shows that where justice and policy demand it a modification of causation principles is not beyond the wit of a modern court.*"

⁹⁹³ See Knutsen, ES, *Clarifying Causation in Tort* (2010) 33 Dalhousie Law Journal 153, 160.

⁹⁹⁴ See Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 420. See also Miller, C, *Judicial approaches to contested causation: Fairchild v Glenhaven Funeral Services in context* (2002) 1 Law, Probability and Risk 119, 139, remarking that "*in a succession of cases from Bonnington onwards, English common law has, in different ways, eased the burden on claimants who can 'prove' breach of duty but, through various forms of uncertainty, not causation.*"

⁹⁹⁵ *Bonnington Castings Ltd v Wardlaw* [1956] AC 613 [HL(SC)].

*"[T]he disease is caused by the whole of the noxious material inhaled and, if that material comes from two sources, it cannot be wholly attributed to material from one source or the other ... and the real question is whether the dust from the swing grinders materially contributed to the disease. ... A contribution which comes within the exception de minimis non curat lex is not material, but I think that any contribution which does not fall within that exception must be material."*⁹⁹⁶

The state of medical knowledge may hinder the claimant from proving that an exposure is a material contributory cause of injury or damage.⁹⁹⁷

A common-sense approach, while appropriate in accident cases, may "*prove unsatisfactory in some non-accident claims for personal injury*".⁹⁹⁸ Scientific knowledge may not be sufficient to yield a satisfactory explanation. The House of Lords held in *McGhee v National Coal Board*⁹⁹⁹ that there was no substantial difference between materially increasing the risk of injury and making a material contribution to the injury. The defendant employers admitted breach of duty through failure to take reasonable care to provide adequate washing facilities, including showers, choosing instead to run the (unsuccessful) defence that causation had not been made out.

*Fairchild v Glenhaven Funeral Services Ltd*¹⁰⁰⁰ was a case (among three appeals heard together) in which an employee had been exposed by different defendants, during different periods of employment, to inhalation of asbestos dust in breach of each defendant's duty to protect him from the risk of contracting mesothelioma. The House of Lords held in *Fairchild* that where the risk of mesothelioma had eventuated but, in current medical knowledge, the onset of the disease could not be attributed to any particular or cumulative wrongful exposure, a modified approach to proof of causation was justified.¹⁰⁰¹ In such a case proof that each defendant's wrongdoing had materially increased the risk of contracting the disease was sufficient to satisfy the causal requirements for his liability. Accordingly, applying that approach and in the circumstances of

⁹⁹⁶ *Bonnington Castings Ltd v Wardlaw* [1956] AC 613, 621, per Lord Reid.

⁹⁹⁷ See *Reay v British Nuclear Fuels* [1994] 5 Med LR 1 (Pre-conception exposure to radiation was at issue).

⁹⁹⁸ See Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 421.

⁹⁹⁹ *McGhee v National Coal Board* [1973] 1 WLR 1.

¹⁰⁰⁰ *Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32.

¹⁰⁰¹ See Bailey, SH, 'Causation in negligence: what is a material contribution?' (2010) 30 *Legal Studies* 167, 169: "To hold a defendant liable in tort where there is significant uncertainty about the causes of the harm requires a strong policy justification; to do so where it seems that the harm would probably have happened anyway requires even more. Justification can readily be provided where the claimant is injured by a combination of causes, each of which is tortious and each of which is sufficient to bring about the whole harm."

each case, the claimants could prove, on a balance of probabilities, the necessary causal connection to establish the defendants' liability. Horsey and Rackley focus on the aetiology of mesothelioma: unlike in *Bonnington* (but like *McGhee*) experts agreed that that mesothelioma could be caused “in a single moment—for example, even by a single asbestos fibre entering the lung”.¹⁰⁰² The difficulty was that the claimants could not prove, on the balance of probabilities, the precise time at which the deleterious exposure occurred or which of the employers “was the factual cause of the harm.”¹⁰⁰³ Charlesworth and Percy note that a “similarly pragmatic approach in the context of clinical negligence was adopted in *Chester v Afshar*”.¹⁰⁰⁴

Lord Rodger identified six conditions¹⁰⁰⁵ to be satisfied for the *Fairchild* exception to apply:

*“First, the principle is designed to resolve the difficulty that arises where it is inherently impossible for the claimant to prove exactly how his injury was caused. It applies, therefore, where the claimant has proved all that he possibly can, but the causal link could only ever be established by scientific investigation and the current state of the relevant science leaves it uncertain exactly how the injury was caused and, so, who caused it.”*¹⁰⁰⁶ ... Secondly, part of the underlying rationale of the principle is that the defendant's wrongdoing has materially increased the risk that the claimant will suffer injury. It is therefore essential not just that the defendant's conduct created a material risk of injury to a class of persons but that it actually created a material risk of injury to the claimant himself. Thirdly, it follows that the defendant's conduct must have been capable of causing the claimant's injury. Fourthly, the claimant must prove that his injury was caused by the eventuation of the kind of risk created by the defendant's wrongdoing. ... By contrast, the principle does not apply where the claimant has merely proved that his injury could have been caused by a number of different events, only one of which is the eventuation of the risk created by the defendant's wrongful act or omission.¹⁰⁰⁷ ... Fifthly, this will usually mean that the claimant must prove that his injury was caused, if not by exactly the same agency as was involved in the defendant's wrongdoing, at least by an agency that operated in substantially the same way. A possible example would be where a workman suffered injury from

¹⁰⁰² See Horsey, K, Rackley, E, *Tort Law*, Second Edition (2011) Oxford University Press, Oxford, 231.

¹⁰⁰³ See Horsey, K, Rackley, E, *loc cit*.

¹⁰⁰⁴ See Charlesworth and Percy, *op cit*, 422 (n), citing *Chester v Afshar* [2005] 1 AC 134.

¹⁰⁰⁵ *Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32, 118-119, per Lord Rodger of Earlsferry.

¹⁰⁰⁶ *McGhee* and the three appeals heard together in the *Fairchild* litigation are examples.

¹⁰⁰⁷ For example, *Wilsher v East Essex Area Health Authority* [1988] AC 1074 (HL).

*exposure to dusts coming from two sources, the dusts being particles of different substances each of which, however, could have caused his injury in the same way.*¹⁰⁰⁸ ... Sixthly, the principle applies where the other possible source of the claimant's injury is a similar wrongful act or omission of another person ... I reserve my opinion as to whether the principle applies where the other possible source of injury is a similar but lawful act or omission of someone else or a natural occurrence."

In *Barker v Corus UK Ltd*,¹⁰⁰⁹ the exposure to asbestos could be broken down to three periods: employment for an insolvent employer (clearly no mark for damages); employment by the defendant; a phase of self-employment. Lord Rodger said in *Barker*, having reserved his opinion on the point in *Fairchild*,¹⁰¹⁰ he "would now hold that the rule should apply in that situation."¹⁰¹¹ Lord Hoffmann agreed:

"It should not therefore matter whether the person who caused the non-tortious exposure happened also to have caused a tortious exposure. The purpose of the Fairchild exception is to provide a cause of action against a defendant who has materially increased the risk that the claimant will suffer damage and may have caused that damage, but cannot be proved to have done so because it is impossible to show, on a balance of probability, that some other exposure to the same risk may not have caused it instead. For this purpose, it should be irrelevant

¹⁰⁰⁸ Lord Rodger inclined to the view that the principle had been properly applied by the Court of Appeal in *Fitzgerald v Lane* [1987] QB 781 (CA), affirmed [1989] AC 328 (HL).

¹⁰⁰⁹ *Barker v Corus UK Ltd* [2006] 2 AC 572 (HL). See Pundik, A, *The epistemology of statistical evidence* (2011) 15 *The International Journal of Evidence & Proof* 117, 120 and 120 (n 15). Pundik offers a paradigmatic example in the 'red and blue buses' scenario, where a lady who has been hit by an unidentified bus claims damages from the red bus company on the basis that 60 per cent of the buses in that area are operated by that company. See however Miller, C, *Liability for negligently increased risk: the repercussions of Barker v Corus UK (plc)* (2009) 8 *Law, Probability and Risk* 39, citing Tillers, P, *If wishes were horses: discursive comments on attempts to prevent individuals from being unfairly burdened by their reference classes* (2005) 4 *Law, Probability and Risk* 33, 48: "Tillers has observed that when such general-to-individual inferences amount to racial stereotyping, they tend to be abjured on moral grounds." Pundik's illustration is a "quantified variation" on *Smith v Rapid Transit Inc* (1945) 58 NE2d 754 (Mass), a popular example in the literature about statistical evidence. In *Smith v Rapid Transit Inc*, the plaintiff, who was struck by a bus on 'Main Street', sued the only operator licensed to run services along that thoroughfare. See also Thomson, JJ, *Liability and Individualized Evidence* (1986) 49 *Law and Contemporary Problems* 199. For an economic argument against "disproportionately burdening larger companies and subsidizing their smaller competitors", see Wells, GL, *Naked Statistical Evidence of Liability: Is Subjective Probability Enough?* (1992) 62 *Journal of Personality and Social Psychology* 739, 742-743.

¹⁰¹⁰ That is to say, the caveat the learned judge entered on the breadth of the Sixth Principle.

¹⁰¹¹ *Barker v Corus UK Ltd* [2006] 2 AC 572, 609, per Lord Rodger.

*whether the other exposure was tortious or non-tortious, by natural causes or human agency or by the claimant himself.”*¹⁰¹²

Lord Scott might depend also on the “*intensity of the exposure*” and type of asbestos for which the defendant was responsible compared with those same factors for which the defendant was not responsible.¹⁰¹³ The House of Lords, in *Barker*, departed from the ‘joint and several liability’ approach in *Fairchild*.

The House of Lords in the *Rothwell v Chemical & Insulating Co*¹⁰¹⁴ litigation (a tetralogy of appeals heard together) held that pleural plaques (indicating exposure to asbestos) had caused no symptoms and did not increase susceptibility to other asbestos-related diseases or shorten life expectancy; their mere presence in the claimants' lungs did not constitute injury capable of giving rise to a claim for damages in tort. In the recent case of *Williams v University of Birmingham*,¹⁰¹⁵ the Court of Appeal held that the correct test for breach of duty in a mesothelioma case was not whether the defendant had taken reasonable measures to ensure that the claimant or victim was not exposed to a material increase in the risk of mesothelioma. Rather, the duty was to take reasonable care, including measures if necessary, to ensure that a person was not exposed to a foreseeable risk of asbestos related injury. It is worthy of note that legislation has been passed in Scotland and in Northern Ireland to reverse the effect of *Rothwell*.¹⁰¹⁶

Mesothelioma litigation came before the United Kingdom Supreme Court for the first time in *Sienkiewicz v Greif (UK) Ltd*.¹⁰¹⁷ The defendants argued that where there was only one employer, the correct test was the ‘but for’ test, not the *Fairchild* exception.¹⁰¹⁸ Section 3 of the Compensation Act 2006 provides that, where a defendant is held liable in a mesothelioma case,

¹⁰¹² *Barker v Corus UK Ltd* [2006] 2 AC 572, 584-585, per Lord Hoffmann.

¹⁰¹³ [2006] 2 AC 572, 599, per Lord Scott.

¹⁰¹⁴ *Rothwell v Chemical & Insulating* [2008] 1 AC 281 (HL). On *Rothwell*, see further Matthews, MH, *Negligent Infliction of Emotional Distress: A View of the Proposed Restatement (Third) Provisions from England* (2011) 44 Wake Forest Law Review 1177, 1182: “*English law is close to the Restatement (Third) proposal.*”

¹⁰¹⁵ [2011] EWCA Civ 1242.

¹⁰¹⁶ The Damages (Asbestos-related Conditions) (Scotland) Act 2009 2009 asp 4, was vigorously challenged by the insurance industry: *AXA General Insurance Ltd and Others, Petitioners* [2009] CSOH 57; *AXA General Insurers and Others, Petitioners* [2010] CSOH 2; *AXA General Insurance Ltd v Lord Advocate* 2011 SC 662 (CSIH First Div) (Reclaiming motion refused); *AXA General Insurance Ltd & Ors v Lord Advocate & Ors (Scotland)* [2011] UKSC 46. The UK Supreme Court held that an Act of the Scottish Parliament which provided, contrary to existing case law, that asbestos-related pleural plaques were actionable, was not incompatible with insurers' property rights and was accordingly not outside the legislative competence of that Parliament. See also the Damages (Asbestos-related Conditions) Act (Northern Ireland) 2011.

¹⁰¹⁷ *Sienkiewicz v Greif (UK) Ltd* [2011] 2 WLR 523 [SC(E)]. See also Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 153, 161.

¹⁰¹⁸ Horsey, K, Rackley, E, *Tort Law*, Second Edition (2011) Oxford University Press, Oxford, 236.

he is liable for the whole of the damage caused, and, if others are also held responsible, they will be liable jointly and severally. In England, the question of any liability in tort for one who has materially increased the risk of a victim's contracting mesothelioma remains a common law controversy. The UK Supreme Court rejected the idea that a different test might apply, which would require a claimant to prove (whether on the basis of doubling of the risk or otherwise) that on the balance of probability the defendant caused or materially contributed to the mesothelioma. The descriptor "material" connoted a degree which was more than minimal. The learned President stated that any room for debate as to the precise basis upon which the House of Lords in *Fairchild* applied the *McGhee* principle to the mesothelioma claims under consideration had been overtaken by the decision of the House in *Barker v Corus UK Ltd*.¹⁰¹⁹

5.5.1 Apportionment between several Defendants or several Causes of Harm

The Court of Appeal *Allen v British Rail Engineering Ltd*¹⁰²⁰ drew five propositions from the case law, the first concerned with liability and the others with quantifying damages:

"(i) The employee will establish liability if he can prove that the employer's tortious conduct made a material contribution to the employee's disability.

(ii) There can be cases where the state of the evidence is such that it is just to recognise each of two separate tortfeasors as having caused the whole of the damage of which the claimant complains; for instance where a passenger is killed as the result of a head on collision between two cars each of which was negligently driven and in one of which he was sitting.

(iii) However in principle the amount of the employer's liability will be limited to the extent of the contribution which his tortious conduct made to the employee's disability.

(iv) The court must do the best it can on the evidence to make the apportionment and should not be astute to deny the claimant relief on the basis that he cannot establish with demonstrable accuracy precisely what proportion of his injury is attributable to the defendant's tortious conduct.

¹⁰¹⁹ [2011] 2 WLR 523, 537-538, per Lord Phillips of Worth Matravers PSC.

¹⁰²⁰ *Allen v British Rail Engineering Ltd* [2001] EWCA Civ 242.

(v) The amount of evidence which should be called to enable a judge to make a just apportionment must be proportionate to the amount at stake and the uncertainties which are inherent in making any award of damages for personal injury.”¹⁰²¹

Usually apportionment cannot arise in cases of indivisible (not cumulative) injury.¹⁰²² Where the injury to the plaintiff is indivisible, the general rule is that “*any tortfeasor whose act has been a proximate cause of the injury must compensate for the whole of it. As between the plaintiff and the defendant it is immaterial that there are others whose acts also have been a cause of the injury*”.¹⁰²³ This general rule does not pertain in cases to which the Fairchild exception applies.¹⁰²⁴

5.5.1.1 Implications for Pharmacists

Many of the cases have recurrent themes of exposure to a noxious agent through periods of either employment or self-employment. It is possible to envisage a situation in which the proprietors of several pharmacies could become potentially liable to a pharmacist who had been, at various times, an employee or self-employed (as a *locum tenens*) through occupational exposure to a known allergen or carcinogen, for example, in magisterial compounding. It is submitted that the range of possible ‘material contribution’ scenarios in which several pharmacies might become liable to a patient is more limited, as the ‘but-for’ test will usually be applicable. However, one such situation would appear plausible, namely, a drug-disease interaction in which the patient has developed gradually an adverse reaction to one or more medicinal products that had been supplied by several pharmacies over a prolonged period; the claimant being unable to pinpoint a particular defendant as responsible for the injury.

¹⁰²¹ *Allen v British Rail Engineering Ltd* [2001] EWCA Civ 242, [20], per Schiemann LJ (for the Court).

¹⁰²² See Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 425. Mesothelioma is an example of indivisible injury, since mesothelioma (as opposed to asbestosis) cannot be attributed to a particular exposure. Psychiatric injury is also usually indivisible.

¹⁰²³ *Dingle v Associated Newspapers Ltd* [1961] 2 QB 162, 188-189, per Devlin LJ. At [189], Devlin LJ continued (immediately): “*and it does not matter whether those others have or have not a good defence. These factors would be relevant in a claim between tortfeasors for contribution, but the plaintiff is not concerned with that; he can obtain judgment for total compensation from anyone whose act has been a cause of his injury.*”

¹⁰²⁴ See *Charlesworth and Percy*, *loc cit*. See also Green, S, *Winner takes all* (2004) 120 Law Quarterly Review 566, 567-568.

5.5.2 Causation in Other Claims for Personal Injury

The trial judge, in *Bailey v Ministry of Defence*,¹⁰²⁵ found that the Ministry's negligent lack of care and the non-negligent pancreatitis both materially contributed to cardiac arrest. This was a 'cumulative causes' case, where medical science could not establish the probability that but for a particular act of negligence the injury would not have occurred, but could establish that the contribution of the negligent cause was material or something more than negligible.

In the 'vaccine case', *Best v Wellcome Foundation Ltd*,¹⁰²⁶ The Supreme Court allowed the plaintiff's appeal, directing a retrial in relation to the issue of damages as between the plaintiff and the first defendant and dismissing the appeal as against the remaining defendants.¹⁰²⁷ On appeal, it was held that the trial judge's conclusion that the first defendant had been negligent in releasing the vaccine was supported by the evidence before him and should not be disturbed. Finlay CJ said that it was undoubtedly clear "*that the establishment of one link in a chain of causation could never make good a failure to establish a further necessary link.*"¹⁰²⁸ Setting aside inferences drawn by the trial judge from circumstantial evidence, the Supreme Court held that neither the presence nor the absence of entries in the GP's diary constituted sufficiently probative evidence of the date of the first seizure to displace the clear-cut evidence of the plaintiff's parents. The Supreme Court held that the first seizure suffered by the plaintiff occurred on the evening of the day upon which he received the first injection, and that the plaintiff's condition was, accordingly, caused by the pertussis vaccine.

O'Flaherty J said it was clear that not every injury from a vaccine will give rise to a cause of action. He stressed the importance of noting that the case concerned "*a batch of vaccine which in the United States of America is referred to as a 'hot lot' - one that on the findings in this case had a potency and toxicity beyond the recommended levels.*"¹⁰²⁹ In *Best*, O'Flaherty J¹⁰³⁰ referred to *Wilsher v Essex Area Health Authority*¹⁰³¹, where Lord Bridge of Harwich, giving the unanimous judgment, stated that a view in *McGhee v National Coal Board*¹⁰³² that the burden of proof of

¹⁰²⁵ *Bailey v Ministry of Defence* [2009] 1 WLR 1052 (CA).

¹⁰²⁶ *Best v Wellcome Foundation Ltd* [1993] 3 IR 421 (Sup Ct).

¹⁰²⁷ The other defendants were the plaintiff's GP, the Southern Health Board, the Minister for Health, Ireland and the Attorney General. The events at the kernel of the case took place during 1969. Under the Health Act 1970, the Southern Health Board became the successor to Cork County Council, Cork Health Authority and Kerry County Council.

¹⁰²⁸ [1993] 3 IR 421, 470, per Finlay CJ.

¹⁰²⁹ [1993] 3 IR 421, 479, per O'Flaherty J.

¹⁰³⁰ [1993] 3 IR 421, 488, per O'Flaherty J.

¹⁰³¹ *Wilsher v Essex Area Health Authority* [1988] AC 1074 (HL).

¹⁰³² *McGhee v National Coal Board* [1973] 1 WLR 1.

causation should be reversed ran counter to another decision of the House of Lords in *Bonnington Castings Ltd v Wardlaw*¹⁰³³ and represented a minority opinion.

5.5.2.1 Application to Pharmacists in Ireland

The factual matrix in the *Best* case dated from a time before the establishment of the General Medical Services (GMS) Scheme in Ireland. Community pharmacists are now involved in some vaccination programmes. While a vaccine's manufacturer will remain the primary target for damages, the community pharmacist must be vigilant for any batch-specific announcements (from the Irish Medicines Board, for example) relating to a vaccine and the pharmacist must ensure proper batch traceability back to the manufacturer to avoid product liability issues.

5.6 Legal Causation and Remoteness of Damage

The 'but for' test "*merely acts as a preliminary filter to eliminate the irrelevant*"¹⁰³⁴ rather than to allocate legal responsibility. When the factually irrelevant causes have been eliminated, "*the inquiry must continue among those causes considered to be factually relevant, to establish whether they are legally relevant to the court's inquiry.*"¹⁰³⁵ Kelley cites *Flower v Adam*¹⁰³⁶ as the conceptual origin of proximate cause.¹⁰³⁷ Remoteness "*operates as a further limiting device, which*

¹⁰³³ *Bonnington Castings Ltd v Wardlaw* [1956] AC 613.

¹⁰³⁴ See Rogers, WVH (Editor), *Winfield & Jolowicz on Tort*, Eighteenth Edition (2010) Sweet & Maxwell, London, 311. See also Pound, R, *Causation* (1957) 67 Yale Law Journal 1, 8, citing Winfield, P, *Torts*, Fourth Edition (1948) Sweet & Maxwell, London, 64. See also Fleming, JG, *Remoteness and Duty: The Control Devices in Liability for Negligence* (1953) 31 The Canadian Bar Review 471, 477. See also Vetri, D, Levine, LC, Vogel, JE, Finley, LM, *Tort Law and Practice*, Third Edition (2006) LexisNexis, Newark (NJ), 438. Vetri and co-authors emphasise the importance of carefully distinguishing between the conceptual tests for causation and the proof necessary to satisfy the tests.

¹⁰³⁵ See McMahon, B, Binchy, W, *op cit*, 64. See also Moore, M, *Causation and Responsibility: An Essay in Law, Morals, and Metaphysics* (2009) Oxford University Press, Oxford, 83. See Broadbent, A, *Fact and Law in the Causal Inquiry* (2009) 15 Legal Theory 173, 173. See also Fleming, JG, *op cit*, 477 (n 10). [Some torts have their own peculiar rules of limitation of liability, e.g., *Peek v Gurney* (1873) LR 6 HL 377 (deceit), *Cox v Burbridge* (1863) 143 ER 171 (cattle trespass)]. Insurance law takes a more nuanced approach to causation. See Smith, RL, Simpson, FA, *Causation in Insurance Law* (2006-2007) 48 South Texas Law Review 305. For example, at [308] (emphasis added), "**efficient proximate cause of loss** [is] the peril which sets subsequent perils 'in motion'." See, however, *Co-operators Life Insurance Co v Gibbens*, 2009 SCC 59, Binnie J, *per curiam*, [57]: "*Efforts by insurers to split hairs on causation issues have traditionally been rebuffed as in Re Etherington and The Lancashire and Yorkshire Accident Insurance Co [1909] 1 KB 591 ... The courts do not favour the self-serving isolation of a particular element in a chain of events that should be considered in its entirety.*" See also Owen, DG, *The Five Elements of Negligence* (2007) 35 Hofstra Law Review 1671, 1674.

¹⁰³⁶ *Flower v Adam* (1810) 127 ER 1098 (CP).

¹⁰³⁷ See Kelley, PJ, *Proximate Cause in Negligence Law: History, Theory, and the Present Darkness* (1991) 69 Washington University Law Quarterly 49, 64-67. See also *Flower v Adam* (1810) 127 ER 1098, 1098 (Headnote): "*If the proximate cause of damage be the Plaintiff's unskilfulness, although the primary cause be the misfeasance of the Defendant, he cannot recover.-At least if the mischief be in part occasioned by the*

may exclude liability even where the defendant's conduct clearly did play a necessary part in the claimant's injury."¹⁰³⁸

The courts distinguish between mere conditions and causes: "[m]ere conditions, which are not sufficient to amount to 'the cause' of the event, tend to be inanimate or normal; a cause, on the other hand, is more likely to be a voluntary human act or abnormal¹⁰³⁹ contingency".¹⁰⁴⁰ There is no precise legal rule in this regard: a commonsense approach is required.¹⁰⁴¹

It was suggested by the Court of Exchequer Chamber in 1870 that "once wrongdoing was established, it was irrelevant that the level of damage was greater than could be expected."¹⁰⁴² The dominant approach of the courts, following the decision of the Privy Council in *The Wagon Mound (No 1)*,¹⁰⁴³ is to begin by considering the nature of the damage that actually materialised and ask whether it was reasonably foreseeable.¹⁰⁴⁴ While questions of causation may not be easily

misfeasance of a third person not sued." This has to be one of those rare cases in which the Headnote would appear more instructive than the reported *dicta* of no less a judicial personage than the Lord Chief Justice of England (Mansfield CJ). At 11 words in length (and fairly recounted in the Headnote), the judgment of Lawrence J is unsurprisingly the shorter of the two handed down, although not by a wide margin. See further Kelley, *op cit*, 68, citing *Lynch v Nurdin* (1841) 113 ER 1041 (QB) (The defendant negligently left his horse and cart unattended in the street).

¹⁰³⁸ See Stauch, M, Wheat, K, Tingle, J, *Sourcebook on Medical Law*, Second Edition (2002) Routledge, London, 345; in such circumstances, the factual causation requirement of the 'but for' test will have been satisfied. See *dicta* of Lord Wright in *Monarch Steamship Co Ltd v Karlshamns Oljefabriker (A/B)* [1949] 1 AC 196, 227: "Causation in law does not depend on remoteness or immediacy in time. So it was held in *Leyland Shipping Co Ltd v Norwich Union Fire Insurance Society Ltd* [[1918] AC 350]. ... The maxim *causa proxima non remota spectatur* is either meaningless or misleading until 'remota' and 'proxima' are defined." See Goodhart, AL, *The Unforeseeable Consequences of a Negligent Act* (1930) 39 Yale Law Journal 449, 455-456, citing Street, TA, *The foundations of legal liability: a presentation of the theory and development of the common law*, Volume 1 (1906) Edward Thompson Company, Northport (NY), 91. See also Pound, R, *Causation* (1957) 67 Yale Law Journal 1, 9-10. See *Hadwell v Righton* [1907] 2 KB 345 (Div Ct), 348, per Phillimore J: "Even if the fowl was wrongly upon the highway it would have done no harm but for the wrongful act of the animal of a third person. In the course of endeavouring to avoid one danger it runs into another. And in such a case[.] 'Causa proxima non remota spectatur'."

¹⁰³⁹ See McMahon, B, Binchy, W, *loc cit.* suggesting that weather conditions, so abnormal as to amount to a hurricane, could be found to be 'the cause' of a road traffic collision as opposed to driver negligence.

¹⁰⁴⁰ See McMahon, B, Binchy, W, *op cit*, 65.

¹⁰⁴¹ See McMahon, B, Binchy, W, *loc cit.* See, for example [(n 31)], the case of *Dunne v Clarke Oil Products Ltd*, Irish Times Law Report, 25 November, 1996, where there was a conflict as to whether the collision was caused by worn tyres or driver negligence. The Supreme Court affirmed the High Court's finding that the more probable cause was that the plaintiff driver was driving too fast.

¹⁰⁴² See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill and Macmillan, Dublin, 456. The somewhat unfashionable allegory underlying Quill's reference is contained in *dicta* from the case of *Smith v London and South Western Railway Company* (1870) LR 6 CP 14, 22-23 (Blackburn J).

¹⁰⁴³ *The Wagon Mound (No 1)* [1961] AC 388 (PC). See also Dias, RWM, *Remoteness of Liability and Legal Policy* (1962) 20 Cambridge Law Journal 178, 182.

¹⁰⁴⁴ See Stauch, M, Wheat, K, Tingle, J, *loc cit.* See also Stanton, KM, *The Modern Law of Tort* (1994) Sweet & Maxwell, London, 79-80, stating that, if the damage that occurred was unforeseeable, the plaintiff's claim can be rejected "at any of the stages of the negligence test."

distinguishable from those relating to duty or remoteness of damage, the enquiries into each are “conceptually distinct”.¹⁰⁴⁵

A well-known illustration of a break in the chain of causation is provided by *Knightley v Johns*.¹⁰⁴⁶ A motor car driven negligently by the first defendant overturned in a tunnel. The Court of Appeal found that the police officer (the fourth defendant) who had given the instruction for two motorcycle police officers (one of whom was the plaintiff) to ride against the flow of traffic in the tunnel had been negligent. The fourth defendant had done so without first closing the tunnel to traffic after an accident, as required by a standing police order. That negligence was sufficient to break the chain of causation between the first defendant’s original negligence and the plaintiff’s injuries.

There was clear disagreement in *Kennedy v Hughes Dairies Ltd*¹⁰⁴⁷ between members of the Supreme Court (Hederman and McCarthy JJ, Finlay CJ dissenting) over damage classification. The majority directed a new jury trial on the basis that there was sufficient evidence to enable a jury reasonably to conclude that there had been a foreseeable risk of injury to the plaintiff in the area in which he was injured, because of the nature of his work. Applying *Bradley v CIE*,¹⁰⁴⁸ there had been sufficient evidence to support a conclusion that the absence of the provision of adequate protective gloves by the defendants could have exposed the plaintiff to unnecessary risks of injury. The learned Chief Justice also referred to *Bradley v CIE*; he differed on the application of that decision from position taken by the majority. Quill has suggested that the Chief Justice’s judgment was more in line with established orthodoxy.¹⁰⁴⁹ McCarthy J opined that if *Bradley’s* case were to be construed as excluding any approach other than that specified in *Morton v William Dixon Ltd*,¹⁰⁵⁰ he would await a conclusion to that effect expressed by a full (then five-judge) court. Quill senses that Hederman J’s judgment showed “a desire to bend the principle to accommodate a deserving plaintiff”.¹⁰⁵¹

¹⁰⁴⁵ See Charlesworth and Percy, *op cit*, 421.

¹⁰⁴⁶ *Knightley v Johns* [1982] 1 WLR 349 (CA). The second defendant was the driver of the vehicle that collided with the plaintiff’s motorcycle. The third defendant was the Chief Constable who was the fourth defendant’s superior officer.

¹⁰⁴⁷ *Kennedy v Hughes Dairies Ltd* [1989] ILRM 117.

¹⁰⁴⁸ *Bradley v CIE* [1976] IR 217.

¹⁰⁴⁹ Finlay CJ cited both *Morton v William Dixon Ltd* 1909 SC 807 and *Paris v Stepney Borough Council* [1951] AC 367, while the majority judgments did not cite either of those cases.

¹⁰⁵⁰ 1909 SC 807.

¹⁰⁵¹ Quill, *op cit*, 459.

Remoteness was analysed in *Egan v Sisk*.¹⁰⁵² The case concerned future loss of profits due to the destruction of business chattels, namely, mail order brochures stored in a warehouse, flooded due to the negligence of the defendant. The defendant contended that it was unforeseeable that the loss of the brochures would have resulted in such a large claim for loss of profits and that the plaintiffs would not have succeeded in getting the brochures reprinted in time to exploit the Christmas market. Carroll J gave judgment for the plaintiffs. She held that economic losses (and possible loss of profits) through negligence in relation to goods stored in a warehouse (part of the commercial world) are foreseeable.¹⁰⁵³ The economic consequences of the loss of the brochures were immediately predictable at the time of the damage. In the circumstances, the court accepted that the plaintiff had made all reasonable attempts to mitigate loss, albeit those attempts had not met with success (it was irrelevant that the plaintiff's inability to mitigate loss had been unforeseeable). It is submitted that in the twenty-first century commercial environment, with low-cost possibilities for Internet marketing and sales, it would be difficult to make out a convincing case to encompass damages of similar magnitude to those awarded in *Egan v Sisk*.

The 'first round' in the celebrated *The Wagon Mound* litigation came before the Judicial Committee of the Privy Council as *Overseas Tankship (UK) Ltd v The Miller Steamship Co Pty*.¹⁰⁵⁴ Applying the test of foreseeability, it was held that the appellants could not reasonably be expected to have known that the oil discharged from their wharf into harbour waters would catch fire, were not liable for the damage.¹⁰⁵⁵

In *The Wagon Mound (No 2)*¹⁰⁵⁶ the Privy Council held the act complained of (equivalent to creating a danger to persons or property on a highway) fell in the class of nuisance in which foreseeability was an essential element in determining liability. It was not sufficient that the injury suffered by the respondents' vessels was the direct result of the nuisance if that injury was in the relevant sense unforeseeable. The Judicial Committee gave this clarification:

¹⁰⁵² *William Egan & Sons Ltd v John Sisk & Sons Ltd* [1986] ILRM 283 (HC), Carroll J.

¹⁰⁵³ See also Quill, *op cit*, 460-461, noting that a distinction between foreseeability of the 'type' (as opposed to the 'extent') of damage was expressly rejected in *In re Polemis and Furness Withy & Co Ltd* [1921] 3 KB 560, 571-572, per Bankes J.

¹⁰⁵⁴ *Overseas Tankship (UK) Ltd v The Miller Steamship Co Pty* [1961] AC 388 (*The Wagon Mound*).

¹⁰⁵⁵ *In re Polemis and Furness Withy & Co Ltd* [1921] 3 KB 560 was not followed. The order of the Supreme Court of New South Wales, so far as it related to damage caused by negligence, was reversed, but action remitted for that court to deal with it so far as it related to damage caused by nuisance.

¹⁰⁵⁶ *Overseas Tankship (UK) Ltd v The Miller Steamship Co Pty* [1967] AC 617 [*The Wagon Mound (No 2)*]. The Judicial Committee's Advice was delivered by Lord Reid, who along with Lord Morris of Borth-y-Gest, was a member of the Panel that adjudicated on *The Wagon Mound*.

“Negligence is not an essential element in nuisance. Nuisance is a term used to cover a wide variety of tortious acts or omissions and in many[,] negligence in the narrow sense is not essential. ... [A]lthough negligence may not be necessary, fault of some kind is almost always necessary and fault generally involves foreseeability”.¹⁰⁵⁷

The *Wagon Mound (No 2)* has been approved in Ireland in *Wall v Morrissey*.¹⁰⁵⁸

5.6.1 The Thin-Skull Rule

The case of *Dulieu v White*¹⁰⁵⁹ is authority for the proposition that damages which result from a nervous shock occasioned by fright unaccompanied by any actual impact may be recoverable in an action for negligence if physical injury has been caused to the plaintiff. The facts of *Smith v Leech Brain & Co Ltd*¹⁰⁶⁰ were these: a workman received a burn on his lip from a piece of molten metal that fell upon him, when he turned around to look at what he was doing, outside the area of protective screening provided by his employer. The burn triggered a cancer at the burn site, from which he died some three years later. The cancer developed in tissues which already had a pre-malignant condition. The court held that the risk that eventuated was one which any reasonable employer should have foreseen and the defendants, in that they had failed to provide adequate protection, were negligent.

Lord Parker CJ opined: *“For my part, I am quite satisfied that the Judicial Committee in the Wagon Mound case did not have what I may call, loosely, the thin skull cases in mind. It has always been the law of this country that a tortfeasor takes his victim as he finds him.”*¹⁰⁶¹ On the test of foreseeability, the learned Chief Justice said the following:

“The test is not whether these employers could reasonably have foreseen that a burn would cause cancer and that he would die. The question is whether these employers could reasonably foresee the type of injury he suffered, namely, the

¹⁰⁵⁷ [1967] AC 617, 639, per Lord Reid. See also Stauch, M, Wheat, K, Tingle, J, *Sourcebook on Medical Law*, Second Edition (2002) Routledge, London, 345-346, citing *obiter dicta* by Beldam LJ in *Brown v Lewisham and North Southwark Health Authority* [1999] Lloyd's Rep Med 110 on the *“public policy of limiting the liability of tortfeasors by the control mechanism of foreseeability”*.

¹⁰⁵⁸ See *Wall v Morrissey* [1969] IR 10 (Sup Ct), 15, *dicta* of Walsh J, adopting the reasoning of Lord Reid in *The Wagon Mound (No 2)*.

¹⁰⁵⁹ *Dulieu v White* [1901] 2 KB 669 (Div Ct), Kennedy and Phillimore JJ.

¹⁰⁶⁰ [1962] 2 WLR 148 (QBD).

¹⁰⁶¹ See *Smith v Leech Brain & Co Ltd* [1962] 2 WLR 148, 155, per Lord Parker CJ.

burn. What, in the particular case, is the amount of damage which he suffers as a result of that burn depends upon the characteristics and constitution of the victim.

Accordingly, I find that the damages which the widow claims are damages for which the defendants are liable.”¹⁰⁶²

Quill distils from the foregoing *dicta* that only the initial injury need be foreseen by the defendant for liability to be imposed.¹⁰⁶³ The decision in *Smith v Leech Brain & Co Ltd* was cited with approval in *Burke v John Paul & Co Ltd*.¹⁰⁶⁴ Budd J delineated the defendant’s sphere of responsibility:

“It cannot, I think, be suggested that it is necessary to have the statement of a medical expert that an employer should know that if one of his employees is forced to use great exertion in the course of his work that may cause a straining, or even a tearing, of muscles, as that is a matter of common knowledge; but the point taken is that it could not be reasonably anticipated that a hernia would result without knowledge that the plaintiff had a predisposition to hernia. The answer to this, I think, is what is generally referred to as ‘the egg-shell skull rule’ and I do not think that that rule has been impugned in any way by the Wagon Mound¹⁰⁶⁵ decision.”¹⁰⁶⁶

Quill suggests that there are two possible interpretations of these kinds of cases¹⁰⁶⁷:

- (1) Injuries of a foreseeable type, with the extent of injury being greater than could have been foreseen;
- (2) Where a reasonably foreseeable injury combines with an existing weakness in the plaintiff to cause a separate and unforeseeable injury and the defendant is liable for the second injury.¹⁰⁶⁸

The second scenario finds support in the later decisions. For example, in *McCarthy v Murphy*,¹⁰⁶⁹ McCracken J said this:

¹⁰⁶² See *Smith v Leech Brain & Co Ltd* [1962] 2 WLR 148, 156, per Lord Parker CJ.

¹⁰⁶³ See also Quill, *op cit*, 461.

¹⁰⁶⁴ *Burke v John Paul & Co Ltd* [1967] IR 277 (Sup Ct).

¹⁰⁶⁵ [1961] AC 388 (*The Wagon Mound*).

¹⁰⁶⁶ *Burke v John Paul & Co Ltd* [1967] IR 277, 283, per Budd J.

¹⁰⁶⁷ See also Quill, *op cit*, 462. *Burke v John Paul* is an example of the first kind and *Smith v Leech Brain* is an illustration of the second.

¹⁰⁶⁸ See also *Reeves v Carthy & O’Kelly* [1984] 1 IR 348 (Sup Ct), which supports the second, broader, view of the defendant’s responsibility.

*“I am of the view, on the medical evidence, that the immediate cause of the Plaintiff’s depression was the soft tissue injury which she suffered in the accident. Of course the Defendant could not have anticipated that she was a person with a pre-disposition to depression, but he could have reasonably foreseen a soft tissue injury, and that being so, he is liable for damage which flows from that injury, as he has to take the Plaintiff as he finds her.”*¹⁰⁷⁰

5.6.1.1 The Impecunious Plaintiff

Factual matrices embracing “the defendant’s tort and the plaintiff’s financial frailty” do not seem apt to the sphere of relationships between health professionals and their patients. Accordingly, it is not proposed to go further into this topic in the thesis text.¹⁰⁷¹

5.6.2 Intervening Causes

5.6.2.1 The independent act of a third party

It may sometimes be shown that the claimant’s damage has resulted from the act of another person independent of the defendant.¹⁰⁷² It has been elusive to find a “comprehensive test to assist in distinguishing situations where the intervening cause extinguishes the defendant’s responsibility from those where it does not”.¹⁰⁷³ The name, *novus actus interveniens*, describes what is required: the modern practice is to name it (literally) in English, a ‘new intervening act’.

¹⁰⁶⁹ *McCarthy v Murphy* [1998] IEHC 23 (McCracken J).

¹⁰⁷⁰ [1998] IEHC 23, [11], per McCracken J. Quill, *op cit*, 462-463, remarks that the psychological injury, in the absence of physical injury, would have been unforeseeable and therefore redress in negligence would have been unobtainable.

¹⁰⁷¹ See Quill, *op cit*, 463-464. See also *Doran v Delaney (No 2)* [1999] IR 303 (HC), 315, per Geoghegan J: “[W]hile the prima facie measure of damages is that set forth in *Ford v White & Co* [1964] 1 WLR 885 as cited above and as approved by the former President in [*Taylor v Ryan (Unreported, High Court, Finlay P, 10 March, 1983)*] this measure is not appropriate where it would be reasonably foreseeable that the person damaged would as a consequence of impecuniosity have been unable to mitigate the loss until recouped by the offending party.” The cases of *Muhammad Issa el Sheikh Ahwad v Ali* [1947] AC 414; *Monarch Steamship Co Ltd v Karlshamns Oljefabriker (A/B)* [1949] AC 196; *Perry v Sidney Phillips & Son* [1982] 1 WLR 1297; *Quinn v Quality Homes Ltd* [1976-7] ILRM 314; *Riordan’s Travel v Acres* [1979] ILRM 3, were considered. The High Court declined to follow *Liesbosch Dredger (Owners of) v Owners of SS Edison, The Liesbosch* [1933] AC 449 (HL).

¹⁰⁷² See Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 430. See also *Rahman v Arearose Ltd* [2000] 3 WLR 1184 (CA), 1198, where Laws LJ stated: “It is true that the idea of a supervening cause—*novus actus interveniens*—is generally deployed in cases where it is suggested that the first tortfeasor should bear responsibility for the effects of the second tort, and this is not such a case.”

¹⁰⁷³ *Charlesworth and Percy, loc cit.*

*“Certain well-known formulæ are invoked, such as that the chain of causation was broken and that there was a novus actus interveniens. These phrases, sanctified as they are by standing authority, only mean that there was not such a direct relationship between the act of negligence and the injury that the one can be treated as flowing directly from the other. Cases have been cited which show great difference of opinion on the true answer in the various circumstances to the question whether the damage was direct or too remote.”*¹⁰⁷⁴

The case of *Hayes v Minister for Finance*¹⁰⁷⁵ recites a useful summary of the law from McMahon and Binchy on the kind of actions which may amount to a *novus actus interveniens* by a third party:

"From the case law we may state the following propositions with some degree of confidence:

(1) If the third party's act is wholly unforeseeable then the original defendant will not be liable

(2) If the third party's act is intended by the original wrongdoer, or is as good as programmed by him, or if it is an inevitable response to the defendant's act or is very likely, then the original defendant is still considered to be the operative cause in law. The third party's intervention in these circumstances is not a novus actus which will break the chain of causation between the plaintiff's damage and the defendant's conduct. This is even more obviously true where the intervening event is not a voluntary act at all: where A pushes B against C.

(3) If the third party's action is foreseeable (though not probable or likely) then the courts will look especially closely at the nature of the intervenor's act in addressing this problem. If the intervenor's act is criminal or reckless in the subjective sense, then it is likely to be considered as a novus actus. Similarly if the third party's act is intentional. ... If the intervenor's act, however, is merely careless, negligent, or perhaps even grossly negligent, it may not be considered sufficiently strong to break the chain of causation between the original defendant and the plaintiff's injury, although much will depend on the facts of the case. In

¹⁰⁷⁴ *The Oropesa* [1943] P 32 (CA), 36, per Lord Wright.

¹⁰⁷⁵ *Hayes v Minister for Finance* [2007] 3 IR 190 (Sup Ct).

Crowley (inf) v AIB Ltd [1987] IR 282 we have seen that a negligent omission by the third party was deemed sufficient to break the chain and relieve the defendant."¹⁰⁷⁶

McMahon and Binchy state: "... that the courts are less likely to find that a *novus actus* is the sole cause of the plaintiff's injury nowadays. It is only in very extreme cases that the nature of the third party's act will break the chain completely between the defendant's original conduct and the plaintiff's damage."¹⁰⁷⁷ Hodgson suggests that courts have "tended to prefer a contributory negligence approach in road accident cases (in which the plaintiff victim is allowed recovery of reduced damages) over a *novus actus* approach (which would deprive the plaintiff of any recovery)."¹⁰⁷⁸

"Not surprisingly",¹⁰⁷⁹ the intervening act of the defendant himself was not allowed to break the chain of causation in the case of *Coudert Brothers v Normans Bay Ltd.*¹⁰⁸⁰ The claimant was denied an investment opportunity in a Russian company when a Russian court declared invalid its tender offering a five-year investment period; a maximum three-year term had been decreed by the Russian government. It sued the defendants for loss of chance. The defendants claimed, in relation to the assessment of the chance that the transaction failed for a cause independent of the pleaded negligence, namely, the defendant's own failure to seek anti-monopoly permission, which broke the chain of causation. The Court of Appeal, "[i]n the absence of authority directly on the point ... appealed to public policy".¹⁰⁸¹

¹⁰⁷⁶ See *Hayes v Minister for Finance* [2007] 3 IR 190 (Sup Ct), 206-207, per Kearns J, citing McMahon, B, Binchy, W, *Irish Law of Torts*, Third Edition (2000) Butterworths, Dublin, 77. McMahon and Binchy go on to suggest that the courts in recent times are more likely to settle for a 'multiple-cause' finding and apportion losses between concurrent wrongdoers.

¹⁰⁷⁷ McMahon and Binchy, *op cit*, 78.

¹⁰⁷⁸ Hodgson, D, *The Law of Intervening Causation* (2008) Ashgate Publishing, Aldershot, 250.

¹⁰⁷⁹ *Charlesworth and Percy*, *op cit*, 431.

¹⁰⁸⁰ *Coudert Brothers v Normans Bay Ltd* [2004] EWCA Civ 215. See in particular, Para [46], per Waller LJ: "Damages would flow from the original act of negligence; why should Coudert be allowed to rely on a further act of negligence to reduce that damage?" See also *Bolitho v City and Hackney Health Authority* [1998] AC 232, 240, per Lord Browne-Wilkinson: "Dr. Horn could not escape liability by proving that she would have failed to take the course which any competent doctor would have adopted. A defendant cannot escape liability by saying that the damage would have occurred in any event because he would have committed some other breach of duty thereafter."

¹⁰⁸¹ See Hodgson, J, Lewthwaite, J, *Tort Law*, Second Edition (2007) Oxford University Press, Oxford, 60.

5.6.2.2 *The intervening act of the claimant*

In the language of late 1942, “[t]he plaintiff’s damage may still be the direct and natural consequence of the defendant’s default, notwithstanding the co-operation of human conduct, whether of the plaintiff or of a third party.”¹⁰⁸²

There is no intervening cause where a person, injured by the defendant’s negligence commits suicide, where that is ultimately a consequence of his injury.¹⁰⁸³ In *Corr v IBC Vehicles*,¹⁰⁸⁴ Lord Bingham said:

*“I have given for holding the suicide of the deceased not to be a novus actus I would find it impossible to hold that the damages attributable to the death were rendered too remote because the deceased’s conduct was unreasonable. It is of course true that, judged objectively, it is unreasonable in almost any situation to take one’s own life. But once it is accepted, as it must be, that the deceased’s unreasonable conduct was induced by the breach of duty of which the claimant complains, the argument ceases in my judgment to have any independent validity.”*¹⁰⁸⁵

Contributory negligence may be a factor, particularly in suicide cases. The Court of Appeal in *Spencer v Wincanton Holdings Ltd*¹⁰⁸⁶ (a successive injuries case) unanimously rejected the defendant’s appeal on liability (for the first injury) and upheld the trial judge’s reduction in damages for contributory negligence (for the second, self-caused, injury).¹⁰⁸⁷

The claimant has a duty “to act reasonably”¹⁰⁸⁸ to mitigate loss/damage. A distinction is drawn between “failure to mitigate damage already occasioned; and damage which probably would not have resulted at all had it not been for the claimant’s failure, by act or omission, to prevent or mitigate loss.”¹⁰⁸⁹ Where a plaintiff had refused medical treatment the burden lay on the defendant to prove that the refusal was unreasonable and thus constituted a failure by the

¹⁰⁸² *Summers v Salford Corporation* [1943] AC 283, 296, per Lord Wright. The “direct and natural consequence” approach is traced from *In re Polemis and Furness Withy & Co Ltd* [1921] 3 KB 560.

¹⁰⁸³ *Charlesworth and Percy*, *op cit*, 436-437.

¹⁰⁸⁴ *Corr v IBC Vehicles* [2008] 1 AC 884. See also Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 171, 173.

¹⁰⁸⁵ *Corr v IBC Vehicles* [2008] AC 884, 905, per Lord Bingham of Cornhill.

¹⁰⁸⁶ *Spencer v Wincanton Holdings Ltd* [2009] EWCA Civ 1404.

¹⁰⁸⁷ See Hughes, K, *Causation: Is it Fair?* (2010) 69 *The Cambridge Law Journal* 228, 228. In the County Court, Judge Bullimore held that the defendant was liable for the second injury and he reduced damages by one third to reflect the claimant’s negligence.

¹⁰⁸⁸ *Charlesworth and Percy*, *op cit*, 437.

¹⁰⁸⁹ *Charlesworth and Percy*, *loc cit*.

plaintiff to mitigate the damage sustained.¹⁰⁹⁰ What is reasonable mitigation of damage is a question of fact (not law).¹⁰⁹¹

5.6.2.3 Failure of an expected act to occur

The topic of reasonable expectation for the conduct of an intermediate examination of goods is covered adequately in the Product Liability Chapter.

5.6.3 Unknown Causes

It is unnecessary for the claimant to give direct evidence of negligence.¹⁰⁹² A case may be proved partly by direct and partly by indirect (circumstantial) evidence,¹⁰⁹³ on facts which are “*beyond a mere surmise or conjecture*”.¹⁰⁹⁴

5.6.4 Concurrent and Successive Causes

5.6.4.1 Concurrent Causes

When separate and independent acts of negligence on the part of two or more persons together result in an accident, any one of which probably would have caused the damage, then each tortfeasor will be liable for the full damage suffered. Each negligent act is a substantive cause in producing the end result.¹⁰⁹⁵

¹⁰⁹⁰ *Geest plc v Lansiquot* [2002] 1 WLR 3111 (PC). See further *Geest plc v Lansiquot* [2002] 1 WLR 3111 (PC), 3116, per Lord Bingham of Cornhill: “*The ruling of the Board in [Selvanayagam v University of the West Indies [1983] 1 WLR 585 (PC)] that the burden lies on a plaintiff who has refused medical treatment to prove that his refusal was reasonable provoked immediate criticism*”. On *novus actus interveniens* and contributory negligence, see *Reeves v Carthy & O’Kelly* [1984] 1 IR 348 (Sup Ct), 367, per Griffin J: “*On behalf of Dr. Carthy, [the First Defendant, it was] submitted that, even assuming negligence on the part of Dr. Carthy, this did not lead to the stroke because Dr. O’Kelly [the Second Defendant] did fully examine the plaintiff later and his intervention broke the chain of causation. In my view, the intervention of Dr. O’Kelly was not novus actus interveniens. He, if at all, merely contributed an additional act of negligence. Dr. Carthy’s original negligence continued to operate until the stroke occurred around midday. The refusal of the plaintiff to accept Dr. O’Kelly’s advice to go to hospital may be a good ground for alleging contributory negligence, but it was not novus actus.*”

¹⁰⁹¹ *Charlesworth and Percy*, *op cit*, 438.

¹⁰⁹² *Charlesworth and Percy*, *loc cit*.

¹⁰⁹³ *Charlesworth and Percy*, *loc cit*. See also *Jones v Great Western Railway* (1930) 47 TLR 39, 41, per Lord Buckmaster: “*It is a mistake to think that because an event is unseen its cause cannot reasonably be inferred.*”

¹⁰⁹⁴ *Charlesworth and Percy*, *op cit*, 440.

¹⁰⁹⁵ *Charlesworth and Percy*, *op cit*, 442.

5.6.4.2 Successive Causes

Successive acts of negligence cause consecutive damage: remoteness of damage can become an issue.¹⁰⁹⁶ In *Baker v Willoughby*,¹⁰⁹⁷ Lord Pearson advocated taking “a comprehensive and unitary view”¹⁰⁹⁸ of the damage caused by the original accident:

*“Itemisation of the damages by dividing them into heads and sub-heads is often convenient, but is not essential. In the end judgment is given for a single lump sum of damages and not for a total of items set out under heads and sub-heads. The original accident caused what may be called a ‘devaluation’ of the plaintiff, in the sense that it produced a general reduction of his capacity to do things, to earn money and to enjoy life. For that devaluation the original tortfeasor should be and remain responsible to the full extent, unless before the assessment of the damages something has happened which either diminishes the devaluation (e.g. if there is an unexpected recovery from some of the adverse effects of the accident) or by shortening the expectation of life diminishes the period over which the plaintiff will suffer from the devaluation. If the supervening event is a tort, the second tortfeasor should be responsible for the additional devaluation caused by him.”*¹⁰⁹⁹

The emergent knowledge of the claimant’s debilitating illness (myelopathy) led to the award of reduced damages in *Jobling v Associated Dairies*.¹¹⁰⁰ It was held that, in assessing damages, the myelopathy could not be disregarded since the court must provide compensation that is not excessive, taking all factors into account. In comparing the situation resulting from the accident with the situation had there been no accident, the court had to recognise that the supervening illness would have overtaken the plaintiff in any event.¹¹⁰¹

Regarding the non-application of *Baker v Willoughby*, their Lordships were “untrammelled by precedent.”¹¹⁰² Lord Edmund-Davies then referred to: “the long-established and eminently reasonable principle that the onset or emergence of illness is one of the vicissitudes of life relevant to the assessment of damages.”¹¹⁰³

¹⁰⁹⁶ *Charlesworth and Percy, op cit*, 443.

¹⁰⁹⁷ *Baker v Willoughby* [1970] AC 467 (HL).

¹⁰⁹⁸ *Baker v Willoughby* [1970] AC 467, 496, per Lord Pearson.

¹⁰⁹⁹ *Baker v Willoughby, loc cit*.

¹¹⁰⁰ *Jobling v Associated Dairies* [1982] AC 794.

¹¹⁰¹ See also *Charlesworth and Percy, op cit*, 444.

¹¹⁰² [1982] AC 794, 809, per Lord Edmund-Davies.

¹¹⁰³ [1982] AC 794, 809, per Lord Edmund-Davies.

The Court of Appeal said in *Rahman v Arearose Ltd*¹¹⁰⁴ that “[t]he law is that every tortfeasor should compensate the injured claimant in respect of that loss and damage for which he should justly be held responsible. To make that principle good, it is important that the elusive conception of causation should not be frozen into constricting rules.”¹¹⁰⁵ Laws LJ observed that the decisions in *Baker* and *Jobling* were not at odds:

“Although the reasoning in Jobling's case involved the raising of some judicial eyebrows as to the approach taken by the House in Baker's case, with great respect I see no inconsistency whatever between the two cases. Once it is recognised that the first principle is that every tortfeasor should compensate the injured claimant in respect of that loss and damage for which he should justly be held responsible, the metaphysics of causation can be kept in their proper place”.¹¹⁰⁶

Operation of the vicissitudes principle and the *Baker* and *Jobling* decisions were considered by O’Neill J in *RL v The Minister for Health and Children*,¹¹⁰⁷ where he said that the occurrence of a natural illness was one of the vicissitudes of life to be considered in the assessment of future loss. The learned judge also pinpointed an area of the law that had been left open by the Supreme Court:

*“Amongst the events listed by Griffin J in Reddy v Bates*¹¹⁰⁸ *was that of ‘accident’... That case however did not deal at all with the question of whether tortiously caused accidents were to be regarded in the same way as the other vicissitudes of life. Logically it would seem hard to argue against the inclusion of tortiously caused accidents.”*

¹¹⁰⁴ *Rahman v Arearose Ltd* [2000] 3 WLR 1184 (CA).

¹¹⁰⁵ [2000] 3 WLR 1184 (CA), 1198, per Laws LJ.

¹¹⁰⁶ [2000] 3 WLR 1184 (CA), 1199, per Laws LJ.

¹¹⁰⁷ *RL v The Minister for Health and Children* [2001] 1 IR 744 (HC), O’Neill J. See, in particular, [756], where, *inter alia*, the learned judge stated: “Where a claimant has suffered injuries from two or more successive and independent tortious acts, policy should lean against the application of any rule or principle which would have the effect of preventing a claimant from being fully compensated for the aggregate effects of all his injuries. Hence the necessity in my view to remove subsequent tortious acts from the list of life's vicissitudes.”

¹¹⁰⁸ *Reddy v Bates* [1983] IR 141 (Sup Ct).

5.7 Principle of *Res Ipsa Loquitur*

The principle arose first in *Byrne v Boadle*,¹¹⁰⁹ although that case was soon overshadowed. Counsel for the defendants sought to distinguish *Scott v The London and St Katherine Docks Company*,¹¹¹⁰ from that of *Byrne v Boadle* (concerning an accident on a public highway), because in *Scott*, the public had no right to walk in front of the warehouses. From the general import of the Chief Justice's judgment, the attempted distinction must be taken to have failed:

*"There must be reasonable evidence of negligence. But where the thing is sh[ow]n to be under the management of the defendant or his servants, and the accident is such as in the ordinary course of things does not happen if those who have the management use proper care, it affords reasonable evidence, in the absence of explanation by the defendants, that the accident arose from want of care."*¹¹¹¹

Particular aspects of *res ipsa loquitur* have been covered elsewhere in this thesis.

The question whether to apply the axiom has usually arisen "*where the claimant is able to prove the happening of an accident but little else.*"¹¹¹² The Court of Appeal set, in *Ratcliffe v Plymouth and Torbay Health Authority*,¹¹¹³ the context for the application of *res ipsa loquitur* in medical negligence cases:

"Medical negligence cases often involve factual questions of complexity and difficulty and require the evaluation of highly technical and conflicting expert evidence but the trial procedure is essentially the same as in other cases. Indeed, the judge will normally have the advantage of expert evidence on both sides and an appropriate level of factual evidence both documentary and oral. Medical negligence cases are unlikely to give rise to the stark problems encountered in road traffic accident cases where there may be a total dearth¹¹¹⁴ of evidence or where one or other side may choose, no doubt for tactical reasons, not to present evidence. In my judgment the leading cases already give sufficient guidance to

¹¹⁰⁹ *Byrne v Boadle* (1863) 159 ER 299.

¹¹¹⁰ *Scott v The London and St Katherine Docks Company* (1865) 159 ER 665.

¹¹¹¹ (1865) 159 ER 665, 667, per Erle CJ.

¹¹¹² *Charlesworth and Percy*, *op cit*, 443.

¹¹¹³ *Ratcliffe v Plymouth and Torbay Health Authority* [1998] EWCA Civ 2000.

¹¹¹⁴ The cause must be unknown. See *Bolton v Stone* [1950] AC 850, 859 (Lord Porter). See also *Barkway v South Wales Transport Co Ltd* [1950] 1 All ER 392, 394 (Lord Porter). (The court had before it evidence that the system of vehicle tyre inspection was negligent; *res ipsa loquitur* did not apply in those circumstances). See also *Barkway v South Wales Transport Co Ltd* [1950] 1 All ER 392, 402 (Lord Normand).

*litigators and judges about the proper approach to the drawing of inferences and if I were to say anything further it would be confined to suggesting that **the expression res ipsa loquitur should be dropped from the litigator's vocabulary and replaced by the phrase a prima facie case.***¹¹¹⁵ *Res ipsa loquitur is not a principle of law*¹¹¹⁶: *it does not relate to or raise any presumption. It is merely a guide to help to identify when a prima facie case is being made out. Where expert and factual evidence has been called on both sides at a trial[,] its usefulness will normally have long since been exhausted.*¹¹¹⁷

In the previous quotation, general facets of the maxim, *res ipsa loquitur* have been annotated.

5.7.1 Rebuttal of negligence

Rebuttal of a prima facie case does not require the defendant to prove how the accident happened:

*"I think that, if the defenders can show a way in which the accident may have occurred without negligence, the cogency of the fact of the accident by itself disappears, and the pursuer is left as he began, namely, that he has to show negligence. I need scarcely add that the suggestion of how the accident may have occurred must be a reasonable suggestion."*¹¹¹⁸

It is not enough for the defendants merely to show that the accident could have happened without negligence on their part: they must show that they have taken all reasonable precautions to ensure that the accident did not happen.¹¹¹⁹

5.7.2 Reasonable explanation

Whether negligence is proved is a question of fact.¹¹²⁰ A reasonable explanation may exculpate a sole defendant or advance the suggestion that a co-defendant or other party has been responsible.¹¹²¹

¹¹¹⁵ Those elements within the *dicta* of Erle CJ [*Scott v The London and St Katherine Docks Company* (1865) 159 ER 665, 667] form the basis of the *prima facie* case.

¹¹¹⁶ See *Barkway v South Wales Transport Co Ltd* [1950] 1 All ER 392, 399, per Lord Normand.

¹¹¹⁷ *Ratcliffe v Plymouth and Torbay Health Authority* [1998] EWCA Civ 2000, per Hobhouse LJ (Emphasis added).

¹¹¹⁸ *Ballard v North British Railway Co* 1923 SC (HL) 43, 45, per Lord Dunedin.

¹¹¹⁹ See *Esso Petroleum Co Ltd v Southport Corporation* [1956] AC 218, 243, per Lord Ratcliffe.

5.7.3 Latent defect

Where the defendant relies upon a latent defect (one which cannot be detected by reasonable skill and care) as explaining some event, there is an evidential burden to establish facts from which such a defect may be inferred.¹¹²² It is not enough merely to establish that a latent defect was probably present; the defendant has to show that the event complained of “*would have occurred, despite all reasonable care having been taken.*”¹¹²³ There is a requirement for full proof: a mere denial will not suffice.¹¹²⁴

5.7.4 Negligence need not be disproved

The defendant need merely neutralize the effect of the presumption, “*raised by the res.*”¹¹²⁵

5.8 Conclusions

Proving causation, particularly through negligence, in proceedings brought against a pharmacist is considerably easier than might apply to most other professionals, suppliers or retailers. Ancillary trading activities apart, the pharmacist most often supplies to a patient or consumer some medicinal item that is ingested, or applied to or otherwise worn on the body.

The material contribution cases tend to involve factual matrices with multiple exposures to noxious substances in workplace settings. It is likely that a particular pharmacy amongst several could be held liable to, say, a locum pharmacist or pharmacy technician for material contribution

¹¹²⁰ *Charlesworth and Percy, op cit*, 455.

¹¹²¹ *Charlesworth and Percy, loc cit*.

¹¹²² *Charlesworth and Percy, op cit*, 456.

¹¹²³ See *Charlesworth and Percy, loc cit*. See also *Henderson v Henry E Jenkins & Sons* [1970] AC 282 (HL), 291, per Lord Reid: “*It is said that salt can cause corrosion but most lorries encounter salt not infrequently either near the sea or when passing over snow which has been treated with salt. But there is nothing in the evidence to suggest that any case has occurred where corrosion from this cause has caused a sudden brake failure.*”

¹¹²⁴ See *Ludgate v Lovett* [1969] 1 WLR 1016 (CA), 1022, per Edmund Davies LJ: “*The judge evolved the theory exculpating the driver ... although it was flatly contradictory to the expert and other evidence which he expressly accepted. This is, accordingly, not a case where the simple denial of negligence of a defendant has convinced the court, but rather one where the defendant's undoubtedly attractively presented denial of negligence has been accepted because the judge considered it consistent with certain assumed facts. In my judgment, since those assumed facts had no basis, the whole foundation for acceptance of the denial of negligence by the defendant goes.*”

¹¹²⁵ See *Charlesworth and Percy, op cit*, 457: “*In practice, the difference between neutralising the effect of the prima facie case and disproving the negligence may be so small as to be immaterial.*”

or increased risk of exposure to a hazardous chemical (e.g. dithranol in extemporaneously compounded dermatological products) within the dispensary. The possibility of avoidable exposures to radiopharmaceuticals in hospital compounding suites can serve as another example.

In *Todd v Merrell Dow Pharmaceuticals Inc*,¹¹²⁶ Billie Todd fell short of producing any evidence of causation, even after receiving several time extensions, failing to identify any expert witness or to come forward with any scientific evidence in support of the alleged causal relationship between the single subcutaneous injection of Bricanyl (terbutaline) on a given date, and her son David's injuries. It is possible that terbutaline's favourable safety profile¹¹²⁷ may have conditioned reluctance in any expert, who had been approached to do so, to 'lend weight' to the plaintiff's allegation.

In the case of *Horton v Evans*,¹¹²⁸ a US-based physician had not been negligent; as he had merely been requested to provide a prescription, on the basis of the medication that the claimant had been dispensed by the defendant British pharmacy chain. The US physician had no reason to suspect that the information printed on the container was not accurate. The judge concluded that the deterioration in the claimant's health could be attributed to the negligence of the defendants, and that the act of the pharmacist in the US did not break the chain of causation, because it was reasonable to suppose that a reasonably competent pharmacist would have foreseen that the label on the bottle might be used by a doctor to identify what the prescription had been.¹¹²⁹

For a pharmacist not to refer a patient for medical attention, when such a course is warranted, is negligence. If engaged in conduct tantamount to 'practising medicine without a licence', it is submitted that a pharmacist could deny a patient the possibility or probability of a better outcome, in like manner to a physician or surgeon. The circumstances in which a pharmacist could become vulnerable to an action in negligence for loss of a chance have yet to be analysed by the courts.

¹¹²⁶ *Todd v Merrell Dow Pharmaceuticals Inc* (1991) 942 F2d 1173 (USCA, 7th Cir). See further *Todd v Merrell Dow Pharmaceuticals Inc* (1991) 942 F2d 1173, 1178, per Cudahy, Ct J: "Merrell Dow fully complied with all Todd's discovery requests regarding the issue of causation. Todd's speculation that Merrell Dow must possess unspecified additional information is not sufficient grounds to embark upon a virtually boundless fishing expedition." See also Bower, PA, *Lack of Evidence and Causation relieves Drug Manufacturer from Liability* (1992) 1 *Journal of Pharmacy and Law* 112.

¹¹²⁷ A recent warning and change to the Bricanyl labelling does not impinge on terbutaline administration to children, as in *Todd*. See United States Food and Drug Administration, *FDA warns against certain uses of asthma drug terbutaline for preterm labor* (2011) Food and Drug Administration, Silver Spring (MD). Available from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm243840.htm>. (Last accessed 12 January, 2011).

¹¹²⁸ *Horton v Evans* [2006] EWHC 2808 (QB).

¹¹²⁹ This foreseeable conduct comes clearly within the spectrum of outcomes that will not break the chain of causation; see McMahon, B, Binchy, W, *Irish Law of Torts*, Third Edition (2000) Butterworths, Dublin, 77.

It is not exactly groundbreaking to say that the law, once proclaimed, must be applied by non-jurists to everyday situations. In *Geest plc v Lansiquot*,¹¹³⁰ Lord Bingham stated where a plaintiff had refused medical treatment the burden lay on the defendant to prove that the refusal was unreasonable and thus constituted a failure by the plaintiff to mitigate the damage sustained.¹¹³¹ Addressing the information asymmetry in medical care, one submits that the professional person (even if unfamiliar with ‘failure to mitigate damage’ theory) has better insight than the patient into the practical consequences of the patient’s non-compliance with therapy. A pharmacist has a duty to alert the prescriber to a significant non-compliance with pharmacotherapy.

It is submitted that in product liability the test for remoteness of damage should be reasonable foreseeability because “professional liability” and product liability theories embrace contract, negligence and statutory tort: this would accord with the reasoning in the *Wagon Mound (No 2)*, which concerned the extensive overlap between nuisance and negligence.¹¹³²

While there does not appear to have been a case involving a pharmacist’s liability, a pharmacy’s failure to detect a drug-therapy-related problem could become a cause of a loss-of-chance injury.¹¹³³

¹¹³⁰ [2002] 1 WLR 3111 (PC).

¹¹³¹ A decision with the effect of placing the burden of explanation on the claimant, *Selvanayagam v University of the West Indies* [1983] 1 WLR 585 (PC), must now be ‘doubted’.

¹¹³² *Overseas Tankship (UK) Ltd v Miller Steamship Co Pty (The Wagon Mound (No 2))* [1967] 1 AC 617 See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin., *op cit*, 464-465. See also Coetzee, LC, Carstens, P, *Medical Malpractice and Compensation in South Africa* (2011) 86 Chicago-Kent Law Review 1263, 1288, citing *Silver v Premier, Gauteng Provincial Government* 1998 (4) SA 569 (W), in which the court refused to distinguish between the test for causation in considering the contractual as opposed to the delictual claim of the patient. Coetzee and Carstens noted: “*This is particularly relevant in the context of claims involving health care services since the facts upon which the claim is based, whether in contract or in delict, are likely to be the same in many instances.*”

¹¹³³ Fassett, WE, *Emerging Trend in Torts: “Loss of Chance” as a New Cause of Action* (2012) 39(2) *Rx Ipsa Loquitur* 3. On *Philp v Ryan*, see Hayden, E, ‘Loss of chance’ actions are already among us (2012) *Irish Medical Times*, 02 October, 2012. Available from <http://www.imt.ie/opinion/2012/10/loss-of-chance-actions-are-already-among-us.html>. (Last accessed 10 October, 2012).

Chapter 6 Liability for Defective Products

Introduction

Pharmacists occupy a unique position within the product liability sphere. The typical community pharmacy is a supplier of prescription medicines, a manufacturer of magisterial (extemporaneous) preparations and a retailer of medicines and ancillary goods. The production, distribution, prescription (where necessary), supply and proper ultimate consumption of medicinal products are all matters of great societal value.¹¹³⁴ Pharmacists do not usually function as repairers, installers, assemblers or, for that matter, suppliers of component parts: accordingly, such economic activities receive limited attention in this thesis. Liability for economic loss has already been covered elsewhere in this thesis.

6.1 The Historical Background

The case of *Winterbottom v Wright*¹¹³⁵ limited recovery in tort to those who were embraced by privity of contract. The stifling effect of *Winterbottom v Wright* on the law's development was perceptible in Ireland also. McMahon and Binchy offer a 'mild' criticism of the court's exposition in *Corry v Lucas*¹¹³⁶ of the 'privity of contract fallacy', which was "*perhaps encouraged by the plaintiff's pleadings which laid great stress on the defendant's contractual undertakings to the employer rather than attempting to base liability in negligence on broader principles.*"¹¹³⁷

¹¹³⁴ See Swazey, JP, *Prescription Drug Safety and Product Liability*, Chapter in Huber, PW, Litan RE (Editors), *The Liability Maze: the Impact of Liability Law on Safety and Innovation* (1991) Brookings Institution Press, Washington (DC), 291, citing Dubos, RJ, *The Mirage of Health: Utopias, Progress & Biological Change* (1987) Rutgers University Press, Piscataway (NJ), 2: "[T]he idea of a drug that is both perfectly safe and effective, at least with our present knowledge, 'is but a dream remembered from imaginings of a Garden of Eden designed for the welfare of man'."

¹¹³⁵ *Winterbottom v Wright* (1842) 152 ER 402. In *Winterbottom v Wright*, Alderson B opined: "If we were to hold that the plaintiff could sue in such a case, there is no point at which actions would stop. The only safe rule is to confine the right to recover to those who enter into the contract: if we go one step beyond that, there is no reason why we should not go fifty." [(1842) 152 ER 402, 404-405].

¹¹³⁶ (1868) IR 3 CL 208 (Com Pleas). The Court of Common Pleas held, on demurrer, that in the absence of any statement that the defendants were, in fact, aware of the defects in the boiler, or that there was any fraudulent statement by them, and it not appearing that the deceased was aware of the warranty made to the boiler's purchaser (A), or entered into A's employment or used the boiler on the faith of any such warranty, the pleadings disclosed no cause of action in the representatives of the plaintiff's deceased husband (B), who was no party to the contract with the defendants. It is interesting to note that [(1868) IR 3 CL 208, 212], opposing the demurrer, Counsel posed a topical question for which no authority would have been necessary: "Would an apothecary be justified in sending oxalic acid to the father of a family in such a way as to be probably used as Epsom salts?" The allusion doubtlessly would have been recognised by a contemporary audience as being to a popular book of the day: Dickens, C, *The Pickwick Papers* (1837) Chapman & Hall, London, [114].

¹¹³⁷ See McMahon & Binchy, *op cit*, 251. *Corry v Lucas* predated *Heaven v Pender* (1883) 11 QBD 503. See also Seanad Éireann Debates - Volume 130 - 14 November, 1991, *Liability for Defective Products Bill, 1991: Second Stage*, [788]. Available from <http://historical-debates.oireachtas.ie/S/0130/S.0130.199111140004.html>. (Last accessed 12 January, 2012).

In America, it would appear that the earliest case to consider a strict liability-type theory,¹¹³⁸ as applied to a defendant pharmacy was *Fleet & Semple v Hollenkamp*.¹¹³⁹ Brushwood and Abood noted that the Kentucky Court of Appeals, in 1852, had no problem accepting the fact that to adopt strict liability would cause the pharmacy to become an insurer of the product.¹¹⁴⁰ The authors contrast the *milieu* of 1852 with the emergence of a ‘sealed container’ doctrine, both in case law and by statute in some jurisdictions whereby pharmacists are immunized from liability for a product defect that cannot be visualized or tested for at the time of dispensing. Brushwood and Abood make a comment of general application: “[p]resent-day pharmacies are not manufacturers; they are dispensers ... whose negligence in dispensing may lead to liability for malpractice.”¹¹⁴¹ That statement is likewise applicable to modern pharmacists in Ireland.

6.2 *Butterfield v Forrester*: the Origin of Contributory Negligence

The basis of the old common law ‘defence’ of contributory negligence, thought to have originated in *Butterfield v Forrester*¹¹⁴² was that the damages suffered by a contributorily negligent party were not totally the fault of a tortfeasor.¹¹⁴³ In *Butterfield v Forrester*, Lord Ellenborough CJ stated that:

¹¹³⁸ For the rationale for imposing strict liability in products cases, see Waddams, SM, *New Directions in Products Liability*, Chapter in Mullany, NJ, Linden, AM, *Torts Tomorrow: A Tribute to John Fleming* (1998) LBC Information Services, Sydney, 126, analysing a case in nuisance, *Bamford v Turnley* (1862) 122 ER 27. The relevant passage is (1862) 122 ER 27, 33, per Bramwell B: “The public consists of all the individuals of it, and a thing is only for the public benefit when it is productive of good to those individuals on the balance of loss and gain to all. So that if all the loss and all the gain were borne and received by one individual, he on the whole would be a gainer. But whenever this is the case,—whenever a thing is for the public benefit, properly understood, —the loss to the individuals of the public who lose will bear compensation out of the gains of those who gain.”

¹¹³⁹ (1852) 52 Ky (13 B Mon) 219, 221 (Ky CA).

¹¹⁴⁰ See Rustad, M, Koenig, T, *The Historical Continuity of Punitive Damages Awards: Reforming the Tort Reformers* (1993) 42 *The American University Law Review* 1269, 1292 (n 118). (Cantharides had accidentally been mixed in with a snake root and Peruvian bark tea prescribed by the plaintiff’s physician.) See also Mabry, CR, *Warning--The Manufacturer of This Product May Have Engaged in Cover-Ups, Lies, and Concealment: Making the Case for Limitless Punitive Awards in Product Liability Lawsuits* (1997-1998) 73 *Indiana Law Journal* 187, 188: *Fleet & Semple v Hollenkamp* was the first product liability case in which punitive damages were awarded. See also Brushwood, DB, Abood, RR, *Strict Liability in Tort: Appropriateness of the Theory for Retail Pharmacists* (1987) 42 *Food Drug Cosmetic Law Journal* 269, 271.

¹¹⁴¹ See Brushwood, DB, Abood, RR, *loc cit*.

¹¹⁴² *Butterfield v Forrester* (1809) 103 ER 926 (KB).

¹¹⁴³ *Butterfield v Forrester* (1809) 103 ER 926 (KB). See Solomon, JM, *Judging Plaintiffs* (2007) 60 *Vanderbilt Law Review* 1749, 1761 (n): “The origin of contributory negligence in Anglo-American tort law is somewhat unclear, although most scholars agree it made its first appearance in *Butterfield v Forrester*, ... where the court announced the principle as if it were well-established and uncontroversial.” See also Little, WBL, “It is much easier to find Fault with others, than to be Faultless ourselves”: *Contributory Negligence as a Bar to a Claim for Breach of the Implied Warranty of Merchantability* (2007) 30 *Campbell Law Review* 81, 87 (n): “Contributory negligence was adopted much earlier as a part of the common law”, citing *Bayly v Merrell* (1606) 79 ER 331, 331. See also Hayden, PT, *Butterfield Rides Again: Plaintiff’s Negligence as Superseding or*

“[a] party is not to cast himself upon an obstruction which has been made by the fault of another, and avail himself of it, if he do not himself use common and ordinary caution to be in the right. In cases of persons riding upon what is considered to be the wrong side of the road, that would not authorise another purposely to ride up against them. One person being in fault will not dispense with another’s using ordinary care for himself. Two things must concur to support this action, an obstruction in the road by the fault of the defendant, and no want of ordinary care to avoid it on the part of the plaintiff.”¹¹⁴⁴

The Canadian common law, according to the Supreme Court of Canada in *Bow Valley Husky (Bermuda) Ltd v Saint John Shipbuilding Ltd*, inherited from Britain the old common law ‘defence’ of contributory negligence, thought to have originated in *Butterfield v Forrester*, which barred a contributorily-negligent plaintiff from recovery.¹¹⁴⁵ Courts were reluctant to allow the injured party to recover where the tortfeasor was not fully responsible for the damage. In essence, this was a ‘causation’ rationale. The Court took the view that the injured party had failed to prove that the tortfeasor caused the damage. The South African Law Commission has underlined the enthusiasm with which the rule in *Butterfield v Forrester* has been adopted in that jurisdiction.¹¹⁴⁶

Lunney and Oliphant remark that the civil law jurisdiction of admiralty adopted the “*eminently more sensible*” practice of apportioning the loss equally where both parties’ negligence was to blame for a collision,¹¹⁴⁷ an approach expanded by the Maritime Conventions Act 1911.¹¹⁴⁸ The

Sole Proximate Cause in Systems of Pure Comparative Responsibility (2000) 33 Loyola of Los Angeles Law Review 887, 896.

¹¹⁴⁴ *Butterfield v Forrester* (1809) 103 ER 926, 927.

¹¹⁴⁵ *Bow Valley Husky (Bermuda) Ltd v Saint John Shipbuilding Ltd* [1997] 3 SCR 1210, [90]. See also Kretzmer, D, *Transformation of Tort Liability in the Nineteenth Century: The Visible Hand* (1984) 4 Oxford Journal of Legal Studies 46, 74. See also *Marriott v Stanley* (1840) 133 ER 458, 461, where Tindal CJ opined that the question was put to the jury more favourably for the plaintiff than in *Butterfield v Forrester*, although the jury perhaps did not apply the law correctly to the facts of the case; a conditional rule for a new trial was confirmed for cause shown.

¹¹⁴⁶ See South African Law Commission Discussion Paper 67, Project 96, *The Apportionment of Damages Act, 1956* (1996) South African Law Commission, Pretoria, 21. Available from http://salawreform.justice.gov.za/dpapers/dp67_prj96_1996.pdf. (Last accessed 12 January, 2012): “*In fact, our courts have gone further than the English courts in their acceptance of the rule, for they have applied it not only in cases involving negligence by the plaintiff, but also in cases involving negligence by the plaintiff [, which also involve] negligence by a third person*”, citing: McKerron, RG, *The Apportionment of Damages Act 1956* (1956) Juta, Cape Town, 2.

¹¹⁴⁷ American courts followed the early English equally divided damages rule until 1975, when, in *United States v Reliable Transfer Co* (1975) 421 U.S 397, the Supreme Court adopted a comparative negligence rule in admiralty cases.

¹¹⁴⁸ See Lunney, M, Oliphant, K, *Tort Law: Cases and Materials* Fourth Edition (2010) Oxford University Press, Oxford, 302, citing the Maritime Conventions Act 1911, 1&2 Geo 5 c57. See also Volk, KH, *Some Legal*

authors mention that the philosophy of the Maritime Conventions Act 1911 led ultimately to the enactment of the Law Reform (Contributory Negligence) Act 1945.¹¹⁴⁹

In principle, contributory negligence by the buyer is not a defence to an action based in contract.¹¹⁵⁰ However, where concurrent tortious and contractual duties to take care exist, the House of Lords decision in *Forsikringsaktieselskapet Vesta v Butcher*¹¹⁵¹ suggests that contributory negligence by the consumer may be raised as a defence, at least having the effect of reducing the level of compensation recoverable. The 'Vesta insurance company' case does not appear to have been analysed by the Irish Superior Courts.

The US jurisdictions differentiate between contributory negligence (which can be a complete bar to recovery) and comparative negligence (where the respective degrees of fault of the plaintiff and the defendant are compared in order to assess liability).¹¹⁵² Abraham posits that the contributory negligence doctrine was influenced by judicial mistrust of juries.¹¹⁵³ While the British and Irish jurisdictions speak of the concept of 'contributory negligence', those legal systems have essentially a 'comparative negligence' regime.¹¹⁵⁴ An awareness of the differing terminology on both sides of the Atlantic is necessary to reconcile the application of the law in the various jurisdictions.

Aspects of Collisions between Radar Equipped Ships (1957-1958) 36 North Carolina Law Review 30, 37(n), citing *inter alia*: *The Sobieski* [1949] P 313 (Duty of radar-equipped ship to warn another vessel if she is perceived to be steaming into danger).

¹¹⁴⁹ The Law Reform (Contributory Negligence) Act 1945, 8 & 9 Geo 6, c28, following the Law Revision Committee, Eighth Report (*Contributory Negligence*) (Cmd 6032) (1939) His Majesty's Stationery Office, London.

¹¹⁵⁰ Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 735.

¹¹⁵¹ [1989] AC 852 (HL).

¹¹⁵² The author does not go into the concept of 'slight negligence' (recognised in some US jurisdictions), which is of marginal significance to this treatment of negligence.

¹¹⁵³ See Abraham, KS, *The Common Law Prohibition on Party Testimony and the Development of Tort Liability* (2009) 95 Virginia Law Review 489, 509-510. See also Malone, WS, *The Formative Era of Contributory Negligence* (1946-1947) 41 Illinois Law Review 151, 151, where the scene is set: "In America the idea of contributory negligence lay virtually dormant until about the middle of the [Nineteenth C]entury; then suddenly it sprang to life and found its way into virtually every piece of litigation over a negligent injury to person or property. Even in Louisiana, whose Civil Code fairly interpreted would deny the notion".

¹¹⁵⁴ See, for example: Law Reform (Contributory Negligence) Act 1945 (c28); Civil Liability Act 1961 (No 41 of 1961), s34. See also: Devaney, M, *The Defence of Contributory Negligence: A Critical Assessment* (2009) Inaugural Law Student Colloquium, Trinity College Dublin, 04 April, 2009.

6.3 Abolition of the Privity Requirement

Aspects of the privity doctrine have already been discussed.¹¹⁵⁵ It is useful here to make a comparison with Scottish Law, which does not require a contract to be supported by consideration. Differing in this respect from the law of England, Scots law holds that consent will infer an obligation, although there may be no consideration. An obligation to give, or to do or abstain from doing something, without asking for any return is, in so far as its enforceability by legal process is concerned, on a par with an obligation for which a return or consideration is demanded and promised.¹¹⁵⁶

The distinction in this respect between the laws of England and Scotland is most clearly brought out in the case of an offer to sell, with an undertaking to keep the offer open for a certain period. Assuming that nothing is paid for the engagement to keep the offer open, it is an undertaking without consideration, and consequently, in English law, is not binding unless made in a deed.¹¹⁵⁷ In Scotland, where consideration is not necessary, it is a binding obligation, and the offeree, if he accepts the offer within the time specified, and his acceptance be rejected, will be entitled to damages.¹¹⁵⁸ While the law of Scotland has rejected consideration as an essential element in the constitution of a voluntary obligation, this does not mean that the question of consideration is in all cases irrelevant, or that a gratuitous promise and a mutual contract stand in all respects on the

¹¹⁵⁵ See also Hird, NJ, *Negligence*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 219.

¹¹⁵⁶ Lord Coulsfield, MacQueen, HL (General Editors), *Gloag and Henderson, The Law of Scotland*, Twelfth Edition (2007) Thomson, W Green & Sons, Edinburgh, 125, citing *Morton's Trustees v Aged Christian Friendly Society* (1899) 2 F 82. See also Wood Renton, A, *French Law within the British Empire III Points of Departure* (1910) 10 (ns) *Journal of the Society of Comparative Legislation* 250, 251: "The Act of Union checked the incorporation of Roman law into the law of Scotland, and whatever tendency to argue on principle instead of on precedent may still be inherent in the Scotch forensic mind, it firmly established the authority of the rule *stare decisis* in the practice of the Courts."

¹¹⁵⁷ Lord Coulsfield, MacQueen, HL (General Editors), *op cit*, 125, citing *Dickinson v Dodds* (1876) 2 Ch D 463. See also *Dunlop Pneumatic Tyre Co Ltd v Selfridge* [1915] 1 AC 847 (HL), 853 (Viscount Haldane LC). See also MacQueen, HL, *Third Party Rights in Contract: Jus Quaesitum Tertio*, Chapter in Reid, KGC, Zimmermann, R (Editors), *A History of Private Law in Scotland*, Vol 2 (2000) Oxford University Press, Oxford, 221: "Oddly, in this respect English law became the most Roman of all modern legal systems in Europe."

¹¹⁵⁸ *Littlejohn v Hadwen* (1882) 20 SLR 5; approved by Lord Dunedin in *Paterson v Highland Railway* 1927 SC (HL) 32, 38.

same footing.¹¹⁵⁹ Where a promise is made, other than one made in the course of business, writing is required for its constitution.¹¹⁶⁰

If it were not intended by the United Kingdom Parliament that interdict should be more restricted in availability, within civil proceedings against the NHS,¹¹⁶¹ than its equitable analogue, the injunction, it is submitted that Parliament likewise did not intend that differing contractual rights (based on the presence or absence of contractual consideration or of *jus quaesitum tertio*) should obtain in lands of the Realm served by differing legal systems.

The formation of a contract in the course of business “*according to what people say*”¹¹⁶² is difficult to imagine between a pharmacist (who already holds a health service contract) and a patient (or her representative) presenting a prescription. It is submitted that whatever discussion that takes place probably will centre on optimising medication use or minimising harm; in Ireland and elsewhere.

6.3.1 A Prelude to *Donoghue v Stevenson*

Linden notes the irony “*that, despite the undoubted significance of Donoghue v Stevenson on the development of Canadian negligence law dealing with products, a judge in Nova Scotia actually came to the same conclusion 12 years earlier in Buckley v Mott.*”¹¹⁶³ The plaintiff was injured by some powdered glass which found its way into a chocolate cream bar that he had purchased from a retailer. In the suit against the manufacturer, he contended that he owed no duty to the plaintiff, since he had no contract with the manufacturer, but only with the retailer. Linden has

¹¹⁵⁹ See Smith, TB, *Pollicitatio - Promise and Offer: Stair v Grotius* (1958) 1958 Acta Juridica 141, 148: “*Founding on Stair[’s Institutions of the Law of Scotland (1681)], it is submitted that Scots Law recognizes (a) bilateral contracts where each party undertakes obligations; (b) unilateral contracts concluded by offer and acceptance where one party alone is bound to performance; (c) promises (pollicitationes) which bind the declarant by his own unilateral act of will.*” See also *NBS Boland Bank v One Berg River Drive and Others; Deeb and Another v ABSA Bank Ltd; Friedman v Standard Bank of South Africa Ltd* [1999] ZASCA 60, [12]: “*Scottish institutional writers also hold that a term in a contract of sale empowering either party to determine the price is unobjectionable.*”

¹¹⁶⁰ Requirements of Writing (Scotland) Act 1995, s 1(2)(a)(ii). To be formally valid, subscription by promisor will be sufficient: s 2(1).

¹¹⁶¹ See *British Medical Association v Greater Glasgow Health Board* [1989] 1 AC 1221 (HL), 1225-1226, per Lord Jauncey of Tullichettle.

¹¹⁶² See Lord Coulsfield, MacQueen, HL (General Editors), *Gloag and Henderson, The Law of Scotland*, Twelfth Edition (2007) Thomson, W Green & Sons, Edinburgh, 126, citing *Muirhead and Turnbull v Dickson* (1905) 7 F 686, 694, per Lord President Dunedin: “*Commercial contracts cannot be arranged by what people think in their inmost minds. Commercial contracts are made according to what people say.*”

¹¹⁶³ *Buckley v Mott* (1920) 50 DLR 408 (NSSC). See also *Ross v Dunstall* (1921) 62 SCR 393. See also Linden, AM, *Good Neighbour on Trial: A Fountain of Sparkling Wisdom* (1983) 17 University of British Columbia Law Review 67, 82-83.

declared, with justification, that “[b]ecause of the absence of penetrating analysis and the modesty of prose, however, *Buckley v Mott* has been largely ignored”.¹¹⁶⁴

6.3.2 Transfer by Way of Gift

McMahon and Binchy identify those areas in which the law is certain¹¹⁶⁵: warning of known dangers; preventing the transferred item from falling into the hands of children or incompetent persons.¹¹⁶⁶

*“The onward march of negligence in relation to licensors and to those who give advice gratuitously suggests that the mere absence of consideration should no longer exempt a donor or gratuitous lender from a duty of care. Of course, in assessing the scope and content of the duty the courts would have regard to all the circumstances of the case, including the likelihood of reliance by donee or borrower on the donor’s or lender’s having taken care in relation to the item transferred.”*¹¹⁶⁷

6.3.2.1 Pharmaceutical Samples

In Ireland, the provision of *free samples* of medicinal products is regulated by the Medicinal Products (Control of Advertising) Regulations 2007.¹¹⁶⁸ The main purpose of these Regulations is to implement Titles VIII and VIIIa of EU Directive 2001/83/EC (as amended by Directive 2004/27/EC) relating to the advertising of medicinal products for human use. They cover advertising both to health professionals and to the general public. Regulation 22 provides that a person shall not supply¹¹⁶⁹ a free sample of a medicinal product to any person unless that person

¹¹⁶⁴ Linden, AM, *op cit*, 83. See also Ferrari, F, *Donoghue v Stevenson’s 60th Anniversary* (1994) 1(1) Annual Survey of International & Comparative Law 81, 84 (n). See Klar, L, *Downsizing Torts*, Chapter in Mullany, NJ, Linden, AM, Editors, *Torts Tomorrow: A Tribute to John Fleming* (1998) LBC Information Services, Sydney, 305, 307: “*In theory, the major elements of a tort action—duty, breach causing injury and cause—reflect the principle of moral wrongdoing which is the basis of the negligence law.*”

¹¹⁶⁵ McMahon & Binchy, *op cit*, 265.

¹¹⁶⁶ See *Campbell v O’Donnell* [1967] IR 226 (Sup Ct), 229-230, per Walsh J: “*The present state of the law on the subject is probably correctly described in The Law of Tort by Fleming (3rd Ed at p 487) where the learned author states that ‘the modern attitude has become distinctly unsympathetic to continuing discrimination against gratuitous relations.’*”

¹¹⁶⁷ McMahon & Binchy, *op cit*, 265.

¹¹⁶⁸ SI No 541 of 2007, Regulation 22 (Free samples).

¹¹⁶⁹ For example, on the meaning of ‘supply’, within the product liability context, see *inter alia* the UK Consumer Protection Act 1987, s 46(1)(f) “*giving the goods as a prize or otherwise making a gift of the goods*”.

is qualified to prescribe¹¹⁷⁰ such product, and then only where certain conditions are satisfied.¹¹⁷¹ The Irish Pharmaceutical Healthcare Association has instigated even greater restrictions for its member companies than legally required.¹¹⁷² The provision of free drug samples is more widely tolerated in the United States than in Europe.¹¹⁷³ Unsurprisingly, a gratuitous drug sample is no metaphorical 'free lunch'.¹¹⁷⁴

6.3.3 Developments in the US

Prior to the 1960s, manufacturers in the US were rarely held liable for defective products: the two principal theories of recovery were implied warranty of merchantability and negligence.¹¹⁷⁵ Geistfeld states that, during the years preceding the adoption of strict products liability, courts were increasingly willing to find that an implied warranty governed apparent dangers that had been inspected by the purchaser, "*turning these otherwise open or obvious dangers into latent defects not subject to the patent-danger rule*".¹¹⁷⁶

The modern movement towards strict liability for defective products in the US is reasonably traceable to a *dictum* of Cardozo J in *Ultramares Corporation v Touche Niven & Co*,¹¹⁷⁷ where the learned judge said that "[a]n assault upon the citadel of privity is proceeding in these days

¹¹⁷⁰ Direct-to-consumer provision of sample medicinal products is clearly not permitted within the EEA.

¹¹⁷¹ Most importantly, in Regulation 22(2) it is stated that a person shall not supply a sample of a medicinal product which is a controlled drug under section 2 of the Misuse of Drugs Act 1977 or which is an antidepressant, hypnotic, sedative or tranquilliser.

¹¹⁷² See Irish Pharmaceutical Healthcare Association, *Code of Marketing Practice for the Pharmaceutical Industry, Edition 7.5* (2012) Irish Pharmaceutical Healthcare Association, Dublin, 18-20 and 19 (n). Available from <http://www.ipha.ie/alist/pub-codes-of-practice.aspx?article=fe8a856e-50b5-4f8b-a941-697ba8f98c41>. (Last accessed 09 January, 2012). According to Clause 13 of the Code, such samples in respect of a medicinal product shall not exceed four in number per year; sampling shall not extend beyond the two years after the person qualified to prescribe such a product first requested samples of each particular 'new medicine' (restrictively defined). This provision of the Code is effective from 01 January, 2012 for products placed on the market after that date—for products already on the market prior to 01 January, 2011 the requirements were to become effective from 01 June, 2012.

¹¹⁷³ See, for example, a system for computer-implemented method for distributing and tracking free pharmaceutical samples, which is subject to patent protection in the US; US Patent, Inventor: Werner, DJ, *Computer-implemented method for distributing and tracking free pharmaceutical samples*, Application number: 11/396,011, Publication number: US 2006/0224417 A1, Filing date: 31 March, 2006, US Classification: 705002000.

¹¹⁷⁴ See Taira, DA, Iwane, KA, Chung, RS, *Prescription Drugs: Elderly Enrollee Reports of Financial Access, Receipt of Free Samples, and Discussion of Generic Equivalents Related to Type of Coverage* (2003) 9 American Journal of Managed Care 305, 311.

¹¹⁷⁵ Vetri, D, Levine, LC, Vogel, JE, Finley, LM, *Tort Law and Practice*, Third Edition (2006) LexisNexis, Newark (NJ), 932. Theories of express warranty (by contract terms, product literature or advertising) and misrepresentation (by false claims of safety in the marketing of goods) may also have been available.

¹¹⁷⁶ Geistfeld, MA, *The Value of Consumer Choice in Products Liability* (2009) 74 Brooklyn Law Review 1, 15, citing Prosser, WL, *The Implied Warranty of Merchantable Quality* (1942-1943) 27 Minnesota Law Review 117, 156.

¹¹⁷⁷ (1931) 174 NE 441 (Cardozo J).

apace.¹¹⁷⁸ This was the clarion call answered by Dean Prosser in his celebrated article, *The Assault upon the Citadel (Strict Liability to the Consumer)*¹¹⁷⁹ in 1960. In the field of products liability, the date on which the citadel of privity fell can be fixed with some certainty: it was “May 9, 1960, when the Supreme Court of New Jersey announced the decision in *Henningsen v Bloomfield Motors Inc*”¹¹⁸⁰: under the doctrine of implied warranty of merchantability.¹¹⁸¹ The American Law Institute (ALI) followed the decisions in *Henningsen* and *Greenman v Yuba Power Products Inc*¹¹⁸² and adopted the principle of strict liability in the *Restatement (Second) of Torts*, on Products Liability, § 402A.¹¹⁸³ Quill states that the American courts have developed strict liability for personal injury and property damage caused by dangerous products through an evolution of the common law.¹¹⁸⁴ Section 402A, subject to a Caveat,¹¹⁸⁵ has been criticised by Henderson and Twerski for causing “analytic confusion” between manufacturing defects and

¹¹⁷⁸ (1931) 174 NE 441, 445 per Cardozo J. The US *locus classicus*, *MacPherson v Buick Motor Co* (1916) 111 NE 1050 (NYCA) is discussed in Chapter 3.

¹¹⁷⁹ Prosser, WL, *The Assault upon the Citadel (Strict Liability to the Consumer)* (1960) 69 Yale Law Journal 1099. See also Low, JB, *Federal Rule of Evidence 407 and Strict Products Liability - The Rule against Subsequent Repairs Lives on* (1982-1983) 48 Journal of Air Law & Commerce 887, 889, citing Prosser, WL, *op cit*, 1142 (internal citations omitted): “According to Professor Prosser, the plaintiffs may include not only the purchaser, but ‘any user or consumer of the product’ which may be defined as ‘members of [the final purchaser’s] family, his guest, his employees, his lessee, and his donee’.” Inherently dangerous products, such as knives, are not normally included in the definition of unreasonably dangerous articles and are therefore not within the purview of strict liability.

¹¹⁸⁰ Prosser, WL, *op cit*, 791, citing *Henningsen v Bloomfield Motors Inc* (1960) 161 A2d 69 (NJ Sup Ct), in particular, (1960) 161 A2d 69, 83-84, *dicta* of Francis J. See also Hird, NJ, *Negligence*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 219: “The US courts developed a regime of strict liability, initially through the concept of a transmissible warranty of fitness, then via a strict tortious duty.”

¹¹⁸¹ See Chun, JH, *The New Citadel: A Reasonably Designed Products Liability Restatement* (1994) 79 Cornell Law Review 1654, 1656. In theory, at least, privity was already on the wane. See also Cochran, Jr, RF, “Good Whiskey”, *Drunk Driving, and Innocent Bystanders: The Responsibility of Manufacturers of Alcohol and Other Dangerous Hedonic Products for Bystander Injury* (1993-1994) 45 South Carolina Law Review 269, 319, citing Harper, FV, James, Jr, F, *The Law of Torts*, Vol 2 (1956) Little, Brown and Company, Boston, § 28.16, at 1572, [n 6]: “As Harper and James said of Other Dangerous Hedonic Products for Bystander Injury, limiting the bystander to the consumer expectation test is a ‘distorted shadow of a vanishing privity which is itself a reflection of the habit of viewing the problem [of product injury] as a commercial one between traders, rather than as part of the accident problem’.”

¹¹⁸² *Greenman v Yuba Power Products Inc* (1963) 377 P2d 897 (Cal).

¹¹⁸³ Section 402A (Special Liability of Seller of Product for Physical Harm to User or Consumer). See also Vetri, D, Levine, LC, Vogel, JE, Finley, LM, *op cit*, 933.

¹¹⁸⁴ See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 169. See also *Restatement (Second) of Torts*, §402A; the American Law Institute’s *Restatement (Second) of Torts: Products Liability* confines strict liability to production defects and uses a fault standard for design defects and information deficiencies, requiring the plaintiff to show a better alternative that could have been used by the defendant.

¹¹⁸⁵ In the Caveat, the Institute expressed no opinion as to whether the rules stated in this section may not apply: (1) to persons other than users and consumers; (2) to the seller of a product expected to be processed or otherwise substantially changed before it reaches the user or consumer; or (3) to the seller of a component part of a product to be assembled. The Caveat’s three propositions are subject to the final three of the 17 expert comments on § 402A: *cmt o*; *cmt p*; *cmt q*, respectively.

other types of defect.¹¹⁸⁶ These authors state that strict liability does not apply equally well to cases involving manufacturing defects, design defects, and failures to warn. The concept of strict liability can be applied coherently in manufacturing defect cases because a product's defectiveness can be determined without resort to negligence-oriented cost-benefit balancing. But in both defective-design and failure-to-warn cases, cost-benefit balancing (also a core negligence concept) is inevitably required to determine product defectiveness. In design and warning cases it is difficult to distinguish between strict liability and negligence.

These comparative materials are illustrative of the interplay between the defective-design and failure-to-warn factors that arise in the Irish courts in the Product Liability Directive context.

6.3.3.1 Successor Corporation Liability

In the US, stockholding in corporations has a wider demography than in Europe. Mobility of investment capital should not be allowed to deny compensation to victims of defective products: however, a firm that *"buys assets from another firm ordinarily does not acquire liability to the seller's creditors simply by buying its assets."*¹¹⁸⁷ In *Leannais v Cincinnati Inc*,¹¹⁸⁸ Markey CJ stated the exceptions to the general rule under which liability may be imposed on a corporate purchaser (preceded by a finding of fact):

*" (1) when the purchasing corporation expressly or impliedly agreed to assume the selling corporation's liability; (2) when the transaction amounts to a consolidation or merger of the purchaser and seller corporations; (3) when the purchaser corporation is merely a continuation of the seller corporation; or (4) when the transaction is entered into fraudulently to escape liability for such obligations."*¹¹⁸⁹

¹¹⁸⁶ See Henderson, Jr, JA, Twerski, AD, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn* (1990) 65 New York University Law Review 265, 271-272.

¹¹⁸⁷ See Reilly, MT, *Making Sense of Successor Liability* (2003) 31 Hofstra Law Review 745, 745. See *Restatement (Third) of Torts: Products Liability* (1998) The American Law Institute, Philadelphia, § 12 (Liability of Successor for Harm Caused by Defective Products Sold Commercially by Predecessor). See also Steenson, M, *A Comparative Analysis of Minnesota Products Liability Law and The Restatement (Third) of Torts: Products Liability* (1998) 24 William Mitchell Law Review 1, 75.

¹¹⁸⁸ (1977) 565 F2d 437 (CA, 7th Ct).

¹¹⁸⁹ See *Leannais v Cincinnati Inc* (1977) 565 F2d 437 (CA, 7th Ct), 439, per Markey CJ. See also Reilly, MT, *Making Sense of Successor Liability* (2003) 31 Hofstra Law Review 745, 793: *"The drafters of the Restatement (Third) Torts: Products Liability [(in particular, § 12)] missed an important opportunity to clarify the role of fraud in successor liability cases."* See also Phillips, JJ, *Product Line Continuity and Successor Corporation Liability* (2004-2005) 72 Tennessee Law Review 753. [This Article was originally published at (1983) 58 New York University Law Review 906]. The late Professor Phillips proposed that successor corporation product liability should depend on *"product line continuity"*, which he described as the successor's purchase of the predecessor's *"entire business"*. He suggested that product line continuity may justify subjecting the successor to a duty to warn consumers about hazards associated with the

Evidence of continuity can be probative on the question of collusion and on that of the transferee's access to information about a future fraud on creditors.¹¹⁹⁰ Absent this critical evidence, *"the fact that a transferee uses the acquired assets in the same way as the transferor did, or continues to manufacture a similar product line, does not make the transfer sufficiently 'unfair' to the transferor's creditors to justify imposition of their loss on the transferee."*¹¹⁹¹ Howells¹¹⁹² suggests that the *Leannais* category (1) could be addressed in the UK by the Contracts (Rights of Third Parties) Act 1999. Category (4) may require piercing the corporate veil, although the courts *"will be slow to infer impropriety"*.¹¹⁹³ Categories (2) and (3) would present problems to the claimant if the original entity has ceased to exist.¹¹⁹⁴

In the worldwide pharmaceutical marketplace, the wider implications for pharmacists in Ireland are that there may be no corporation, let alone a successor corporation, to satisfy judgments granted to persons injured by defective products, and in scenarios of shared fault, the pharmacist may be required to shoulder a greater proportion of the responsibility for a defective medicinal product.

6.3.4 Unfair Commercial Practices Directive

The Unfair Commercial Practices Directive¹¹⁹⁵ has been implemented in Ireland by the Consumer Protection Act 2007. The word *"consumer"* is defined as *"a natural person (whether in the State or not) who is acting for purposes unrelated to the person's trade, business or profession"*.¹¹⁹⁶ Part 3

predecessor's products or, in some cases, to repair such products. See further Kuney, GW, *Jerry Phillips' Product Line Continuity and Successor Corporation Liability: Where are we Twenty Years later?* (2004-2005) 72 *Tennessee Law Review* 777, 796: *"[T]he so-called demise of continuity of enterprise and product line theories has been overstated by the pundits and the Restatement."* See also Choi, AH, *Successor Liability and Asymmetric Information* (2007) 9 *American Law and Economics Review* 408, 428: *"An optimal successor liability regime should consist of (i) higher punishment against the seller whether or not the seller had an opportunity to sell its assets and (ii) reduction of damages against the buyer who purchases the seller's assets."*

¹¹⁹⁰ See Reilly, MT, *op cit*, 793.

¹¹⁹¹ See Reilly, MT, *op cit*, 793-794.

¹¹⁹² See Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 321-322.

¹¹⁹³ See Howells, *op cit*, 322.

¹¹⁹⁴ See Howells, *loc cit*; the court would treat the new corporation as a separate entity.

¹¹⁹⁵ Directive 2005/29/EC. See also Schuster, A, *Impact on Tort Litigation of the Consumer Protection Act 2007* (2008) 3(2) *Quarterly Review of Tort Law* 7.

¹¹⁹⁶ Consumer Protection Act 2007, s 2: *"consumer transaction"* means a promotion or supply of a product to a consumer; *"trader"* means *"(a) a person who is acting for purposes related to the person's trade, business or profession, and (b) a person acting on behalf of a person referred to in paragraph (a)"*

of the Act covers Commercial Practices.¹¹⁹⁷ Section 41 lays down a general prohibition on unfair commercial practices, which blends a requirement for good faith in the trader's field of activity with a reasonably expected standard of skill and care in respect of consumers relevant to that field.¹¹⁹⁸ Part 3, Chapter 2 regulates misleading commercial practices; it is submitted that, apart from ancillary trading activities, a pharmacist is unlikely to infringe the Act's provisions.¹¹⁹⁹

6.3.5 Australian Contract-Based Approach

Australian Sale of Goods legislation is based on the English Sale of Goods Act 1893.¹²⁰⁰ Trindade, Cane and Lunney acknowledge that:

*"[t]here are good arguments, which have nothing to do with the doctrine of privity, for making manufacturers pay for losses caused by their products: such liability may give manufacturers an incentive to produce safer and better products; and anyway, it is important that the price of a product should reflect not only the cost of producing it, but also the cost of any injuries or damage suffered in the course of its proper and normal use. The arguments justify allowing recovery by consumers of products but also by intermediate suppliers of the product."*¹²⁰¹

¹¹⁹⁷ Consumer Protection Act 2007, Part 3, Chapter 3 covers *Aggressive Commercial Practices*, the commission of which by members of the health professions seems improbable.

¹¹⁹⁸ Consumer Protection Act 2007, s 41(2)(a) describing "*the requirements of professional diligence*".

¹¹⁹⁹ A medicinal product is labelled and the package contains a leaflet that, in most circumstances, obviates sale or supply by description or by trader representation

¹²⁰⁰ Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 624.

¹²⁰¹ Trindade, F, Cane, P, Lunney, M, *op cit*, 626. See, however, section 55(1) of the Property Law Act 1974 (Qld), which provides: "(1) A promisor who, for a valuable consideration moving from the promisee, promises to do or to refrain from doing an act or acts for the benefit of a beneficiary shall, upon acceptance by the beneficiary, be subject to a duty enforceable by the beneficiary to perform that promise." Section 55(3)(a) of the Property Law Act 1974 (Qld) further provides: "(3) Upon acceptance— (a) the beneficiary shall be entitled in the beneficiary's own name to such remedies and relief as may be just and convenient for the enforcement of the duty of the promisor, and relief by way of specific performance, injunction or otherwise shall not be refused solely on the ground that, as against the promisor, the beneficiary may be a volunteer." By virtue of s 55(6) of the Property Law Act 1974 (Qld): 'promise' "means a promise— (a) which is or appears to be intended to be legally binding; and (b) which creates or appears to be intended to create a duty enforceable by a beneficiary; and includes a promise whether made by deed, or in writing, or, subject to this Act, orally, or partly in writing and partly orally." See also the Property Law Act 1969 (WA), s 11 (Persons taking who are not parties) and the Law of Property Act 2000 (NT), s 56 (Contracts for the benefit of third parties). See also Jones, N, *Gift vouchers and expiry dates: when the gift stops giving* (2009) 9 Queensland University of Technology Law and Justice Journal 213.

In several jurisdictions, legislation has been enacted imposing what are usually called ‘manufacturer’s warranties’.¹²⁰² The various Australian statutes differ in detail but share two characteristics.¹²⁰³ Firstly, there is imposition on manufacturers of similar warranties to those applicable under Sale of Goods legislation: aimed at ‘vertical privity’, not addressing ‘horizontal privity’. Secondly, the statutes impose on the ‘manufacturer’ liability for statements as to quality made in advertising material, although such matter is not normally directed at any particular individual or group, which would make this task difficult.¹²⁰⁴

6.3.6 Canada

Product liability law in Canada is governed both by the law of contract and the law of tort.¹²⁰⁵ In the case of *ter Neuzen v Korn*,¹²⁰⁶ the Supreme Court of Canada analysed warranties under Sale of Goods legislation and at common law. In order for the Sale of Goods Act to apply, a contract must be primarily for the purpose of selling goods. If the sale of a good is merely incidental to what is primarily a contract for services, then the statute will not imply a warranty. Apart from the Act, a court must consider whether a common law warranty of fitness and merchantability should be implied into the contract for ‘work and materials’. However, such a warranty will not be implied in all circumstances. While it is true that the primary purpose of the implied warranty is to hold the supplier of goods liable notwithstanding the absence of negligence, different considerations apply in the context of the medical profession compared with the ordinary commercial context. A doctor will not be in a position to trace the liability back to the initial manufacturer. Moreover, it must be recognised that biological products such as blood and semen, unlike manufactured products, carry certain inherent risks. It was held to be inappropriate to imply a warranty of fitness and merchantability in the circumstances of this case: any warranty would simply be to take reasonable care.

¹²⁰² The Commonwealth of Australia’s legislation also deems consumers to be persons who acquire goods for less than AUD40,000 [Trade Practices Act 1974 (Cth), s 48].

¹²⁰³ Trindade, F, Cane, P, Lunney, M, *loc cit*.

¹²⁰⁴ See *loc cit*. It is very difficult, in either contract or tort, to bring home such liability for such statements: in contract because it has to be proved that the statement was meant to have the force of a contractual warranty of quality or that it was a misrepresentation of fact (as opposed to a promise) that would likely to induce a reasonable person to contract; and in tort because of the need to establish a special relationship under *Hedley Byrne v Heller* principles. See also *Lambert v Lewis* [1982] AC 225, 264, per Stephenson J.

¹²⁰⁵ Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 363. See also Murphy, L, Mason, M, *Canada*, Chapter in Dodds-Smith, I, Spencer, M (Contributing Editors), *The International Comparative Legal Guide to: Product Liability 2010* (2010) Global Legal Group Ltd, London, 112: “In Canada, there is no nominate tort of breach of statute and the civil consequences of breach of statute are subsumed in the law of negligence. Breach of statutory obligations may be evidence of negligence and provides a useful standard of reasonable conduct. In some instances, liability can be imposed for breach of statutory obligations where a statute specifically provides for a right of action, as is the case with some consumer protection and sale of goods statutes.” See, in particular, *The Queen (Canada) v Saskatchewan Wheat Pool* [1983] 1 SCR 205.

¹²⁰⁶ [1995] 3 SCR 674.

6.3.7 New Zealand

Strict liability is imposed in New Zealand through the statutory framework hereinafter described: the common law liability regime is negligence-based.¹²⁰⁷ The supplier's liability is governed by the Sale of Goods Act 1908¹²⁰⁸ and the Consumer Guarantees Act 1993.¹²⁰⁹ The New Zealand Consumer Guarantees Act is based on the Saskatchewan Consumer Products Warranties Act 1977.¹²¹⁰ Section 4 provides that the 1993 Act is not a code.¹²¹¹ Section 6 provides for a guarantee as to *acceptable* quality.¹²¹² This is not merely a guarantee of *merchantable* quality, since under Part 3 of the Act the consumer may have a right of redress against the manufacturer (a valuable erosion of vertical privity from the consumer perspective).¹²¹³ There is a prohibition on contracting out contained in section 42(1) of the 1993 Act.¹²¹⁴

In the case of *Rolls-Royce New Zealand Ltd v Carter Holt Harvey Ltd & Anor*,¹²¹⁵ the Contracts (Privity) Act 1982¹²¹⁶ was not mentioned; the appellant arguably could have sought to establish

¹²⁰⁷ See Todd, S, *Negligence: Particular Categories of Duty*, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 297.

¹²⁰⁸ See the New Zealand statute, the Sale of Goods Act 1908, section 16 (Implied conditions as to quality or fitness).

¹²⁰⁹ Consumer Guarantees Act 1993.

¹²¹⁰ See generally Hawes, C, *Consumer Law Reform: The Consumer Guarantees Bill* (1992) 5 Canterbury Law Review 17. The Consumer Products Warranties Act, RSS 1978, c C-30 has been replaced by the Consumer Protection Act, SS 1996, c C-30.1 (Current version in force since 10 November, 2008 – Verified 12 January, 2012). See also Waddams, SM, *New Directions in Products Liability*, Chapter in Mullany, NJ, Linden, AM, *Torts Tomorrow: A Tribute to John Fleming* (1998) LBC Information Services, Sydney, 121, referring to statutory warranties in two Canadian Provinces - the other is New Brunswick - coming "very close to a general principle of strict liability, but fall[ing] short of it in that the provisions only apply to consumer products, as defined, and, in Saskatchewan, apply[ing] only against the retailer and manufacturer, as defined." See further the Consumer Product Warranty and Liability Act, SNB 1978, c C-18.1 (Current version in force since 15 September, 2010 - Verified 12 January, 2012).

¹²¹¹ See Consumer Guarantees Act 1993, section 4 (Act not a code). Subsection (1) provides: "The rights and remedies provided in this Act are in addition to any other right or remedy under any other Act or rule of law unless the right or remedy is expressly or impliedly repealed or modified by this Act. Subsection (2) provides: "No provision of this Act shall be construed as repealing, invalidating, or superseding the provisions of any other Act unless this Act by express provision or by necessary implication clearly intends such a provision to be so construed." Section 4 of the 1993 Act may be compared with the Consumer Products Warranties Act 1977 (Sask) s 3.

¹²¹² Section 6 of the 1993 Act (Guarantee as to acceptable quality). Part 2 may give the consumer a right of redress against the supplier.

¹²¹³ See s 6(2)(b) of the 1993 Act.

¹²¹⁴ Hawes, C, *Consumer Law Reform: The Consumer Guarantees Bill* (1992) 5 Canterbury Law Review 17, 19: "The Saskatchewan [Consumer Products Warranties] Act [1977] is more detailed in its drafting with respect to the matter of contracting out than is the new Bill, but it would seem likely that the New Zealand courts would take a similar approach, given the apparently absolute prohibition on contracting out contained in cl 42(1)."

¹²¹⁵ [2005] 1 NZLR 324 (CA).

¹²¹⁶ Contracts (Privity) Act 1982. See also Kelly, C, *Privity of Contract - The Benefits of Reform* [2008] Judicial Studies Institute Journal 145, 155-156 (generally); 162 ("when the third party relies on or materially alters

pursuant to section 4¹²¹⁷ that it was “a sufficiently designated beneficiary”¹²¹⁸ of the contract between Carter Holt Harvey Ltd and the Electricity Corporation of New Zealand Ltd and was intended to have the benefit of that contract.

6.3.8 Review of the Traditional Australian, Canadian and New Zealand Approaches

Aspects from the contract law and tort law approaches in those other jurisdictions can be at best persuasive authorities in the Irish Courts. While pharmacy sales of non-prescription medicines are governed by Irish contract law, the supply of prescription medicines in the health services does not involve a contract between the pharmacist and the patient. The Irish pharmacist is faced with a negligence system for professional services and a strict liability products liability regime.

6.4 Duty of Manufacturers and other Non-Retailers

The High Court judgment in *Kirby v Burke & Holloway*¹²¹⁹ has been criticised by McMahon & Binchy as an imposition of liability through a straightforward standard of care that was “unencumbered by further conceptual refinements,”¹²²⁰ a case having scant influence in the further development of the law. In the Supreme Court decision in *Power v Bedford Motor Co*,¹²²¹ Lavery J stated that the *Donoghue v Stevenson* principle “must now be taken as settled”.¹²²² The

their position in reliance on the contract”). Footnote 76 on page [162] invites the reader to draw a comparison between the New Zealand Contracts (Privity) Act, 1982, s 5(1), and s 311 (Variation of a Duty to a Beneficiary) in the American Law Institute, *Restatement (Second) of Contracts* (1981) American Law Institute Publishers, St Paul. See also Summers, DM, *Third Party Beneficiaries and the Restatement (Second) of Contracts* (1981-82) 67 Cornell Law Review 880, generally and [899]: “Courts should not restrict recovery merely because the primary purpose of the contract is not to benefit the third party.” See also Attorney General of Singapore, Law Reform and Revision Division Report LRRD No 2 / 2001, *Report on the Proposed Contracts (Rights of Third Parties) Bill 2001* (2001) Law Reform and Revision Division, Attorney General’s Chambers, Singapore, 11. Available from the United Nations Public Administration Website: <http://unpan1.un.org/intradoc/groups/public/documents/apcity/unpan002118.pdf> (Last accessed 12 January, 2012). The US and New Zealand require material reliance, *i.e.* that the third party must have materially changed his position in justifiable reliance on the promise: *Restatement of the Law (Second) Contracts* (1981), s 311(3) and New Zealand Contracts, s 5(1).

¹²¹⁷ See the New Zealand statutory provision, the Contracts (Privity) Act 1982, s 4 (Deeds or contracts for the benefit of third parties).

¹²¹⁸ See Todd, S, *Torts* (Review Article) [2004] New Zealand Law Review 585, 591.

¹²¹⁹ [1944] IR 207, Gavan Duffy J.

¹²²⁰ McMahon, B, Binchy, W, *op cit*, 253 (n).

¹²²¹ *Power v Bedford Motor Co* [1959] IR 391.

¹²²² [1959] IR 391, 408, per Lavery J. See also Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 41, citing *Paris v Stepney Borough Council* [1951] AC 367 (HL): “The degree of care involved must have regard to the seriousness of the consequences of failure.” The width of the rule is sufficiently broad to catch gratuitous bailers: see Todd, S, *Negligence: Particular*

Power case applied the principle to “persons doing work on an article which they foresee would be used by others without examination.”¹²²³ The principle has, of course, also arisen in cases involving installers/assemblers and suppliers.¹²²⁴

*Wright v Dunlop Rubber Co Ltd & Imperial Chemical Industries Ltd*¹²²⁵ concerned the negligence of a manufacturer to prevent foreseeable danger to a purchaser's employees exposed to chemical containing carcinogen. The case was originally reported in the Knight's Industrial Reports series. More recently, it was analysed by Lord Nimmo Smith extensively in *McTear v Imperial Tobacco Ltd*.¹²²⁶ His Lordship turned (at [7.16]) to the relevant law in *Wright*, from which the following quotation is taken:

“It is obvious that the answer to the question: ‘What are reasonable steps?’ must depend upon the particular facts. ... the manufacturer has failed in his duty if he has failed to do whatever may have been reasonable in the circumstances in keeping up to date with knowledge of such developments and acting with whatever promptness fairly reflects the nature of the information and the seriousness of the possible consequences.

If the manufacturer discovers that the product is unsafe, or has reason to believe that it may be unsafe, his duty may be to cease forthwith to manufacture or

Categories of Duty, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 289, citing *Fraser v Jenkins* [1968] NZLR 816 (CA).

¹²²³ [1959] IR 391, 408, per Lavery J.

¹²²⁴ See *Brown v Cotterill* (1934) 51 TLR 21 (KBD) (Incompetent erection of a tombstone, which structure fell upon a girl visiting the cemetery, causing her injury); *Keegan v Owens* [1953] IR 267 (Sup Ct) (Supplier of swing-boats for fairground amusements owed a duty to the organising committee's employee who was operating that equipment). For a recent review of “[a]dditional factors sufficient to give rise to a duty of care between a vendor and purchaser or vendor and end user”, see *Rivett Arboricultural & Waste Equipment Hire Pty Ltd & Ors v Conor Patrick Evans & Ors* [2007] SASC 108, [192], citing *inter alia*: *Clarke v Army and Navy Co-operative Society Ltd* [1903] 1 KB 155 (Circumstances in which the vendor had actual knowledge that the product was likely to cause danger to the purchaser or end user); *Andrews v Hopkinson* [1957] 1 QB 229 (Where the vendor represented to the purchaser that the product was in good condition and was in a position to have discovered the defect); *Fisher v Harrods Ltd* [1966] 1 Lloyd's Rep 500 (Where the vendor had knowledge that should have put the vendor on inquiry); *Imperial Furniture Pty Ltd v Automatic Fire Sprinklers Pty Ltd* [1967] 1 NSWLR 29 (Where the product was so notoriously dangerous that the vendor could not say that he was unaware of the danger); *Bendix Mintex Pty Ltd v Barnes* (1997) 42 NSWLR 307 (Where the vendor did not simply supply the product but was also the manufacturer); *Hardchrome Engineering Pty Ltd v Kambrook Distributing Pty Ltd* [2000] VSC 359 (Where the vendor was involved in the design and inspection of the product after its manufacture but before sale).

¹²²⁵ *Wright v Dunlop Rubber Co Ltd & Imperial Chemical Industries Ltd* (1972) 113 KIR 311 (QBD) (O'Connor J), *affirmed* (1973) 133 KIR 255 (CA).

¹²²⁶ *McTear v Imperial Tobacco Ltd* [2005] CSOH 69. The trial judge in *McTear*, Lord Nimmo Smith, quoted from the judgment of the Court of Appeal in *Wright v Dunlop Rubber Co Ltd & Imperial Chemical Industries Ltd* [(1973) 133 KIR 255 (CA)]. Lord Nimmo Smith stated (at [7.12]) that the judgment of the appellate court in *Wright* had been read by Sachs J and Lawton J (without individual attribution of specific passages).

*supply the product in its unsafe form. It may be that in some circumstances the duty would be fulfilled by less drastic action ... Factors which would be relevant would be the gravity of the consequences if the risk should become a reality, and the gravity of the consequences which would arise from the withdrawal of the product.”*¹²²⁷

The staggered withdrawal of Lipobay (cerivastatin) from the pharmaceutical marketplace around the world in 2001 has been criticised.¹²²⁸ European agencies were said to have been somewhat slow to react.¹²²⁹ In Europe, there was to be no future opportunity for unhelpful news management by a marketing authorisation holder.¹²³⁰

Pharmacists employed in the pharmaceutical industry particularly may be liable in negligence on the principles in *Donoghue v Stevenson*,¹²³¹ as adumbrated by the courts. The number of potential claimants whom industrial pharmacists must bear in mind is obviously far greater than for pharmacists in community or hospital practice. Industrial pharmacists are required to perform adequate and up-to-date scientific literature searches to discharge the duties to warn fully of the dangers that products pose or to provide instructions for safe use: *Vacwell Engineering Co Ltd v BDH Chemicals Ltd*.¹²³² In the light of more recent technological advances, it may be submitted that scientific researchers (industrial pharmacists included) may be challenged for negligently

¹²²⁷ *Wright v Dunlop Rubber Co Ltd & Imperial Chemical Industries Ltd* (1972) 13 KIR 255, 272. See also Hua, X, *Product Recall and Liability* (2011) 27 Journal of Law, Economics and Organizations 113. (The article examines a firm's incentives to recall its product after learning that the product may harm consumers, although the position of 'medical equipment' is discussed, different considerations apply to medicinal products).

¹²²⁸ See Smillie, M, Brueton, G, *Pharmacovigilance*, Chapter in Shorthose, S, (Editor), *EU Pharmaceutical Regulatory Law* (2010) Kluwer Law International, Alphen aan den Rijn (NL), 108. Lipobay was marketed as Baycol in the US.

¹²²⁹ Greater co-ordination ensued through the European Heads of Medicines Agencies framework. When 'the story broke' (August 2001), the pharmaceutical company attempted to derive some short-lived solace from the continued presence of Baycol on the Japanese market (from which the chief adversely-interacting medication was absent).

¹²³⁰ See Directive 2001/83/EC, art 104(9).

¹²³¹ [1932] AC 562.

¹²³² [1971] 1 QB 88. See, in particular, the comments of Rees J [1971] 1 QB 88, 98-99. In the past, it was not expected that written judgments would cite non-legal publications (essentially part of the evidence in the case) with the same thoroughness that legal authorities receive. To demonstrate the comparative ease with which enquiries may be executed in the twenty-first century, through a *Google Books* search, this author retrieved complete citations for the three books mentioned by Rees J in *Vacwell*, as follows: (1) Mellor, JW, *A Comprehensive Treatise on Inorganic and Theoretical Chemistry, Vol 5* (1924) Longmans, Green & Co, London.; (2) Deutsche Chemische Gesellschaft, *Gmelin Handbuch der anorganischen Chemie, 8 Auflage, System Nr 13 "Bor"* (1926) Verlag Chemie GmbH, Leipzig, Berlin; (3) Thorpe, JF, *A Dictionary of Applied Chemistry, Vol 1* (1938) Longmans, Green & Co, London. His Lordship found that a copy of each book was available in the defendant's library at Poole, Dorset, and the learned judge suggested that any of them, if consulted, would have alerted the defendant to the dangerous nature of boron tribromide.

failing to act upon or to relay an appropriate warning, as the case may be, having regard to the contents of the employer institution's Online Public Access Catalogue (OPAC).

A doctor's poor handwriting can be a cause of injury, where as a result the wrong product (or the right product in the wrong dose) has been supplied to a patient on prescription.¹²³³ Herxheimer and Young describe an English case in which the plaintiff was exposed to hypertrichosis and facial hyperpigmentation through minoxidil, prescribed at a high dosage rate, over a prolonged period.¹²³⁴ The case was settled for reasons including persistent failure to warn about the likelihood of unsightly hair growth.

6.5 Retailers' Duty

Apart from wide-ranging contractual obligations to purchasers, retailers owe a duty of care in tort to prevent reasonably foreseeable injury to persons using the products sold by them. Commercial buyers can only be deprived of contractual redress "*where a fair exclusion clause has been incorporated in the contract of sale.*"¹²³⁵ While manufacturers are expected to have a quality control system in place, retailers are not expected to make an intermediate examination of goods when to do so would disrupt the packaging, thereby undermining consumer confidence in the product.¹²³⁶

Laffoy J stated in the case of *Duffy v Rooney and Dunne Stores (Dundalk) Ltd*¹²³⁷:

"However, I am of the view that a reasonably prudent manufacturer¹²³⁸ or retailer, had he properly addressed the issue, would have, and the second defendant ought

¹²³³ See Cook, T, Doyle, C, Jabbari, D, *Pharmaceuticals Biotechnology and The Law* (1991) Stockton Press, New York, 371-372, citing *Prendergast v Sam & Dee Ltd & Others* [1989] Med LR 36 (CA): "*It was argued on behalf of Dr Miller that because [the pharmacist's] mistakes were so glaring, Dr Miller's bad handwriting could not be said to be a cause of the injury to the plaintiff. The trial judge and the Court of Appeal both rejected this view however. Both courts stated that the negligence of the pharmacist was just the sort of thing a doctor should take into account when writing a prescription, since a pharmacist may be busy or tired. Dr Miller's handwriting was below the standard of legibility expected by the law.*"

¹²³⁴ See Herxheimer, A, Young, N, *A Prescriber's Duty of Care* (1990) 140 *New Law Journal* 859: "*The prescriber has a clear duty to inform a patient about a likely adverse effect which might worry the patient, but how far this duty extends to a prescriber who continues treatment begun by a colleague does not seem to have been considered by the courts.*"

¹²³⁵ See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 92-93.

¹²³⁶ See McMahon, B, Binchy, W, *op cit*, 255.

¹²³⁷ *Duffy v Rooney and Dunne Stores (Dundalk) Ltd* [1997] IEHC 102; *affirmed*, Supreme Court, 23 April, 1998. See also Binchy, W, *Recent Developments in Tort Law* [2004] 1 *Judicial Studies Institute Journal* 8, 28, 46.

to have, affixed a label to Amy's coat warning that it should be kept away from fire."¹²³⁹

However, the learned judge exonerated the second defendant on the basis that had a warning been given, the child plaintiff would still have been wearing the raincoat (at the material time).¹²⁴⁰ Thus the case failed on principles of causation.

The case of *O'Byrne v Gloucester*¹²⁴¹ was notable for a failure on the part of the makers of a brushed cotton skirt to attach a warning to the effect that it was highly flammable.

The foregoing two unreported cases were reviewed in *Cassells v Marks and Spencer plc*¹²⁴²:

*"Of the cases opened to the court by counsel on both sides the two most relevant are Duffy v Rooney ... and O'Byrne v Gloucester ... In both these cases children were badly burnt as a result of their clothes catching fire. It should be noted, however, that in neither case did the garment in question bear any label whatsoever warning of the dangers of fire."*¹²⁴³

The Supreme Court held in *Cassells* that there were no standards for flammability or warnings (written content) for day clothes in Britain or Ireland. The Court made the further holdings that: the defendant did owe a duty of care to provide a warning label; the warning required by the regulations as to children's nightwear¹²⁴⁴ in its terms, 'keep away from fire', would be a sufficiently clear warning.

¹²³⁸ See Wade, JW, *On the Nature of Strict Tort Liability for Products* (1973) 44 Mississippi Law Journal 825, 839-840: "A [product] is not duly safe if it is so likely to be harmful to persons [or property] that a reasonable prudent manufacturer [or supplier], who had actual knowledge of its harmful character would not place it on the market. It is not necessary to find that this defendant had knowledge of the harmful character of the [product] in order to determine that it was not duly safe. This language gives the tort flavor."

¹²³⁹ Per Laffoy J, [46]. The court would appear to have tacitly recognised the reality that the second-named defendant was connected with the holding company of a major retailer that is heavily involved in direct procurement of 'own brand' clothing and other consumer goods.

¹²⁴⁰ McMahon, B, Binchy, W, *op cit*, 255.

¹²⁴¹ *O'Byrne v Gloucester*, Unreported, Supreme Court, 03 November, 1988. See also Binchy, *op cit*, 46. See also Schuster, A, *The New Irish Product Liability Regime* (1994-1995) 39 St Louis University Law Journal 917, 921 (n).

¹²⁴² [2002] 1 IR 179 (Sup Ct).

¹²⁴³ [2002] 1 IR 179, 186 (Sup Ct), per McGuinness J.

¹²⁴⁴ See also *Rodgers v Adams Children's Wear Ltd*, Unreported, 11 February, 1993 (HC, Carroll J). The plaintiff's case was unsuccessful on the grounds that if a fire warning is given the duty of care owed by a manufacturer or retailer is discharged irrespective of where that warning is placed on the garment, and that accordingly the labelling was adequate. As normal reasonably intended use of the garment did not involve exposure to fire, sample testing was not appropriate under regulation 6 of the European Communities (General Product Safety) Regulations, 1997 (SI 197 of 1997). There were no statutory requirements, apart from children's night-dresses, to treat the fabric in children's clothing with fire retardant. In all the

In *Tesco Stores Ltd v Pollard*,¹²⁴⁵ the Court of Appeal held that the Consumer Protection Act 1987 did not import any duty on those responsible under the Act to fulfil the British Standard. To do so would effectively mean that a producer warranted that the product would fulfil the relevant standard, when the producer may never have had any contact with the purchaser. Neither would the purchaser be likely to have the faintest idea¹²⁴⁶ what safety standard, if any, applied to a product. The only requirement that persons generally would be entitled to expect¹²⁴⁷ of a child resistant closure (CRC) is that it would be harder to open than a normal closure, and that requirement was met. As one of their basic professional obligations, pharmacists are required to supply a wider range and more potent medication in CRCs than is obviously the case with non-pharmacy outlets.

6.5.1.1 Reasonably Prudent Manufacturer

There is no consensus for a separate ‘reasonably prudent manufacturer’¹²⁴⁸ test among the commentators: it is submitted therefore that the reasonably prudent manufacturer is merely an entrepreneurial incarnation of the ‘reasonable man’ (or person).¹²⁴⁹ One is fortified in this view by the following *dictum* in *Conte v Wyeth Inc*,¹²⁵⁰ which is familiar territory:

*“Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about.”*¹²⁵¹

circumstances the dress was a safe product within the terms of the 1997 Regulations. See also European Communities (General Product Safety) Regulations 2004.

¹²⁴⁵ [2006] EWCA Civ 393. Officially reported *sub nom Tesco Stores Ltd & Anor v CFP (A Minor) & Anor* [2006] EWCA Civ 393.

¹²⁴⁶ [2006] EWCA Civ 393, [17], per Laws LJ. It is submitted that this reasoning in *Tesco Stores Ltd v Pollard* will apply *a fortiori* to consumer expectations in export markets.

¹²⁴⁷ [2006] EWCA Civ 393, [18], per Laws LJ, referring to the Consumer Protection Act 1987, s 3.

¹²⁴⁸ See *Cepeda v Cumberland Engineering Company Inc* (1978) 386 A2d 816 (NJ Sup Ct) and specifically (1978) 386 A2d 816, 821, per Conford PJAD (emphasis added): “... the remaining determinative question as to affirmative liability is whether a **reasonably prudent manufacturer** with such foreknowledge would have put such a product into the stream of commerce after considering the hazards as well as the utility of the machine, the ease of incorporating a remedial interlock, the likelihood *vel non* that the machine would be used only with the guard, and such other factors as would bear upon the prudence of a reasonable manufacturer in so deciding whether to market the machine.” The *Cepeda* case was overruled in *Suter v San Angelo Foundry & Machine Co* (1979) 406 A2d 140 (NJ Sup Ct), on the issue of employee contributory negligence for the purposes of a strict liability theory of liability, although its usefulness as an application of the reasonably prudent manufacturer test endures. See also Wade, JW, *On the Nature of Strict Tort Liability for Products* (1973) 44 Mississippi Law Journal 825, 839-840.

¹²⁴⁹ See *Blyth v Birmingham Waterworks Co* (1856) 156 ER 1047, 1049.

¹²⁵⁰ *Conte v Wyeth Inc and ors* (2009) 105 BMLR 122, 130-131 (Cal Ct App, 1st Div, Dist 3).

¹²⁵¹ (2009) 105 BMLR 122, 130-131, per Siggins J.

The hindsight test is a version of the ‘reasonably prudent manufacturer’ test, which imputes knowledge of the product’s dangers (foreseeable or not) “*as a matter of law from time of trial back to time of distribution, thereby relieving the plaintiff of the burden of proving the manufacturer’s knowledge of a dangerous condition.*”¹²⁵²

The pharmacist in Ireland cannot derive much solace from the foregoing US commentary. It is likely that the pharmacist’s standard of care will demand specificity of warning to the patient/consumer, which may well be laid out in detailed guidance from the Pharmaceutical Society of Ireland.

6.6 Liability of Manufacturers for Negligence of Supplier of Component

In *Fleming v Henry Denny & Sons Ltd*,¹²⁵³ Kingsmill-Moore J. stated that it would not be possible to lay down a universal rule:

*“ ... The nature of the material purchased, the reputation of the dealer from whom it is purchased, the obligation imposed by law on a vendor, the processes through which the materials have already passed in the hands of the manufacturer dealer, the past experience of the purchaser and the general experience of mankind; all these have their bearing on the remoteness or otherwise of the contingency. The manufacturer is not bound to take precautions against any contingency however remote and the nature of the precautions which he is obliged to take must bear a relation to the probability or improbability of the risk. A manufacturer of cakes may well be bound to take great care that stones are not incorporated in the currants which he uses, for the occasional presence of such stones is notorious, but it does not follow that if he purchases flour from millers of unblemished reputation he is bound to test it for the presence of Ergot, and still less would he be bound to examine the sugar, which he purchases from reliable sources, to see that it is not contaminated with strychnine or other poisonous crystals.”*¹²⁵⁴

¹²⁵² See Chun, JH, *The New Citadel: A Reasonably Designed Products Liability Restatement* (1994) 79 Cornell Law Review 1654, 1672.

¹²⁵³ Unreported, Supreme Court, 29 July, 1955.

¹²⁵⁴ Unreported, Supreme Court, 29 July, 1955, [7]-[8].

6.7 Ultimate Consumer

In the US, drugs and medical devices are an exception to the rule requiring a warning of danger to the ultimate consumer.¹²⁵⁵ From *Buckner v Allergan Pharmaceuticals Inc*, there would appear to be a blurring of who can fulfil the ‘learned intermediary’¹²⁵⁶ role, so as to act upon “*an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs*”¹²⁵⁷ in the consumer’s interest. In the majority of cases there is no duty to warn the patient directly except in the case of drugs marketed directly to the consumer.¹²⁵⁸ The ultimate consumer of prescribed medication is readily determinable.¹²⁵⁹ The ultimate consumer of non-prescription medication may well require the pharmacist to make enquiry, on legal and/or ethical grounds.¹²⁶⁰ Prescription drugs will not be produced to the specifications of the ultimate consumer.¹²⁶¹

In *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd*,¹²⁶² Jessup J rejected the applicant, Peterson’s submission that “*a duty of care will only arise in respect of risks that are ‘material’.*”¹²⁶³ The

¹²⁵⁵ Lehv, MS, *Medical Product Liability*, Chapter in Sanbar, SS (Editor), *Legal Medicine*, Seventh Edition (2007) Mosby Elsevier, Philadelphia, 401, citing *Buckner v Allergan Pharmaceuticals Inc* (1981) 400 So2d 820, 822, per Cowart J (Fla, Dist Ct of Appeals, 5th Dist): “*A manufacturer of a dangerous commodity, such as a drug, does have a duty to warn but when the commodity is a prescription drug we hold that this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs.*” (Internal citations omitted). See further Owen, DG, *Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate* (2010) 42 Connecticut Law Review 733, 756-757 (Internal citations omitted): “*Other aspects of a drug warning’s adequacy include such matters as the effect of a manufacturer’s ‘overpromotion’ of a drug’s safety and whether warnings should be made in foreign languages.*”

¹²⁵⁶ For a statement the uniform applicability of which has been overtaken by the passage of time, see *Reyes v Wyeth Laboratories* (1974) 498 F2d 1264, 1276 (CA, 5th Ct), per Wisdom (Ct J): “*Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. [T]he prescribing physician[’s choice] is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a ‘learned intermediary’ between manufacturer and consumer.*”

¹²⁵⁷ *Buckner v Allergan Pharmaceuticals Inc* (1981) 400 So2d 820, 822, per Cowart J.

¹²⁵⁸ See Lehv, MS, *op cit*, 401.

¹²⁵⁹ The ultimate consumer of prescribed medication certainly ought to be readily determinable. It is not normally to be reasonably foreseen that persons who reside together would use their similar medication interchangeably.

¹²⁶⁰ See also McMahon & Binchy, *op cit*, 257, citing *Barnett v H & J Packer & Co Ltd* [1940] 3 All ER 575 (KBD) (A confectioner placing a sweet in a display tray, was injured by a piece of metal or steel, which pierced his skin causing blood poisoning. The plaintiff clearly could not have been the intended ultimate consumer).

¹²⁶¹ Contrast with *Hunter Engineering Co v Syncrude Canada Ltd* [1989] 1 SCR 426. In *Hunter*, one of the issues was where responsibility lay for design faults, in a design created from buyer’s specifications as to proposed use; whether or not the company supplying specifications or the company creating design was to be held liable. So-called ‘designer drugs’ occur outwith legitimate consumer markets.

¹²⁶² *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* (includes Corrigendum dated 18 June 2010) [2010] FCA 180, Jessup J.

¹²⁶³ [2010] FCA 180, [784], per Jessup J.

learned judge opined that the “*test of materiality was formulated [in Rogers v Whitaker¹²⁶⁴ and Rosenberg v Percival¹²⁶⁵] in the context of the question whether the discharge of the duty of care required a medical practitioner to warn his or her patient of risks – even very unlikely risks – known to be involved in a procedure under contemplation.*”¹²⁶⁶ Jessup J went on to contrast the product liability case at hearing. The notion of materiality, he said, found no express mention in the classic formulation of Lord Atkin in *Donoghue v Stevenson*:

“... a manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer’s life or property, owes a duty to the consumer to take that reasonable care.”¹²⁶⁷

The judge considered, in the circumstances, that the applicant was wrong to submit that a duty of care arises only in respects of risks which are ‘material’: “*the duty of care was a general and universal one arising from the proximity between the respondents and all who fell within the class of persons for whom Vioxx was intended.*”¹²⁶⁸ The ‘ultimate consumer’ concept in *Donoghue* and *Kirby* includes any user of the product, such as the driver of a car or even a passenger.¹²⁶⁹

The US cases and commentaries on this topic, accommodating the learned intermediary doctrine (by no means accepted in every US jurisdiction), serve as a contrast to the finding of Jessup J that a “*general and universal*” duty to warn existed in relation to the medicinal product, Vioxx. It is submitted that the approach of Jessup J in *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* would be a persuasive authority of considerable value to the Irish courts in a similar case.

¹²⁶⁴ (1992) 175 CLR 479.

¹²⁶⁵ [2001] HCA 18.

¹²⁶⁶ [2010] FCA 180, [785], per Jessup J.

¹²⁶⁷ [2010] FCA 180, [786], per Jessup J, citing *Donoghue v Stevenson* [1932] AC 562, 599.

¹²⁶⁸ [2010] FCA 180, [786], per Jessup J.

¹²⁶⁹ See Quill, *op cit*, 92-93.

6.7.1 Intermediate Examination

The principle for liability in *Donoghue v Stevenson* was circumscribed by the proviso of “no reasonable possibility of intermediate examination”.¹²⁷⁰ Powers, Harris and Barton make a telling observation:

*“However, the meaning of ‘intermediate examination’ has been severely qualified in decisions of the courts and, as a result, it is probably correct to say that, if a product is defective, the possibility of intermediate examination will only assist the manufacturer if he could reasonably have anticipated that the examination conducted by the intermediary would be of such a type as to reveal the defect.”*¹²⁷¹

*Mustapha v Culligan of Canada Ltd*¹²⁷² was a case in which the plaintiff sought to recover damages for a psychiatric injury he suffered as a result of seeing dead flies in a bottle of water supplied by Culligan. The question of whether Culligan owed a duty of care to Mustapha was determined solely on the basis of their manufacturer-consumer relationship, rather than on the basis of any unusual susceptibility on the part of the plaintiff.¹²⁷³

¹²⁷⁰ See McMahon & Binchy, *op cit*, 258, citing: *Farr v Butters Bros & Co* [1932] 2 KB 606 (CA) (Plaintiff actually aware of the danger, which was disregarded); *Holmes v Ashford* [1950] 2 All ER 76 (Careless examination failing to reveal defect). See also *Conole v Red Bank Oyster Co Ltd* [1976] 191 (Sup Ct), 196-197, *dicta* of Henchy J. There must be an expectation of intermediate examination strong enough to justify the person who has created a dangerous situation that such an inspection would be an adequate safeguard: see Todd, S, *Negligence: Particular Categories of Duty*, Chapter in Todd, S (Editor), *The Law of Torts in New Zealand*, Fifth Edition (2009) Thomson Reuters, Wellington, 291, citing *Jull v Wilson and Horton Ltd* [1968] NZLR 88. See also Mildred, M, *Product Liability: Law and Insurance* (2000) LLP Professional Publishing, London, 12: “It is not essential for liability to exist that the consumer of the product has had no reasonable opportunity to examine the product. The test is whether the manufacturer intended the consumer to receive the product in the same state as that in which it left the manufacturer. This principle was laid down in *Grant v Australian Knitting Mills* [[1936] AC 65 (PC)]”. The manufacturer’s intention is particularly relevant to thermolabile medication in ‘cold chain distribution’. A thermal indicator is frequently included with such a consignment; the device will automatically and irreversibly change colour, once the vulnerable product has been exposed (more than momentarily) to an unacceptably-high temperature.

¹²⁷¹ Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 732, citing: *Griffiths v Arch Engineering Co (Newport) Ltd* [1968] 3 All ER 217; *Hurley v Dyke* [1979] RTR 265 (HL). See also Kramer, A, *Proximity as principles: Directness, community norms and the tort of negligence* (2003) 11 Tort Law Review 70, 80 (n), also citing these two cases and stating: “Provided that a notice is not invalid under the Unfair Contract Terms Act 1977 (UK), it should serve to pass responsibility to the party that later encounters the goods”.

¹²⁷² [2008] 2 SCR 114 (SCC).

¹²⁷³ Klar, LN, *loc cit*. See also *Mustapha v Culligan of Canada Ltd* [2008] 2 SCR 114, [6], per McLachlin CJ: “The relationship between the parties in this case does not belong to a novel category. It has long been established that the manufacturer of a consumable good owes a duty of care to the ultimate consumer of that good: *Donoghue v Stevenson*. It follows that Culligan owed Mr Mustapha a duty of care in the supplying of bottled water to him.”

The Civil Liability Act 1961 provides that the possibility of intermediate examination does not necessarily negative the defendant's duty:

*“where an action is brought for negligence in respect of a thing that has caused damage, fact that there was a reasonable possibility or probability of examination after the thing had left the hands of the defendant shall not, by itself, exclude the defendant's duty, but may be taken as evidence that he was not in the circumstances negligent in parting with the thing in its dangerous state.”*¹²⁷⁴

The statutory provision was described by McMahon J in *Colgan v Connolly Construction (Ireland) Ltd*¹²⁷⁵ as having “*shifted the onus of proof to the defendants in products liability cases*”.

Given the high production standards required of the pharmaceutical industry, wide-scale pre-packaging of medication and the demise of pharmacy magisterial compounding, it is submitted that there is now very little scope for intermediate inspection to detect anything untoward in modern medicinal products (or the raw materials used in compounding).

6.8 Standard of Care

Pharmaceuticals causing adverse side effects raise fundamental questions as to the appropriate balance between social utility and magnitude of risk.¹²⁷⁶ Here the law is required to judge the degree of risk to which individuals may be exposed in the development of medicinal products, which will ultimately benefit society as a whole. The drawback of a negligence standard is that the victim remains uncompensated if other parties behave non-negligently.¹²⁷⁷

Pharmaceutical companies have long argued, with varying degrees of scientific support, that the extended testing periods required in the United States, when “*compared with other advanced countries,*” prolong suffering and cause death to many who would otherwise have been cured.¹²⁷⁸ An even greater problem is uncertainty in determining liability, and the threat of high damages if

¹²⁷⁴ Civil Liability Act 1961, s 34(2)(f).

¹²⁷⁵ [1980] ILRM 33.

¹²⁷⁶ See Quill, *op cit*, 93-95.

¹²⁷⁷ See Sage, WM, *Drug Product Liability and Health Care Delivery Systems* (1988) 40 Stanford Law Review 989, 1014.

¹²⁷⁸ See Sage, WM, *op cit*, 1008-1009, citing: Newdick, C, *Strict Liability for Defective Drugs and the Pharmaceutical Industry* (1985) 101 Law Quarterly Review 405. The FDA's Abbreviated New Drug Application process was acknowledged as aiding the expedition of drug marketing, especially for new generic products.

liability is found.¹²⁷⁹ Human populations recruited for therapeutic trials are far too small to reveal most Adverse Drug Reactions, which occur with fairly low probability.¹²⁸⁰

In general, product liability cases require much evaluation of factual matters against points of principle.¹²⁸¹ The courts will examine issues such as safety testing, quality control, comparison with competitors' practices, for example.¹²⁸² It is submitted that the jurisprudence relating to warnings on flammable materials in apparel, while important *per se*, may be of limited application to sphere of pharmaceuticals, which is a heavily regulated product sector.

The standard of care imposed in Canada on manufacturers or distributors of products is based on ordinary negligence principles.¹²⁸³ The duty of care extends to three general areas: design, manufacture and marketing.¹²⁸⁴

6.9 Learned Intermediary Doctrine (LID)

6.9.1 The Position of LID in Various Jurisdictions

According to Powers, Harris, and Barton, “[i]t is settled English law, however, that the duty to supply information may, in certain circumstances, be discharged by supplying the relevant

¹²⁷⁹ See Sage, WM, *op cit*, 1010. The author attributes the problem to various judicial innovations that courts have introduced in litigation over prescription drug injuries, such as alternative liability [*Summers v Tice* (1948) 199 P2d 1: the theory of alternative liability requires that all the possible defendants come before the court in order to assign responsibility to each. For this reason, the theory has not been used very successfully by victims of diethylstilbestrol (DES)]; concert of action [*Bichler v Eli Lilly & Co* (1982) 436 NE2d 182] market share liability [see *Sindell v Abbott Laboratories* (1980) 607 P2d 924, *cert denied* (1980) 449 US 912] and risk-contribution liability [the risk-contribution theory allows recovery against a maker who could have supplied the drug taken because the maker produced and marketed the drug, thereby contributing to the risk of injury: see, for example, *Collins v Eli Lilly & Co* (1984) 342 NW2d 37; *cert denied sub nom ER Squibb & Sons Inc v Collins* (1984) 469 US 826]. See also Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 736, stating that there has been no English decision inclined to impose liability on the basis in *Sindell*.

¹²⁸⁰ See Sage, WM, *op cit*, 1020, citing Newdick, C, *Strict Liability for Defective Drugs and the Pharmaceutical Industry* (1985) 101 Law Quarterly Review 405, 421, for the proposition that “a drug which caused a five percent increase in the incidence of fairly common birth defects (such as anencephaly or ventricular septal defect) in the offspring of women who ingested it, would likely remain unsuspected for over ten years.” For a more nuanced comment, see Herxheimer, A, Mintzes, B, *Antidepressants and Adverse Effects in Young Patients: Uncovering the Evidence* (2004) 170 Canadian Medical Association Journal 487, 487: “Pre-market trials are often carried out in restricted patient populations that inadequately represent the users of a drug once it is on the market.”

¹²⁸¹ See Quill, *op cit*, 95.

¹²⁸² Quill, *loc cit*.

¹²⁸³ Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 366.

¹²⁸⁴ Klar, LN, *loc cit*.

information to a responsible intermediary".¹²⁸⁵ It is submitted that 'responsible intermediary' is not necessarily synonymous with 'learned intermediary': a tyre fitter may fulfil the role of 'responsible intermediary' in relation to warnings about temporary tyres and their improper use. In most villages, market towns and other communities, few will rival the erudition of medical practitioners, at least in healthcare matters. This reality found expression in *Reyes v Wyeth Laboratories*.¹²⁸⁶ The US Court of Appeals focused on the physician's "*knowledge of both patient and palliative*".¹²⁸⁷ Hird has ventured: "[w]hat makes the doctor 'learned' on this view is the unique combination of his knowledge of the product together with his knowledge of his patient's idiosyncrasies."¹²⁸⁸ By no means all US jurisdictions accept the LID. For example, a recent decision from West Virginia underlines this reality.¹²⁸⁹ When it comes to actual patient compliance with the prescribed medication, the pharmacist may have a greater insight into the patient's idiosyncratic behaviour.

The learned intermediary doctrine has not been accepted in Australia.¹²⁹⁰ The doctrine has been acknowledged in Canada. Robins JA (for Ontario Court of Appeal), while accepting the learned intermediary doctrine as appropriate to prescription drugs generally, rejected its application to oral contraceptives in *Buchan v Ortho Pharmaceutical (Canada) Ltd.*¹²⁹¹ The learned judge relied on recent jurisprudence from the US.¹²⁹² The court was influenced by the reality that medical practitioners were prescribing oral contraceptives for socioeconomic reasons.¹²⁹³ Accordingly, the court held that manufacturers of oral contraceptives should be obliged to satisfy the general common law duty to warn the ultimate consumer as well as prescribing physicians. The rule was

¹²⁸⁵ Powers, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 756. "*It is settled English law, however, that the duty to supply information may, in certain circumstances, be discharged by supplying the relevant information to a responsible intermediary*", citing: *Holmes v Ashford* [1950] 2 All ER 76 (CA) (Manufacturer's warning given to hairdresser) and *Kubach v Hollands* [1937] 3 All ER 907 (Chemicals supplied for experiments in school came with an instruction that the products were to be tested before use). See also Hedley, S, *Tort*, Seventh Edition (2011) Oxford University Press, Oxford, 90.

¹²⁸⁶ (1974) 498 F2d 1264 (5th Ct); *cert denied* (1974) 419 US 1096.

¹²⁸⁷ (1974) 498 F2d 1264, 1276.

¹²⁸⁸ See Hird, NJ, *Negligence*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 237.

¹²⁸⁹ *State Ex Rel Johnson & Johnson Corp v Karl* (2007) 647 SE2d 899 (W Va: Sup Ct), analysed in Gourley, SJ, Knutson, SJ, *Update on US Product Liability Law*, Chapter in Dodds-Smith, I, Spencer, M (Editors), *The International Comparative Legal Guide to Product Liability 2011* (2011) Global Legal Group, London. Available from <http://www.iclg.co.uk/khadmin/Publications/pdf/4491.pdf> (Last accessed 15 March, 2012).

¹²⁹⁰ *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* [2010] FCA 180, [796], per Jessup J.

¹²⁹¹ (1986) 35 CCLT 1 (ONCA). See also Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 373.

¹²⁹² Robins JA stated that the reasoning which prompted several state courts to hold the learned intermediary rule inapplicable to birth control pills was clearly articulated by the Supreme Judicial Court of Massachusetts in *MacDonald v Ortho Pharmaceutical Corp* (1985) 475 NE2d 65 (Mass); *cert denied* 106 S Ct 250.

¹²⁹³ The court acknowledged that there was no treatment of illness or injury that was to undergo medical treatment in such circumstances.

also applied to a manufacturer of breast implants in *Hollis v Dow Corning*,¹²⁹⁴ where the Supreme Court of Canada found that the manufacturer's general duty to warn consumers about risks is discharged by providing the surgeon with adequate disclosure.¹²⁹⁵ In both *Buchan* and *Hollis*, the courts held that the manufacturers did not provide the doctors with adequate information and therefore had failed to discharge their duties in accordance with the learned intermediary rule.¹²⁹⁶

6.9.2 Exceptions to the Learned Intermediary Doctrine

The most established exception to the learned intermediary¹²⁹⁷ rule is for mass immunization programs where no health professional mediates information for the patient's benefit about drug risks.¹²⁹⁸ Another exception concerns oral contraceptives ('birth control pills').¹²⁹⁹ It is submitted that this should also include newer technologies such as a hormone-eluting vaginal ring. A third exception, developed more recently, arose in response to direct-to-consumer advertising.¹³⁰⁰

The provision of such patient-oriented information, to be placed within medication packaging, in Ireland is governed by EU Law. For the EU (and the wider EEA), the package leaflet must be based on the Summary of Product Characteristics (SPC).¹³⁰¹ The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.¹³⁰² The

¹²⁹⁴ *Hollis v Dow Corning Corp* [1995] 4 SCR 634 (SCC) (On appeal from the Court of Appeal for British Columbia).

¹²⁹⁵ [1995] 4 SCR 634, [62], per La Forest J: "On the basis of the foregoing, it is my view that Dow breached its duty to warn Dr Birch concerning the risks of post-surgical rupture in the Silastic implant and because of this failure to warn is liable to Ms Hollis for her injuries. Accordingly, I would dismiss the appeal."

¹²⁹⁶ See Torrens, L, *Informed Consent and the Learned Intermediary Rule in Canada* (1994) 58 Saskatchewan Law Review 399, 399-400. This author refers to the reasoning in the provincial appellate court in *Hollis*, which was upheld by the Supreme Court of Canada.

¹²⁹⁷ Compare with the 'sophisticated intermediary'; see Nelson, K, *Case Note: Tort Law—Shades Of Gray: The Sophisticated Intermediary Defense is now available for Minnesota Industrial Failure to Warn Actions—Gray v Badger Mining Corp* (2004) 31 William Mitchell Law Review 659.

¹²⁹⁸ Owen, DG, *Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate* (2010) 42 Connecticut Law Review 733, 762.

¹²⁹⁹ Owen, DG, *op cit*, 763.

¹³⁰⁰ Owen, DG, *op cit*, 765. See further Owen, DG, *op cit*, 767: "While the Restatement (Third) of Torts: Products Liability adopts the learned intermediary rule, it provides a general exception wide enough to accommodate all three exceptions, and it specifically leaves open the question of whether a new exception should be created for drugs that are mass-marketed directly to consumers" [§ 6(d), cmt e]. See also Owen, DG, *op cit*, 767 (n): "The Restatement (Third) of Torts [§ 6(d)] provides that a prescription drug or medical device is defective if the manufacturer fails to provide reasonable warnings of foreseeable risks to: (1) the doctor or other healthcare provider, or (2) the patient, if the manufacturer should know that healthcare providers are "not in a position to reduce the risks of harm in accordance with the instructions or warnings'."

¹³⁰¹ Article 59 of EU Council Directive 2001/83/EC, as "replaced" by Article 44 of EU Council Directive 2004/27/EC.

¹³⁰² Article 59(3) of EU Council Directive 2001/83/EC, as "replaced" by Article 44 of EU Council Directive 2004/27/EC.

PIL must also be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market.¹³⁰³

6.10 Manufacturing Defects

6.10.1 Overview

Owen mentions the foreign/natural doctrine of manufacturing defects that was supplanted by the doctrine in the 1950s.¹³⁰⁴ Manufacturing defects from errors in production are normally quite easy to understand. Because physical flaws can often be established by the manufacturer's own design specifications, defects of this type often are also quite easy to prove.¹³⁰⁵ In some cases (for example, almost all medicinal products and some medical devices), "*the physical evidence to prove or disprove the accident was attributable to a production error may vanish with the product*".¹³⁰⁶ Mirroring *res ipsa loquitur*, the malfunction doctrine, which in recent years has spread silently across the US, now provides a safe harbor for plaintiffs whose injuries probably were caused by manufacturing defects, the tangible proofs of which have left this world.¹³⁰⁷ It is relatively easy to make the inference in the case of an electrical appliance.

¹³⁰³ Article 63, Paragraphs (2) and (3), of EU Council Directive 2001/83/EC, as "*replaced*" by Article 48 of EU Council Directive 2004/27/EC.

¹³⁰⁴ Owen, DG, *Manufacturing Defects* (2001-2002) 53 South Carolina Law Review 851, 897: "*Although a number of courts applied the foreign/natural doctrine [enunciated in *Mix v Ingersoll Candy Co* (1936) 59 P2d 144 (Cal)] as a method for determining the defectiveness of food in certain types of cases, the test was never adopted in more than a handful of jurisdictions. In 1951, America's leading food-law scholar, Professor Reed Dickerson, argued that the foreign/natural inquiry should be rejected in favor of a determination of consumer expectations*", citing Dickerson, R, *Products Liability and the Food Consumer* (1951) Little, Brown and Company, Boston, 185: "*The better test of what is legally defective appears to be what consumers customarily expect and guard against. Canned foods are expected to be found already washed, cleaned, and trimmed, while the same foods in fresh form normally call for work of that sort by the customer*".

¹³⁰⁵ Owen, DG, *op cit*, 905. See also Owen, DG, *op cit*, 885 (n). "*The hot coffee cases normally involve claims of defective design (too high a temperature) or warnings (failure to warn adequately of the high temperature and its capacity to burn), rather than manufacturing defects.*" See, e.g., *Olliver v Heavenly Bagels Inc* (2001) 729 NYS2d (Sup Ct) (involving injury from hot coffee; summary judgment for defendants; discussing other cases). While the defective design model might be applied, for example, to an internationally-franchised coffee establishment, it could be more difficult to convince a court that a 'kettle, coffee powder, sugar and milk' process, conducted in plain sight of the customer at a neighbourhood cafe, involved either design or warning defects.

¹³⁰⁶ Owen, DG, *op cit*, 905.

¹³⁰⁷ See Owen, DG, *Products Liability Law* (2005) Thomson West, Eagan (MN), 450 (n), citing (although not quoting from) *Cassisi v Maytag Co* (1981) 396 So2d 1140 (Fla: Dist Ct of Appeals, 1st Dist). See, in particular, 396 So2d 1140, 1148, the *dicta* of Ervin J: "*[T]he case most often cited as so holding is *Greco v Bucciconi Engineering Co* [(1967) 283 FSupp 978 (WD Pa); affirmed (1969) 407 F2d 87 (3d Cir)]. We approve the *Greco* rule and apply it to the case now before us. That rule, applying Pennsylvania law, simply states that when a product malfunctions during normal operation, a legal inference, which is in effect a mirror reflection of the Restatement's standard of product defectiveness, arises, and the injured plaintiff thereby establishes a *prima facie* case for jury consideration.*" The court cited *Greco* further [1149]: "*The plaintiff is not obliged to negate alternative grounds of causation*", for which the pinpoint is 283 FSupp 978, 984.

From earlier days, “cases involving the sale of contaminated food and drink gave birth to early products liability law.”¹³⁰⁸ The types of foodstuffs consumed today have “multiplied enormously, and modern products liability law must still deal with the hazards of contaminated food and drink.”¹³⁰⁹ The defectiveness of food and drink is “now widely ascertained by a consumer’s reasonable expectations, and an injured consumer must trace the injury to such a defect and to the defendant food supplier.”¹³¹⁰ Responsibility for manufacturing defects is “the most fundamental obligation of product manufacturers[; t]he law governing production errors is now quite settled, and it remains the first pillar of modern products liability law.”¹³¹¹

Res ipsa loquitur was applied, on the basis of the manufacturer’s exclusive control, in the case of *Escola v Coca Cola Bottling Co.*¹³¹²

6.10.2 Canada

In a product liability case such as this there are three requirements the plaintiff must prove on a balance of probabilities in order to recover damages: (1) the product was defective, (2) the injury was caused by the defect, and (3) the manufacturer was negligent in allowing the defect to occur.¹³¹³ Waddams has stated the position thus:

"Where the plaintiff proves that the product left the manufacturer's hands in a defective condition and that the defect has caused his injuries his cause of action is not complete unless he satisfies the court also that the defect was caused by the manufacturer's negligence. ... Where the defect arises in the manufacturing process controlled by the defendant, the inference of negligence is practically irresistible. The argument is that either the manufacturer's system was at fault, or, if the system was sound, that an individual employee must have been negligent.

¹³⁰⁸ Owen, DG, *Manufacturing Defects* (2001-2002) 53 South Carolina Law Review 851, 905.

¹³⁰⁹ Owen, DG, *loc cit.*

¹³¹⁰ Owen, DG, *loc cit.*

¹³¹¹ Owen, DG, *loc cit.*

¹³¹² *Escola v Coca Cola Bottling Co* (1944) 24 Cal2d 453 (Ca Sup Ct), 461 (Gibson CJ). See also Prosser, WL, *Strict Liability to the Consumer in California* (1998-1999) 50 Hastings Law Journal 813, 854: “Strictly speaking, and since proof of negligence is not in issue, *res ipsa loquitur* has no application to strict liability; but the inferences which are the core of the doctrine remain, and are no less applicable.”

¹³¹³ Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 368. The position in the Anglophone Caribbean countries appears similar; see Ramlogan, R, Persadie, N, *Commonwealth Caribbean Business Law*, Second Edition (2010) Routledge-Cavendish, Abingdon, 249-270.

In either case the manufacturer is liable, and the plaintiff need not prove exactly how the defect arose."¹³¹⁴

Case law has held that a manufacturer of a product which uses a component part supplied by a third party remains responsible for a defect in that component.¹³¹⁵

6.11 Design Defects

The *Restatement (Third)* provides for a “reasonable alternative design is obvious and understandable to lay persons” to be established without expert evidence.¹³¹⁶ While lay persons may have little difficulty with demonstrating unaided a reasonable alternative design for machinery that caused injury,¹³¹⁷ it is submitted that establishing a reasonable alternative design for a medicinal product may be outwith their knowledge and experience. Henderson and Twerski note that in “product cases alleging defective design, causation doctrine operates reasonably well. A plaintiff typically sets forth a hypothetical alternative design and seeks to prove that, had the safer alternative been in place, the injury would have been avoided or reduced.”¹³¹⁸ These authors point out that in “the typical failure-to-warn case, the very opposite is true. To establish causation a plaintiff should, in theory, be required to prove not only that she would have read, understood, and remembered the warning, but also that she would have altered her conduct to avoid the injury.”¹³¹⁹

Owen states that the only factors ordinarily relevant in the risk-utility balance of the plaintiff’s alternative design are:

¹³¹⁴ *Meisel v Tolko Industries Ltd*, 1991 CanLII 120 (BCSC), citing Waddams, SM, *Products Liability*, Second Edition (1980) Carswell, Toronto, 61.

¹³¹⁵ Klar, LN, *op cit*, 369, citing David, H, Draper, A, Bowolska, G, *Tort Liability of a Manufacturer for Defective Components* (2007) *Advocates’ Quarterly* 152. Klar states these authors argue that since product liability in Canada is based on negligence principles, a manufacturer should not be held liable for a defective component used in its product, unless there was fault on the manufacture, with respect to its use of that defective part.

¹³¹⁶ Murrian, RP, *Products Liability - Tennessee’s Prudent Manufacturer Test* (1999-2000) 67 *Tennessee Law Review* 307, 318-319, referring to *Restatement (Third)*, § 2, cmt f. See also Murrian, *op cit*, 319 (n): under § 2, cmt f, the plaintiff may be able to establish a product defect under § 3 by introducing circumstantial evidence indicating that a product failure was not likely caused solely by factors other than a product defect. See *Potter v Chicago Pneumatic Tool Co* (1997) 694 A2d 1319 (Conn).

¹³¹⁷ Henderson, Jr, JA, Twerski, AD, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn* (1990) 65 *New York University Law Review* 265, 304-307.

¹³¹⁸ Henderson and Twerski, *op cit*, 304.

¹³¹⁹ Henderson and Twerski, *op cit*, 305.

*“the incremental or ‘marginal’ precaution costs and safety benefits of adopting the particular design safety feature proposed by the plaintiff. The notion of marginal costs and benefits implies a move which here involves the move from the chosen design to the alternative design. And so the proper balance is between the expected precaution costs and the expected safety benefits involved in altering the chosen design in the particular fashion proposed by the plaintiff—those costs and benefits incurred in moving from the manufacturer’s actual chosen design to the plaintiff’s hypothetical alternative design.”*¹³²⁰

It is submitted that an extreme and commercially unattractive example of an alternative design would lead to presenting the product in a manner that will automatically attract prescription control.¹³²¹

Concerning claims of defective designs in pharmaceuticals, section 6(c) of the *Restatement (Third) of Torts: Products Liability* provides as follows:

*“A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients.”*¹³²²

Better instructions on safe use, opines Conk, do not discharge the duty of the manufacturer and designer of a drug: making the product itself safer reduces the risks of *“patient noncompliance and of physicians’ ignorance, among other foreseeable dangers.”*¹³²³ Various tactics are used by the pharmaceutical industry to inhibit the emergence or retention of a safer alternative design.¹³²⁴

¹³²⁰ Owen, DG, *Toward a Proper Test for Design Defectiveness: Micro-Balancing Costs and Benefits* (1996-1997) 75 *Texas Law Review* 1661, 1687 (Internal citations omitted).

¹³²¹ For example, in Ireland, see the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI No 540 of 2003), art 5(1) (Medicinal Products subject to Prescription Control): *“Subject to the provisions of these Regulations a person shall not supply a medicinal product of any of the following classes except in accordance with a prescription, namely ... (b) any medicinal product which is intended for parenteral administration”*.

¹³²² *Restatement (Third) of Torts: Products Liability* (1998), § 6(c) (omitting parallel references to “medical device”). See also Noah, L, *This is your Products Liability Restatement on Drugs* (2009) 74 *Brooklyn Law Review* 839, 842.

¹³²³ Conk, GW, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market* (2001-2002) 49 *UCLA Law Review* 737, 764.

¹³²⁴ See, for example, Conk, GW, *op cit* 737: at 737, arguing that in patent-monopolized markets the burden on the plaintiff to produce an alternative design should be lighter than in robust markets open to

Conk describes this type of enquiry as the ‘net benefit test’.¹³²⁵ Thus, if the medicinal product does more harm than good for at least one class of users, it will not be considered defective: “[t]his is true even if the product unnecessarily causes harm, in the sense that there is a feasible safer alternative design.”¹³²⁶

Section 6(c) is also notable in that it represents a ‘product category’ approach to liability rules even though the ALI elsewhere rejected the categorical approach.¹³²⁷ The net benefit rule is a standard under which liability rarely will be imposed. Indeed, a design-defect claim will not survive “even the summary judgment stage” unless the court determines that a reasonable person could conclude that the product as defective under this narrow standard.¹³²⁸

Henderson and Twerski have taken issue with what they contend are errors in Conk’s thesis.¹³²⁹ They maintain that the *Restatement (Third)* is correct in not allowing plaintiffs to argue that a drug manufacturer should have developed a safer alternative drug.¹³³⁰ These authors take issue with critics of the *Restatement (Third)* who advocate an aggregative approach in which the defectiveness of a prescription drug’s design is determined by considering the drug’s potential

competition; at 763, indicating that process patents may be used to discourage or prevent the emergence of generic alternatives.

¹³²⁵ See Conk, GW, *Is there a Design Defect in the Restatement (Third) of Torts: Products Liability?* (2000) 109 *Yale Law Journal* 1087, 1102 [Text and n (62)], citing the judicial interpretation of the net benefit test in *Reyes v Wyeth Laboratories* (1974) 498 F2d 1264 (5th Ct). *Reyes* was a suit by a child who contracted polio from the Sabin oral live polio vaccine in which the court held that an unavoidably unsafe product is unreasonably dangerous only if it is “so dangerous that a reasonable man would not sell the product if he knew the risk involved” (498 F2d 1264, 1273-74).

¹³²⁶ Conk, GW, *op cit*, 1102.

¹³²⁷ See Conk, GW, *op cit*, 1102 (n 64), stating that *Restatement (Third) of Torts: Products Liability*, §2, cmt d has clarified that the reasonable alternative-safer-design standard “applies in most instances even though the plaintiff alleges that the category of product sold by the defendant is so dangerous that it should not have been marketed at all”).

¹³²⁸ See Conk, GW, *op cit*, 1102. See also *Restatement (Third) of Torts: Products Liability*, §2, cmt e. The section 6 (c) standard also bears some resemblance to a negligence-based marketing liability standard proposed for generic product-defect cases; Page, JA, *Liability for Unreasonably and Unavoidably Unsafe Products: Does Negligence Doctrine Have a Role to Play?* (1996-1997) 72 *Chicago-Kent Law Review* 87, 127-128 (arguing that a product’s dangers may be so great as to make its sale unreasonable even in the absence of a feasible safer alternative design).

¹³²⁹ Henderson, Jr, JA, Twerski, AD, *Drug Designs Are Different* (2001) 111 *Yale Law Journal* 151.

¹³³⁰ Henderson, Jr, JA, Twerski, AD, *op cit*, 162-163. The new *Restatement’s* refusal to consider not-yet-approved alternative drugs in assessing the defendant’s drug design does not rest on judicial deference to the FDA’s expertise. Section 6(c) tacitly admits that the FDA occasionally makes mistakes by approving worthless drugs that no competent provider would prescribe for any class of patients. § 6, cmt b (noting that “unqualified deference [to] ... regulatory mechanisms is considered by a growing number of courts to be unjustified” and that “[a]n approved prescription drug or medical device can present significant risks without corresponding advantages”). The authors acknowledge an understandable reluctance to allow courts to determine whether a proposed alternative drug would have received FDA approval.

impact on all patients for whom it might, properly or improperly, be prescribed.¹³³¹ Henderson and Twerski also reject as unhelpful suggestions by critics for reducing the complexity of drug design litigation.¹³³² They also contend it to be clear upon reflection that any “*reduction in safety incentives under section 6(c) is likely to be insignificant.*”¹³³³

Owen has suggested that “*responsibility for unavoidable dangers of which consumers are aware, because such dangers are warned about or are plainly visible, generally should reside with consumers themselves, as regular risks of life.*”¹³³⁴

Restatement (Third) of Torts: Products Liability - The Test for Design Defects

The *Restatement (Third) of Torts: Products Liability* clarifies the extent to which liability for product defects is, and is not, strict liability. Most importantly, in connection with design defects, section 2(b) provides that the test is whether the foreseeable risks posed by a product could have been reduced by the adoption of a reasonable alternative design. This is essentially a risk-utility test.¹³³⁵ The risk-utility test is negligence-like, whereas liability based on the failure to satisfy consumer expectations is a form of strict liability.¹³³⁶ Therefore, under the consumer-expectations test, a product design may be defective even if that design is [in the *Restatement (Third)* sense] “reasonable”, even if the utility of the product outweighs the risks posed by its design.¹³³⁷ Conk has criticised the *Restatement (Third)*, by comparison with the *Restatement (Second)*, for lacking “*a robust statement of the affirmative duties owed by manufacturers*”.¹³³⁸

¹³³¹ Henderson, Jr, JA, Twerski, AD, *op cit*, 168. Section 6(c) of the *Restatement* considers only the welfare of patients who are helped by a defendant’s prescription drug, refusing to deem a drug defective in design if it benefits any class of patients.

¹³³² Henderson, Jr, JA, Twerski, AD, *op cit*, 175. See further, *loc cit*: “*Replicating the FDA process is the task beyond judicial competence, not reviewing the designs themselves[:]* ... *as long as marketing of such safer drugs requires FDA approval, in-court replication of the formal approval process will continue to exceed the limits of adjudication.*”

¹³³³ Henderson, Jr, JA, Twerski, AD, *op cit*, 178; they state: “*... failure to warn is by far the more important basis of drug companies’ exposures to liability. In contrast, under the relevant provisions of the new Restatement dealing with nonprescription products generally, the duty to design reasonably safe products logically precedes the duty to warn.*”

¹³³⁴ See Owen, DG, *Inherent Products Hazards* (2004-2005) 93 Kentucky Law Journal 377, 422, where the author continues: “*Normal insurance mechanisms, rather than the products liability litigation system, are preferable institutions to address the inevitable losses from widely known inherent product hazards.*”

¹³³⁵ *Restatement (Third) of Torts: Products Liability*, § 2(b), cmt a. See also Rutherford, RT, *Changes in the Landscape of Products Liability Law: An Analysis of the Restatement (Third) of Torts* (1997-1998) 63 Journal of Air Law & Commerce 209, 247: “*... the Restatement (Third) presents a workable rule—a rule that closely resembles the risk-utility approach currently followed in several jurisdictions. Furthermore, the Restatement (Third) is supported by carefully reasoned policy considerations: policies that recognize the need for consumer protection and that attempt to balance such needs against a manufacturer’s ability to design reasonably safe products.*”

¹³³⁶ See Abraham, KS, *Stable Divisions of Authority* (2009) 44 Wake Forest Law Review 963, 969.

¹³³⁷ See Abraham, KS, *op cit*, 969.

¹³³⁸ Conk, GW, *Punctuated Equilibrium: Why Section 402A Flourished and the Third Restatement Languished* (2007) 26 Review of Litigation 799, 880-881: the *Restatement (Third)* lacked “*a robust statement of the*

6.11.1 The Risk-Utility Test

Owen remarks that the US courts have turned away over time from the consumer expectations test in design danger cases: they have substituted some form of a cost-benefit (“risk-utility,” “risk-benefit,” or “benefit-risk”) standard of liability, which is the liability standard for design defectiveness adopted by the *Restatement (Third) of Torts: Products Liability*.¹³³⁹ On entering the new millennium, “*despite the tenacity of consumer expectations in a decreasing number of jurisdictions, the risk-utility test had become America’s dominant test for design defectiveness.*”¹³⁴⁰

According to Twerski, the *Restatement (Third)*’s treatment of *res ipsa loquitur* is a vast improvement over the *Restatement (Second)*’s formulation.¹³⁴¹ Twerski continues: “[i]f it has

affirmative duties owed by manufacturers to those who will encounter their products. That failure may explain courts’ slow and partial embrace of the Third Restatement even though its centerpiece—the reasonable alternative design test—is an accurate summation of prevailing practice. Recent experience, particularly with drugs and medical devices, shows the importance of recognizing an affirmative duty of product stewardship for producers of products that should essentially remain in development and subject to revision during their entire period of use by patients.”

¹³³⁹ See Owen, DG, *Design Defects* (2008) 73 *Missouri Law Review* 291, 308-309. See also Gray, OS, *Reflections on the Historical Context of Section 402A* (1993-1994) 10 *Touro Law Review* 75, 92 (n): “See *Restatement (Second) of Torts* §§ 291, 292, 293 (1965). To determine negligence, §§ 291, 292 and 293 implement a balancing test between the social utility of the product and its harm.” Section 291 provides: “Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.” Section 292 provides as factors to determining utility of an actor’s conduct: (a) social value which the law attaches to the interest which is advanced or protected by the conduct; (b) the extent of the chance that this interest will be advanced or protected by the particular course of conduct; (c) the extent of the chance that such interest can be adequately advanced or protected by another and less dangerous course of conduct. Section 293 provides as factors to determining risk: (a) the social value which the law attaches to the interests which are imperiled; (b) the extent of the chance that the actor’s conduct will cause an invasion of any interest of the other or of one of a class of which the other is a member; (c) the extent of the harm likely to be caused to the interests imperiled; (d) the number of persons whose interests are likely to be invaded if the risk takes effect in harm. On abnormally dangerous activities, see *Restatement (Second) of Torts*, §520.

¹³⁴⁰ See Owen, DG, *Design Defects* (2008) 73 *Missouri Law Review* 291, 309.

¹³⁴¹ See Twerski, AD, *Negligence Per Se and Res Ipsa Loquitur: Kissing Cousins* (2009) 44 *Wake Forest Law Review* 997. 1003; *The Restatement (Third) of Torts: Liability for Physical Harm* (§ 17 *Res Ipsa Loquitur*) provides: “The factfinder may infer that the defendant has been negligent when the accident causing the plaintiff’s physical harm is a type of accident that ordinarily happens as a result of the negligence of a class of actors of which the defendant is the relevant member.” See also the *Restatement (Second) of Torts* (1965), § 328D, cmt g (entitled “Defendant’s exclusive control” and stating that the plaintiff is usually able to prove that the defendant is responsible for the event that caused the injury by showing that the defendant was in exclusive control of the instrumentality that caused the harm). See also the *locus classicus* on negligence *per se*; *Martin v Herzog* (1920) 126 NE 814 (NYCA), 815, per Cardozo J: “We think the unexcused omission of the statutory signals is more than some evidence of negligence. It is negligence in itself. Lights are intended for the guidance and protection of other travelers on the highway.”

forever banished the requirement of 'exclusive control' as a requisite for applying res ipsa, it will be an occasion for rejoicing."¹³⁴²

Section 3 of the *Restatement (Third) of Torts: Products Liability* adopts the consumer expectations test in *res ipsa loquitur* cases. The section provides for liability when the incident that caused the plaintiff's harm is of a kind that ordinarily occurs as a result of product defect and did not solely result from other causes. Liability is imposed regardless of whether the product failed due to a manufacturing defect.¹³⁴³

It may be submitted that consumers do not expect things to occur that would not ordinarily do so but for want of care.¹³⁴⁴ In contrast to the US, European strict liability is, "*at least formally, the test for all types of product defects.*"¹³⁴⁵

6.11.2 The Two-Pronged Test for Design Defect

In *Barker v Lull Engineering Co*¹³⁴⁶ adopted a two-pronged test or standard which incorporates a consumer expectation test with what the court calls the 'risk-benefit' test. Kysar has advocated such a twin-test approach to design defect litigation, "*resting manufacturer liability either on a product's failure to pass risk-utility analysis or on its failure to comport with the firmly established safety expectations of consumers.*"¹³⁴⁷

¹³⁴²See Twerski, *op cit*, 1003 (n 38), citing *Restatement (Third) of Torts: Liability for Physical Harm*, § 17, cmt b (Proposed Final Draft No 1, 2005). See also the *Restatement (Third) of Torts: Liability for Physical Harm*, § 17, Reporters' Note, Comment j (Tentative Draft No 1, Mar. 28, 2001) ("*[O]n some occasions the force of circumstantial evidence can be such as to call for a directed verdict for the plaintiff*"), cited in *Morejon v Rais Construction Co* (2006) 851 NE 2d 1143 (NYCA), Note [8]. See also the *Restatement (Third)*, § 3 (Circumstantial Evidence Supporting Inference of Product Defect). See also Steenson, M, *A Comparative Analysis of Minnesota Products Liability Law and The Restatement (Third) of Torts: Products Liability* (1998) 24 William Mitchell Law Review 1, 28.

¹³⁴³Henderson, Jr, JA, Twerski, AD, *The Politics of the Products Liability Restatement* (1996-1997) 26 Hofstra Law Review 667, 676-677.

¹³⁴⁴See also Howells, G, Mildred, M, *Is European Products Liability More Protective than the Restatement (Third) of Torts: Products Liability?* (1998) 65 Tennessee Law Review 985, 1024: "*[I]t is clear that, if the Restatement (Third) is adopted, the United States would abandon strict liability for design and failure to warn defects.*"

¹³⁴⁵Howells, G, Mildred, M, *op cit*, 1025.

¹³⁴⁶*Barker v Lull Engineering Co* (1978) 573 P2d 443 (Cal Sup Ct).

¹³⁴⁷See Kysar, DA, *The Expectations of Consumers* (2003) 103 Columbia Law Review 1700, 1704-1705.

6.11.3 Australia – Production and Design

The concept of *res ipsa loquitur* is of most assistance to the plaintiff in cases of production negligence.¹³⁴⁸ Whereas in the case of production-negligence the design is accepted as safe and the plaintiff's case is that the product did not conform to the design, in 'design-negligence' cases the plaintiff accepts that the product conformed to the design but argues that the design was unsafe or defective.¹³⁴⁹

Unless laid down by statute,¹³⁵⁰ a design's standard of reasonable safety "*must be determined by balancing the risk of harm against the cost of reducing or preventing it by an alternative design[; relatively simple] where the design is self-defeating, like a collapsing crane*"¹³⁵¹

Courts are somewhat unwilling to decide whether the design of a product was negligent. There are, perhaps, three reasons for this unwillingness.¹³⁵² One is the difficulty in proving in many cases that it would have been practicable for the manufacturer to design its product or its production line in some different way that would have eliminated the defect in the design of the product while maintaining its utility.¹³⁵³ On the other hand, there are cases in which courts have been prepared to hold the design of a product to have been negligent.¹³⁵⁴ A second difficulty in design-negligence cases is that if the court decides that the defendant ought to have introduced some precaution into a large system or production line or that it ought to have designed a product differently, it is going well beyond the limits of the case before it.¹³⁵⁵ A third issue raised by negligence in design is that of custom and practice: "*To what extent ought a defendant to be able to plead that it took the same precautions as everyone else and therefore that it was not*

¹³⁴⁸ Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 626.

¹³⁴⁹ Trindade, F, Cane, P, Lunney, M, *loc cit*.

¹³⁵⁰ The Competition and Consumer Act 2010 (Cth), Part V Div 1A provides for the declaration and enforcement of product safety and information standards and the publication of warning notices about hazardous products. See also Sappideen, C, Vines, P, *Fleming's The Law of Torts*, Tenth Edition (2011) Lawbook Co, Sydney, 139.

¹³⁵¹ See Sappideen, C, Vines, P, *loc cit*.

¹³⁵² Trindade, F, Cane, P, Lunney, M, *op cit*, 627.

¹³⁵³ Trindade, F, Cane, P, Lunney, M, *loc cit*.

¹³⁵⁴ Trindade, F, Cane, P, Lunney, M, *loc cit*, citing *O'Dwyer v Leo Buring Pty Ltd* [1966] WAR 67. See also Beerworth, E, *Australia*, Chapter in Campbell, C (Editor), *International Product Liability [2007]* (2007) Yorkhill Law Publishing, Salzburg, 61.

¹³⁵⁵ Trindade, F, Cane, P, Lunney, M, *loc cit*. The authors state additionally: "*Furthermore, design 'defects' are often the result of conscious design decisions that take account of cost, efficiency and other factors. The tort of negligence is aimed at providing compensation for injury inadvertently caused. No social or economic arguments can be adduced in favour of inadvertence; but such arguments can often be adduced in favour of conscious design choices that allow for a certain probability of mishaps.*"

*negligent?*¹³⁵⁶ Fourthly, the plaintiff may allege that the loss was as a result of what is often called a ‘development risk’.¹³⁵⁷

6.11.4 Canada

Canadian courts have applied the risk-utility test. In *Rentway Canada Ltd v Laidlaw Transport Ltd*,¹³⁵⁸ Granger J. compiled a list of factors similar to that in *Sacks v Phillip Morris*,¹³⁵⁹ which may be considered when balancing the risks inherent in the product, as designed, against its utility and cost:

“(1) the utility of the product to the public as a whole and to the individual user;

(2) the nature of the product—that is, the likelihood that it will cause injury;

(3) the availability of a safer design;

(4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced;

(5) the ability of the plaintiff to have avoided injury by careful use of the product;

(6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and

*(7) the manufacturer’s ability to spread any costs related to improving the safety of the design.”*¹³⁶⁰

¹³⁵⁶ Trindade, F, Cane, P, Lunney, M, *op cit*, 628.

¹³⁵⁷ Trindade, F, Cane, P, Lunney, M, *loc cit*.

¹³⁵⁸ *Rentway Canada Ltd v Laidlaw Transport Ltd* [1989] OJ No 786 (HCJ), *affirmed* [1994] OJ No 50 (CA).

¹³⁵⁹ *Sacks v Phillip Morris Inc* 1996 WL 780311 (D Md), (Not Reported in F Supp); *affirmed Sacks v Phillip Morris Inc* (1998) 139 F3d 892 (Table) (4th Ct).

¹³⁶⁰ Klar, LN, *op cit*, 367-368, citing (1989) 49 CCLT 150, 164, per Granger J. Klar goes on to attribute the factors that Granger J analysed to those laid down by Jasen J in *Voss v Black & Decker Mfg Co* (1983) 450 NE2d 204 (NYCA). Further research has pinpointed the relevant *dicta* to 450 NE2d 204, 208. See also Owen, DG, *Design Defects* (2008) 73 Missouri Law Review 291, 317, for criticism of “over-broad formulations of risk-utility analysis for design defect decisionmaking,” traceable to a widely quoted set of liability factors proposed in an early, influential article: Wade JW, *On the Nature of Strict Tort Liability for Products* (1973) 44 Mississippi Law Journal 825, 837-838, which proposed that a list of factors that a court should consider.

6.12 Warning and Product Information Defects

Persons whose prior conduct has generated a risk are under an affirmative duty in negligence to give a warning.¹³⁶¹ An example is where a manufacturer releases a product onto the market in a non-negligent manner, but subsequently discovers a defect or danger, as occurred in *Rivtow Marine Ltd v Washington Iron Works*.¹³⁶² The duty is a continuous one requiring that the manufacturer warn, not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered.¹³⁶³ Quill has stated¹³⁶⁴ that there is no definitive legal authority for the proposition that one manufacturer is required to give a warning in relation to its own products, based on a known risk in another's product. It is submitted that, not infrequently, too many imponderables may present themselves in comparing ostensibly similar products from different manufacturers. Even if one manufacturer's product is made under licence from the other, the protected intellectual property right may be subject to a process patent only (as available in the United States), leaving open the question of raw material sourcing.

Madden has described the basis for assessing the adequacy of a warning and its consequences:

"The adequacy of the manufacturer's warning is ordinarily a question for the finder of fact.¹³⁶⁵ The sufficiency of the seller's discharge of its informational obligation is measured in terms of whether the cautionary information sufficiently conveys the nature, the scope, and the severity of the risk, together with a plain statement of how the user may avoid such risks and safely use the product. If the adequacy issue is determined favourably to the manufacturer, that finding will preclude liability even where 'the plaintiff's use of the drug was, in fact, causally connected¹³⁶⁶ to the plaintiff's injury'."¹³⁶⁷

¹³⁶¹ Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 43-44.

¹³⁶² *Rivtow Marine Ltd v Washington Iron Works* (1973) 40 DLR (3d) 530 (SCC). See particularly (1973) 40 DLR (3d) 530, 536. See also Giliker, P, *Revisiting Pure Economic Loss: Lessons to be learnt from the Supreme Court of Canada?* (2005) 25 Legal Studies 49, 53 (n), 55 (n).

¹³⁶³ See *Buchan v Ortho Pharmaceutical (Canada) Ltd* (1986) 35 CCLT 1 (ONCA). See also *Rivtow Marine Ltd v Washington Iron Works* (1973) 40 DLR (3d) 530, 536. See further Giliker, P, *Revisiting Pure Economic Loss: Lessons to be learnt from the Supreme Court of Canada?* (2005) 25 Legal Studies 49, 53 (n), 55 (n).

¹³⁶⁴ Quill, *op cit*, 44.

¹³⁶⁵ See *Tatum v Schering Corp* (1986) 795 F2d 925, 927 (11th Ct); *Lawson v GD Searle & Co* (1976) 356 NE2d 779, 783 (Ill) [Warning adequacy central to determination of unreasonable danger under the *Restatement (Second) of Torts*, §402A].

¹³⁶⁶ See *Seley v GD Searle & Co* (1981) 423 NE2d 831, 836 (Ohio).

¹³⁶⁷ Madden, MS, *The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals* (2001) 21 Pace Law Review 313, 340, 345-346. In *Stewart v Janssen Pharm Inc* (1989) 780 SW2d 910, 912 (Tex App), Fuller J (for the Court) found that an anaesthesiologist, who selected the anaesthetic drug Sufenta, had been aware of the risks of renarcotization. The Texas Court of Appeals rejected all points of error (grounds of appeal) advanced by the appellant.

The untoward effects of warning about relatively remote risks have been described by Henderson and Twerski.¹³⁶⁸

In the US, federal law will not necessarily oust the common law jurisdiction to entertain an action based on failure to warn, although there have been US Supreme Court decisions in recent times that are not easy to reconcile. The Supreme Court, in *Wyeth v Levine*,¹³⁶⁹ “reaffirmed the existence of the presumption against preemption in a case asking whether a common law damages action alleging failure to warn regarding a prescription pharmaceutical was impliedly preempted by a federal Food and Drug Administration approval of the product’s warning label.”¹³⁷⁰ In the immediately preceding term, however, the US Supreme Court decided an express preemption problem; whether a common law damages action alleging design defect based on a federally approved medical device was preempted, without mentioning the presumption at all: *Riegel v Medtronic Inc.*¹³⁷¹

6.12.1 Obvious-Danger Cases

Henderson and Twerski categorize obvious risk cases under two rubrics.¹³⁷² The first category consists of cases in which courts label an arguably obvious risk as non-obvious simply to allow a plaintiff whose design-defect claim has failed a chance to recover on a warning claim. The second category of cases comprises those in which courts improperly characterize obvious risks as non-obvious results when courts reason by hindsight. In *Low-Foreseeability Cases*, courts rarely use foreseeable low risk or remote risk as an independent basis for dismissing failure-to-warn products cases: “no obvious monetary costs counterbalance what appear to be costless additional warnings”.¹³⁷³ In *Specificity-of-Warning Cases*, an appreciable number of warning claims concern

¹³⁶⁸ Henderson, Jr, JA, Twerski, AD, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn* (1990) 65 New York University Law Review 265, 296. See also Hedley, S, *Tort*, Seventh Edition (2011) Oxford University Press, Oxford, 90 (Distributors have no general duty to make a check of goods. However, there are special circumstances in which such a duty will be imposed: where the goods came from another supplier with a dubious reputation: where the manufacturer’s instructions are that there should be a check).

¹³⁶⁹ *Wyeth v Levine* (2009) 129 S Ct 1187; (2009) 555 US 135.

¹³⁷⁰ See also Davis, MJ, *The “New” Presumption Against Preemption* (2010) 61 Hastings Law Journal 1217, 1220.

¹³⁷¹ *Riegel v Medtronic Inc* (2008) 552 US 312. See also Davis, MJ, *loc cit*.

¹³⁷² Henderson, Jr, JA, Twerski, AD, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn* (1990) 65 New York University Law Review 265, 314-315.

¹³⁷³ Henderson, Jr, JA, Twerski, AD, *op cit*, 317.

themselves with the relative specificity of warnings.¹³⁷⁴ Once the warning moves from the general to the specific, it becomes necessary to list all risks of the same or similar magnitude. Henderson and Twerski caution that judicial decisions that “*impose liability for the failure of defendants to be slightly more specific, would seem to run afoul of the requirement that causation be proved.*”¹³⁷⁵

6.12.2 Post-Sale Warnings

If a producer is not liable for the condition of the product when he supplied it, the Product Liability Directive’s British and Irish legislative transpositions impose no post-marketing obligations on such a producer.¹³⁷⁶ Howells clarifies that this is so “*even when the product is clearly dangerous and the reason for the lack of liability was the pleading of a defence, such as the development risks defence.*”¹³⁷⁷ In *A v National Blood Authority* Burton J seemed attracted by the idea that Directive 1985/374/EC, art 12 placed some limits on the effectiveness of warnings.¹³⁷⁸ Howells states (correctly, it is submitted) that the better view is that a proper warning probably prevents liability from arising rather than excludes such liability.¹³⁷⁹

In this respect the law of negligence is more demanding and would require the producer to take reasonable steps to avoid harm, “*which might include attempting to notify customers and possibly seeking to recall the products for repair, exchange or refund.*”¹³⁸⁰ The ‘repair, exchange or refund’ options do not appear feasible in relation to medicinal products, although such possibilities may be acceptable in the case of medical devices (*e.g.* an insulin pump apparatus).

¹³⁷⁴ Henderson, Jr, JA, Twerski, AD, *op cit*, 318, citing *MacDonald v Ortho Pharmaceutical Corp* (1985) 475 NE2d 65, *cert denied* (1985) 474 US 920: “*The court opined that a jury might conclude that the failure of the manufacturer specifically to mention the risk of a ‘stroke’ minimized the warning’s impact. The deficiency was not cured by the fact that the warnings given emphasized the risk of death, since a jury might conclude that permanent disability was a fate worse than death.*”

¹³⁷⁵ Henderson, Jr, JA, Twerski, AD, *op cit*, 319.

¹³⁷⁶ Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 381.

¹³⁷⁷ Howells, G, *loc cit*. In *Commission v France* Case C-52/00, [2002] ECR I-3827, France was found in breach of its obligations under Directive 85/374/EC for imposing the additional condition that the producer must prove that he took appropriate steps to avert the consequences of a defective product in order to invoke the compliance with mandatory requirements and the development risks defence.

¹³⁷⁸ See *A and Others v National Blood Authority and Another* [2001] 3 All ER 289, 338-339, per Burton J.

¹³⁷⁹ Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 379.

¹³⁸⁰ Howells, G, *op cit*, 381. Under Directive 2001/83/EC (on the Community code relating to medicinal products for human use), article 80 (d), holders of the distribution authorization must fulfil a minimum requirement: “*they must have an emergency plan which ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or marketing authorization holder for the medicinal product concerned.*”

6.12.3 Drugs and Vaccines - Unavoidably Unsafe Products

The US rationale for treating drugs and vaccines as not unreasonably dangerous is posited in *Restatement (Second) of Torts* (1965), § 402A, cmt k:

"k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies,¹³⁸¹ which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability¹³⁸² for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."¹³⁸³

¹³⁸¹ Predictably enough, rabies prophylaxis and treatment have progressed since 1965. See, for example, Rupprecht, CE, Gibbons, RV, *Prophylaxis against Rabies* (2004) 351 *New England Journal of Medicine* 2626, 2629: *Table 3, Biologic Agents Licensed in the United States for Human Rabies Prevention*, the product categories of which may be summarised thus: *Vaccines* (Preexposure or postexposure - Intramuscular); *Human rabies immune globulins* (Postexposure only - Local to wound site).

¹³⁸² See Hylton, KN, *The Theory of Tort Doctrine and the Restatement (Third) of Torts* (2001) 54 *Vanderbilt Law Review* 1413, 1423.

¹³⁸³ *Restatement (Second) of Torts* (1965), § 402A, cmt k (Underlining substituted for original italicised emphasis). See also the *Restatement (Second)*, § 402A, cmt j, which states that "[i]n order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warnings ... as to its use." See also Owen, DG, *The Puzzle of Comment j* (2003-2004) 55 *Hastings Law Journal* 1377, 1397, clarifying that Comment j applies only to "the narrow class of inherently dangerous products--notably, food, alcoholic beverages, tobacco, and pharmaceutical drugs--whose hazards are unavoidable and, hence, cannot be designed away."

Comment k is “widely perceived as having set a negligence standard for drug design liability as opposed to a strict liability standard”.¹³⁸⁴ Ossorio has remarked that a line of cases has developed in which comment k is not automatically applied to medical products: those causes are rather examined on a case-by-case basis.¹³⁸⁵ Through the approach of utilising consumer expectations and risk-utility calculations to determine the reasonableness of product designs, the factfinder determines whether a reasonable and feasible alternative design, at a reasonable cost, would have reduced the risk of foreseeable harm. This assessment involves a reasonable person's comparison of the actual design to a hypothetical alternative design or competing design already on the market.¹³⁸⁶ Comment k has been roundly criticised by Henderson and Twerski,¹³⁸⁷ who are the Reporters to the *Restatement (Third)*.

It is submitted that it is sometimes difficult to separate design issues from warning issues for discrete analysis. Golanski has noted that while strict liability and negligence are “analytically distinct claims, they become one where liability rests on a failure to warn.”¹³⁸⁸

6.12.3.1 Application to Pharmacists in Ireland

The comparative legal materials from the US have some inferential legal significance to the position of pharmacists in Ireland. Irish pharmacists are unlikely to be engaged in the manufacture of ‘unavoidably unsafe products’ in hospital or community pharmacy establishments. Appropriate warnings will of course be required and the format may have already been expressed in Pharmaceutical Society of Ireland guidance. Where the ‘unavoidably unsafe’ product to be

¹³⁸⁴ See Ossorio, PN, *Product Liability for Predictive Genetic Tests* (2000-2001) 41 *Jurimetrics* 239, 246 (n). See also See *Design Defect Balancing Tests by State, II Prescription Drug Cases*, Appendix to Owen, DG, *Risk-Utility Balancing in Design Defect Cases* (1996-1997) 30 *University of Michigan Journal of Law Reform* 239, 258-259: “Idaho—Comment k ‘contemplates a weighing of the benefit of the product against its risk. Obviously, for comment k to apply, the benefit must outweigh the risk.’” citing *Toner v Lederle Lab* (1987) 732 P2d 297, 306.

¹³⁸⁵ Ossorio, PN, *Product Liability for Predictive Genetic Tests* (2000-2001) 41 *Jurimetrics* 239, 246.

¹³⁸⁶ See Ossorio, PN, *op cit*, 246 (n). See also Davison, SG, *The Uncertain Search for a Design Defect Standard* (1981) 30 *The American University Law Review* 643, 643, citing *Micallef v Miehle Co* (1976) 348 NE2d 571, 578 (Printing press manufacturer failed to use guards that would have protected operator from hand injury).

¹³⁸⁷ See Henderson, Jr, JA, Twerski, AD, *Drug Designs Are Different* (2001) 111 *Yale Law Journal* 151, 180: “Most observers are in general agreement that the guidelines set forth a half-century ago in section 402A, comment k of the *Restatement (Second)* are unintelligible and that the cases seeking to interpret that section are confusing. In connection with section 6(c) of the *Restatement (Third)*, we plead guilty to the charge that we did not restate existing case law. One could hardly be expected to restate gibberish. Instead, we opted for a fresh look at the question of design liability for prescription products and utilized the case law to illuminate the underlying issues in this difficult area.”

¹³⁸⁸ See Golanski, A, *Paradigm Shifts in Products Liability and Negligence* (2009-2010) 71 *University of Pittsburgh Law Review* 673, 690 (n), citing: *McCullock v HB Fuller Co* (1995) 61 F3d 1038, 1044 (2d Cir).

supplied is an imported unauthorised medicinal product, with minimal information for patient safety,¹³⁸⁹ the pharmacist must ensure that a comprehensive warning is given to the patient or carer.

6.12.4 Canada

Even if due care was exercised in the design and manufacture of a product, a manufacturer can be held liable for failing to adequately warn the consumer of the appropriate use of the product or the risks associated with its use. This duty is said to be a basic one involved with the manufacture of a product, stemming from *Donoghue v Stevenson*.¹³⁹⁰

Manufacturers who are aware of their product's dangerous character cannot, without more, pass the risk of injury to the consumer.¹³⁹¹ The leading Canadian case on warnings is *Lambert v Lastoplex Chemicals*¹³⁹² in which Laskin J propounded the applicable principle of law:

*“Where manufactured products are put on the market for ultimate purchase and use by the general public and carry danger (in this case, by reason of high inflammability), although put to the use for which they are intended, the manufacturer, knowing of their hazardous nature, has a duty to specify the attendant dangers, which it must be taken to appreciate in a detail not known to the ordinary consumer or user. A general warning, as for example, that the product is inflammable, will not suffice where the likelihood of fire may be increased according to the surroundings in which it may reasonably be expected that the product will be used. The required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product.”*¹³⁹³

The *Lambert v Lastoplex Chemicals* case, it is submitted is consistent with the existing jurisprudence of the Irish courts.

¹³⁸⁹ The packaging and any associated information may have been prepared for a territory in which the learned intermediary doctrine applies.

¹³⁹⁰ See also *Buchan v Ortho Pharmaceutical (Canada) Ltd* (1986) 35 CCLT 1, 12.

¹³⁹¹ Klar, LN, *Tort Law*, Fourth Edition (2008) Thomson Carswell, Toronto, 370.

¹³⁹² [1972] SCR 569 (SCC).

¹³⁹³ *Lambert v Lastoplex Chemicals* [1972] SCR 569, 574-575, per Laskin J.

6.12.5 Patient Information Leaflet (PIL)

In Europe, the original reference to ‘package leaflet’ provision was in the earliest Medicines Directive.¹³⁹⁴ Belgium was the first Member State to make PIL provision obligatory in national law (in 1983-1984).¹³⁹⁵ Patient information provision became mandatory within the EU in 1992.¹³⁹⁶ The current Directive in force, 2001/83/EC (as amended),¹³⁹⁷ defines ‘package leaflet’ as “[a] leaflet containing information for the user which accompanies the medicinal product”. The package leaflet is required to be drawn up in accordance with the summary of the product characteristics¹³⁹⁸; the information presented must follow the order specified in the Directive.¹³⁹⁹ It is submitted that that the PIL, which is intended for a lay readership,¹⁴⁰⁰ may at times reflect the present or influence the future in consumer expectations.

6.13 Consumer Expectations

It is submitted that consumer expectations should be reasonable, although consumers may become conditioned towards unrealistic expectations.¹⁴⁰¹ For example, one cannot sensibly expect the laws of physics to be set aside, so that a household dishwasher appliance might remove thoroughly from a dinner plate particles with the negligible mass and the fluid-dispersible characteristics of broccoli seeds, as opposed to ‘baking’ such specks onto the plate’s surface during the drying phase. A research subject faces an immediate difficulty in showing that a product undergoing clinical trial was ‘defective’: the same level of safety cannot reasonably be expected from a product under research as a product that has a marketing authorisation.¹⁴⁰² Even if the product was shown to be defective, the sponsoring manufacturer may be able to rely upon

¹³⁹⁴ Council Directive 65/65/EEC.

¹³⁹⁵ See Wahlroos, H, *Control of medicines in the European Union and drug information* (2005) 6 Journal of Pharmaceuticals Policy and Law 59, 62.

¹³⁹⁶ Directive 92/27/EEC on the labelling of medicinal products for human use and on package leaflets. This Directive *inter alia* was repealed by Directive 2001/83/EC (without prejudice to the obligations of the Member States concerning the time-limits for implementation).

¹³⁹⁷ Article 59(3) of EU Council Directive 2001/83/EC, as “replaced” by Article 44 of EU Council Directive 2004/27/EC.

¹³⁹⁸ It has become usual for the Summary of Product Characteristics (SPC or SmPC) and the Patient Information Leaflet (PIL) to be made available on the Internet; see for example, the Website, www.medicines.ie.

¹³⁹⁹ Directive 2001/83/EC, art 59(1).

¹⁴⁰⁰ See Directive 2001/83/EC, art 59(3), which provides that the “package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.”

¹⁴⁰¹ See, however, Abraham, KS, *Stable Divisions of Authority* (2009) 44 Wake Forest Law Review 963, 970: Manufacturers “are responsible for unduly high consumer expectations regarding a product’s safety, either because their advertising creates the expectations or because manufacturers fail to dispel expectations that are independently acquired.”

¹⁴⁰² See Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 783.

the 'development risks defence'. Cochran suggests that a consumer expectation theory should cover risk of injury not within the domain of common knowledge,¹⁴⁰³ and the same author has supported a limited strict liability rule, which would limit to bystanders recovery for harm caused by hazardous hedonic products.¹⁴⁰⁴

When it comes to consumer expectations, commentators can be understandably sceptical. Wade criticised fundamentally use of consumer expectations test in cases where "*the consumer would not know what to expect, because he would have no idea how safe the product could be made*".¹⁴⁰⁵

In *Potter v Chicago Pneumatic Tool Co*,¹⁴⁰⁶ the Connecticut Supreme Court, reasoning that "*a consumer's expectations may be viewed in light of various factors that balance the utility of the product's design with the magnitude of its risks,*"¹⁴⁰⁷ materially altered Connecticut's design defect jurisprudence. Holding that this risk-utility formulation of a "*modified consumer expectation test*" should be used for complex design cases, the court concluded, citing *Soule v Gen Motors Corp*,¹⁴⁰⁸ that the "*ordinary consumer expectation test [should be reserved for use] when the everyday experience of the particular product's users permits the inference that the product did not meet minimum safety expectations.*"¹⁴⁰⁹

A test of (reasonable) consumer expectations was applied by Kiefel J in *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd*¹⁴¹⁰:

*"This is not a case where the purpose was made known to the manufacturer.
Given that the only purpose of the valve is to replace damaged natural mitral*

¹⁴⁰³ Cochran, Jr, RF, "Good Whiskey", *Drunk Driving, and Innocent Bystanders: The Responsibility of Manufacturers of Alcohol and Other Dangerous Hedonic Products for Bystander Injury* (1993-1994) 45 South Carolina Law Review 269, 317-318.

¹⁴⁰⁴ See also Page, JA, *Liability for Unreasonably and Unavoidably Unsafe Products: Does Negligence Doctrine Have a Role to Play?* (1996-1997) 72 Chicago-Kent Law Review 87, 92 (n) citing Cochran, jr, RF, "Good Whiskey", *Drunk Driving, and Innocent Bystanders: The Responsibility of Manufacturers of Alcohol and Other Dangerous Hedonic Products for Bystander Injury* (1993-1994) 45 South Carolina Law Review 269, 329, as advancing an argument supporting a limited strict liability rule, which would permit only bystanders to recover for harm caused by hazardous products used primarily for enjoyment.

¹⁴⁰⁵ Wade, JW, *On the Nature of Strict Tort Liability for Products* (1973) 44 Mississippi Law Journal 825, 829.

¹⁴⁰⁶ *Potter v Chicago Pneumatic Tool Co* (1997) 694 A2d 1319 (Conn Sup Ct).

¹⁴⁰⁷ Owen, DG, *Design Defects* (2008) 73 Missouri Law Review 291, 352, citing *Potter v Chicago Pneumatic Tool Co* (1997) 694 A2d 1319, 1333 (Conn Sup Ct) (Redefining consumer expectations in risk-utility terms).

¹⁴⁰⁸ *Soule v Gen Motors Corp* (1994) 882 P2d 298, 308 (Cal) (indicating that no design defect exists if "*the benefits of the . . . design outweigh the risk of danger inherent in such design*") (quoting *Barker v Lull Engineering Co* (1978) 573 P2d 443, 454).

¹⁴⁰⁹ *Potter v Chicago Pneumatic Tool Co* (1997) 694 A2d 1319, 1333 (Emphasis added)

¹⁴¹⁰ *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853 (Kiefel J).

valves it would not seem to be necessary that there be communication. In such a case the manufacturer's knowledge may be assumed: Grant v Australian Knitting Mills, Ltd [1936] AC 85 at 99. The St Jude Medical valve cannot however be regarded as unfit for that purpose because there was a known risk that thromboembolisms might develop and cause injury of the kind the applicant suffered. The applicant has identified only that she fell within the category of persons who develop such a complication. The question whether goods which have a use are reasonably fit for it must be assessed not only by reference to the fact that they failed to accomplish their purpose, but also by reference to what a consumer could reasonably expect from the goods.

The evidence here clearly establishes that the risk in question was well known to medical practitioners. The applicant was advised of this risk, as I later discuss. In my view, for the reasons I give later it could not therefore have been reasonable for the applicant to expect that there was no prospect that the valve would cause the development of thrombi. This claim is not made out.”¹⁴¹¹

It is submitted that the concept of consumer expectations does not receive in-depth analysis in the framework of the Product Liability Directive. This would appear to smooth over any tensions that might arise between civilian and common law jurisprudence. It is further submitted that in the context of the Product Liability Directive that the bifurcation of the modified/ordinary consumer expectation test would not find favour in the European strict liability regime.

6.13.1.1 Application to Pharmacists in Ireland

An Irish pharmacist should be cautious of off-label or experimental indications for authorised medicinal products. This is because a court might well hold that the patient-consumer's expectation of product safety from the fact that a product is authorised may still be justified if the deviation from the therapeutic norm from the product concerned has not been properly explained (and consent obtained) by the patient's health professionals. The pharmaceutical company that has submitted a dossier to a regulatory agency (such as the Irish Medicines Board) may avoid liability under the Directive by disavowing any responsibility for the off-label use.

¹⁴¹¹ *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853, [212]-[213], per Kiefel J.

6.14 Development Risks Defence

6.14.1 Knowledge must be 'accessible'

Citing *Commission v United Kingdom*,¹⁴¹² Burton J clarified, in *A and Others v National Blood Authority*,¹⁴¹³ that it seemed to him that “*the right approach is to look at 'accessibility'*¹⁴¹⁴ *and to regard as [restricted to] Manchuria*¹⁴¹⁵ *perhaps an unpublished document or unpublished research not available to the general public, retained within the laboratory or research department of a particular company.*”¹⁴¹⁶ It is unclear whether these categories of ‘knowledge’ are intended to be exhaustive.¹⁴¹⁷

The *dicta* of Burton J, it is submitted, are a persuasive authority of potential assistance to the Irish courts. Since the *A and Others v National Blood Authority* case was reported in 2001, access to information through the Internet has grown exponentially. However, the basic question of access remains, if a restrictive approach to documents or research is maintained.

6.14.2 Regulatory Authorities and Accountability

6.14.2.1 The National Drugs Advisory Board (NDAB)

The NDAB¹⁴¹⁸ operated from 1966 to 1995: it was the forerunner of the Irish Medicines Board (IMB). The NDAB *advised* the Minister for Health in relation to human and veterinary medicines.

¹⁴¹² *Commission v United Kingdom* (Case C-300/95) [1997] All ER (EC) 481, 490, [22]-[24].

¹⁴¹³ [2001] 3 All ER 289.

¹⁴¹⁴ See Fairgrieve, D, Howells, G, *Introduction to Product Liability*, Chapter in McDougall, A, Popat, P (Editors), *International Product Law Manual* (2010) Kluwer Law International, Alphen aan den Rijn (NL), 31, citing *Hartman v Stichting Sanquin Bloedvoorziening* NJ 1999, 621, where the Amsterdam District Court permitted the development risks defence on the basis that it was scientifically impossible to detect HIV contamination during the so-called “window-period”. It is submitted that the Netherlands Court’s analysis is flawed: otherwise the development risks defence should be available during the incubation period of any infection; most incubation periods have been scientifically described.

¹⁴¹⁵ An allusion to the metaphor for what on any reasonable view constitutes ‘inaccessible information’ that was used by the European Court of Justice in *Commission v United Kingdom* (Case C-300/95) [1997] All ER (EC) 481, 490, [22]-[24].

¹⁴¹⁶ [2001] 3 All ER 289, 326-327. See also McKechnie, W, *Consumer Protection under the European Product Liability Directive and the Restatement (Third) of Torts: Products Liability* (2001) 9 Irish Student Law Review 52, 59-60, 65.

¹⁴¹⁷ See Howells, G, Mildred, M, *Infected Blood: Defect and Discoverability a First Exposition of the EC Product Liability Directive* (2002) 65 Modern Law Review 95, 104.

¹⁴¹⁸ The National Drugs Advisory Board (NDAB) was established through the National Drugs Advisory Board (Establishment) Order 1966 (SI No 163 of 1966) by the Minister for Health under the Health (Corporate Bodies) Act 1961, s 3-6, with the function to advise the Minister for Health on matters relating to the safety and quality of drugs. By virtue of the National Drugs Advisory Board (Establishment) Order 1966 (Amendment) Order 1974 (SI No 176 of 1974), the National Drugs Advisory Board was empowered to advise the Minister on arrangements for licensing the manufacture, importation and sale of drugs and on the certification of drugs for certain other purposes. Additional powers relating to the marketing of veterinary

The Minister retained the function of issuing marketing authorisations (based on the NDAB's advice). For much of its existence, the NDAB remained unaffected by litigation. However, the Hepatitis C controversy brought the NDAB's role and that of the Department of Health into focus. In the case of *Roe v The Blood Transfusion Service Board*,¹⁴¹⁹ the Minister for Health and the NDAB were joined as parties. The Irish Government established a non-statutory Compensation Tribunal in 1995. Its remit was to compensate, *inter alia*, persons infected with Hepatitis C as a result of the use of Human Immunoglobulin Anti-D or as a result of the receipt of a blood transfusion or blood product within the Republic of Ireland.¹⁴²⁰ The Tribunal became a Statutory Body with the enactment of the Hepatitis C Compensation Tribunal Act 1997. In addition, the Hepatitis C Compensation Tribunal (Amendment) Act 2002 makes provision to compensate, *inter alia*, persons infected with HIV as a result of the receipt of a relevant blood product within the Republic of Ireland.¹⁴²¹

The frailties of the pre-1995 system were laid bare in *Genmark Pharma Ltd v Minister for Health*.¹⁴²² It may be argued that, with the enactment of the Irish Medicines Board Act 1995, the *Genmark Pharma* case had been overtaken by events. However, the case proceeded to hearing: the court held that failure to observe the time limits resulting in delay in circumstances where no default authorisation issued would have been relevant in the context of an application for *mandamus*, however not for *certiorari*. In other words, the court exercised its discretion so as to decry the impugned administrative acts, in the context of the parties' interaction alone.

It was held the NDAB was established for the purpose of giving advice to the Minister. Accordingly, the Minister was entitled to seek its advice but he was not entitled to rely on advice

medicinal products were conferred through the National Drugs Advisory Board (Establishment) Order 1966 (Amendment) Order 1985 (SI No 220 of 1985).

¹⁴¹⁹ *Roe v The Blood Transfusion Service Board* [1996] 3 IR 67 (HC) Laffoy J. The parties were *Bridget M Roe, Plaintiff v The Blood Transfusion Service Board, The Minister for Health, The National Drugs Advisory Board, Ireland and The Attorney General, Defendants*. The plaintiff was unsuccessful in her attempt to bring proceedings using the quoted pseudonym.

¹⁴²⁰ Hepatitis C and HIV Compensation Tribunal (Undated Web Resource) Available from <http://www.hepccomptrib.com/> (Last accessed 12 January, 2012).

¹⁴²¹ The Hepatitis C Compensation Tribunal (Amendment) Act 2006 bears the Long Title: "*An Act to amend the Hepatitis C Compensation Tribunal Acts 1997 and 2002, to provide for the Establishment of an Insurance Scheme to enable Certain Persons diagnosed positive for Hepatitis C or HIV to be provided with Certain Classes of Insurance which would otherwise be either unavailable to them or available only upon the Payment of a Higher Premium and to make a Related Amendment to the Health (Amendment) Act 1996.*"

¹⁴²² *Genmark Pharma Ltd v Minister for Health* [1998] 3 IR 111. The legal proceedings entered the Judicial Review List with the Case Number: 1994 JR 410.

in the form of conclusions without reference to the basic material on which those conclusions were based.¹⁴²³

6.14.2.2 The UK Regulatory Authorities

Under the UK Medicines Act 1968, 'licensing authority' functions were conferred on the Minister for Health: the statutory coyness with which this had been done was clarified by the House of Lords in the *Smith Kline & French Laboratories Ltd v Licensing Authority* litigation.¹⁴²⁴ It was held that the licensing authority had a right and duty to make use of all the information supplied by the appellants when considering the generic companies' applications for product licences; accordingly the appeal failed. Licensing functions are now performed by the Medicines and Healthcare Regulatory Authority (MHRA).

According to Barton, the former Committee on Safety of Medicines (CSM)¹⁴²⁵ was a "*recognised but minority body of responsible medical opinion*"¹⁴²⁶ that had been judged on the *Bolam* standard (and on Barton's proposition presumably, in due course, on the *Bolitho*¹⁴²⁷ standard, since the CSM's functions were subsumed into the MHRA's Committee on Human Medicines on the 30th

¹⁴²³ The court followed the reasoning in the cases, *Flanagan v UCD* [1988] IR 724 and *Jefferies v New Zealand Dairy Production and Marketing Board* [1967] 1 AC 551. A further holding was that the applicant was entitled to know the final grounds put forward by the NDAB so that it could respond to them before the Minister made his decision. The failure to disclose all the grounds to the applicant was a flaw in the decision making process. It was also held that the respondent failed to give reasons for his decision in breach of the requirements of European law which required that detailed reasons be given. The applicant's entitlement to be given reasons for the decision of the Minister was not dependent upon the applicant's asking the respondent to specify in more detail the reasons for his refusal.

¹⁴²⁴ *R v Licensing Authority, ex p Smith Kline & French Laboratories Ltd (Generics (UK) Ltd intervening)* [1989] 1 All ER 175, affirmed, sub nom *Smith Kline & French Laboratories Ltd v Licensing Authority (Generics (UK) Ltd and another intervening)* [1989] 1 All ER 578 (HL). See, in particular, [1989] 1 All ER 578, 580, per Lord Templeman: "*By s 7(2) of the [Medicines Act] 1968 Act, no person shall, in the course of a business, sell, manufacture or import any medicinal product except in accordance with a product licence granted by the appropriate licensing authority, in this case the Minister of Health.*" The House of Lords' primary holding in the case was that the licensing authority had a duty to safeguard public health and ensure fairness to all applicants for product licences and it could not discharge that duty without having recourse to all the information available to it, whether confidential or not, which assisted it in considering whether to grant any application for a product licence or which assisted it in performing its other functions under the 1968 Act.

¹⁴²⁵ On 30 October, 2005, the Commission on Human Medicines (CHM) was established, which combines the functions of the Committee on Safety of Medicines and the Medicines Commission (established under the Medicines Act 1968). See Medicines and Healthcare Regulatory Authority, *Committee on the Safety of Medicines* (2006) Available from:

<http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/CommitteeonSafetyofMedicines/index.htm>. (Last accessed 12 January, 2012).

¹⁴²⁶ See Barton, A, *The basis of liability of the licensing authority and its advisers under the Medicines Act 1968 to an individual*, Chapter in Sir A Goldberg, Dodds-Smith, I (Editors), *Pharmaceutical medicine and the law: legal responsibility, product liability, Europe* (1991) Royal College of Physicians of London and Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK, London, 100-101.

¹⁴²⁷ *Bolitho v City and Hackney Health Authority* [1998] 1 AC 232 (HL).

October, 2005¹⁴²⁸). It is noted that the CSM had a majority of medical members, one lay member and some other non-medical professional members: the CSM therefore was not a medical monolith.

Judicial review in domestic legislation is less relevant than before the establishment of the European Medicines Agency¹⁴²⁹ in 1995 as a decentralised body of the European Union.¹⁴³⁰ Although there are still nationally issued marketing authorisations at the level of EEA member states, there is a large measure of co-ordination,¹⁴³¹ through the Heads of Medicines Agencies, in the decentralised procedure for marketing authorisations.

Powers, Harris and Barton suggest that the control exercised by the competent regulatory authority may indirectly be evidence that the manufacturer's research or prescribing information was acceptable on the grounds that an independent body, such as the Committee on Safety of Medicines or more recently the Commission for Human Medicines (CHMP), had reviewed the same data and information and reached the same conclusion as the manufacturer on the

¹⁴²⁸ See the Medicines (Advisory Bodies) (No 2) Regulations 2005 (2005 No 2754). See also Committee on the Safety of Medicines, *Summary of the Committee on Safety of Medicines Meeting Held on Thursday 27 October 2005* (2005) Medicines and Healthcare Regulatory Agency, London. Available from <http://www.mhra.gov.uk/home/groups/l-cs-el/documents/committeedocument/con2023196.pdf> (Last accessed 12 January, 2012). See also Medicines and Healthcare Regulatory Authority, *Commission on Human Medicines* (2010) Medicines and Healthcare Regulatory Authority, London. Available from <http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/CommissiononHumanMedicines/index.htm> (Last accessed 12 January, 2012). See also Medicines and Healthcare Regulatory Authority, *Commission on Human Medicines Annual Report 2009*, in *Medicines Act 1968 Advisory Bodies Annual Reports 2009* (2010) Medicines and Healthcare Regulatory Authority, London. Available from http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON091081&RevisionSelectionMethod=Latest (Last accessed 12 January, 2012).

¹⁴²⁹ The European Medicines Evaluation Agency (EMA) has been repositioned as the European Medicines Agency, although without a current official acronym. At least confusion can now be avoided because many transnational corporations (including those in the pharmaceutical sector) had staked out EMA as their acronym for the 'Europe, Mid[dle] East, Africa' sphere of operations.

¹⁴³⁰ The author has noted that of the 16 Opinions, Judgments or other Court matters involving the European Medicines Agency, reported by 15 November, 2010, in which the 'EMA' was named as a defendant, 5 concerned *Environment and consumers*, 2 concerned *Law governing the institutions*, 1 concerned *Procedure* and 8 concerned *Staff Regulations*.

¹⁴³¹ Occasionally, and notably, consensus does not emerge between the national medicines agencies. The drug, nimesulide, is a case in point. See Traversa, G, Bianchi, C, Da Cas, R, Abraha, I, Menniti-Ippolito, F, Venegoni, M, *Cohort study of hepatotoxicity associated with nimesulide and other non-steroidal anti-inflammatory drugs* (2003) 327 *British Medical Journal* 18. Oral (although not topical) nimesulide products were withdrawn in Ireland in May 2007. See Irish Medicines Board *Notice Information: Human Medicines - Recall - 15/05/2007* (2007) Irish Medicines Board, Dublin. Available from <http://www.imb.ie/EN/Safety--Quality/Advisory-WARNING--Recall-Notices/Human-Medicines/Nimesulide-for-Oral-Use.aspx>. (Last accessed 12 January, 2012). Nimesulide products continued to be marketed in Italy; not without controversy, however: see Pappagallo M, «*Mazzetta per evitare controlli sull' Aulin*» [Bribe to avoid controls on Aulin] (2008) *Corriere Della Sera*, 23 May, 2008, Milano. Available from http://archiviostorico.corriere.it/2008/maggio/23/Mazzetta_per_evitare_controlli_sull_co_9_080523004.shtml (Last accessed 12 January, 2012).

probable safety of the product or, as the case may be, the adequacy of the prescribing information put in the Summary of Product Characteristics (SmPC).¹⁴³²

Dodds-Smith, writing in 1991, stated that very few product liability claims involving medicinal products have ever come to trial “*and none ha[d] proceeded as far as a decision on liability following full discussion of whether the duty of care has been discharged.*”¹⁴³³ Mann remarks that unlicensed (or exempt) medicines may be considered defective on the basis of a consumer test (of what the patient is entitled to expect) and that this test “*can be affected by the verbal and written information given to the patient and the warnings therein*”.¹⁴³⁴ Therefore a producer’s ‘failure to warn’ that a medicinal product is unlicensed¹⁴³⁵ would expose the ‘producer’ to risk of liability for injury.

6.14.2.3 Application to Pharmacists in Ireland

It is submitted that familiarity with (and preference for) a medicinal product, that a medical practitioner has acquired outside the EEA, is not of itself a sufficient reason for causing the importation of an unlicensed medicine into the EEA. Where a medical practitioner (typically a hospital consultant now practising in Ireland) has trained in the US, for example, the fact of and the legal basis for official antipathy among federal agencies towards importation of foreign unlicensed medicines should be well known to such a practitioner. That is to say nothing of potential liability under the law of obligations. Such medical practitioners should not overlook similar factors, in Ireland or the wider EEA.

¹⁴³² See Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 733-734.

¹⁴³³ See Dodds-Smith, I, *Product liability issues arising out of the introduction of strict liability and procedures for dealing with multi-claimant cases*, Chapter in Sir A Goldberg, Dodds-Smith, I (Editors), *Pharmaceutical medicine and the law: legal responsibility, product liability, Europe* (1991) Royal College of Physicians of London and Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK, London, 48.

¹⁴³⁴ See Mann, RD, *Unlicensed medicines and the use of drugs in unlicensed indications*, Chapter in Sir A Goldberg, Dodds-Smith, I (Editors), *Pharmaceutical medicine and the law: legal responsibility, product liability, Europe* (1991) Royal College of Physicians of London and Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK, London, 109.

¹⁴³⁵ Raising the possibility that such a product may be less comprehensively reviewed in terms of its scientific data than a licensed product; see Mann, *loc cit.*

6.14.2.4 The US Food and Drug Administration – Labelling Requirements

The FDA is responsible for licensing medicinal products in the US. The US counterpart of a market authorisation is product labelling. ‘Patient labeling’ will be required “if the FDA determines that one or more of the following circumstances exists:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects.

(2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product.

(3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.”¹⁴³⁶

The foregoing system, which leaves some room for uncertainty on the part of manufacturers, may be contrasted with the regulatory regime of the European Union, which has evolved over a period of more than 40 years.

6.14.2.5 Pharmacovigilance

Pharmacovigilance¹⁴³⁷ embraces defects that cause damage, issues in patient safety and quality defects. Incidents reported by physicians and other healthcare professionals yield important information on which manufacturers (producers) may base decisions on pharmaceutical products. In Directive 2001/83/EC, it was provided that “*Member States shall take all appropriate measures to encourage doctors and other health care professionals to report suspected adverse reactions to the competent authorities.*”¹⁴³⁸ Clearly, the Parliament and Council felt the need to expand on what appropriate measures should embrace. The Member States were given the possibility to impose specific requirements¹⁴³⁹ on doctors and other health-care professionals in respect of the reporting of suspected serious or unexpected adverse reactions.¹⁴⁴⁰ It is submitted that mandatory pharmacovigilance reporting by doctors and other health professionals, in some EEA member states and not others, might lead to fears of unfair stigmatisation of such professionals

¹⁴³⁶ US Code of Federal Regulations, 21CFR208.1 (c). See CFR - Code of Federal Regulations Title 21, Part 208 -- Medication Guides for Prescription Drug Products. (Undated Web Resource) Available from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=208.1>. (Last accessed 19 April, 2012).

¹⁴³⁷ See generally Smillie, M, Brueton, G, *Pharmacovigilance*, Chapter in Shorthose, S, (Editor), *EU Pharmaceutical Regulatory Law* (2010) Kluwer Law International, Alphen aan den Rijn (NL) 73-124.

¹⁴³⁸ Directive 2001/83/EC, art 101.

¹⁴³⁹ However, there is no guidance on the nature of any penalties that may be imposed for non-compliance with the relevant national law.

¹⁴⁴⁰ Directive 2001/83/EC, as amended by Directive 2004/27/EC.

by some regulatory authorities. There might also be reluctance by pharmaceutical companies to place medicinal products on the market in the affected territories and, consequently, an unintended partition of the EEA-wide pharmaceutical market might ensue.

In relation to pharmacovigilance, the European Parliament has recently brought into effect Directive 2010/84/EU to amend Directive 2001/83/EC.¹⁴⁴¹ Directive 2010/84/EU has been implemented in Ireland by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012, which amended the Medicinal Products (Control of Placing on the Market) Regulations 2007.

6.15 Strict Liability in the European Context

6.15.1 The Strasbourg Convention

The Strasbourg Convention¹⁴⁴² was an attempt to harmonise European law: the Convention, which placed no limit on claims, covered personal injuries only, and is now purely of historical interest.¹⁴⁴³

¹⁴⁴¹ The Report underlying this legislative measure is the following: European Parliament, *Report A7-0159/2010 - Pharmacovigilance - Proposal for a Directive to amend Directive 2001/83/EC* (2010) Available from <http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2010-0159&language=EN> (Last accessed 12 January, 2012).

¹⁴⁴² Council of Europe (CoE), *European Convention on Products Liability in Regard to Personal Injury and Death CETS No 091* (1977). Available from <http://www.conventions.coe.int/Treaty/en/Treaties/Html/091.htm>. (Last accessed 12 January, 2012). The Treaty was signed by Austria, Belgium, France and Luxembourg. A requirement for three ratifications/accessions was set down for the Treaty to come into effect: none has been made. The Annex permits to States a Reservation so as “to exclude the retailer of primary agricultural products from liability under the terms of paragraph 3 of Article 3 providing he discloses to the claimant all information in his possession concerning the identity of the persons mentioned in Article 3.” Article 3 provides:

“1. The producer shall be liable to pay compensation for death or personal injuries caused by a defect in his product.

2. Any person who has imported a product for putting it into circulation in the course of a business and any person who has presented a product as his product by causing his name, trademark or other distinguishing feature to appear on the product, shall be deemed to be producers for the purpose of this Convention and shall be liable as such.

3. When the product does not indicate the identity of any of the persons liable under paragraphs 1 and 2 of this Article, each supplier shall be deemed to be a producer for the purpose of this Convention and liable as such, unless he discloses, within a reasonable time, at the request of the claimant, the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.

4. In the case of damage caused by a defect in a product incorporated into another product, the producer of the incorporated product and the producer incorporating that product shall be liable.

5. Where several persons are liable under this Convention for the same damage, each shall be liable in full (in solidum).”

6.15.2 The European Product Liability Directive

6.15.2.1 Introduction

The first report on the application of the Product Liability Directive was published in 1995¹⁴⁴⁴: it did not make any criticism of Ireland's implementation of the Directive.¹⁴⁴⁵

The common law position on product liability requires the plaintiff to show negligence in the manufacture, design or marketing of the product.¹⁴⁴⁶ Strict liability is based on the concept of 'defectiveness' under the Product Liability Directive. It has been suggested that few cases brought under the transposed Directive would not also succeed at common law.¹⁴⁴⁷ The goal of strict liability for damage done by defective products is "*an allocation of risks between manufacturer and consumer, and in this respect it represents a compromise.*"¹⁴⁴⁸

The Treaty has been overtaken effectively by Directive 85/374/EEC for EEA member states and ultimately EU candidate states. The Hague Convention on the Law Applicable to Products Liability (1973), which came into force on 10 January, 1977, is another international agreement that has not lived up to expectations: *Hague Convention on the Law Applicable to Products Liability* (1973) Hague Conference on Private International Law, The Hague (NL). Available from <http://www.hcch.net/upload/conventions/txt22en.pdf>. (Last accessed 22 April, 2012). Some of the successor States to Yugoslavia (one of the original parties to the Convention) have declared themselves to be bound by the Convention: see Davies, M, *Product Liability in International Markets*, Chapter in Mullany, NJ, Linden, AM, *Torts Tomorrow: A Tribute to John Fleming* (1998) LBC Information Services, Sydney, 131 (n).

¹⁴⁴³ Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 268.

¹⁴⁴⁴ COM(1995) 617 final - *First report on the application of Directive 85/374/EEC concerning liability for defective products*. The First Report was effectively a verification of the kind of 'progress reports' that Member States would have provided at a *tour de table* during a Council of Ministers Meeting or similar gathering. See also European Commission, Enterprise and Industry, *Reference documents on liability for defective products* (2012) Available from http://ec.europa.eu/enterprise/policies/single-market-goods/documents/liability/index_en.htm. (Last accessed 12 April, 2012).

¹⁴⁴⁵ The principle in *Francovich and Bonifaci v Republic of Italy* (Cases C-6 and 9/90) [1991] ECR I-5375 would have been known to the authors of the relevant report. In *Shanahan & Ors v PJ Carroll & Ors* [2007] IEHC 229 (Gilligan J), there was a *Francovich* allegation (which did not get off the ground) that the State defendants had failed to implement Council Directive 85/374/EEC "*promptly or within the time limit for implementation as set out in the Directive, and as a result of this failure, the plaintiff has been wrongfully denied a recourse for damages pursuant to that Directive against the second named defendant in respect of damage caused between 7th August, 1988, and 16th December, 1991, and has suffered loss.*"

¹⁴⁴⁶ See Steele, J, *Tort Law: Text, Cases and Materials*, Second Edition (2010) Oxford University Press, Oxford, 850.

¹⁴⁴⁷ Steele, J, *op cit*, 851.

¹⁴⁴⁸ Steele, J, *op cit*, 847. See Wertheimer, E, *Calabresi's Razor: A Short Cut to Responsibility* (1998) 28 *Stetson Law Review* 105, 112 (Text and n 21): *Restatement (Second) of Torts*, § 402A, cmt c (1965) summarizes many of the policy elements behind strict products liability:

"On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by

The Product Liability Directive (85/374/EC)¹⁴⁴⁹ is “*expressly concerned with the apportionment of risks associated with products.*”¹⁴⁵⁰ Taschner has said that “[t]he user of outmoded products is acting at his own risk. Article 6(2) of the Product Liability Directive says this clearly, even if this rule is superfluous.”¹⁴⁵¹ It is submitted that, when applied to consumers of prescription medicinal products, this statement is an oversimplification. It seems trite to say that patients may not have the ultimate choice of medicinal product when it is their GP and/or hospital consultant who ‘wields the pen’.

Unfortunately, the Product Liability Directive was introduced as an internal market measure under art 100 of the EU Treaty.¹⁴⁵² This has the regrettable consequence that Directive 85/374/EC does not come within the remit of the Health and Consumers Directorate-General, which is responsible for the General Product Safety Directive¹⁴⁵³ and, in the private law field, Directives on the sale of goods¹⁴⁵⁴ and on unfair terms.¹⁴⁵⁵ Liability will not automatically arise because the Directive¹⁴⁵⁶ allows a defence for the producer where “*the state of scientific and technical knowledge at the time when [the producer] put the product into circulation was not such as to enable the existence of the defect to be discovered*”.¹⁴⁵⁷ Most member states have legislated to

products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.”

¹⁴⁴⁹ Council Directive 85/374/EEC was amended by Directive 1999/34/EC to extend coverage to primary agricultural products, in the wake of the Bovine Spongiform Encephalopathy (BSE) controversy. See also Valverde, JL, *Toward a global legal statute for medicinal products* (2007) 9 *Pharmaceuticals Policy and Law* 273, 296.

¹⁴⁵⁰ Steele, J, *op cit*, 851.

¹⁴⁵¹ See also Taschner, HC, *Product liability: basic problems in a comparative law perspective*, Chapter in Fairgrieve, D (Editor), *Product Liability in Comparative Perspective* (2005) Cambridge University Press, Cambridge, 163.

¹⁴⁵² See Howells, G, *Product Liability – a History of Harmonisation*, Chapter in Fairgrieve, D (Editor), *Product Liability in Comparative Perspective* (2005) Cambridge University Press, Cambridge, 202-203.

¹⁴⁵³ Directive 2001/95/EC amending Directive 92/59/EC. See, however, Polinsky, AM, Shavell, S, *The Uneasy Case for Product Liability* (2010) 123 *Harvard Law Review* 1437, 1480 (internal citations omitted): “*The ... Restatement (Third) of Torts: Products Liability ... mentions the safety justification in only a few sentences, assuming its importance, and does not consider that market forces and regulation may encourage product safety. The Restatement (Second) merely notes in a phrase that the provision of safety is a rationale for product liability.*”

¹⁴⁵⁴ Directive 1999/44.

¹⁴⁵⁵ Directive 1993/13.

¹⁴⁵⁶ Art 7(e).

¹⁴⁵⁷ Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 751, citing Art 7(e). See also Steele, J, *op cit*, 850 (n): “*Defects which could not be discovered for reasons unconnected with lack of knowledge (for example, because there is no known method for detection) are not within the defence.*”

include the 'development risks defence': there are some notable exceptions.¹⁴⁵⁸ Only Germany, Spain and Portugal have introduced a ceiling on personal injury damages.¹⁴⁵⁹

6.15.2.2 *The Liability for Defective Products Act 1991*

The Liability for Defective Products Act 1991 defines "damage" thus:

“(a) death or personal injury, or

(b) loss of, damage to, or destruction of, any item of property other than the defective product¹⁴⁶⁰ itself:

Provided that the item of property—

¹⁴⁵⁸ See Fondazione Roselli, *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products, Final Report* (2004) Available from http://www.fondazioneroselli.it/User.it/index.php?PAGE=Sito_en/centri_ricer1&unit_id=14&rice_id=231 (Last accessed 12 January, 2012). Fondazione Roselli was appointed by the Directorate for the Internal Market of the European Commission (Contract No ETD/2002/85) to carry out this study on the economic impact of the development risk clause as in the Directive 85/374/EEC on the liability for defective products. The principle findings in the Report ([4]) have been summarised thus:

“In conclusion, the findings presented in this report seem to indicate that the often-used argument of the Development Risk Clause [(DRC)] being a significant factor in achieving the Directive’s balance between the need to preserve incentives to innovation and consumers’ interests is well-founded and is based on the following:

- *the DRC protects incentives to innovate by reducing the innovation-related risks, by not diverting resources from R&D to insurance policies and by pushing firms to align to state of the art knowledge*
- *the DRC is probably one key factor in determining the relative stability of product liability insurance costs in European industry and keeping litigation at a reasonable level*
- *in a strict liability regime, companies in high-tech / high risk sectors would find it very difficult to obtain a reasonable insurance policy which covers their developmental risks.*

The combination of these factors leads us to conclude that the costs of letting the producers innovate their products in a full strict liability environment would be extremely high, especially for companies but also for consumers in the long term.”

Finland and Luxembourg have excluded the defence entirely. Spain has excluded the defence in the case of high risk products. See Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 270-271: Spain’s outwardly illogical position is satisfactorily explained by the earlier introduction of a stricter regime for high risk products in the Consumer Protection Act 1984 following the Colza cooking oil scandal. In Spain, the development risks defence is not available for food and medicinal products. See also Hedley, S, *Tort*, Seventh Edition (2011) Oxford University Press, Oxford, 96, stating that the ‘development risks’ defence leaves manufacturers with all the benefits of technical innovation and consumers of their products with all the risks.

¹⁴⁵⁹ See Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 270.

¹⁴⁶⁰ In the 1991 Act, "product" means all movables with the exception of primary agricultural products (the ‘primary agricultural products’ exemption was removed by the Directive 99/34/EC) which have not undergone initial processing, and includes (a) movables even though incorporated into another product or into an immovable, whether by virtue of being a component part or raw material or otherwise, (b) electricity where damage is caused as a result of a failure in the process of generation of electricity.

*(i) is of a type ordinarily intended for private use or consumption*¹⁴⁶¹, and

*(ii) was used*¹⁴⁶² *by the injured person mainly for his own private use or consumption*".

Section 2(1) provides that the producer shall be liable in damages in tort for damage caused wholly or partly by a defect in his product. The definition of 'producer' in the Irish Act is set out in section 2(2).¹⁴⁶³ The statutory profile of an 'importer' in the Irish Act is comparatively terse.¹⁴⁶⁴

The 1991 Act provides for redress by identification of the producer: the supplier may be treated as the producer in the event of non-compliance with a request for assistance within the meaning

¹⁴⁶¹ Compare with the UK Consumer Protection Act, s 5(3), which adds the concept of 'occupation' to support the notion that damage to a building by another product is recoverable:

"A person shall not be liable under section 2 above for any loss of or damage to any property which, at the time it is lost or damaged, is not—

(a) of a description of property ordinarily intended for private use, occupation or consumption; and

(b) intended by the person suffering the loss or damage mainly for his own private use, occupation or consumption."

See also *Leo Laboratories Limited v Crompton BV (Formerly Witco BV)* [2005] IESC 31, Fennelly J (*per curiam*): "The Court has not been addressed at all on the basis of the Respondent's claim under [the 1991] Act or under the Directive. I will assume for the purposes of this judgment that the claim can be made under the Act, though section 1 would appear, at first sight, to relate to damage suffered by a person using goods 'for his own private use or consumption'."

¹⁴⁶² Compare with the UK Consumer Protection Act, s 5(3)(b), where the second limb of the test is "clearly a subjective one": see Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 397.

¹⁴⁶³ Liability for Defective Products Act 1991, s 2(2) defines "producer" thus:

"(a) the manufacturer or producer of a finished product, or

(b) the manufacturer or producer of any raw material or the manufacturer or producer of a component part of a product, or

(c) in the case of the products of the soil, of stock-farming and of fisheries and game, which have undergone initial processing, the person who carried out such processing, or

(d) any person who, by putting his name, trade mark or other distinguishing feature on the product or using his name or any such mark or feature in relation to the product, has held himself out to be the producer of the product, or

(e) any person who has imported the product into a Member State from a place outside the European Communities in order, in the course of any business of his, to supply it to another, or

(f) any person who is liable as producer of the product pursuant to subsection (3) of this section."

The 'primary agricultural products' exemption was removed by the Directive 99/34/EC.

¹⁴⁶⁴ The Irish provision has been drafted more economically than the comparison provided by an Accession State in the 1990s. For section 5 of the Finnish Product Liability Act, see Ministry of Justice, Finland (Unofficial Translation), *Product Liability Act (694/1990; amendments up to 880/1998 included)* (1998) Available from <http://www.finlex.fi/en/laki/kaannokset/1990/en19900694.pdf> (Last accessed 12 January, 2012).

of s 2(3).¹⁴⁶⁵ Suppliers may be in a position to avoid liability by identifying an antecedent provider, if the producer is unknown.¹⁴⁶⁶

Under s 4, the onus is on the injured person concerned to prove the damage, the defect and the causal relationship between the defect and damage.¹⁴⁶⁷ The 'causal relationship' is considered in Chapter 5. Property damage of less than €445 is not recoverable.¹⁴⁶⁸

Section 5 of the Irish Act provides a definition of 'defective product'¹⁴⁶⁹:

"(1) For the purposes of this Act a product is defective if it fails to provide the safety which a person is entitled to expect,¹⁴⁷⁰ taking all circumstances into account, including—

¹⁴⁶⁵ See 1991 Act, s 2(3): "Without prejudice to subsection (1) of this section, where damage is caused wholly or partly by a defect in a product, any person who supplied the product (whether to the person who suffered the damage, to the producer of any product in which the product is comprised or to any other person) shall, where the producer of the product cannot by taking reasonable steps be identified, be liable, as the producer, for the damage if—

- (a) the injured person requests the supplier to identify any person (whether still in existence or not) to whom paragraph (a), (b), (c), (d) or (e) of subsection (2) of this section applies in relation to the product,*
- (b) that request is made within a reasonable time after the damage occurs and at a time when it is not reasonably practicable for the injured person to identify all those persons, and*
- (c) the supplier fails, within a reasonable time after receiving the request, either to comply with the request or to identify the person who supplied the product to him."*

¹⁴⁶⁶ See Quill, *op cit*, 162.

¹⁴⁶⁷ See Schuster, A, *The New Irish Product Liability Regime (1994-1995)* 39 St Louis University Law Journal 917, 932 if the consumer "can establish a causative link between the defective product and his injury, the manufacturer will be faced with the onerous task of disproving liability." See further Schuster, A, *op cit*, 932 (n 40): "In many instances this particular advantage will prove more illusory than real. The law of negligence often shifts the burden of proof in product liability cases through the mechanism of the *res ipsa loquitur* principle", citing *Mills v Coca-Cola Bottling Co (Dublin) Ltd*, Unreported, District Court, 08 May, 1984.

¹⁴⁶⁸ See the 1991 Act, s 3(1). Only Germany, Portugal and Spain availed of the opportunity under art 16 of the 1985 Directive to impose a ceiling on liability. See also Quill, *op cit*, 163-164.

¹⁴⁶⁹ Compare with the Australian Trade Practices Act 1974 (Cth), s 75AC(2):

"In determining the extent of the safety of goods, regard is to be given to all relevant circumstances including:

- (a) the manner in which, and the purposes for which, they have been marketed; and*
- (b) their packaging; and*
- (c) the use of any mark in relation to them; and*
- (d) any instructions for, or warnings with respect to, doing, or refraining from doing, anything with or in relation to them; and*
- (e) what might reasonably be expected to be done with or in relation to them; and*
- (f) the time when they were supplied by their manufacturer."*

¹⁴⁷⁰ The concept of what one is 'entitled to expect' has its origins in the (effectively moribund) Council of Europe Convention to which reference has been made in Section 6.15.1. See Council of Europe, *European Convention on Products Liability in Regard to Personal Injury and Death (ETS No 091)*, Explanatory Report (1977) Available from <http://conventions.coe.int/Treaty/en/Reports/Html/091.htm>. (Last accessed 12

(a) the presentation of the product,

(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.¹⁴⁷¹

(2) A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.”

This definition may be contrasted with the *Restatement (Third)*, which continues from *Restatement (Second)* the classification of manufacturing, design and warning defects.¹⁴⁷²

Quality defects are outside the scope of the 1991 Act.¹⁴⁷³ In *Delahunty v Player & Wills (Ireland) Limited & Ors*,¹⁴⁷⁴ Fennelly J noted a defence submission that the Act of 1991 does not cover products which carry an inherent risk; here cigarettes, which product could not fulfil the consumer expectation test in s 5 of the Act.¹⁴⁷⁵ The Supreme Court refused to strike out proceedings, under the Rules of the Superior Courts or inherent jurisdiction, since there were complex issues of law and fact to be ventilated at plenary hearing.

Liability under the 1991 Act is not truly strict,¹⁴⁷⁶ given the availability of several defences under section 6:

“A producer shall not be liable under this Act if he proves—

January, 2012), Paragraph 15 “In conclusion, the committee decided to consider the notion of ‘defect’ as the basis of liability, which is defined in Article 2, paragraph c, as the absence of safety which a person is entitled to expect.”

¹⁴⁷¹ Although the Product Liability Directive does not provide one, there is a (not particularly instructive) definition of “put into circulation” in European Convention on Products Liability in regard to Personal Injury and Death (1977), article 2 d: “a product has been ‘put into circulation’ when the producer has delivered it to another person.” The UK Consumer Protection Act 1987 eschews the word ‘circulation’ entirely for the concept of supply to another (of which there are 11 instances in the Act). Patent protection for pharmaceuticals can inhibit severely the putting into circulation of a similar (let alone ‘better’) product containing the same active ingredients. It is rarely advantageous to pharmaceutical companies to grant a licence to a competitor to exploit a patent-protected invention, unless within a joint-marketing venture.

¹⁴⁷² *Restatement (Third) of Torts: Products Liability*, § 2 (Categories of Product Defect).

¹⁴⁷³ See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 163.

¹⁴⁷⁴ [2006] 1 IR 304 (Sup Ct). See also Schuster, A, Binchy, W, *Product Liability Litigation in Ireland: Recent Developments* (2007-2008) 2(4) Quarterly Review of Tort Law 13, 14-16.

¹⁴⁷⁵ [2006] 1 IR 304, 308, per Fennelly J.

¹⁴⁷⁶ See Quill, *op cit*, 169, on the strict liability regime in the US.

(a) that he did not put the product into circulation, or

(b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that that defect came into being afterwards, or

(c) that the product was neither manufactured by him for sale or any form of distribution for an economic purpose nor manufactured or distributed by him in the course of his business, or

(d) that the defect concerned is due to compliance¹⁴⁷⁷ by the product with any requirement imposed by or under any enactment or any requirement of the law of the European Communities, or

(e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered,¹⁴⁷⁸ or

(f) in the case of the manufacturer of a component or the producer of a raw material, that the defect is attributable entirely to the design of the product in

¹⁴⁷⁷ For a somewhat 'remote' aspect of compliance with the *Acquis Communautaire*, see Nykänen, A, *Lääkkeiden Vapaa Liikkuvuus Euroopan Unionissa Kohti Yhtenäisiä Lääkemarkkinoita* [Freedom of Movement for Medicines within the European Union: Towards a Single Pharmaceutical Market] (2006) Masters Thesis, Faculty of Law, University of Helsinki, [85]. Available from <http://www.edilex.fi/lakikirjasto/4401.pdf>. (Subscription required) (Last accessed 02 November, 2010):

"In practice, the EU Court of Justice's protection of parallel imports may cause the actual risk to the consumer to increase in Finland. A good example of potential consumer protection-related risks is the Finnish medical injury compensation system, based on both the product liability law and the voluntary pharmaceutical insurance [pool. This organisation] maintains a pharmaceutical injury insurance scheme in which compensation for damage caused by drugs to the consumer is much more feasible than the normal product liability framework. For pharmaceutical companies, medical insurance pool participation is voluntary, with the result that a number of parallel importers do not become participants. Generic substitution as an actual source of injury, mindful that the patient's possibilities to control drug origin and drug substitution are weak, may lead to unreasonable consequences for the patient." (This author's translation).

¹⁴⁷⁸ The 'development risks' defence; see also Stapleton, J, *Bugs in Anglo-American Products Liability*, Chapter in Fairgrieve, D (Editor), *Product Liability in Comparative Perspective* (2005) Cambridge University Press, Cambridge, 323, citing *inter alia*: Newdick, C, *Strict Liability for Defective Drugs and the Pharmaceutical Industry* (1985) 101 *Law Quarterly Review* 405, 408.

which the component has been fitted or the raw material has been incorporated or to the instructions given by the manufacturer of the product."¹⁴⁷⁹

It is important to distinguish failure to warn defects from inadequate instruction.¹⁴⁸⁰

Section 7(2)(a) provides an unusual limitation period of ten years from the date on which the producer put into circulation the actual product which caused the damage unless the injured person has in the meantime instituted proceedings against the producer.¹⁴⁸¹ In *O'Byrne v Aventis Pasteur SA*,¹⁴⁸² on a reference for a preliminary ruling, the European Court of Justice held that article 11 of Directive 85/374 precluded national legislation, which allowed the substitution of one defendant for another during proceedings, from being applied in a way which permitted a "producer", within the meaning of article 3 of the Directive, to be sued, after the expiry of the period prescribed by article 11, as defendant in proceedings brought within that period against another person.¹⁴⁸³ The European Court found further that article 11 did not preclude a national court from holding that, in proceedings instituted within the period prescribed by that article against the wholly-owned subsidiary of the "producer", within the meaning of article 3(1) of the Directive, that producer could be substituted for that subsidiary if the court found that the putting into circulation of the product in question was, in fact, determined by that producer. The Court held that, where the person injured by an allegedly defective product was not reasonably able to identify the producer of the product before exercising his rights against the supplier of the

¹⁴⁷⁹ Compare with the position in the US - Rutherford, RT, *Changes in the Landscape of Products Liability Law: An Analysis of the Restatement (Third) of Torts* (1997-1998) 63 *Journal of Air Law & Commerce* 209, 229 (n). Prior to the promulgation of the *Restatement (Third)*, the ALI had expressed no opinion as to whether the rule of section 402A of the *Restatement (Second)* applied to the seller of a component part of the product.

¹⁴⁸⁰ Howells, G, *Introduction*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 13-14.

¹⁴⁸¹ Except where that right of action has already terminated under the standard limitation period; see Quill, *op cit*, 160-161.

¹⁴⁸² *O'Byrne v Aventis Pasteur SA* (Case C-358/08) [2010] 1 WLR 1375 (ECJ) (Reference for a preliminary ruling).

¹⁴⁸³ For an analysis of the issues in *O'Byrne* at an earlier point in the proceedings, see Hodges, C, *Product liability: suppliers, limitation and mistake* (2006) 122 *Law Quarterly Review* 393, 397 which states that *Horne-Roberts v SmithKline Beecham Plc* [2002] 1 WLR 1662 (CA), was "wrongly decided, since it failed to recognise the fundamental point that the English procedural law permitting substitution in certain circumstances of mistake is simply inapplicable after the expiry of the 10-year period as it is contrary to the clear 10-year rule provided for by Community law." The *Horne-Roberts* case was not noted in the judgment, *O'Byrne v Sanofi Pasteur MSD Ltd (formerly Aventis Pasteur MSD Ltd)* (Case C-127/04) [2006] 1 WLR 1606, (ECJ). Contrast with *Flickinger v Preble* (2005) Supreme Court of Jamaica, CLF 013 of 1997, Unreported, per Sykes J, [23]: "[T]he mistake there is intending to sue A but calling him B. In this situation, the correct defendant is before the court but he is sued in the wrong name. There is no question here of depriving the defendant of any limitation defence. It is simply getting the name right." *Flickinger v Preble* is cited in Kodilinye, G, Kodilinye, V, *Commonwealth Caribbean Civil Procedure*, Third Edition (2009) Routledge-Cavendish, Abingdon, 85-86.

product, the supplier was, in accordance with article 3(3), to be treated as a "producer" for the purposes, in particular, of the application of article 11, if it did not inform the injured person, on its own initiative and promptly, of the identity of the producer or its own supplier.¹⁴⁸⁴ In the United Kingdom Supreme Court,¹⁴⁸⁵ Lord Rodger of Earlsferry JSC (for the Court) explained the dicta of the Court of Justice.¹⁴⁸⁶

*"...the court is explaining how that [core] decision may fall to be applied, depending on the domestic court's assessment of the practical relationship between the manufacturer ... and the distributor ..."*¹⁴⁸⁷

Section 8 provides for joint and several liability among concurrent wrongdoers.¹⁴⁸⁸ Section 9 provides:

"(1) Without prejudice to Part III of the Civil Liability Act 1961, concerning the right of contribution, the liability of the producer shall not be reduced when damage is caused both by a defect in a product and by the act or omission of a third party.

(2) Where any damage is caused partly by a defect in a product and partly by the fault of the injured person or of any person for whom the injured person is responsible, the provisions of the Civil Liability Act 1961, concerning contributory negligence, shall have effect as if the defect were due to the fault of every person liable by virtue of this Act for the damage caused by the defect."

The Directive provides for a prohibition on exclusion from liability.¹⁴⁸⁹ Section 11 provides, importantly, that other rights of action not precluded.

¹⁴⁸⁴ The mere denial by the supplier that it was the producer of the product is not sufficient to constitute the provision of such information: [2010] 1 WLR 1375, paras [52], [53], [63], operative part, second paragraph.

¹⁴⁸⁵ *O'Byrne v Aventis Pasteur MSD Ltd* [2010] 1 WLR 1412 (UKSC).

¹⁴⁸⁶ *Dicta* of the Court of Justice of the European Union in *O'Byrne v Aventis Pasteur SA (Case C-358/08)* [2010] 1 WLR 1375, paras [34]-[48] (the 'core ruling'), as clarified in paras [50]-[52].

¹⁴⁸⁷ *O'Byrne v Aventis Pasteur MSD Ltd* [2010] 1 WLR 1412 (UKSC), [17], per Lord Rodger of Earlsferry JSC.

¹⁴⁸⁸ Within the meaning of Part III of the Civil Liability Act 1961.

¹⁴⁸⁹ Section 10 of the 1991 Act (Prohibition on exclusion from liability) is more economically drafted than the UK Consumer Protection Act 1987, s7 (Prohibition on exclusions from liability): "*The liability of a person by virtue of this Part to a person who has suffered damage caused wholly or partly by a defect in a product, or to a dependant or relative of such a person, shall not be limited or excluded by any contract term, by any notice or by any other provision.*" (Emphasis added).

In *Abouzaid v Mothercare (UK) Ltd*,¹⁴⁹⁰ the Court of Appeal said that the defectiveness of the product was to be determined by reference not to its fitness for use but to the lack of the safety to which the public at large were entitled to expect.¹⁴⁹¹

In *Worsley v Tambrands*¹⁴⁹² it was argued that tampons were unsafe because they did not provide adequate health warnings on the box, although warnings were contained on an enclosed leaflet.¹⁴⁹³ It was held that “[t]he defendant had done what a menstruating woman was, in all the circumstances, entitled to expect” the manufacturer to do, and the way in which the warnings were given was sufficient.¹⁴⁹⁴

*Richardson v LRC Products Ltd*¹⁴⁹⁵ involved a claim only under the Consumer Protection Act 1987 (CPA) for pregnancy resulting from a fractured condom. Ian Kennedy J held that the development risks defence was not available to cover a defendant in the case of a defect of a known character merely because there was no test that could reveal its existence in every case.

In *Foster v Biosil*,¹⁴⁹⁶ the Recorder held that Directive did not reverse the burden of proof in respect of causation. On the balance of probabilities, she held that the claimant had failed to establish that a silicone implant ruptured due to a defect.

Riordan suggests that the European “emulates the American product liability law as presented in the *Restatement (Third) of Torts, with several differences*”,¹⁴⁹⁷ which ignores the reality that the Product Liability Directive ‘got there first’.¹⁴⁹⁸ Riordan asserts that the Directive “diverges” from

¹⁴⁹⁰ *Abouzaid v Mothercare (UK) Ltd* [2000] All ER (D) 2436 (CA, Civ).

¹⁴⁹¹ See *Commission v United Kingdom* (Case C-300/95) (1997) ECR I-2649.

¹⁴⁹² *Worsley v Tambrands* [2000] PIQR 95.

¹⁴⁹³ See Williamson, S, *Compensation for Infected Blood Products: A and Others v National Blood Authority and Another* (2003) 7(5) Electronic Journal of Comparative Law: negligence and strict liability were not distinguished in *Worsley v Tambrands*.

¹⁴⁹⁴ *Worsley v Tambrands*, [2000] PIQR 95, 104, per Ebsworth, J.

¹⁴⁹⁵ *Richardson v LRC Products Ltd* (2000) 59 BMLR 185 (Ian Kennedy J). In essence, it was not a reasonable consumer expectation that a condom should never rupture. The court excluded the costs of upbringing for a healthy child: *McFarlane v Tayside Health Authority* [2000] 2 AC 59 [HL(SC)]. See also Williamson, S, *op cit*.

¹⁴⁹⁶ *Foster v Biosil* (2000) 59 BMLR 178, Recorder Booth QC.

¹⁴⁹⁷ See Riordan, BJ, *Unravelling the Mystery - A Comparative Introduction to Product Liability Law in the US and Europe* (2003-2004) 1 South Carolina Journal of International Law & Business 27, 36.

¹⁴⁹⁸ See further Riordan, *op cit*, 37. The Directive adopts strict liability for products that are defective in that they fail the consumer expectations test, but presents some risk utility concepts by allowing the use of the development risks (‘state of the art’) defence and misuse defence. In this way, the Directive is like the *Restatement (Third)*. Compare *the Restatement (Third)* (1998): §1; §2, cmt d, with Council Directive 85/374/EC, arts 1 (liability for defective product), 6 (consumer expectation model of defectiveness), and 7(c) (in summary, the product was neither manufactured nor distributed by defendant). However the *Restatement (Third)* does not frame the state of the art defence as an affirmative defense but rather as a

the *Restatement (Third)*—surely it is the opposite position—by allowing a ‘statute of repose’ (the 10-year long-stop period, favouring producers) and also by placing the burden of proof on the injured party (also favouring producers in a two-way fee shifting legal system). One may compare the *Restatement (Third)*, §3, cmt c (1997) with Council Directive 85/374/EC, art 10 (limitation periods) and art 4 (causation and proof), respectively.

In a series of cases, it has been established that, in the matters regulated by it, the Directive is one of maximum harmonisation,¹⁴⁹⁹ with the effect that Member States may not enact provisions which are more generous to consumers than provided for in the Directive.¹⁵⁰⁰ Accordingly, in *Skov Æg v Bilka Lavprisvarehus A/S*,¹⁵⁰¹ the European Court of Justice held that Member States “may not by their national laws impose strict liability on suppliers as well as producers, except in the special circumstances envisaged in the Directive where a supplier fails within a reasonable time to respond to a request from an injured consumer to identify either the person who supplied him or the producer.”¹⁵⁰² The Court has, however, re-affirmed that the Directive does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects.¹⁵⁰³

6.15.3 Liability of Public Hospitals

In the pharmacy sphere, a producer may range from a major pharmaceutical company to a hospital pharmacist compounding a product small-scale from supplier-sourced materials (*Veedefald*).¹⁵⁰⁴

The issue of the extent to which public healthcare establishments are responsible in respect of defective products used by them during the provision of medical services, was finally addressed by the European Court of Justice (CJEU), more than a decade after *Veedefald*, in a recent case

question of whether a reasonable alternative design existed at time of sale, thus folding in a discussion of state of the art.

¹⁴⁹⁹ See Powers, M, Harris, N, Barton, A, *Clinical Negligence*, Fourth Edition (2008) Tottel Publishing, Haywards Heath, 735.

¹⁵⁰⁰ See *Gonzales Sanchez v Medicinia Asturiana SA* (Case-183/00) [2002] ECR I-3901; *Commission v France* (Case C-52/00) [2002] ECR I-3827 and *Commission v Greece* (Case C-154/00) [2002] ECR I-3879. See also Riordan, BJ, *Unravelling the Mystery - A Comparative Introduction to Product Liability Law in the US and Europe* (2003-2004) 1 South Carolina Journal of International Law & Business 27, 35.

¹⁵⁰¹ *Skov Æg v Bilka Lavprisvarehus A/S* (Case C-402/03) [2006] ECR I-0000. Denmark’s law impermissibly retained a cause of action against intermediaries for the actions of those higher in the distribution chain. Pharmacy was formerly a state monopoly in Denmark. It will have come as a relief to Danish pharmacists, in the liberalised market, that they face no longer such liability.

¹⁵⁰² See Powers, M, Harris, N, Barton, A, *loc cit*.

¹⁵⁰³ See Powers, M, Harris, N, Barton, A, *loc cit*.

¹⁵⁰⁴ *Veedefald v Århus Amtskommune* (Case C-203/99) [2001] ECR I-3569.

concerning a French hospital. In *Centre hospitalier universitaire Besançon v Dutruieux*,¹⁵⁰⁵ a 13-year-old boy sustained burns during surgery carried out at the *Centre hospitalier universitaire* (CHU) in Besançon. The burns were caused by a defect in the temperature control mechanism of a heated mattress on which he been placed prior to surgery. In France the liability of public healthcare establishments *vis-à-vis* their patients is based on a special system of non-contractual liability arising from “*the specific relationships which are formed between the public hospitals and the persons taken into their care.*”¹⁵⁰⁶ Under French law, a public hospital is obliged to pay compensation, even in the absence of fault, in respect of personal injuries sustained by reason of the failure or inadequacy of equipment or products used in connection with the patient’s treatment.

The CHU appealed the matter to the French *Conseil d’État* (Council of State), which requested a ruling from the CJEU in respect of the liability or otherwise of persons who use defective equipment or products while providing services and, in so doing, cause injury to the recipients of such services.

The CJEU ruled that the non-contractual liability incurred by a hospital, under domestic law, in respect of injuries sustained by a hospital patient during treatment was not covered by the Product Liability Directive. The special French system of liability in respect of public healthcare establishments was acceptable because it did not impinge upon the regime of maximum harmonisation applicable to producers, suppliers and importers subject to the provisions of the Directive. The operative part of the Court’s judgment is the following:

“The liability of a service provider which, in the course of providing services such as treatment given in a hospital, uses defective equipment or products of which it is not the producer within the meaning of Article 3 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, and thereby causes damage to the recipient of the service does not fall within the scope of the directive. Directive 85/374 does not therefore prevent a Member State from applying rules, such as those at issue in the main proceedings, under which such a provider is liable for damage thus caused, even in

¹⁵⁰⁵ Case C-495/10, *Centre hospitalier universitaire Besançon v Dutruieux*, Unreported Judgment of the Grand Chamber of the European Court of Justice, 21 December, 2011. See also Schuster, A, *Tortious Liability for Defective Pharmaceutical and Medical Products* (2012) Quarterly Review of Tort Law (Forthcoming).

¹⁵⁰⁶ Page 3 of the Grand Chamber’s Judgment.

the absence of any fault on its part, provided, however, that the injured person and/or the service provider retain the right to put in issue the producer's liability on the basis of the directive when the conditions laid down by the latter are fulfilled."¹⁵⁰⁷

The operative part of the judgment refers to 'hospital'; the position here is that the CHU is a public hospital.

The implications in the case of the *Centre hospitalier universitaire Besançon v Dutrueux* case are that in Ireland (or elsewhere in the EU) no-fault liability may be introduced (where it does not already exist) for a category of products, such liability going beyond merely complying with the conditions laid down in the Product Liability Directive.

6.15.4 Recent French Case Law on the Product Liability Directive

The decision of the Cour de Cassation (the French Supreme Court) in *X v Ferring SAS*¹⁵⁰⁸ affected the availability of the development risks defence in France.¹⁵⁰⁹

The claimant, X, suffered from ulcerative colitis. He was treated with Pentasa, a medicinal product manufactured by the defendant company, for a period exceeding two years. During the course of his treatment, X suffered serious renal problems and he was hospitalised in March 1997. He instituted civil proceedings against the defendant company, claiming that Pentasa had caused him to suffer immuno-allergic interstitial nephritis. The Civil Court in Creteil found the defendant company "entirely" liable for the injury suffered by X and awarded him damages.

On appeal, the Court of Appeal in Paris reversed the lower court, rejecting the claim entirely. The Court of Appeal afforded the defendant company the benefit of the development risks defence, notwithstanding the fact that, at the time Pentasa was put into circulation, the Product Liability Directive had not been transposed into French domestic law. The Court of Appeal held that French domestic law should be interpreted in the light of the directive [including the development risks defence in Article 7(e)]. According to the Court of Appeal, this reasoning was underpinned by the CJEU decision in *Von Colson & Kamann v Land Nordrhein-Westfalen*,¹⁵¹⁰ in which it was held

¹⁵⁰⁷ Official Journal of the European Union, 18.2.2012.

¹⁵⁰⁸ *X v Ferring SAS* [2008] ECC 337.

¹⁵⁰⁹ Schuster, A, *Tortious Liability for Defective Pharmaceutical and Medical Products* (2012) Quarterly Review of Tort Law (Forthcoming).

¹⁵¹⁰ *Von Colson & Kamann v Land Nordrhein-Westfalen* [1984] ECR 189.

that the courts in the Member States of the European Union are required to interpret domestic laws “*in light of the wording and the purpose*” of Directives, including those Directives which have not been implemented into domestic law in a timely manner.

On appeal by X, the Cour de Cassation reversed the ruling of the Court of Appeal in Paris and restored the decision of the Civil Court in Creteil, holding that the defendant company could not escape liability by relying on the development risks defence. Although the Cour de Cassation concurred with the Court of Appeal’s reasoning that French domestic law should be interpreted in the light of the Directive, it ruled that the development risks defence could not be relied upon by the defendant company because the directive gave Member States the option of whether or not to include that defence within their respective legal systems. In other words, a national court is bound to interpret domestic law in the light of the Product Liability Directive only with respect to binding provisions within that European legislation. It also bears emphasis that this judgment is only relevant in the context of personal injuries caused by drugs which were placed into circulation during the ten year period in which France delayed implementation of the directive, namely, between 30 July, 1988 and 25 May, 1998.

While the case of *X v Ferring SAS* has no immediate significance to the position of Irish pharmacists, dealing as it did with France’s delay in implementing a Directive, the invocation of *Von Colson* should serve as a reminder that any putative refinement of the Directive, if not transposed into Irish law in timely fashion, may well have implications for pharmacists as suppliers.

6.15.5 Australian and Asian Adaptation of the Product Liability Directive

6.15.5.1 Trade Practices Act 1974 (Cth), Part VA

The background to the enactment of the Trade Practices Act 1974 (Cth)¹⁵¹¹ Part VA¹⁵¹² is as follows. In 1989 the Australian Law Reform Commission (ALRC) made radical proposals for reform of product liability law, perhaps the most radical feature of which was the definition of the causal factor that would attract liability: not ‘a defect in a product’ but ‘something that the goods did’.¹⁵¹³ In other words, the ALRC did not propose liability for loss caused by *defective* products

¹⁵¹¹ The provisions of the Trade Practices Act 1974 (Cth) are not based on the existence of a contractual relationship between the parties.

¹⁵¹² Part VA was inserted by the Trade Practices (Amendment) Act 1992 (Cth).

¹⁵¹³ Loss covered by other factors, such as the plaintiff’s own conduct, was not to be compensable. See also *Trindade, F, Cane, P, Lunney, M, loc cit.*

but liability for loss caused by products. In this respect, the proposed liability was very 'strict'. The ALRC proposed a unitary system of recovery, although this did not come to pass.¹⁵¹⁴

Trade Practices Act 1974 (Cth) Part VA¹⁵¹⁵ (TPA Pt VA) claims are on a strict liability basis, modelled on the EC Product Liability Directive (generally understood to be a statutory tort).¹⁵¹⁶

Kellam and Nottage remark that

"Part VA of the TPA is another statutory cause of action, based on the EC Directive. The latter, and offshoots such as Japan's Product Liability Law of 1994, are generally construed as creating a special statutory tort. The provisions of Pt VA of the TPA apply only to goods supplied after 9 July 1992, and their application cannot be excluded or modified."¹⁵¹⁷ After a slow start,¹⁵¹⁸ there is now a body of Australian case law considering their application."¹⁵¹⁹

6.15.5.2 European Product Liability Harmonisation comes to Asia

Davies has criticised the notion that Part VA is a harmonisation measure on the basis that Australia and the EU have insufficient trade to require a harmonised trade policy.¹⁵²⁰ Of course, when Japan enacted legislation based on the Product Liability Directive, there was then an

¹⁵¹⁴ See Trade Practices Act 1974 s 75AR (Saving of other laws and remedies) Section 75AR (1) provides that Part VA is not intended to exclude or limit the concurrent operation of any law, whether written or unwritten, in force in a State or Territory. Section 75AR (2) provides that Part VA is not to be taken to limit, restrict or otherwise affect any right or remedy a person would have had if this Part had not been enacted. See also *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853, [215], *dicta* of Kiefel J declining, in the light of her earlier findings of fact, to go into the (ultimately pointless) question as to whether Parts V and VA of the Trade Practices Act 1974 operate as a statutory 'pre-emption' of the general law of negligence in relation to the supply of defective goods.

¹⁵¹⁵ Trade Practices Act 1974 (Cth), Part VA (Liability of Manufacturers and Importers for Defective Goods). Section 75AI (No liability action where workers' compensation or law giving effect to an international agreement applies) provides that sections 75AD (Liability for defective goods causing injuries--loss by injured individual), 75AE (Liability for defective goods causing injuries--loss by person other than injured individual), 75AF (Liability for defective goods--loss relating to other goods) and 75AG (Liability for defective goods--loss relating to buildings etc), do not apply to a loss in respect of which an amount has been, or could be, recovered under a law of the Commonwealth, a State or a Territory that relates to workers' compensation or gives effect to an international agreement.

¹⁵¹⁶ Kellam, J, Nottage, L, *Happy 15th birthday, Part VA TPA! Australia's product liability morass* (2007) 15 *Competition & Consumer Law Journal* 1, 3-4.

¹⁵¹⁷ Section 75AP (Application of provisions not to be excluded or modified).

¹⁵¹⁸ See Kellam and Nottage, *op cit*, 22 (n), citing the first "*reported judgment on a substantive issue*" as *Glendale Chemical Products Pty Ltd v ACCC* (1998) 90 FCR 40.

¹⁵¹⁹ See Kellam and Nottage, *op cit*, 22. See, for example, *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd (includes Corrigendum dated 18 June 2010)* [2010] FCA 180.

¹⁵²⁰ See Davies, M, *Product Liability in International Markets*, Chapter in Mullany, NJ, Linden, AM, *Torts Tomorrow: A Tribute to John Fleming* (1998) LBC Information Services, Sydney, 134. See also Kellam, J, Nottage, L, *Europeanisation of Product Liability in the Asia-Pacific Region: A Preliminary Empirical Benchmark* (2008) 31 *Journal of Consumer Policy* 217, 220. (Indonesia, Korea, Malaysia, Philippines, and Taiwan have introduced statutes based on the EU Product Liability Directive).

effective product liability harmonisation between Japan and Australia.¹⁵²¹ The European paradigm has been adopted also by China.¹⁵²²

6.15.5.3 The Australian Jurisprudence

The decision in *Ryan v Great Lakes Council*¹⁵²³ has been criticised for emphasising the question of the manufacturer's behaviour in relation to the risk of Hepatitis A transmission through oysters, rather than the possibility of detecting the risk of infection.¹⁵²⁴ It is submitted that, in the absence of a non-destructive scientific test, a manufacturer's responsible behaviour would have offered the best prospect for detecting by inference the said risk.¹⁵²⁵

The effect of the doctrine of *res ipsa loquitur* is that the common law may impose liability that is effectively strict at least in production-negligence and simple design-negligence cases. On the other hand, the decision in *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd*¹⁵²⁶ suggests that 'defect' in the Act will be interpreted in such a way that the standard of liability under the Act is, to all intents and purposes, indistinguishable from common law negligence.¹⁵²⁷

¹⁵²¹ See Welsh, F, *Australia: A New History of the Great Southern Land* (2008) Overlook Press, New York, 407: "The Far East is our Near North".

¹⁵²² See Kellam, J, Nottage, L, *Europeanisation of Product Liability in the Asia-Pacific Region: A Preliminary Empirical Benchmark* (2008) 31 *Journal of Consumer Policy* 217. China has recently adopted aspects of the European Product Liability Directive. The Chinese Tort Law came into force on 01 July, 2010. See Koziol, H, Zhu, Y, *Background and Key Contents of the New Chinese Tort Liability Law* (2010) 1 *Journal of European Tort Law* 328, 335. On the application of the risk utility test in Chinese Law, see Brüggemeier, G, Zhu, Y, *Entwurf für ein chinesisches Haftungsgesetz: Text und Begründung - ein Beitrag zur internationalen Diskussion um die Reform des Haftungsrechts* [A Design for a Chinese Product Liability Law: Text and Justification – a Contribution to International Discussion of Legal Liability Reform] (2009) Mohr Siebeck, Tübingen, 68.

¹⁵²³ *Ryan v Great Lakes Council* [1999] FCA 177. The case in the High Court of Australia is reported *sub nom Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54; 211 CLR 540. See also Walton, C (General Editor), *Charlesworth and Percy on Negligence*, Twelfth Edition (2010) Sweet & Maxwell, London, 130-131, noting that the public authority defendants owed no private duty to the plaintiff.

¹⁵²⁴ Trindade, F, Cane, P, Lunney, M, *The Law of Torts in Australia*, Fourth Edition (2007) Oxford University Press, Oxford, 644. The case against one defendant was reserved and ultimately determined by the High Court of Australia in *Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54; 211 CLR 540.

¹⁵²⁵ See *Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54, [329] (The trial judge had made a finding that Barclay could have made a significant contribution to the reduction of risk by causing an inspection to be made of the foreshores of the lake. Barclay was armed with the knowledge of outbreaks of Hepatitis A on other occasions in other places.)

¹⁵²⁶ [2004] FCA 853, Kiefel J.

¹⁵²⁷ See also Walton, C, *op cit*, 27-28, stating that the High Court of Australia has rejected the House of Lords' approaches, in both *Anns v Merton London Borough Council* [1978] AC 728 and *Caparo Industries plc v Dickman* [1990] 2 AC 605, and some of the later decisions from the High Court of Australia "tend simply to revert to *Donoghue v Stevenson*".

The only respect in which the Act imposes any significant measure of strict liability is that it allows claims to be made against persons other than the manufacturer, who may in no real sense be responsible for the condition of the product.¹⁵²⁸

In *Peterson v Merck Sharp & Dohme (Aust) Pty Ltd*,¹⁵²⁹ the claim in negligence founded on causation: Jessup J found that even if the prescriber had not been exposed to the sales executives making representations that Vioxx was safe, he would have still prescribed Vioxx to the patient and that Mr Peterson would have taken it.¹⁵³⁰ Claims relating to breaches of various provisions in the Trade Practices Act 1974 (Cth), which involved allegations that the drug manufacturers: engaged in misleading or deceptive conduct¹⁵³¹; traded in defective goods causing injuries or loss to the injured individual¹⁵³²; traded in goods not reasonably fit for purpose¹⁵³³; traded in goods of unmerchantable quality.¹⁵³⁴ Pharmaceutical sales representatives used the product information in their 'sales pitch' to doctors and this would, Jessup J held should be considered conduct in trade or commerce.¹⁵³⁵ He relied on High Court of Australia *dicta* in *Concrete Constructions (NSW) Pty Ltd v Nelson*¹⁵³⁶ that:

*"Such conduct includes, of course, promotional activities in relation to, or for the purposes of, the supply of goods or services to actual or potential consumers, be they identified persons or merely an unidentifiable section of the public."*¹⁵³⁷

In the absence of the provision of any information, advice or warning, the risk of myocardial infarction made the safety of Vioxx less than what persons generally were entitled to expect; so implied the product's withdrawal from the market.¹⁵³⁸ In relation to the allegations that Vioxx was not reasonably fit for the purpose implicitly made known by him to the first respondent, or of merchantable quality, Jessup J accepted that Vioxx involved an approximate doubling in risk of

¹⁵²⁸ See Trindade, F, Cane, P, Lunney, M, *op cit*, 645; these authors add: "*Of course, such persons can be liable only if the product was defective, so that although the liability is strict as far as they are concerned, it is not strict in any absolute sense.*"

¹⁵²⁹ (2010) 184 FCR 1. See also Faunce, T, *The Vioxx Pharmaceutical Scandal: Peterson v Merck Sharp & Dohme (Aust) Pty Ltd* (2010) 184 FCR 1 (2010) 18 Journal of Law and Medicine 38.

¹⁵³⁰ (2010) 184 FCR 1, [873].

¹⁵³¹ Trade Practices Act 1974 (Cth), s 52.

¹⁵³² Trade Practices Act 1974 (Cth), s 75AD.

¹⁵³³ Trade Practices Act 1974 (Cth), s 74B.

¹⁵³⁴ Trade Practices Act 1974 (Cth), s 74D.

¹⁵³⁵ *Peterson v Merck Sharp & Dohme (Aust) Pty Ltd* (2010) 184 FCR 1, [887].

¹⁵³⁶ (1990) 169 CLR 594 (HCA).

¹⁵³⁷ *Peterson v Merck Sharp & Dohme (Aust) Pty Ltd* (2010) 184 FCR 1, [604].

¹⁵³⁸ (2010) 184 FCR 1, [917].

heart attack and was not fit for the purpose of being used for the relief of arthritic pain which was the purpose implicitly for which Mr Peterson bought the goods.¹⁵³⁹

As the case of *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* suggests, the mere fact that the text of the Product Liability Directive has been written into the Commonwealth of Australia's Statute Book does not mean that the Directive's strict liability philosophy will necessarily be embraced by the Australian federal and state courts. As the unfolding Australian jurisprudence on a statute textually derived from the European Directive may diverge from the development of the relevant law within the European Economic Area, Australian case law may have to be treated with circumspection by academic writers and legal practitioners advising Irish manufacturers, suppliers and pharmacists.

6.15.6 Regulatory Compliance Defence

Mildred and Howells state that the mere fact of obtaining a product licence will be "*powerful evidence that the product is as safe as persons generally are entitled to expect.*"¹⁵⁴⁰ If the authority requires that the product information omits reference to minority opinion,¹⁵⁴¹ the producer will have a defence¹⁵⁴² If the authority leaves the decision to the producer, the latter only suffers where: (a) the consumer establishes the defect; (b) the defect is the result of the existing minority view being vindicated; and (c) the injury is caused by the defect "*rather than by a characteristic of the product which does not depend on that vindication.*"¹⁵⁴³ This type of defence in the US would appear to be weaker than in Europe.¹⁵⁴⁴ However, a general defence of regulatory compliance

¹⁵³⁹ See Faunce, T, *op cit*, [45].

¹⁵⁴⁰ See Mildred, M, Howells, G, *Comment on Development Risks: Unanswered Questions* (1998) 61 *Modern Law Review* 570, 572.

¹⁵⁴¹ See Hodges, C, *Development Risks: Unanswered Questions* (1998) 61 *Modern Law Review* 560, 566, referring to *Commission v United Kingdom*, and citing the Opinion of Advocate General Tesaro of 23 January, 1997, [21]: "[T]he state of scientific knowledge cannot be identified with the views expressed by the majority of learned opinion, but with the most advanced level of research which has been carried out at a given time."

¹⁵⁴² The Product Liability Directive provides a regulatory compliance defence where the producer can show that the defect was attributable to compliance with any requirement imposed by or under any enactment or with any Community obligation: Consumer Protection Act 1987, s 4(1)(a).

¹⁵⁴³ See Mildred, M, Howells, G, *loc cit*.

¹⁵⁴⁴ See Ausness, RC, Barfield (II), HL, King, DA, Denton, JR, Jasper, SJ, *Providing a Safe Harbor for Those Who Play by the Rules: The Case for a Strong Regulatory Compliance Defense* [2008] *Utah Law Review* 115, 157, for criticism of the poor availability of the regulatory compliance defence in the US, which endures under the *Restatement (Third)*. See also Goldberg, JCP, Zipursky, BC, *The Easy Case for Products Liability Law: A Response to Professors Polinsky and Shavell* (2010) 123 *Harvard Law Review* 1919, 1920 (n), citing: *Beshada v Johns-Mansville Products Corp* (1982) 447 A2d 539, 546 (NJ Sup Ct) (Permitting recovery on a failure-to-warn theory even on the assumption that the danger to be warned of was not knowable at the time of the product's sale). The New Jersey Supreme Court quickly and substantially limited *Beshada's* reach; see

does not yet exist in Europe: it is a possibility, which the Commission will examine, although it should not be isolated from product safety “as well as the practice and debate in other jurisdictions”.¹⁵⁴⁵

6.15.6.1 Parallel Importation (Re-importation)

In the context of regulatory compliance, it is necessary to consider parallel imports. In the US, the corresponding term is re-importation, a term which would appear deceptively parochial. While many products (*e.g.* clothing, electrical goods, automobiles) may find their way into parallel (gray) trade,¹⁵⁴⁶ the US has a closed pharmaceutical system. The Prescription Drug Marketing Act 1987¹⁵⁴⁷ prohibits the re-importation of FDA-approved drugs, manufactured in the US and exported to other countries, except by the manufacturer. The Federal Food, Drug, and Cosmetic Act¹⁵⁴⁸ prohibits the importation into the US of unapproved, misbranded¹⁵⁴⁹ and adulterated¹⁵⁵⁰ drugs. This includes drugs that are foreign versions of FDA-approved medications, and drugs that are dispensed without a prescription.¹⁵⁵¹

According to Stothers, manufacturers often allege that parallel trade encourages piracy and counterfeiting, particularly where repackaging is involved: this is invoked as a justification for

Feldman v Lederle Labs (1984) 479 A2d 374, 387–88. See further Tobias, C, *FDA Regulatory Compliance Reconsidered* (2008) 93 Cornell Law Review 1003, 1025-1027.

¹⁵⁴⁵ See Fairgrieve, D, Howells, G, *Rethinking Product Liability: A Missing Element in the European Commission’s Third Review of the European Product Liability Directive* (2007) 70 Modern Law Review 962, 973.

¹⁵⁴⁶ Parallel trade is conducted without authorisation by the original owner of the intellectual property rights. See Arfwedson, J, *Re-importation (Parallel Trade) in Pharmaceuticals*, Institute for Policy Innovation: Policy Report 182 (2004) Institute for Policy Innovation, Lewisville (TX), ii. Available from [http://www.ipi.org/IPI/IPublications.nsf/PublicationLookupFullTextPDF/4A9821E11C0B539086256ED60072AB13/\\$File/PR182-ParallelTrade.pdf?OpenElement](http://www.ipi.org/IPI/IPublications.nsf/PublicationLookupFullTextPDF/4A9821E11C0B539086256ED60072AB13/$File/PR182-ParallelTrade.pdf?OpenElement). (Last accessed 28 February, 2011).

¹⁵⁴⁷ Prescription Drug Marketing Act 1987, 21 USC 381(d)(l) & (2).

¹⁵⁴⁸ Federal Food, Drug, and Cosmetic Act 1938. (The Act was enacted in its original version by the US Congress in 1938).

¹⁵⁴⁹ Misbranded drugs are, for example, those that have a false or misleading label, or those that are health-endangering when used as prescribed. See further US Food and Drug Administration, *SEC 502 [21 USC §352] Misbranded Drugs and Devices* (2009) US Food and Drug Administration, Silver Spring (MD). Page Last Updated: 03 March, 2009. Available from <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm108061.htm>. (Last accessed 28 February, 2011).

¹⁵⁵⁰ US Food and Drug Administration, *SEC. 501. [21 USC §351] Adulterated Drugs and Devices* (2009) US Food and Drug Administration, Silver Spring (MD). Page Last Updated: 30 April, 2009. Available from <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm108055.htm>. (Last accessed 28 February, 2011).

¹⁵⁵¹ Hubbard, WK, *The Importation of Drugs into the United States*, Congressional Testimony 2002, Testimony to the Subcommittee on Health, House Committee on Energy and Commerce, July 25, 2002 (2002) US Food and Drug Administration, Silver Spring (MD). Available from <http://www.fda.gov/NewsEvents/Testimony/ucm115170.htm> (Last accessed 28 February, 2012).

tighter control or even prohibition of parallel trade.¹⁵⁵² Cahoy identifies the predominance of generics in the developing world as one of the most important factors in regard to counterfeiting, which is said to “create a lack of private industry incentives to devote significant resources to the effort.”¹⁵⁵³

Howells suggests that genuine traders will not be liable for counterfeit goods as producers, suppliers or ‘own-branders’; “[h]owever, producers should have the means of proving that counterfeit products were in fact just that or else they may be unable to avoid liability if the court cannot be persuaded that they were not in fact the producer.”¹⁵⁵⁴ There are clear implications here for Irish pharmacists, among others. Pharmacists should not become entangled in dubious parallel exportation schemes, and particularly if re-importation from outside the European Economic Area is involved. Section 2(2)(e) of the Liability for Defective Products Act 1991 defines “producer” as *inter alia* “any person who has imported the product into a Member State from a place outside the European Communities in order, in the course of any business of his, to supply it to another”.

6.15.6.2 Class Actions

There is no provision in Irish law to deal with mass disasters by way of a class action, as occurs in American law.¹⁵⁵⁵ A representative case, if successful, forms the basis of scheme of compensation covering all victims and wrongdoers. Quill states (justifiably) that without such a process in Ireland, “the system will continue to operate on the basis of *ad hoc* response to unusual situations, which strain the effectiveness of the tort system in delivering a just solution”.¹⁵⁵⁶

¹⁵⁵² Stothers, C, *Counterfeit Pharmaceuticals enter the Parallel Supply Chain* (2007) 2 *Journal of Intellectual Property Law & Practice* 797, 797.

¹⁵⁵³ Cahoy, DR, *Addressing the North-South Divide In Pharmaceutical Counterfeiting* (2007 – 2008) 3 *Wake Forest Intellectual Property Law Journal* 407, 432.

¹⁵⁵⁴ See Howells, G, *Strict Liability*, Chapter in Howells, G (General Editor), *The Law of Product Liability*, Second Edition (2007) LexisNexis Butterworths, London, 407. See also Minsk, A, Rusk, D, *An ounce of prevention: Dealing with the threat of counterfeit pharmaceuticals* (2009) 11 *Pharmaceuticals Policy and Law* 153, 157.

¹⁵⁵⁵ See Quill, E, *Torts in Ireland*, Third Edition (2009) Gill & Macmillan, Dublin, 619-620.

¹⁵⁵⁶ See Quill, *op cit*, 620. See also Law Reform Commission, *Report on Multi-Party Litigation (LRC 76-2005)* (2005) Law Reform Commission, Dublin, which recommended the introduction of a class action process in Ireland.

6.16 Conclusions

While the British and Irish jurisdictions speak of the concept of ‘contributory negligence’, those legal systems have essentially a ‘comparative negligence’ regime. An awareness of the differing terminology on both sides of the Atlantic is necessary to reconcile the application of the law in the various jurisdictions.

The formation of a contract in the course of business “*according to what people say*”¹⁵⁵⁷ is difficult to imagine between a pharmacist (who already holds a health service contract) and a patient (or her representative) presenting a prescription. It is submitted that whatever discussion that takes place probably will centre on optimising medication use or minimising harm; in Ireland and elsewhere.

EU Directive 2001/83/EC (as amended by Directive 2004/27/EC) provides that a person shall not supply a free sample of a medicinal product to any person unless that person is qualified to prescribe such product, and then only where certain conditions are satisfied. The Irish Pharmaceutical Healthcare Association has instigated even greater restrictions for its member companies than legally required. The provision of free drug samples is more widely tolerated in the United States than in Europe.

While pharmacy sales of non-prescription medicines are governed by Irish contract law, the supply of prescription medicines in the health services does not does not involve a contract between the pharmacist and the patient.

Pharmacists employed in the pharmaceutical industry particularly may be liable in negligence on the principles in *Donoghue v Stevenson*, as adumbrated by the courts. The number of potential claimants whom industrial pharmacists must bear in mind is obviously far greater than for pharmacists in community or hospital practice. Industrial pharmacists are required to perform adequate and up-to-date scientific literature searches to discharge the duties to warn fully of the dangers that products pose or to provide instructions for safe use.

The US cases and commentaries on warnings to the ultimate consumer, accommodating the learned intermediary doctrine (by no means accepted in every US jurisdiction), serve as a contrast

¹⁵⁵⁷ See Lord Coulsfield, MacQueen, HL (General Editors), *Gloag and Henderson, The Law of Scotland*, Twelfth Edition (2007) Thomson, W Green & Sons, Edinburgh, 126, citing *Muirhead and Turnbull v Dickson* (1905) 7 F 686, 694, per Lord President Dunedin: “*Commercial contracts cannot be arranged by what people think in their inmost minds. Commercial contracts are made according to what people say.*”

to the finding of Jessup J that a “*general and universal*” duty to warn existed in relation to the medicinal product, Vioxx. It is submitted that the approach of Jessup J in *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* would be a persuasive authority of considerable value to the Irish courts in a similar case.

In contrast to the US, European strict liability is, “*at least formally, the test for all types of product defects.*”¹⁵⁵⁸

Lay persons may have little difficulty with demonstrating unaided a reasonable alternative design for machinery that caused injury. One concludes that establishing a reasonable alternative design for a medicinal product may be outwith their (or the court’s) knowledge and experience (and expert evidence will be required).

Given the high production standards required of the pharmaceutical industry, wide-scale pre-packaging of medication and the demise of pharmacy magisterial compounding, it is submitted that there is now very little scope for intermediate inspection to detect anything untoward in modern medicinal products (or the raw materials used in compounding).

Irish pharmacists are unlikely to be engaged in the manufacture of ‘unavoidably unsafe products’ in hospital or community pharmacy establishments. Appropriate warnings will of course be required and the format may have already been expressed in Pharmaceutical Society of Ireland guidance. Where the ‘unavoidably unsafe’ product to be supplied is an imported unauthorised medicinal product, with minimal information for patient safety,¹⁵⁵⁹ the pharmacist must ensure that a comprehensive warning is given to the patient or carer.

An Irish pharmacist should be cautious of off-label or experimental indications for authorised medicinal products. This is because a court might well hold that the patient-consumer’s expectation of product safety from the fact that a product is authorised may still be justified if the deviation from the therapeutic norm from the product concerned has not been properly explained (and consent obtained) by the patient’s health professionals. The pharmaceutical company that has submitted a dossier to a regulatory agency (such as the Irish Medicines Board) may avoid liability under the Directive by disavowing any responsibility for the off-label use.

¹⁵⁵⁸ Howells, G, Mildred, M, *Is European Products Liability More Protective than the Restatement (Third) of Torts: Products Liability?* (1998) 65 Tennessee Law Review 985, 1025.

¹⁵⁵⁹ The packaging and any associated information may have been prepared for a territory in which the learned intermediary doctrine applies.

Since the *A and Others v National Blood Authority* case was reported in 2001, access to information through the Internet has grown exponentially. However, the basic question of access remains, if a restrictive approach to documents or research is maintained.

It is submitted that familiarity with (and preference for) a medicinal product, that a medical practitioner has acquired outside the EEA, is not of itself a sufficient reason for causing the importation of an unlicensed medicine into the EEA. Where a medical practitioner (typically a hospital consultant now practising in Ireland) has trained in the US, for example, the fact of and the legal basis for official antipathy among federal agencies towards importation of foreign unlicensed medicines should be well known to such a practitioner. That is to say nothing of potential liability under the law of obligations. Such medical practitioners should not overlook similar factors, in Ireland or the wider EEA.

The common law position on product liability requires the plaintiff to show negligence in the manufacture, design or marketing of the product.¹⁵⁶⁰ Strict liability is based on the concept of ‘defectiveness’ under the Product Liability Directive. It would appear that few cases brought under the transposed Directive would not also succeed at common law.¹⁵⁶¹

The implications in the case of the *Centre hospitalier universitaire Besançon v Dutrueux* case are that in Ireland (or elsewhere in the EU) no-fault liability may be introduced (where it does not already exist) for a category of products, such liability going beyond merely complying with the conditions laid down in the Product Liability Directive.

Pharmacists should not become entangled in dubious parallel exportation schemes, and particularly if re-importation from outside the European Economic Area is involved. Section 2(2)(e) of the Liability for Defective Products Act 1991 defines “*producer*” as *inter alia* “*any person who has imported the product into a Member State from a place outside the European Communities in order, in the course of any business of his, to supply it to another*”.

In overview, pharmacists may be fixed with ‘producer’ liability: through poor recordkeeping so that they cannot point to a supplier further up the line¹⁵⁶²; own branding (e.g. vitamins/minerals); their own magisterial compounding (extemporaneous preparations) to medical prescription;

¹⁵⁶⁰ See Steele, J, *Tort Law: Text, Cases and Materials*, Second Edition (2010) Oxford University Press, Oxford, 850.

¹⁵⁶¹ Steele, J, *op cit*, 851.

¹⁵⁶² In accordance with the provisions of section 2(3) of the Liability for Defective Products Act 1991.

hospital compounding (including intravenous additives, perfusion solutions and total parenteral nutrition).

Chapter 7 Emerging Issues, Conclusions and Proposals for Reform

Introduction

7.1 Emerging Issues

7.1.1 Healthcare Legal Forum for Ireland

Ireland does not have a single body with an oversight function for the various health professions and their respective regulators. The medical, dental, nursing, pharmaceutical and other regulated health professional bodies have no formal structure through which to consult on (actually impending or desirable) legal reforms. One result from this deficit can be seen in the sometimes fragmented response to consultation on EU proposals. It is left to individual regulators in the health sector to assess from their own sectoral perspective whether the official proposal(s) could be positive or negative or neutral.

The extensive output of the Irish Law Reform Commission (LRC) in particular continues to yield consultation papers and reports, some with implications for pharmacists. The most recent document is the *Report on Legal Aspects of Professional Home Care*.¹⁵⁶³ Aspects of Medication Management considered included polypharmacy and inappropriate prescription of anti-psychotic medicines.¹⁵⁶⁴ The Commission has expressed the view that “*strong guidelines*” must be put in place, which “*promote a restraint free environment in the home care setting and also regarding the use of medication in the delivery of these services and that the issue of the appropriate use of prescribed medication is to be dealt with in the contract for care.*”¹⁵⁶⁵ It is submitted that a pharmacist is a health professional by training and experience well suited to advising on appropriate use of medication, which could be achieved at a minimum by attendances on a sessional basis at a professional care home. The omission of a reference to the Pharmacy Regulator in the Commission Recommendation “... *that a review of the administration of medicines in the home be carried out, involving representatives of the Department of Health, HIQA, the Medical Council, An Bord Altranais and carer groups*” is therefore regrettable; it represented a missed opportunity to put forward the pharmacist’s input to a patient care solution.

¹⁵⁶³ Law Reform Commission, *Report on Legal Aspects of Professional Home Care (LRC 105-2011)* (2011) Law Reform Commission, Dublin.

¹⁵⁶⁴ Law Reform Commission, *op cit*, 59-62.

¹⁵⁶⁵ Law Reform Commission, *op cit*, 61.

The establishment of a Healthcare Legal Forum would facilitate the various health sector regulators to exchange views and information on legislative change. Such an environment would enhance the material available on which to base decisions for the Law Reform Commission, the Department of Health and other interested bodies.

7.1.2 Patient Group Directions

Fundamentally distinguishable from medical and dental prescriptions, Patient Group Directions (PGDs) originated in the United Kingdom in 2000. PGDs are “*written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment*”.¹⁵⁶⁶ Unlike nurse and pharmacist prescribing, health care professionals entitled to work with a PGD require no additional formal qualification.¹⁵⁶⁷ Organisations also have a responsibility to ensure that only fully competent, trained health care professionals use PGDs.

7.1.2.1 United Kingdom

National Health Service

The keystone of statutory control over medicinal products in the UK is the Medicines Act 1968. Modifications relevant to the NHS in and under the 1968 Act are contained in three statutory

¹⁵⁶⁶ See Medicines and Healthcare Regulatory Authority, *Patient Group Directions in the NHS* (2010) Available from <http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm> (Last accessed 09 February, 2011). See also NHS National Prescribing Centre, *Patient Group Directions December 2009* (2009) National Prescribing Centre, Liverpool. Available from http://www.npc.nhs.uk/non_medical/resources/patient_group_directions.pdf. (Last accessed 25 March, 2012).

¹⁵⁶⁷ East Lancashire Medicines Management Board, *Patient Group Directions* (2012) NHS Blackburn with Darwen, Blackburn. Available from <http://www.elmmb.nhs.uk/patient-group-direction/>. (Last accessed 25 March, 2012).

instruments from 2000.¹⁵⁶⁸ These pieces of legislation apply to the NHS including private and voluntary sector activity funded by the NHS.¹⁵⁶⁹

The patient group direction must be signed by a senior doctor (or, if appropriate, a dentist) and a senior pharmacist, both of whom should have been involved in developing the direction. Additionally the patient group direction must be authorised by the relevant appropriate body as set out in the legislation. The Clinical Governance Lead¹⁵⁷⁰ in a Primary Care Trust (PCT) or Primary Care Team is said to be best placed to fulfil this role.

The legislation specifies that each PGD must contain the following information¹⁵⁷¹:

- The name of the business to which the direction applies;
- The date the direction comes into force and the date it expires;
- A description of the medicine(s) to which the direction applies;
- Class of health professional who may supply or administer the medicine;
- Signature of a doctor or dentist, as appropriate, and a pharmacist;
- Signature by an appropriate organisation;
- The clinical condition or situation to which the direction applies;
- A description of those patients excluded from treatment under the direction;
- A description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral;

¹⁵⁶⁸ The statutory instruments are the Prescription Only Medicines (Human Use) Amendment Order 2000, the Medicines (Pharmacy and General Sale - Exemption) Amendment Order 2000 and the Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000. See also Medicines and Healthcare Regulatory Agency (MHRA), *Patient Group Directions in the NHS* (2010) Available from <http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm> (Last accessed 09 February, 2011). The qualified health professionals who may supply or administer medicines under a PGD are: nurses; midwives; health visitors; optometrists; pharmacists; chiropodists; radiographers; orthoptists; physiotherapists; ambulance paramedics; dietitians; occupational therapists; speech and language therapists; prosthetist; orthotists; dental hygienists; dental therapists. Members of those classes of health professionals may only do so as named individuals.

¹⁵⁶⁹ The regime embraces treatment provided by NHS trusts, primary care trusts (PCTs), health authorities — including Strategic Health Authorities (SHAs), GP or dentist practices, walk-in centres and NHS funded family planning clinics.

¹⁵⁷⁰ See Van Zwanenberg, TD, Edwards, C, *Clinical Governance in Primary Care*, Chapter in Van Zwanenberg, TD, Harrison, J (Editors), *Clinical Governance in Primary Care*, Second Edition (2004) Radcliffe Medical Press, Abingdon, 28, See also Baker, R, Lakhani, M, *Quality Improvement Processes*, Chapter in Van Zwanenberg, TD, Harrison, J (Editors), *Clinical Governance in Primary Care*, Second Edition (2004) Radcliffe Medical Press, Abingdon, *op cit*, 90-95.

¹⁵⁷¹ See Medicines and Healthcare Regulatory Authority, *Patient Group Directions in the NHS* (2010) Available from <http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm> (Last accessed 09 February, 2011).

Details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered;
Relevant warnings, including potential adverse reactions;
Details of any necessary follow-up action and the circumstances;
A statement of the records to be kept for audit purposes.

PGDs in the Private, Prison and Police Sectors

A separate suite of statutory instruments was made in 2003 to regulate these sectors.¹⁵⁷² The specified information content in a PGD is similar to that pertaining to the NHS. The legislation specifies the person by whom or on whose behalf the Direction must be signed. Taking the Police Service of Northern Ireland as an example, the specified signatories are the Chief Constable and a doctor who is neither employed nor engaged in providing services to any police force.

7.1.2.2 Republic of Ireland

In late 2010, a company which operates community pharmacies in the Republic of Ireland announced the introduction, under a PGD, of a novel service for the administration of vaccines within neighbourhood pharmacies. In January 2011, the same company publicised a pharmacy-based service for contraceptive advice and administration of post-coital contraception. Challenged by the Irish Medicines Board, the company was obliged to discontinue its PGD regime in the following month.¹⁵⁷³ The putative Irish statutory underpinning for a PGD was said by its proponents to have been found in the explicit statement that it is not a contravention of the provisions of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 “*[for] any person, other than a registered medical practitioner or registered dentist, to administer to a patient, in accordance with the directions of a registered medical practitioner or registered dentist,*

¹⁵⁷² These are: the Prescription Only Medicines (Human Use) Amendment Order 2003; the Medicines (Pharmacy and General Sale – Exemption) Amendment Order 2003; the Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment Regulations 2003.

¹⁵⁷³ See Donnellan, E, *Morning after all the legal wrangling*, The Irish Times, 22 February, 2011. Available from <http://www.irishtimes.com/newspaper/health/2011/0222/1224290506415.html>. (Last accessed 21 March, 2012). The Irish Medicines Board confirmed to the pharmacy operating company that “*[t]here is no provision for PGDs in Irish legislation*”. See also Donnellan, E, *Morning after pill on sale over the counter*, The Irish Times 16 February, 2011, Available from <http://www.irishtimes.com/newspaper/ireland/2011/0216/1224289929512.html> (Last accessed 16 February, 2011); “*It emerged yesterday that the manufacturers of ... one of two brands of morning after pill licensed by the [Irish Medicines Board] for use in the State, lodged [a fresh] application to have its product made available over the counter last month after seeing the demand for emergency contraception when it was available without prescription*”.

any medicinal product subject to control by ... these Regulations."¹⁵⁷⁴ There is no mention of PGDs in the aforementioned provision or the wider Regulations, which would lean against a sustainable statutory interpretation in favour of their authorisation. Also, a separate suite of Regulations was introduced in the UK to provide for PGDs.

Clearly there is value, for example, in relieving a hospital consultant from any requirement to write individual prescriptions for persons to whom medication (otherwise subject to prescription control) is to be administered by paramedical staff prior to a medical/surgical examination. To 'administer' obviously means not permitting the patient to carry away the medication for later self-administration (a 'supply'): a serious limitation, since providing a 'course' of antibiotics (or other prescription-controlled medication) is not permissible under current Irish law in such circumstances.

7.1.2.3 Unauthorised (Exempt) Medicinal Products

Given the present state of development of PGDs, it is improbable that a community pharmacy in any jurisdiction would wish to base a service routinely on administration or supply of such medication. There may be an impetus to use unauthorised medicinal products¹⁵⁷⁵ when the authorised version is temporarily unavailable.

¹⁵⁷⁴ The Medicinal Products (Prescription and Control of Supply) Regulations 2003, Regulation 4A(c), as inserted by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005, Regulation 3(b).

¹⁵⁷⁵ The Medicines and Healthcare Regulatory Agency (MHRA) or the Irish Medicines Board (IMB), respectively, would have to be contacted first by the pharmaceutical company involved.

7.2 Conclusions

This doctoral thesis has sought to present a multidisciplinary and legal-comparative examination of the position of pharmacists in Ireland. It has considered the merits of a Healthcare Legal Forum for Ireland as a co-ordinated approach by the health professions to domestic and European Union law reform and advocated legislation for Patient Group Directions in Ireland to enhance patient access to medicines.

It is difficult to conceive of a scenario in which pharmacist could escape liability for omissions, since a health professional is both ethically and legally bound to act in the patient's best interests.

It was concluded that in the context of the Retail Pharmacy Businesses Regulations 2008, statutory duties framed around 'health' could give rise to a cause of action to a particular member of the pharmacy-utilising class within the general public. In the pharmacy setting, particular damage to one member of a class is readily imagined.

One concludes that a significant obstacle to a judicial holding that a pharmacist is liable to a patient in negligent misstatement is the difficulty in proving the existence of a contractual or fiduciary relationship between the two.

Unlike in financial transactions, the consequences of negligent Drug Information provision may well proceed to the point that the patient ultimately affected cannot be restored to her previous position.

It was concluded that it is not enough for a pharmacist to prevent a sportsperson from going 'offside' with respect to the WADA regime. There is a duty also to warn, in appropriate cases, about the questionable or proven deleterious health effects of supplements. The author concludes that the WADA 'modified' strict liability regime is basically a mandate to apply fair procedures. Regarding athletes, one concludes that rural pharmacists would be particularly vulnerable to suit in negligence or negligent misstatement because a court could be persuaded that they should have known the 'sport stars' in their own community (or county).

One concludes that liability would be imposed a general surgeon practising in a city (as opposed to a rural general hospital), with an 'interest' in hand surgery, for failure to refer to an appropriate specialist.

As a decision that preceded *Hunter v Hanley*, it is concluded that the case of *Daniels v Heskin*, covered the same territory, although with greater attention paid to the role of the jury.

The duty to be reasonably aware of developments in the core journals of one's field, as understood in the 1950s) has widened due to the wider availability of (institutional and individual) paper-based and Internet subscriptions, also open access databases, which professional persons may consult.

Healthcare provision does not demand regimentation of the medical profession by reference to 'post' or 'office'; in a medical negligence case, the courts will not entertain disputes over the organisational standing of a post or the status (permanent, temporary or otherwise) of a post holder.

There is scope for some confusion, in comparative analysis of the reported malpractice cases, between the concepts of 'irrationality' and 'unreasonableness'. Irrationality, it is submitted, is not synonymous with unreasonableness. To be irrational, something will not have been elaborated completely through a proper deliberative process; such a defect may adversely affect the interests of the flawed thinker, much as it may impinge negatively on any potential litigious opponent or disputant.

Where a psychiatric patient is, in the pharmacist's opinion, incapable of safely and effectively managing the medication regimen, and the GP has not requested phased dispensing, it is concluded that such a belief should be brought to the GP's attention. The pharmacist may have a greater insight than the GP into the patient's actual compliance with the prescribed medication: the pharmacist may be the only person routinely monitoring this aspect of pharmacotherapy.

Where a pharmacist's professional activities can be viewed through the lens of ordinary negligence, expert evidence is not required. Therefore, there is an incentive to settle proceedings. Cases involving pharmacist that reach the law reports usually involve shared (or at least contested) liability with medical practitioners: almost certainly expert medical evidence will be required.

It is usually obvious what the patient requires by way of professional services from a doctor or a pharmacist: in the United Kingdom and Republic of Ireland, negligence is of greater practical relevance than contract. However, it is important for any professional to know when it is

appropriate to refer the patient/client for specialist advice (and treatment, where appropriate). In medicine, this will usually be within the same profession, whilst in pharmacy it will not be so.

Health authorities may not be doing enough, particularly in the out-of-hours context, to ensure that hospital consultants shoulder a realistic burden for supervision of medical practitioners in training. It mostly appears from medical negligence cases where a health authority is a defendant that argument focuses on the authority's management procedures rather than critically analysing any possible tortious liability arising from the hospital consultant's mentoring role (bearing in mind that lay managerial support is irrelevant to health professional formation).

While there does not appear to have been a case involving a pharmacist's liability, a pharmacy's failure to detect a drug-therapy-related problem could become a cause of a loss-of-chance injury.¹⁵⁷⁶

While much of the literature on *res ipsa loquitur* is concerned with medical practitioners, there is some scope for relevance to pharmacists. The United States jurisdictions use the applicability of *res ipsa loquitur* to determine whether expert evidence is required. Most pharmaceutical products are not compounded in the pharmacy nowadays; a product liability theory may obviate discussion around 'the exclusive management of the defendant'.

While the British and Irish jurisdictions speak of the concept of 'contributory negligence', those legal systems have essentially a 'comparative negligence' regime. An awareness of the differing terminology on both sides of the Atlantic is necessary to reconcile the application of the law in the various jurisdictions.

The formation of a contract in the course of business "*according to what people say*"¹⁵⁷⁷ is difficult to imagine between a pharmacist (who already holds a health service contract) and a patient (or her representative) presenting a prescription. It is submitted that whatever discussion that takes place probably will centre on optimising medication use or minimising harm; in Ireland and elsewhere.

¹⁵⁷⁶ Fassett, WE, *Emerging Trend in Torts: "Loss of Chance" as a New Cause of Action* (2012) 39(2) *Rx Ipsa Loquitur* 3. On *Philp v Ryan*, see Hayden, E, 'Loss of chance' actions are already among us (2012) *Irish Medical Times*, 02 October, 2012. Available from <http://www.imt.ie/opinion/2012/10/loss-of-chance-actions-are-already-among-us.html>. (Last accessed 10 October, 2012).

¹⁵⁷⁷ See Lord Coulsfield, MacQueen, HL (General Editors), *Gloag and Henderson, The Law of Scotland*, Twelfth Edition (2007) Thomson, W Green & Sons, Edinburgh, 126, citing *Muirhead and Turnbull v Dickson* (1905) 7 F 686, 694, per Lord President Dunedin: "*Commercial contracts cannot be arranged by what people think in their inmost minds. Commercial contracts are made according to what people say.*"

EU Directive 2001/83/EC (as amended by Directive 2004/27/EC) provides that a person shall not supply a free sample of a medicinal product to any person unless that person is qualified to prescribe such product, and then only where certain conditions are satisfied. The Irish Pharmaceutical Healthcare Association has instigated even greater restrictions for its member companies than legally required. The provision of free drug samples is more widely tolerated in the United States than in Europe.

While pharmacy sales of non-prescription medicines are governed by Irish contract law, the supply of prescription medicines in the health services does not involve a contract between the pharmacist and the patient.

Pharmacists employed in the pharmaceutical industry particularly may be liable in negligence on the principles in *Donoghue v Stevenson*, as adumbrated by the courts. The number of potential claimants whom industrial pharmacists must bear in mind is obviously far greater than for pharmacists in community or hospital practice. Industrial pharmacists are required to perform adequate and up-to-date scientific literature searches to discharge the duties to warn fully of the dangers that products pose or to provide instructions for safe use.

The US cases and commentaries on warnings to the ultimate consumer, accommodating the learned intermediary doctrine (by no means accepted in every US jurisdiction), serve as a contrast to the finding of Jessup J that a “*general and universal*” duty to warn existed in relation to the medicinal product, Vioxx. It is submitted that the approach of Jessup J in *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* would be a persuasive authority of considerable value to the Irish courts in a similar case.

In contrast to the US, European strict liability is, “*at least formally, the test for all types of product defects.*”¹⁵⁷⁸

Lay persons may have little difficulty with demonstrating unaided a reasonable alternative design for machinery that caused injury. One concludes that establishing a reasonable alternative design for a medicinal product may be outwith their (or the court’s) knowledge and experience (and expert evidence will be required).

¹⁵⁷⁸ Howells, G, Mildred, M, *Is European Products Liability More Protective than the Restatement (Third) of Torts: Products Liability?* (1998) 65 Tennessee Law Review 985, 1025.

Given the high production standards required of the pharmaceutical industry, wide-scale pre-packaging of medication and the demise of pharmacy magisterial compounding, it is submitted that there is now very little scope for intermediate inspection to detect anything untoward in modern medicinal products (or the raw materials used in compounding).

Irish pharmacists are unlikely to be engaged in the manufacture of ‘unavoidably unsafe products’ in hospital or community pharmacy establishments. Appropriate warnings will of course be required and the format may have already been expressed in Pharmaceutical Society of Ireland guidance. Where the ‘unavoidably unsafe’ product to be supplied is an imported unauthorised medicinal product, with minimal information for patient safety,¹⁵⁷⁹ the pharmacist must ensure that a comprehensive warning is given to the patient or carer.

An Irish pharmacist should be cautious of off-label or experimental indications for authorised medicinal products. This is because a court might well hold that the patient-consumer’s expectation of product safety from the fact that a product is authorised may still be justified if the deviation from the therapeutic norm from the product concerned has not been properly explained (and consent obtained) by the patient’s health professionals. The pharmaceutical company that has submitted a dossier to a regulatory agency (such as the Irish Medicines Board) may avoid liability under the Directive by disavowing any responsibility for the off-label use.

Since the *A and Others v National Blood Authority* case was reported in 2001, access to information through the Internet has grown exponentially. However, the basic question of access remains, if a restrictive approach to documents or research is maintained.

It is submitted that familiarity with (and preference for) a medicinal product, that a medical practitioner has acquired outside the EEA, is not of itself a sufficient reason for causing the importation of an unlicensed medicine into the EEA. Where a medical practitioner (typically a hospital consultant now practising in Ireland) has trained in the US, for example, the fact of and the legal basis for official antipathy among federal agencies towards importation of foreign unlicensed medicines should be well known to such a practitioner. That is to say nothing of potential liability under the law of obligations. Such medical practitioners should not overlook similar factors, in Ireland or the wider EEA.

¹⁵⁷⁹ The packaging and any associated information may have been prepared for a territory in which the learned intermediary doctrine applies.

The common law position on product liability requires the plaintiff to show negligence in the manufacture, design or marketing of the product.¹⁵⁸⁰ Strict liability is based on the concept of ‘defectiveness’ under the Product Liability Directive. It would appear that few cases brought under the transposed Directive would not also succeed at common law.¹⁵⁸¹

The implications in the case of the *Centre hospitalier universitaire Besançon v Dutrueux* case are that in Ireland (or elsewhere in the EU) no-fault liability may be introduced (where it does not already exist) for a category of products, such liability going beyond merely complying with the conditions laid down in the Product Liability Directive.

Pharmacists should not become entangled in dubious parallel exportation schemes, and particularly if re-importation from outside the European Economic Area is involved. Section 2(2)(e) of the Liability for Defective Products Act 1991 defines “*producer*” as *inter alia* “any person who has imported the product into a Member State from a place outside the European Communities in order, in the course of any business of his, to supply it to another”.

In overview, pharmacists may be fixed with ‘producer’ liability: through poor recordkeeping so that they cannot point to a supplier further up the line¹⁵⁸²; own branding (e.g. vitamins/minerals); their own magisterial compounding (extemporaneous preparations) to medical prescription; hospital compounding (including intravenous additives, perfusion solutions and total parenteral nutrition).

Reviewing the case law, in the context of health service provision, it is concluded that the UK Parliament did not intend that differing contractual rights (based on the presence or absence of contractual consideration or of *jus quaesitum tertio*) should obtain in lands of the Realm served by differing legal systems.

Within a more open ‘pharmaceutical economy’ than the US market, such as that of the European Economic Area, one concludes that there are difficulties in assessing market share liability taking into account parallel importation (although perhaps not parallel distribution).

In the context of informed consent, the author concludes that the correct standard on which to assess the disclosure or otherwise of information essential to a lay patient’s deliberations is

¹⁵⁸⁰ See Steele, J, *Tort Law: Text, Cases and Materials*, Second Edition (2010) Oxford University Press, Oxford, 850.

¹⁵⁸¹ Steele, J, *op cit*, 851.

¹⁵⁸² In accordance with the provisions of section 2(3) of the Liability for Defective Products Act 1991.

‘ordinary negligence’ (based on matters coming within the knowledge and experience of ordinary persons).

The author concludes that the ‘patient centred’ test of informed consent favoured by the Irish Supreme Court in *Fitzpatrick v White*,¹⁵⁸³ is ultimately more satisfactory from the point of view of both doctor and patient alike, than any ‘doctor centred’ approach.

Regarding the question of why loss of a chance is recoverable in professional negligence cases resulting in economic loss “*but not where the professional negligence is that of a doctor,*”¹⁵⁸⁴ this author concludes that the multifactorial nature of human physiology and human pathology give rise to more imponderables than an economic relationship between parties (possibly an ongoing nexus and of which there may be documentary evidence) and where the occurrence of losses in any event may be discerned by the court.

In lost chance litigation, this author concludes that decisions on medical treatment are so personalised that regard to what a third party might choose to do, presented with the same options (so as to defeat the claim), may be inappropriate.

While there does not appear to have been a case involving a pharmacist’s liability, a pharmacy’s failure to detect a drug-therapy-related problem could become a cause of a loss-of-chance injury.¹⁵⁸⁵

It is concluded that in product liability the test for remoteness of damage should be reasonable foreseeability because “professional liability” and product liability theories embrace contract, negligence and statutory tort: this would accord with the reasoning in the *Wagon Mound (No 2)*, which concerned the extensive overlap between nuisance and negligence.

Proving causation, particularly through negligence, in proceedings brought against a pharmacist is considerably easier than might apply to most other professionals, suppliers or retailers. Ancillary

¹⁵⁸³ *Fitzpatrick v White* [2008] 3 IR 551 (Sup Ct).

¹⁵⁸⁴ Murphy, J, Witting, C (Editors), *Street on Torts*, Thirteenth Edition (2012) Oxford University Press, Oxford, 155 (n). These writers suggest (in light of the general hierarchy of protected interests in tort law) that it is objectionable to permit claims in respect of the loss of a chance of financial gain but not the loss of a chance of physical cure, citing *Gouldsmith v Mid-Staffordshire General Hospitals NHS Trust* [2007] EWCA Civ 397.

¹⁵⁸⁵ Fassett, WE, *Emerging Trend in Torts: “Loss of Chance” as a New Cause of Action* (2012) 39(2) *Rx Ipsa Loquitur* 3. On *Philp v Ryan*, see Hayden, E, ‘Loss of chance’ actions are already among us (2012) *Irish Medical Times*, 02 October, 2012. Available from <http://www.imt.ie/opinion/2012/10/loss-of-chance-actions-are-already-among-us.html>. (Last accessed 10 October, 2012).

trading activities apart, the pharmacist most often supplies to a patient or consumer some medicinal item that is ingested, or applied to or otherwise worn on the body.

7.3 Proposals for Reform

7.3.1 Healthcare Legal Forum for Ireland

The establishment of a Healthcare Legal Forum would facilitate the various health sector regulators to exchange views and information on legislative change. Such an environment would enhance the material available on which to base decisions for the Law Reform Commission, the Department of Health and other interested bodies.

7.3.2 Patient Group Directions

Ireland should legislate for the introduction of Patient Group Directions on a similar basis to the United Kingdom, for the reasons stated above.

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