

DRUG/VACCINE RISKS: PATIENT DECISION-MAKING AND HARM REDUCTION IN THE PHARMACEUTICAL COMPANY DUTY TO WARN ACTION

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In this article, the duty of pharmaceutical companies to warn is explored in relation to the underlying values of patient control of decision-making and the avoidance of harm. The "learned intermediary" rule, applicable to the duty to warn with respect to prescription drugs and vaccines, is examined and the rationale for its existence criticized, particularly with respect to reproductive products. The adequacy of the warning is considered in the context of the system of testing, research, reporting and promotion within which adverse effects arise. Causation in drug/vaccine cases poses many of the classic dilemmas, along with novel problems and combinations. Patient safety and participation in decision-making require changes to some legal standards and a continuing awareness of the power relationships among the pharmaceutical company, doctor and patient.

L'auteur de cet article étudie la responsabilité qui incombe à l'industrie pharmaceutique de mettre en garde le malade dans le cadre des valeurs telles que son droit de prendre les décisions qui le concernent et celui d'éviter les traitements dangereux. L'auteur considère aussi la règle de "l'intermédiaire compétent", qui s'applique à la responsabilité de mettre en garde le malade contre les dangers des médicaments et vaccins prescrits, et critique la raison d'être de cette règle, particulièrement pour les produits de reproduction. La mise en garde adéquate est vue dans le cadre du système des analyses de la recherche, du reportage des effets néfastes et de la publicité qui leur est donnée. Dans les procès concernant les effets des médicaments ou vaccins, la cause pose un grand nombre des dilemmes classiques, de même que l'ordre des événements et les problèmes qui se manifestent pour la première fois. La sécurité du malade et sa participation à la prise de décision demandent que certaines normes de droit soient changées et qu'on ne perde jamais de vue la relation de supérieur à inférieur qui existe entre la compagnie pharmaceutique, le docteur et le malade.

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I am very grateful to Sandy Tallen for her skilful word-processing of the manuscript, Catherine Valestuk and Kate Karn for their careful research assistance, the Faculty of Law and the Law Foundation of Ontario for their financial assistance, and the students and mooters who have worked on aspects of this issue, in particular Joanne Glover, Linda Fung and David Fleming. I would like to thank Richard MacLachlan, Gordon Bale, Beverley Baines and Donald Galloway for their helpful comments on earlier drafts.

Introduction

Patient control of treatment decision-making and the avoidance of harm are twin purposes underlying both products liability and informed consent law. In the products liability area, where a patient is suing a pharmaceutical company for a breach of the duty to warn of risks inherent in the pharmaceutical product, the manufacturer's duty to warn the patient operates indirectly through the "learned intermediary",¹ the physician. As a result, the information transmitted to the patient is subject not only to the dynamics of the manufacturer-consumer relationship but also to the mediation of the doctor.

Dependence and inequality characterize these relationships, colouring the legal principles and affecting their impact. The patient is dependent both on the company and on the doctor to provide sufficient information for an informed decision to be made, as well as for treatment to heal the body, prevent a disease or palliate the pain. Dependency characterizes the relationship between vulnerable patient and the experts who exercise control over the patient's bodily fate. The physician's relationship with the pharmaceutical company also exhibits a dependency of the doctor, because of his or her limited pharmaceutical knowledge, on the company's information; but the relationship is also one in which the physician is courted through the company's marketing efforts and one in which the doctor is immune from physical harm and vulnerability.

Another element of the context within which the legal principles operate is the widespread use of pharmaceutical products apparently unaccompanied by significant public knowledge of the inherent risks. As a society, we have been the beneficiaries of the scientific innovations in the field of drugs and vaccines which have resulted in prevention of disease, relief of suffering, and cure. Tragic harm has also been caused by pharmaceutical products, particularly in the area of women's reproduction where diethylstilbestrol, thalidomide and the Dalkon Shield have caused injury to countless women and children. These pharmaceutical disasters should alert us to the risks inherent in pharmaceutical products as well as the potential cost in having innovation diffused through a profit-driven marketing system.

The causation dilemmas posed by drug and vaccine cases are particularly difficult. Creative solutions have been found for factual and legal causation problems, but some principles need to be more closely aligned with the underlying purposes.

The question explored in this article is the impact of the legal principles in protecting patient decision-making and reducing harm. The article begins with an examination of products liability principles. Following this, the constituent elements of the action against the pharmaceutical company

¹ *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 25 D.L.R. (4th) 658, 54 O.R. (2d) 92 (Ont. C.A.).

are identified and compared with the elements of the informed consent action against the doctor. The article examines in turn the duty to warn, the adequacy of the warning, and causation. The concluding section returns to the question of the operation of the tort principles in the context of drug/vaccine risks.

I. *Products Liability and the Duty to Warn*

Products liability is governed in tort by negligence law, following the familiar products liability case of *Donoghue v. Stevenson*.² The manufacturer owes a duty of reasonable care to the consumer in the following circumstances:³

... 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.

The duty is owed to third persons who are reasonably foreseeable as being affected by the negligent conduct, as was the friend who drank, but had not bought, the ginger beer, and allegedly found the decomposed snail.

The kind of products affected are, as Allen Linden has stated, "[v]irtually every type of product",⁴ from underwear to weedspray. The duty binds manufacturers, bottlers, assemblers, repairers, installers, inspectors, and even beyond.⁵ As Linden points out: "Someone who merely inspects or recommends the use of a product without giving adequate warning may be caught."⁶ In general the standard of care is the use of reasonable care in the circumstances; where pharmaceutical products are manufactured, the standard is likely to be a very high one, such as exists for food.

With respect to inherently risky or dangerous things, the manufacturer has a duty to warn the consumer of the risks of which the manufacturer had actual knowledge. In *Lambert v. Lastoplex Chemicals Co.*,⁷ the Supreme Court of Canada imposed liability on the manufacturer of a fast-drying lacquer sealer who failed to warn of the danger of using this highly explosive product in the vicinity of a furnace pilot light. The manufacturer had placed three labels on the container, warning the user to keep the product away from open flames. A fire and explosion occurred after the plaintiff, a professional engineer, left on the pilot light in the furnace although he had turned down the thermostats so that the furnace would remain off

² [1932] A.C. 562 (H.L.); in general, see Carol Rogerson and Michael Trebilcock, *Products Liability and the Allergic Consumer: A Study in the Problems of Framing an Efficient Liability Regime* (1986), 36 U.T.L.J. 52.

³ *Ibid.*, at p. 599.

⁴ Allen M. Linden, *Canadian Tort Law* (4th ed., 1988), p. 538.

⁵ *Ibid.*, pp. 540-543.

⁶ *Ibid.*, p. 542.

⁷ [1972] S.C.R. 569, (1971), 25 D.L.R. (3d) 121.

while he used the sealer on his basement floor. Laskin J., for the court, stated that the manufacturer:⁸

... 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. . . . The required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product.

The obligation is a continuing one, applying to defects discovered after the marketing has begun. In *Rivtow Marine v. Washington Iron Works*,⁹ both the majority and minority judges affirmed the existence of the duty to warn of a design flaw discovered after the product had been rented and put to use.

The duty to warn¹⁰ is generally owed to the ultimate consumer, but where prescription drugs are involved, a "learned intermediary" is interposed between the pharmaceutical company and the consumer. The manufacturer is required to warn the "learned intermediary" of the product's inherent risks. The physician is obliged to assess the drug's suitability in relation to the patient's needs and susceptibilities and then to disclose risks to the patient. Any duty owed by the pharmaceutical company to the consumer is an indirect duty, fulfilled by adequately informing the physician. Any duty owed by the pharmaceutical industry itself has been characterized as a non-delegable one.

The learned intermediary rule was set out in the 1980 Ontario High Court case, *Davidson v. Connaught Laboratories*,¹¹ and affirmed and applied by the Ontario Court of Appeal in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*¹²

In *Davidson v. Connaught Laboratories*, a known risk, in the 1/5,000 to 1/8,500 range, arose for a vaccinated individual. Davidson had come into contact with a rabid cow before leaving his family farm in Ontario for a trip to British Columbia. He was fully informed of the vaccine's risks, including the risk of paralysis, when he spoke with Dr. Kettys in British Columbia, although the other doctors involved did not warn him of the risks.

This case put at issue the liability both of the doctors and of the pharmaceutical company. In the informed consent action against the doctors, decided after *Hopp v. Lepp*¹³ was decided in the Supreme Court of Canada

⁸ *Ibid.*, pp. 574-575 (S.C.R.), 125 (D.L.R.).

⁹ [1974] S.C.R. 1189, [1973] 6 W.W.R. 692, (1973), 40 D.L.R. (3d) 530.

¹⁰ Other issues of drug liability have been dealt with in *Graham v. Persyko* (1986), 55 O.R. (2d) 10 (Ont. C.A.) (negligent prescription; *obiter* comment on doctor's duty to disclose); *Cupido v. Sargeant* (breached doctor's duty to disclose), unreported Ont. H.C. decision, March 7, 1989.

¹¹ *Davidson v. Connaught Laboratories* (1980), 14 C.C.L.T. 251 (Ont. H.C.).

¹² *Supra*, footnote 1. The Court of Appeal also commented *obiter* on a duty to warn consumers directly of the risk of oral contraceptives.

¹³ [1980] 2 S.C.R. 192, (1980), 112 D.L.R. (3d) 67.

but before the judgment in *Reibl v. Hughes*,¹⁴ Linden J. said that because the risk was not a probable risk, the information "need not necessarily be given".¹⁵

In *Hopp v. Lepp*, the first of the 1980 Supreme Court of Canada decisions, Laskin C.J.C. discussed the law's treatment of probable as opposed to merely possible risks, noting that the gravity of the consequences must be taken into account, and similarly, with respect to special or unusual risks of a procedure, noting that such risks may go beyond the probable to include possible risks with grave consequences. Laskin C.J.C. stated, for the court, that a doctor was required to disclose to the patient the answers to any specific questions and:¹⁶

... without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation.

In *Reibl v. Hughes*, the Supreme Court found that a doctor has a duty to disclose the material risks of a proposed procedure, including risks with a low probability of occurrence but grave results (for instance, death, or stroke as in *Reibl v. Hughes* itself), risks the patient would deem relevant, the answers to questions asked by the patient, and any special or unusual risks, in addition to the nature and quality of the proposed act.¹⁷ Limited exceptions exist for common risks, waiver and therapeutic privilege.¹⁸ The risk in *Davidson v. Connaught Laboratories* was extremely low, but the gravity of the harm was a serious enough consequence that Linden J. might still have found a breached duty of disclosure on the part of the doctors.

The two Supreme Court decisions have significantly improved the standard of disclosure for patients, attempting to create a transaction between doctors and patients in which information is shared on both sides, a relationship aptly characterized by Bernard Dickens as "informed decision-making".¹⁹ The standard prior to 1980, "professional disclosure", required disclosure of only such information as was customary among like professionals.²⁰ Informed consent, as set out in *Reibl v. Hughes*, is governed primarily by negligence principles, although the action in battery is preserved

¹⁴ [1980] 2 S.C.R. 880, (1980), 114 D.L.R. (3d) 1.

¹⁵ *Supra*, footnote 11, at p. 271.

¹⁶ *Supra*, footnote 13, at pp. 210 (S.C.R.), 82 (D.L.R.).

¹⁷ See also *Videto v. Kennedy* (1981), 125 D.L.R. (3d) 127, 33 O.R. (2d) 497 (Ont. C.A.); *Ferguson v. Hamilton Civic Hospital* (1983), 144 D.L.R. (3d) 214, 40 O.R. (2d) 577 (Ont. H.C.), aff'd (1985), 50 O.R. (2d) 754, 18 D.L.R. (4th) 638 (Ont. C.A.).

¹⁸ See the discussion of these exceptions in Ellen Picard, *Legal Liability of Doctors and Hospitals in Canada* (2d ed., 1984), pp. 96-99.

¹⁹ Bernard M. Dickens, *The Modern Law on Informed Consent* (1982), 37 *Modern Medicine of Canada* 706, at p. 706.

²⁰ Picard, *op. cit.*, footnote 18, pp. 68-69.

in certain circumstances.²¹ Similarly, where consent is absent in the drug/vaccine case, a battery action is appropriate provided that the other requisites of the tort, including the act of touching, are satisfied.

In *Davidson*, the trial judge's finding that the other doctors were not in breach of their duty of disclosure made no difference, since Dr. Kettlys had fully informed the plaintiff. Linden J. found that no causation existed, since the plaintiff would have gone ahead with the treatment, as would the reasonable person. Death was the inevitable consequence of vaccine refusal in the event of exposure to rabies. Following *Reibl v. Hughes*, in an informed consent action against a doctor, legal causation is assessed by determining whether an adequately informed reasonable person in the shoes of the plaintiff would have declined the treatment accepted by the patient. This formulation of the causation link significantly undermines the role of the patient decision-maker. Autonomous decision-making requires that unreasonable as well as reasonable decisions should be supported.²² In addition, the reasonableness test requires proof of a hypothetical and a negative, the onus of proof is on the plaintiff, and the persuasive burden is heavy. Introduction of the reasonable patient standard, even one standing in the shoes of the patient, abstracts the causal sequence from the patient. This standard undermines the duty of disclosure, since the disclosure of risks that might lead to unreasonable decisions is unnecessary. The reasonableness test is also a response to concerns about the "hindsight and bitterness"²³ of patients, concerns that are dealt with in other cases through assessment of the patient's credibility. Replacement of the combined objective patient/subjective context test with a subjective test, assessing what the patient would have done, would improve the protection for the patient's right to determine what is done to her or his body. As we shall see below this problem does not exist in drug litigation following *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*

In the products liability portion of *Davidson v. Connaught Laboratories*,²⁴ the drug company's duty to warn was stated as follows: "In these circumstances, however, there is an obligation on the drug company to warn about potential side-effects." The risks are to be evaluated by

²¹ The action in battery is preserved where no consent at all is given to the proposed procedure (for example, consent to a different procedure but none to the procedure carried out, refusal, invalid consent through incapacity or involuntariness or absence of information as to the nature and quality of the act) or where fraud or misrepresentation vitiate the consent; *Reibl v. Hughes*, *supra*, footnote 14, at pp. 888-892 (S.C.R.), 8-11 (D.L.R.).

²² Gerald Robertson, *Overcoming the Causation Hurdle in Informed Consent Cases: The Principle in McGhee v. N.C.B.* (1984), 22 U.W.O.L. Rev. 75. More than one reasonable choice may exist (two mutually exclusive options may both be reasonable). Robertson has concluded that it is not a test of causation at all.

²³ *Reibl v. Hughes*, *supra*, footnote 14, at pp. 898 (S.C.R.), 15 (D.L.R.), citing Comment, *Informed Consent—A Proposed Standard for Medical Disclosure* (1973), 48 N.Y.U.L. Rev. 548, at p. 550.

²⁴ *Supra*, footnote 11, at p. 273.

the doctors, and by the patients as advised by the doctors. Linden J. stated: "It is only if the warning is incomplete or is insufficiently specific or is inadequately communicated that liability may be imposed."²⁵

The warning given by Connaught Laboratories was found to have been inadequate and unreasonable in the circumstances. Although the company had specific knowledge about the risk of paralysis resulting from the rabies shot, the only warning they gave with the shot was of the risk of encephalitis. The Compendium of Pharmaceuticals and Specialties, prepared by the pharmaceutical industry, contained "equally scant information".²⁶ The dependency relationship between the doctor and the pharmaceutical companies was noted by Linden J.; he indicated that the drug company could not rely on doctors reading all the scientific literature and that doctors rely on the drug companies for information. The drug company was negligent in inadequately informing the learned intermediary; however, as stated above, the action failed on causation. Linden J. commented that "[t]here are risks that one takes in life and, unfortunately, they do not always work out well".²⁷ He went on to advocate government consideration of a compensation plan for persons injured through rare vaccine reactions in the absence of fault.

The learned intermediary rule was affirmed in the leading case of *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*²⁸ Pauline Buchan was twenty-three years old and seemingly healthy at the time she was prescribed Ortho Novum oral contraceptives in 1971. She suffered a stroke which resulted in partial paralysis. The risk of stroke was one of the risks of taking the pill known to the manufacturer at the time. This important decision by Robins J.A., concurred in by four other members of the Ontario Court of Appeal (Lacourcière, Zuber, Morden and Goodman J.J.A.), stated the learned intermediary rule, provided a detailed assessment of the adequacy of the warning in relation to the sources of information provided to doctors, established a subjective test of causation for plaintiff's decision-making, and left intact Holland J.'s assessment at trial that factual causation was met because the contraceptive "probably caused or, at the very least, materially contributed to her stroke".²⁹ In *obiter*, the five judges gave a commentary supportive of the existence of a duty to warn consumers directly where oral contraceptives are prescribed.

Robins J.A. noted that little jurisprudence on the pharmaceutical company's duty to warn existed either in Canada or Great Britain, but that the issue had been canvassed extensively in United States case law.

²⁵ *Ibid.*

²⁶ *Ibid.*, at p. 275.

²⁷ *Ibid.*, at p. 281.

²⁸ *Supra*, footnote 1.

²⁹ The trial judgment in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1984), 8 D.L.R. (4th) 373, at p. 382, 46 O.R. (2d) 113, at p. 123 (Ont. H.C.).

He went on to set out the learned intermediary rule and the rationale underlying it:³⁰

Apart from any regulatory scheme under the *Food and Drugs Act*, the general rule at common law is that the manufacturer of such drugs, like the manufacturer of other products, has a duty to provide consumers with adequate warning of the potentially harmful side-effects that the manufacturer knows or has reason to know may be produced by the drug. There is, however, an important exception to that general rule. In the case of prescription drugs, the duty of manufacturers to warn consumers is discharged if the manufacturer provides prescribing physicians, rather than consumers, with adequate warning of the potential danger.

This exception, which has come to be known in the United States as the "learned intermediary" rule, adopts an approach similar to that taken in cases involving intermediate inspection or intervening cause under the rule in *M'Alister (or Donoghue) v. Stevenson*. The rationale for the exception is that prescription drugs are more likely to be complex medicines, esoteric in formula and varied in effect and, by definition, are available only by prescription. The prescribing physician is in a position to take into account the propensities of the drug and the susceptibilities of his patient. He has the duty of informing himself of the benefits and potential dangers of any medication he prescribes, and of exercising his independent judgment as a medical expert based on his knowledge of the patient and the product. In taking the drug, the patient is expected to, and it can be presumed does, place primary reliance on his doctor's judgment. In this relationship, the prescribing physician is said to act as a learned intermediary between the manufacturer and the ultimate consumer. Thus, while the general rule is that manufacturers of drugs have a duty to warn users of known dangers in the use of their products, manufacturers of prescription drugs, because of the intervention of the learned intermediary, have a duty to warn only prescribing physicians. *Reyes v. Wyeth Laboratories* (1974), 498 F. 2d 1264, certiorari den. 419 U.S. 1096; *Terhune v. A.H. Robins Co.* (1978), 577 P. 2d 975 (Wash.); *Sterling Drug, Inc. v. Cornish* (1966), 370 F. 2d 82 (1966); *McEwen v. Ortho Pharmaceutical Corp.* (1974), 528 P. 2d 522 (Or.).

In the United States, the learned intermediary rule was stated first in 1966 in *Sterling Drug, Inc. v. Cornish*,³¹ one of the suits brought by patients blinded after taking the drug chloroquine. The rule was not "clearly defined" before that.³² The underlying rationale was avoidance of injury to the patient. The rule was considered and elaborated in 1974 in *Reyes v. Wyeth Laboratories*,³³ an oral polio vaccine case arising when infant Anita Reyes contracted polio from the Sabin live polio vaccine. The 5th Circuit Court of Appeals judges noted that the rule was "an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products.

³⁰ *Supra*, footnote 1, at pp. 669 (D.L.R.), 103-104 (O.R.). Quotation marks omitted in the original.

³¹ 370 F. 2d 82 (8th Cir., 1966).

³² Barbara Marticelli McGarey, *Pharmaceutical Manufacturers and Consumer-Directed Information—Enhancing the Safety of Prescription Drug Use* (1984), 34 Catholic Univ. L. Rev. 117, at p. 123.

³³ 498 F. 2d 1264 (5th Cir., 1974), cert. denied 419 U.S. 1096, 95 S. Ct. 687 (1974), cited in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, *supra*, footnote 1, at pp. 669 (D.L.R.), 103-104 (O.R.).

See Restatement (Second) of Torts, Section 388 (1965)".³⁴ *Reyes* outlined the rationale for the rule in the following passage:³⁵

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes 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.

Recent United States cases affirm the learned intermediary rule, usually citing *Reyes*.³⁶ The premise is physician decision-making, an informed choice by the physician rather than by the patient in conjunction with the physician. Because the standard for disclosure was the professional disclosure standard, not all information material to patient choice would be expected to be passed on by the physician to the patient. This underlying view is made explicit in the IUD case, *McKee v. Moore*,³⁷ where the court stated that it is the learned intermediary and not the patient who decides whether the benefits of the IUD outweigh the risks. In a recent case, *Hill v. Searle Laboratories*,³⁸ the Eighth Circuit Court of Appeals rejected the application of the learned intermediary rule to the IUD, instead imposing a direct duty to warn the patient on the manufacturer. Applying the reasoning in the oral contraceptives cases, the court found that patients chose the IUD without intervening individualized medical judgment, and therefore the learned intermediary rule did not apply. This decision affirms the patient's need for adequate information, especially where the decision is largely unmediated by a physician.

The Ontario Court of Appeal in *Buchan* drew on the principle of the learned intermediary but linked it to patient decision-making and

³⁴ *Ibid.*, at p. 1276, footnote omitted. Strict liability and the comment on unavoidably unsafe products are in Restatement (2d) of Torts, Section 402A, comment k (1965). Considerable debate has been taking place over the applicability and role of comment k to section 402A in relation to prescription drugs.

³⁵ *Ibid.*

³⁶ For recent American cases on the learned intermediary rule, see *Stanback v. Parke, Davis & Co.*, 657 F. 2d 642 (4th Cir., 1981); *Abbot v. American Cyanamid Co.*, 844 F. 2d 1108 (4th Cir., 1988), *cert. denied*, 109 S. Ct. 260; *Polley v. Ciba-Geigy Corp.* 658 F. Supp. 420 (D. Alaska, 1987); *Plummer v. Lederle Laboratories*, 819 F. 349 (2nd Cir., 1987), *cert. denied*, 108 S. Ct. 232; *Hurley v. Lederle Laboratories*, 863 F. 2d 1173 (5th Cir., 1988); *Walker v. Merck & Co., Inc.*, 648 F. Supp. 931 (M.D. Ga., 1986), *aff'd* 831 F. 2d 1069 (11th Cir., 1987).

³⁷ *McKee v. Moore*, 648 P. 2d 21 (Okla. Sup. Ct., 1982). The learned intermediary rule has been applied to devices obtained by prescription, for instance, IUDs: *Terhune v. A.H. Robins Co.*, 577 P. 2d 975 (Wash. S.C., 1978); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn., 1988).

³⁸ 884 F. 2d 1064 (8th Cir., 1989), rehearing denied Nov. 9, 1989.

enhanced physician disclosure. The rationale provided by the *Buchan* court reflects this difference from *Reyes*. Finding that the *Reibl* test of proximate causation was inappropriate, the court said that:³⁹

The considerations applicable to and the responsibilities involved in a doctor-patient relationship differ markedly from those of a manufacturer-consumer relationship. As between doctor and patient, there is a direct and intimate relationship in which the relative advantages and disadvantages of a proposed medical treatment, including the taking of a drug, can be considered, discussed and evaluated. As between drug manufacturer and consumer, the manufacturer is a distant commercial entity that, like manufacturers of other products, promotes its products directly or indirectly to gain consumer sales, sometimes, as in this case, accentuating value while under-emphasizing risks. Manufacturers hold an enormous informational advantage over consumers and, indeed, over most physicians. The information they provide often establishes the boundaries within which a physician determines the risks of possible harm and the benefits to be gained by a patient's use of a drug. Manufacturers, unlike doctors, are not called upon to tailor their warnings to the needs and abilities of the individual patient; and, unlike doctors, they are not required to make the type of judgment call that becomes subject to scrutiny in informed consent actions.

In theory, more information should pass through to the patient. As a result the patient should have better protection for her or his autonomy under the Canadian doctrine.

Mass immunization constitutes an exception to the learned intermediary rule in the United States. In *Davis v. Wyeth Laboratories*,⁴⁰ the plaintiff had been vaccinated with oral polio vaccine at a public clinic. The court stated: "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning".⁴¹ The rationale for the rule disappears where no learned intermediary is available to carry out the "individualized balancing . . . of the risks . . .".⁴² After citing the passages quoted above from *Davis*, the court in *Reyes v. Wyeth Laboratories*⁴³ concluded:

In sum, then, the manufacturer is required to warn the ultimate consumer, or to see that he is warned.

More recently, the 5th Circuit Court in *Hurley v. Lederle Laboratories*⁴⁴ stated the exception and the rule as follows:

The learned intermediary doctrine is the rule, and the mass immunization case is the exception. We believe that the rule should stand whenever a physician has made a professional judgment, and that the mass immunization exception should apply only when no informed medical decision came between the manufacturer and the ultimate user . . . In sum, a manufacturer will be liable to the ultimate user of its

³⁹ *Supra*, footnote 1, at pp. 685-686 (D.L.R.), 120 (O.R.).

⁴⁰ 399 F. 2d 121 (9th Circ., 1968).

⁴¹ *Ibid.*, at p. 131.

⁴² *Ibid.*

⁴³ *Supra*, footnote 33, at p. 1276.

⁴⁴ 851 F. 2d 156, at pp. 1541-1542 (1988). (Emphasis in original). On a further consideration of this case, this view of the law was confirmed; see *Hurley v. Lederle Laboratories*, *supra*, footnote 36, at pp. 1178-1179.

drug or vaccine product unless it provided that user with an adequate warning, or an informed professional judgment actually intervened in the application of the product to that user.

Where "no informed medical decision" intervened between the pharmaceutical company and the patient, a direct duty was effectively in existence. The mass immunization exception to the prescription drug exception creates what amounts to the direct duty.

Another situation in which United States courts have sometimes imposed a duty to warn consumers directly is the prescription of oral contraceptives.⁴⁵ The duty to warn patients directly with respect to oral contraceptives, adopted in *MacDonald v. Ortho Pharmaceutical Corp.*⁴⁶ and approved, *obiter*, in *Buchan*, rests on the differences in the doctor-patient relationship where oral contraceptives are involved:

The oral contraceptive thus stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be considered. We conclude that the manufacturer of oral contraceptives is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user. Thus, the manufacturer's duty is to provide to the consumer written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information of concern to the consumer.

Patients do not rely as completely on the doctor's selection; contraception is much more a matter of patient selection. The nature of the doctor-patient relationship differs in terms of time and lack of consultation; a prescription for oral contraceptives is generally given for a year, unlike other drug prescriptions. The product is contraceptive rather than therapeutic.

The Ontario Court of Appeal set out and adopted the reasons in *MacDonald v. Ortho Pharmaceutical Corp.*, reaching the conclusion that not only an indirect duty but also a direct duty to warn should exist for oral contraceptives:⁴⁷

The *rationale* underlying the learned intermediary rule, in my opinion, does not hold up in the case of oral contraceptives. Manufacturers of this drug should be

⁴⁵ *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E. 2d 65 (Mass., 1985), *cert. denied*, 106 S. Ct. 250; *Re Certified Questions*, 358 N.W. 2d 873 (Mich., 1984); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich., 1985); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961 (E.D. Wisc., 1981), all cited in *Buchan*, *supra*, footnote 1, at pp. 670 (D.L.R.), 104 (O.R.).

⁴⁶ *Ibid.*, at p. 70.

⁴⁷ *Supra*, footnote 1, at pp. 688-689 (D.L.R.), 123 (O.R.).

obliged to satisfy the general common law duty to warn the ultimate consumer as well as prescribing physicians.

The burden would not be significant and the doctor-patient relationship would not be interfered with unduly. Appropriate warnings would "promote the desirable objective of ensuring that women are fully apprised of the information needed to balance the benefits and risks of this form of birth control and to make informed and intelligent decisions in consultation with their doctors on whether to use or continue to use oral contraceptives".⁴⁸ At trial, Holland J. took a bolder course and found not only that an indirect duty existed but also a direct duty to warn of the risks of oral contraceptives.⁴⁹

The duty to the ultimate consumer would, in my opinion at common law, not be discharged merely by warning the doctors.

The standard arguments made in favour of the learned intermediary rule for pharmaceutical products in general are the following: (1) the patient places primary reliance on the physician's judgment and advice because the physician must prescribe;⁵⁰ (2) direct communication between the manufacturer and the consumer is "difficult if not virtually impossible";⁵¹ (3) such direct communication would interfere unduly with the doctor-patient relationship; and (4) direct warnings would be read after the purchase, creating the possibility that the patient would be frightened and not take the drug (a result characterized as "non-compliance" in the medical literature).

These arguments in support of the learned intermediary rule are also used as arguments against any proposed requirement that manufacturers transmit information directly to the patient. For example, the Eastman Commission⁵² recommended both the creation of a patient package insert for prescriptions drugs and manufacturers' responsibility for it. Noting that the current practice of repackaging by pharmacists is rooted in the dispensing practices of the nineteenth century when they mixed their own prescriptions, the Eastman Commission recommended that manufacturers package the drug, including a list of ingredients, indications and warnings. The Canadian Medical Association feared that the counter indications "might confuse or frighten vulnerable patients and reduce compliance".⁵³ In response, the Eastman Commission recommended that doctors be allowed to instruct pharmacists to remove the inserts in specific cases, placing the onus on physicians to act on the exception.

⁴⁸ *Ibid.*

⁴⁹ *Supra*, footnote 29, at pp. 393 (D.L.R.), 134 (O.R.).

⁵⁰ *Re Certified Questions, supra*, footnote 45, at p. 882 (dissent).

⁵¹ *Ibid.*

⁵² Canada, Commission of Inquiry into the Pharmaceutical Inquiry, Report (1984), ch. 9, Authorization for Marketing: Safety and Efficacy, pp. 392-394.

⁵³ *Ibid.*, p. 394.

Similarly, the pharmaceutical companies were joined by the American Medical Association and the American College of Obstetricians and Gynecologists to fight against patient package inserts for estrogen replacement therapy.⁵⁴ In *Reyes v. Wyeth Laboratories*,⁵⁵ it was noted that the briefs of the *amici curiae*, the American Academy of Paediatrics and the Conference of State and Territorial Epidemiologists, opposed giving the warning of risks required in *Reyes v. Wyeth Laboratories*, with respect to polio vaccine. They argued that the warning would undermine the social policy purpose based on the need for mass vaccination; that it was too confusing for the patients (the court disagreed) and that a warning was unnecessary because universal vaccination had been adopted (the court said that choices still existed).

The "single-source informational system", providing prescription drug information solely through the physician, led to concern in the United States that not enough information was reaching patients and that safe use of prescription drugs was not encouraged.⁵⁶ As Barbara Marticelli McGarey has described it, in 1970 the Food and Drug Administration was unhappy with the formulation of the learned intermediary rule, leading it to put into place a requirement of information in the form of patient package inserts for oral contraceptives, estrogen products, IUDs, and progestational drugs. In 1979, the Food and Drug Administration proposed Regulations requiring inserts for almost all prescription drugs. "At the heart of this proposal was the FDA's conviction that the learned intermediary rule and the single-source information system it had generated were inadequate to insure the safe and effective use of prescription drugs."⁵⁷ The Food and Drug Administration argued that the inserts would provide a "standing reminder to the patient of the proper purposes and use of the prescribed drug".⁵⁸ The familiar arguments noted above were made by medical and pharmaceutical groups.⁵⁹

These arguments reflect a paternalistic concern for the well-being of the patient. They also reflect what Jay Katz has termed "the silent world of doctor and patient", in which silence, a reluctance to admit to medical uncertainties and a requirement of unilateral trust characterize the doctor-patient relationship. Patient participation in decision-making is a principle given little attention by physicians. "Challenging the long-standing tradition of silence requires nothing less than uprooting the prevailing authoritarian value and belief systems and replacing them with more egalitarian ones.

⁵⁴ Anne Rochon Ford, *Hormones: Getting Out of Hand*, in Kathleen McDonnell (ed.), *Adverse Effects* (1986), pp. 32-33. See also David Cook, *The Patient Package Insert and Its Legal Implications* (1980), 4 *Legal Medical Q.* 258, at p. 260.

⁵⁵ *Supra*, footnote 33, at p. 1293.

⁵⁶ McGarey, *loc. cit.*, footnote 32, at pp. 131-137.

⁵⁷ *Ibid.*, at pp. 132-134.

⁵⁸ *Ibid.*, at p. 135.

⁵⁹ *Ibid.*, at pp. 136, footnote 108, and pp. 144-150.

If my diagnosis is correct, the remedy is barely in sight.”⁶⁰ In a patient choice model, the willingness to explain risks to patients in terms they can understand and the ability to generate an exchange of information are critical elements in the informational system. Possession of information derived from a multiplicity of sources, including patient package inserts, enhances the patient’s ability to question the physician, to act as an informed consumer, to rectify the dependency relationship between the doctor and the patient. To that extent, a traditional doctor-patient relationship may be undermined but a more transactional, more egalitarian model may be substituted. The pharmaceutical company, at the top of the information hierarchy, is given the responsibility of conveying risk information in a comprehensible fashion, when patient package inserts are mandated.

The *Buchan* case provides one way in which information is directed to be transmitted to the patient, but the kind of direct duty stated in some United States oral contraceptives cases has not been made law. Patient package inserts have not been required through the tort system. The duty to warn the “learned intermediary” provides the only legal requirement that information about risks be transmitted to patients.

II. Adequacy of the Warning

A. The General Principle

In *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*,⁶¹ *Robins J.A.*, citing *Donoghue v. Stevenson*,⁶² *Lambert v. Lastoplex*,⁶³ and *Rivtow Marine Ltd. v. Washington Iron Works*,⁶⁴ set out the nature of the warning required:

Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard, and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. The nature and extent of any given warning will depend on what is reasonable having regard to all the facts and circumstances relevant to the product in question.

Later in the judgment he said:⁶⁵

A manufacturer of prescription drugs occupies the position of an expert in the field; this requires that it be under a continuing duty to keep abreast of scientific developments pertaining to its product through research, adverse reaction reports, scientific literature and other available methods. When additional dangerous or potentially dangerous side-effects from the drug’s use are discovered, the manufacturer must make all

⁶⁰ Jay Katz, *The Silent World of Doctor and Patient* (1984), p. 201.

⁶¹ *Supra*, footnote 1, at pp. 667 (D.L.R.), 101 (O.R.).

⁶² *Supra*, footnote 2.

⁶³ *Supra*, footnote 7.

⁶⁴ *Supra*, footnote 9.

⁶⁵ *Supra*, footnote 1, at pp. 678 (D.L.R.), 112 (O.R.).

reasonable efforts to communicate the information to prescribing physicians. Unless doctors have current, accurate and complete information about a drug's risks, their ability to exercise the fully-informed medical judgment necessary for the proper performance of their vital role in prescribing drugs for patients may be reduced or impaired.

Whether a particular warning is adequate will depend on what is reasonable in the circumstances. But the fact that a drug is ordinarily safe and effective and the danger may be rare or involve only a small percentage of users does not necessarily relieve the manufacturer of the duty to warn.

In determining whether a manufacturer has given an adequate warning, the court spoke of the duty to warn "of any dangerous side-effects produced by drugs, of which it knows, or has reason to know".⁶⁶ Applying the principles noted above, the court found that Ortho "was aware or should have been aware of the association between oral contraceptive use and stroke",⁶⁷ because Ortho U.S. was passing on warnings to physicians, based on data from scientific studies. Ortho Canada breached its duty to warn of risks of which it had actual or constructive knowledge.

As noted in Part I, the degree of explicitness depends on the risk, as established in *Lambert v. Lastoplex*, and the duty is continuous, requiring a warning on discovery of dangers unknown at the time the product was put to use, as decided in *Rivtow Marine*. The content of the warning cannot be undermined by the promotional context.

The Court of Appeal in *Buchan* evaluated the forms of communication between Ortho and physicians. "However, none of the Ortho information intended for doctors contained any warning or made any mention of the risk of stroke associated with the use of oral contraceptives."⁶⁸ The Compendium of Pharmaceuticals and Specialties, prepared annually by the pharmaceutical industry, did not mention the risk of stroke or cerebral thrombosis, in contrast with the warning issued by the United States sister company in the United States equivalent, the Physicians' Desk Reference. The "file cards" provided by Ortho for physicians described the product without including information on increased morbidity and mortality rates, whereas Ortho Pharmaceutical Corporation in the United States had revised its file cards in 1968 to include such warnings. Pharmaceutical salespersons (known as detailers) "sell and promote" the product by making personal calls on physicians, leaving behind literature and samples. The sales representatives were instructed in Ortho's sales bulletin, as the court put it, "to stress that Ortho-Novum was a safe, well-proven and effective drug".⁶⁹ Citing the sales bulletins' instructions to alleviate concerns and de-emphasize hazards, as well as the absence of warning of the risks, Robins J.A. contrasted the Canadian with the United States sales bulletins where the responsibility

⁶⁶ *Ibid.*

⁶⁷ *Ibid.*, at p. 679 (D.L.R.), 113 (O.R.).

⁶⁸ *Ibid.*, at pp. 673 (D.L.R.), 107 (O.R.).

⁶⁹ *Ibid.*, at pp. 676 (D.L.R.), 110 (O.R.).

for passing on the warnings and the warnings themselves were set out. Finally, the literature for doctors to hand out to their patients was similarly deficient as it "failed to reflect Ortho's knowledge of the significant risks associated with use of the pill and, like much of its other material, sought to minimize these risks and to downplay concerns about the drug".⁷⁰

After setting out the standard of care in the circumstances, concluding that Ortho was aware or had reason to be aware of the association between oral contraceptives and stroke, and wondering why Canadian physicians and consumers should be given a less explicit warning than in the United States, the Court of Appeal concluded that Ortho "failed to give the medical profession warnings commensurate with its knowledge of the dangers inherent in the use of Ortho-Novum; more specifically, it breached its duty to warn of the risk of stroke associated with the use of Ortho-Novum".⁷¹

As noted above, Linden J. considered that the information given by Connaught Laboratories about the rabies vaccine was insufficient in *Davidson v. Connaught Laboratories*.⁷²

In *Rothwell v. Raes*,⁷³ Osler J. found, *obiter*, that the warning given to physicians by Connaught Laboratories Limited was inadequate. Patrick Rothwell is severely handicapped developmentally and physically, blind and almost deaf. In August 1979, about a month after receiving, at the age of five months, his third shot of a vaccine designed to give protection against pertussis (whooping cough) and other childhood diseases, he showed signs of a developmental abnormality, which might have been attributable to the pertussis vaccine. His family brought an action against Connaught Laboratories, which had manufactured the vaccine, the physicians who had administered the vaccine and the Crown who had distributed the vaccine. The case failed because causation was not proved.

In 1979, it was widely believed among medical professionals that the vaccine caused encephalopathy and serious brain damage in some instances. At that time the package insert for physicians contained only a number of statements indicating that convulsions were not necessarily seriously or permanently damaging. The package insert stated that "... [i]t has been reported on rare occasions that uncontrolled screaming and/or convulsions, sometimes followed by neurological convulsions have resulted from the injection of pertussis vaccine".⁷⁴ Osler J. noted that no authoritative opinion was expressed by the company to practitioners by way of guideline

⁷⁰ *Ibid.*, at pp. 677 (D.L.R.), 112 (O.R.).

⁷¹ *Ibid.*, at pp. 679 (D.L.R.), 113 (O.R.).

⁷² *Supra*, footnote 11.

⁷³ (1989), 54 D.L.R. (4th) 193, 66 O.R. (2d) 449 (Ont. H.C.), affirmed (1991), 76 D.L.R. (4th) 280, 2 O.R. (3d) 332 (Ont. C.A.), application for leave to appeal to S.C.C. dismissed May 23, 1991. The trial judgment is not reported in full in the Ontario Reports; subsequent references are to the Dominion Law Reports only.

⁷⁴ *Ibid.*, at p. 340 (D.L.R.).

or other means. Scientists at Connaught were aware of the literature and had received adverse reaction reports as well. In these circumstances, the trial judge, applying *Buchan*, found the warning insufficient. Connaught had "no excuse for ignoring" what was in 1979 "... the general corpus of medical and scientific learning on the subject ...",⁷⁵ as it had been phrased by Stuart-Smith L.J. in *Loveday v. Renton*.⁷⁶

The finding of inadequate warning by Connaught Laboratories based on the state of knowledge in 1979 leads to an interesting result: a breached duty to warn of risks considered not to be causally related to the pertussis vaccine.

The doctors did not breach their duty to warn. It was not part of professional practice at the time to warn of the possible rare reaction, and therefore the physicians did not breach the professional standard of care in recommending the vaccine. Applying his reading of *Reibl v. Hughes*, Osler J. found that the doctors had not breached the duty to disclose material risks: he weighed the risk of having the vaccination against the risk of contracting the disease, concluding that if the risk of vaccination is lower, the finding favours exoneration of the doctors. However, this evaluation failed to take account of the gravity of the consequences, even where the probability is low. Osler J. took into account the fact that whooping cough is a serious disease as well as the fact that the risk of the vaccine was not established in 1979.⁷⁷ He found that:⁷⁸

... the unexplained risk was not a material risk in the sense that the cases have used that term and also that if it had been explained to her, accustomed as she was to following her doctor's advice, she would not have refused the vaccination.

This analysis seems problematical from two other perspectives. First, the analysis of the risks seems unnecessarily mathematical, focused on the probabilities. Secondly, the trial judge found that the risk of the vaccine was adequately enough established for the company to be required to warn of it, but inadequately enough established for the plaintiff to be able to take it into account in decision-making. From the patient's standpoint, control of decision-making is lessened to the extent that information is filtered out by the doctor. James Britain has noted that the warnings required of the pharmaceutical industry are much more stringent than those required of the medical profession in the United States, and that this difference

⁷⁵ *Ibid.*, at p. 341 (D.L.R.).

⁷⁶ *Loveday v. Renton* is unreported. For a summary, see Clare Dyer, Judge 'not satisfied' that whooping cough vaccine causes permanent brain damage, 296 Br. Med. J. 1189 (Apr. 23, 1988).

⁷⁷ *Supra*, footnote 73, at pp. 272-280 (D.L.R.).

⁷⁸ *Ibid.*, at p. 280 (D.L.R.).

in the standard of adequacy reflects differences in the underlying purposes of products liability and informed consent.⁷⁹

B. *Research and Testing*

The adequacy of the warning from the legal standpoint is measured by these tests of risk and severity of harm. The legal standard operates in a system in which the adequacy of any warning is contingent on a number of other factors. The nature and form of the information transmitted depends on the willingness of pharmaceutical companies to pass on warnings, which may undermine their promotional efforts. The ability to inform depends as well on what the manufacturer knows or should know through its own research and testing, on the amount of information available about adverse effects observed in the post-marketing period and the nature of the reporting mechanisms to make this information available.

The quality of research and testing by the manufacturer in the pre- and post-marketing phases has clear implications for product safety and information adequacy. The major pharmaceutical disasters of the post-war period—DES, thalidomide, the Dalkon Shield—demonstrate the need to demand high standards for research and testing of pharmaceutical products, conducted in a gender-sensitive⁸⁰ and ethically sound manner. Anne Rochon Ford has argued that the pharmaceutical companies' promotion of estrogen replacement therapy for menopause illustrates a pattern of little research and heavy promotion, followed by increased use in the face of evidence of problems and inefficacy.⁸¹

The pattern she has identified is clear in the DES tragedy. Diethylstilbestrol (DES) is a synthetic compound of the hormone estrogen. Discovered by researchers in the 1940s, it was celebrated as a solution to the problem of miscarriage. It was approved in the United States for other purposes in 1941, and for use on pregnant women on an experimental

⁷⁹ For a discussion of the conflict in the principles of injury prevention, marketplace honesty and loss spreading which underlie manufacturer's liability, see James Britain, *Product Honesty is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect* (1984), 79 *Northwestern Univ. Law Rev.* 342.

He argues, at p. 346:

... while the scope of a drug manufacturer's duty to warn extends well beyond that which can be justified under the prevention policy to embrace notions of truthful disclosure that lie at the heart of the marketplace honesty policy, a physician's duty to disclose remains tightly constrained by injury prevention, risk/benefit principles.

⁸⁰ The use of the male body as the norm imposes a homeostatic model on the cyclic, fluctuating female body, leading to the conclusion that nature needs correction. Contributing to the problem are the mechanistic view of the body, analysis of the body by parts, and an unenlightened view of women and reproduction. See Ford in McDonnell, *op. cit.*, footnote 54, p. 35. See also Emily Martin, *The Woman in the Body* (1987).

⁸¹ Ford in McDonnell, *ibid.*, pp. 27-40.

basis in 1947. By 1951, the Food and Drug Administration considered DES safe for this purpose and stopped requiring new drug applications prior to production. In 1971 the Food and Drug Administration ordered the manufacturers to stop marketing it to prevent miscarriages, and to issue warnings about the dangers.⁸² In that year, DES had been identified as a common feature among young women with a rare form of vaginal cancer, clear-cell adenocarcinoma. DES leads as well to other diseases and conditions of the reproductive system among the daughters and sons of women who took it.

*Mink v. University of Chicago*⁸³ was a battery action on behalf of 1,000 women who were "unwitting participants in a drug experiment". The women were given DES as part of a double blind experiment by the University of Chicago and Eli Lilly & Co., between 1950 and 1952, to determine the efficacy of DES in preventing miscarriages. Plaintiffs had entered the university hospital for pre-natal care. They were not told that they were part of an experiment or that the pills were DES. The defendants brought a motion to dismiss the complaints; the defendants' motion with respect to battery was dismissed. The court found no difference in principle between ingesting a pill and administering a drug by injection and found the element of contact necessary for a battery action.

In *Bichler v. Eli Lilly Co.*,⁸⁴ the court concluded that the failure of Eli Lilly Co. to test DES on pregnant mice aided or encouraged other manufacturers. The court upheld the jury verdict of "concerted action" among the manufacturers both on the basis of conscious parallel conduct among the manufacturers and on the basis of substantial assistance or encouragement. Joyce Bichler did not have to prove that Eli Lilly & Co. manufactured the DES taken by her mother. This was not a duty to warn case; instead, it was a failure to test case. On the basis of the tests that should have been carried out, a reasonably prudent manufacturer would not have marketed the drug at all.⁸⁵ Lilly conceded at trial that they knew by 1947 that "DES posed the threat of cancer to the user, that DES had been shown to cross the placental barrier, and that DES had caused malformations in the offspring of pregnant mice to which the drug had been administered".⁸⁶ Lilly argued that "because no human transplacental carcinogen was discovered until 1962, when the first thalidomide babies were born, it could not have foreseen the occurrence of DES-caused cancer

⁸² Terrie A. Rymer, *The Diethylstilbestrol Dilemma*, 251 (24) J.A.M.A. 3228 (June 22/29, 1984); *Sindell v. Abbott Laboratories*, 607 P. 2d 924 (Calif. Sup. Ct., 1980), cert. denied, 101 S. Ct. 285; Roberta J. Apfel and Susan M. Fisher, *To Do No Harm. DES and the Dilemmas of Modern Medicine* (1984), pp. 19-28; *Hymowitz v. Eli Lilly & Co.*, 539 N.E. 2d 1069, at p. 1072 (N.Y.C.A., 1989), cert. denied, Oct. 30, 1989.

⁸³ 460 F. Supp. 713, at p. 717 (Dist. Ct., 1978).

⁸⁴ 436 N.E. 2d 182, at p. 188 (N.Y.C.A., 1982).

⁸⁵ *Ibid.*, at pp. 189-190.

⁸⁶ *Ibid.*, at p. 189.

in human offspring".⁸⁷ The plaintiff's experts testified otherwise; the jury agreed, awarding Joyce Bichler damages. The New York Court of Appeals in *Hymowitz v. Eli Lilly & Co.*⁸⁸ has recently rejected the "modified version of concerted action, which, in effect, substituted the fact of conscious parallel activity by manufacturers for the usual common-law requirement that there be proof of an actual agreement between actors to jointly act tortiously", the latter being the test used by the same court in *Bichler*. An inference of agreement from parallel conduct improperly and unfairly expands concerted action theory. Instead, the court adopted market share liability.

The thalidomide tragedy in 1961-62 shows a company ignoring adverse effects data and its own researchers' concerns,⁸⁹ cover up and denial,⁹⁰ clearly inadequate pre-marketing information, and the handing out of samples by detailers, effectively experimenting on unknowing subjects.⁹¹ In Canada, the regulatory regime was tightened immediately after the thalidomide issue exposed its inadequacies.

The Dalkon Shield litigation is also instructive. Mark Downie and Tracy Johnston, in their investigative article for *Mother Jones* magazine,⁹² revealed that the Dalkon Shield was developed by two friends, one of whom, Dr. Hugh Davis, wrote an influential academic article and a book reporting on his research on the device at Johns Hopkins University. They reported that his research was less scientific than it seemed at first—no consent forms were signed, some of the participants may have used contraceptive foam as well as the IUD on his advice, and the average testing period was 5.5 months.⁹³ After minimal testing, it was rushed to market by A.H. Robins Co., even though an internal study showed it to be fundamentally flawed and less effective than previously indicated.⁹⁴ In the medical community, concerns surfaced immediately, about wicking leading to a high incidence of pelvic inflammatory disease. The company's response was denial of the defect, promotion through intense advertising and a refusal to recall it until ten years later. In 1975, after the Food and Drug Administration began holding hearings on the Dalkon Shield,

⁸⁷ *Ibid.* (Emphasis in the original).

⁸⁸ *Supra*, footnote 82, at p. 1076.

⁸⁹ The War Amputations of Canada, Report of the Thalidomide Task Force (1989), pp. 14-15, 33, 35, 155-157.

⁹⁰ *Ibid.*, pp. 128, 155.

⁹¹ *Ibid.*, pp. 42, 109.

⁹² Mark Downie and Tracy Johnston, A Case of Corporate Malpractice and the Dalkon Shield, reprinted from *Mother Jones Magazine* (1976), in Howard D. Schwartz (ed.), *Dominant Issues in Medical Sociology* (2nd ed., 1987), pp. 629-638.

⁹³ *Ibid.*, p. 631.

⁹⁴ *Ibid.*, p. 634. See also, *The Dalkon Shield Litigation: Revised Annotated Reprimand* by Chief Judge Miles Lord (1986), 9 *Hamline Law Rev.* 7, footnote 7; Ronald C. Bacigal, *The Limits of Litigation: The Dalkon Shield Controversy* (1990); Book Note, Sheldon Engelmayer and Robert Wagman, *Lord's Justice: One Judge's Battle to Explore the Deadly Dalkon Shield I.U.D.* (1986), 99 *Harv. L. Rev.* 875.

the shield was permanently removed from the world market. It was not until 1984 that the company announced that women still wearing the Dalkon Shield should have it removed at Dalkon's expense, eight months after the settlement of litigation before Miles Lord J. and after the judge had issued a reprimand to certain corporate officers and their defence counsel, a reprimand set aside by the Eight Circuit Court of Appeals because it violated due process.⁹⁵ An unknown number of women world-wide still have the device in their uteruses.

Miles Lord J.'s reprimand includes the following devastating indictment:⁹⁶

If one poor young man were by some act of his, without authority or consent, to inflict such damage upon one woman, he would be jailed for a good portion for the rest of his life. And yet your company, without warning to women, invaded their bodies by the millions and caused them injuries by the thousands. And when the time came for these women to make their claims against your company, you attacked their characters, you inquired into their sexual practices and into the identity of their sex partners. You exposed these women and ruined families and reputations and careers in order to intimidate those who would raise their voices against you. You introduced issues that had no relationship whatsoever to the fact that you planted in the bodies of these women instruments of death, mutilation, and of disease.

The data were taken from several exhibits stating that: "Estimated usage of this IUD to date is approximately 2.2 million in the U.S. and 0.8 to 1.0 million in non-U.S. countries, the later (*sic*) including over 100,000 in Canada and 150,000 in the U.K."⁹⁷ The harm created by this device has been devastating.

The commitment of money to research and development is clearly important to the safety of consumers. The Pharmaceutical Manufacturers Association of Canada (PMAC) advertises in 1991 that "[e]very year, PMAC companies invest more than \$200 million in research and development".⁹⁸ Joel Lexchin, in an article in the March 20, 1989, *Globe & Mail* stated that "[i]n 1987, drug companies operating in Canada spent almost \$400 million on advertising, more than three times the amount that went into research and development".⁹⁹

⁹⁵ *Gardiner v. A.H. Robins Co. Inc.*, 747 F. 2d 1180. (8th Cir., 1984).

⁹⁶ The Dalkon Shield Litigation, Revised Annotated Reprimand by Chief Judge Miles Lord, *supra*, footnote 94, at p. 9.

⁹⁷ *Ibid.*, at p. 27, footnote 12:

See Exhibit 733a Memo, dated January 28, 1974, from Lester W. Preston Jr., Ph.D., to Allan Polon, Ellen Preston and Dave Jones regarding Dalkon Shield Distribution Data; and Exhibit 758—Statement on Septic Spontaneous Abortion on the Dalkon Shield presented to the Food and Drug Administration Bureau of Medical Devices and Diagnostic Agents and its Ob/Gyn Device Panel on June 11, 1974, by Frederick A. Clark Jr., M.D., Vice-President and Medical Director, A.H. Robins Company.

⁹⁸ Print ad, inside back cover, *Maclean's*, February 25, 1991.

⁹⁹ Joel Lexchin, *Globe & Mail*, March 20, 1989. See also Joel Lexchin, *The Real Pushers* (1984).

In Ontario alone, the total expenditure on prescription drugs in 1985 was \$932.6 million, while non-prescribed drugs added \$710.8 million, and eyeglasses, hearing aids, other appliances and prostheses cost \$318.4 million, for a total cost of almost \$2 billion (\$1,961.8 million).¹⁰⁰ The Pharmaceutical Inquiry of Ontario estimated the 1988 sales of prescription drugs in Ontario at \$1.2 billion. Almost half of the expenditure is made up by government, through the Ontario Drug Benefit Plan and public hospital drug expenditures.¹⁰¹ The profits at stake are enormous. For instance, the vaccine market alone in the United States was estimated at \$500-600 million per annum.¹⁰² The promotional activities are extensive, involving sponsorship of lectures, conferences and continuing education seminars, as well as advertising in physicians' magazines, visits by drug representatives and handouts of samples. A. Paul Williams and Rhonda Cockerill carried out a survey of physicians' prescribing practices and attitudes for the Pharmaceutical Inquiry of Ontario. The summary discusses the "perks" offered by drug companies:¹⁰³

Small numbers report the receipt of more significant benefits including conference fees, travel expenses and computer hardware and software. While failing to demonstrate that industry contacts and benefits received directly influence prescribing patterns, the data show that those physicians who have the highest frequency of contacts with the industry and who receive the widest range of benefits are also the highest volume prescribers.

Although the pharmaceutical industry is involved in the health care system it is not bound by ethical codes or professional self-regulation.

C. Reporting of Adverse Effects

The ability to transmit warnings that will be effective in informing patients depends as well on the information available. Reliable information is critical for internal industry decision-making and government regulation. Adverse effects data are not collected systematically by either the federal government or the pharmaceutical companies.

In October 1987, the Report of the Auditor General to the House of Commons for the Fiscal Year ended March 31, 1987,¹⁰⁴ stated:

The Department does not have an adequate system for monitoring adverse drug reactions caused by the use of drug products it has approved for marketing in Canada. The result is that some Canadians may be facing unnecessary risk.

¹⁰⁰ National Health Expenditures in Canada 1975-1985, Health & Welfare Canada, Nov. 1987, cited in Report of the Pharmaceutical Inquiry of Ontario, Prescription for Health (1990), p. 144.

¹⁰¹ *Ibid.*, p. 21.

¹⁰² Joseph Earley, Can Biotechnology Immunize Vaccine Manufacturers from the Products Liability Crisis? (1990), 30 *Jurimetrics Journal* 351, footnote 4, citing Goldbaum and Hunter, A Big Shot in the Arm, *Chemical Week*, March 22, 1989, at p. 13.

¹⁰³ A. Paul Williams and Rhonda Cockerill, Report on the 1989 Survey of the Prescribing Experiences and Attitudes Toward Prescription Drugs of Ontario Physicians, Appendix A, Vol. II, Report, *op. cit.*, footnote 100, p. 69-70.

¹⁰⁴ Report of the Auditor General to the House of Commons for the Fiscal Year ended March 31, 1987. The audit's scope was as follows:

The Report recommended:¹⁰⁵

- 12.36 The Department of National Health and Welfare should take steps to:
- improve reporting of adverse drug reactions by drug manufacturers, physicians, pharmacists and hospitals;
 - co-ordinate and consolidate the information it receives on adverse drug reactions, whether that information is submitted to comply with regulatory requirements or on a voluntary basis; and
 - analyse and use the adverse drug reaction information to monitor and control the safety of all drug products marketed in Canada.

In the latter part of 1989, a workshop was held under the auspices of the College of Family Physicians of Canada and sponsored by the College and by the Drugs Directorate of Health & Welfare Canada. This workshop, "The Consensus Workshop to Explore a Framework for Determining Risk of Unexpected Events Following Medical Intervention", brought together participants from a broad range of backgrounds, to evaluate the existing means of monitoring adverse reactions¹⁰⁶ to drugs, devices and other medical treatments. The workshop made ten recommendations for action in this area:¹⁰⁷

- 1) The Federal Government should establish a national system for monitoring unexpected/adverse reactions to medical interventions. This system and its satellite expert networks should be sponsored and supervised by a collaboration of governments, industry, academia, and professional organizations.
- 2) Spontaneous observation and reporting of adverse reactions should be encouraged and a standardized national mechanism adopted.
- 3) Education institutions should take immediate steps to foster improved health education relevant to the optimal use of drugs. Key areas are: a) undergraduate education; b) graduate education; and c) public education.
- 4) The Federal and Provincial governments must foster the development of specialized health care professionals, skilled in the recognition and evaluation of adverse reactions.
- 5) New health information systems should be developed with a view to compatibility, both technical and conceptual, with other systems to encourage intra- and inter-provincial links, to facilitate epidemiological evaluation.
- 6) Drug information must be improved.
- 7) Funding agencies should be encouraged to treat studies of adverse reactions as a high priority. Creative approaches to seeking funding, to expand the pool of additional research resources, should be developed.

12.14 We examined the process for reviewing and approving new drug submissions, as well as initiatives taken to improve it. We also reviewed how the Department manages the Emergency Drug Release Program. Finally, we examined the information management uses to monitor adverse reactions to approved drug products and looked at how drug manufacturing plants are inspected.

¹⁰⁵ *Ibid.*, paragraph 12.36.

¹⁰⁶ See also Walter O. Spitzer, Tom Hutchinson and David Lane, Postmarketing management of drug use: Toward rational public policy (May 15, 1987), 136 CMAJ 1022-1024.

¹⁰⁷ Final Report, Consensus Workshop to Explore a Framework For Determining Risk of Unexpected Events Following Medical Intervention, held October 31, Nov. 1-2, 1989 (Ottawa), pp. 6-7. (I was one of the participants).

- 8) The Health Protection Branch (HPB) of Health and Welfare Canada should maintain and expand a detailed inventory of all endeavors related to prescription and non-prescription drugs, medical devices, vaccines, etc. The inventory should be kept up-to-date and regularly published.
- 9) Post-approval evaluation of drugs, vaccines and medical devices should be mandated by Health and Welfare Canada.
- 10) These issues must be addressed by the Conference of the Deputy Ministers of Health.

Two of the themes of the Workshop are worth emphasizing. First, the need for better understanding and evaluation of adverse effects was noted in the Workshop's Final Report:¹⁰⁸

It has long been recognized that the benefits of certain medical interventions, either drugs, devices or vaccines, do not accrue to all who use them. Reactions to medical therapies, either drug, vaccine or device, can be both efficacious and harmful. The cost to individuals and society is high, as adverse therapy effects are estimated to account for 2.5% of hospital admissions alone. Morbidity and mortality can occur as an unexpected event, or at an unexpected frequency once a medical intervention is widely implemented. Only some of the reasons for these reactions are presently understood after the event; even fewer potential reactions can be anticipated on an a priori basis. It is probable that some rarer events are not attributed to the medical intervention which should be, and the intervention continues in use, while some efficacious therapies are withdrawn, due to the fear of unproven harmful effects. Unfortunately, systems currently available worldwide to monitor long-term drug safety are far from perfect.

Second, the Report points to significant deficiencies which have an impact on patient safety and the adequacy of information transmitted. The current inadequacy of adverse effects reporting in the pre-marketing trials makes it impossible to determine issues of attribution of the risk and subpopulation risk. Spontaneous reporting of adverse effects observed by physicians, hospitals and pharmacists often lacks the details necessary to draw reliable inferences; the record linkage systems in place suffer from the same shortcoming. These factors affect subsequent efforts to collect adverse reaction data.¹⁰⁹

Insufficient perspective of what patients with a specific adverse reaction really look like leads to missed diagnoses, increased morbidity, and expense to the health care system.

As Francine Lortie has noted:¹¹⁰

Clinical trials of a drug before it is approved involved rather homogeneous groups of patients and are limited in numbers of patients and duration. Consequently, new information on unanticipated effects and on how the body's handling of the drug is modified by factors such as illness or concomitant treatments must be obtained from postmarketing surveillance.

¹⁰⁸ *Ibid.*, p. 1.

¹⁰⁹ *Ibid.*, pp. 8-9.

¹¹⁰ Francine Lortie, Postmarketing surveillance of adverse drug reactions: Problems and solutions (July 1, 1986), 135 CMAJ 27, pp. 27-28, footnote omitted.

For instance, the fact that pre-market testing of drugs is not conducted on pregnant women, for obvious reasons, means that the adverse effects of newly licensed drugs in that particular group of women will be unpredictable. Similarly, the Pharmaceutical Inquiry of Ontario recommended that whenever reasonable, drug trial data submitted in support of licensing applications include data from older persons as well as prescribing data and recommendations for that group.¹¹¹

Physician education about drugs was identified as a problem area in the Report of the Pharmaceutical Inquiry of Ontario (the Lowy Commission), which stated:¹¹²

Physicians are not as well prepared educationally for prescribing the thousands of drug products available as they might be, especially with regard to the elderly. The continuing education of physicians with respect to the use of new drug products requires improvement.

The evaluation of drugs, vaccines, devices and medical treatments needs to be carried out on a systematic basis as the techniques are introduced and on a continuing basis for approved products. Medical devices are subject to much less rigorous pre-marketing examination by federal regulatory authorities than are drugs and vaccines.

Gerald Tietz has identified the pervasiveness of prescription drugs as one factor which should limit deference to the medical profession in informed consent cases. He has said that, "while no statistics exist as to the exact number of adverse reactions each year, there is little doubt that the number is in the hundred thousands".¹¹³ The other factors he identifies are the tendency to over-prescribe drugs, the need for constant monitoring, which depends for success on patients' awareness of adverse effects and their indications, and the limited pharmaceutical knowledge of physicians.

D. Novel Treatments

In a recent article in the *New England Journal of Medicine*, Drs. Linton and Naylor have pointed to problems in the way in which drugs,

¹¹¹ *Op. cit.*, footnote 103, p. (x).

¹¹² *Op. cit.*, footnote 103, p. (ii).

¹¹³ Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case* (1986), 61 Wash. L. Rev. 367, at pp. 385-386, citing T. Preston, *The Clay Pedestal* (1981), p. 133: "Drug reactions or complications are responsible for 5% of all hospital admissions in the United States, or as many as 1,500,000 persons per year, which may represent just a small part of those harmed by drugs". Preston cites Spencer Klaw, *The Great American Medicine Show* (1975), p. 26.

¹¹⁴ Adam Linton and C. David Naylor, *Organized Medicine and the Assessment of Technology* (1990), 323(21) *New England Journal of Medicine* 1463-1467, at p. 1463. See also Lawrence C. Wiser, Richard H.M. Plain and John B. Dossetor, *Kidney stones and lithotripters: Critical analysis of the introduction of extracorporeal shock wave lithotripsy into Canada* (1990), 143 (12) *CMAJ* 1299-1303.

devices and procedures are introduced into Ontario's health care system, demonstrating these problems with three cases:¹¹⁴

In Ontario, as elsewhere in Canada, however, the approach to the diffusion and use of medical technology is at best haphazard. Even as concerns are voiced about waiting lists for surgical procedures, stifled innovation, and a lack of funding for capital expenditures among the hospitals, the system in Ontario has failed to stem the tide of drugs and devices of questionable usefulness that can be introduced without large investment by hospitals. The same lack of assessment and control is evident for novel or more intensive applications of established techniques or equipment. Furthermore, accepted practice patterns are rarely scrutinized in part because there are no formal criteria for assessing the indications for a host of medical and surgical testing and procedures, ranging from pulmonary-function testing and exercise electrocardiography to tonsillectomy and cholecystectomy.

Novel and experimental techniques of potential benefit to the patient must be acknowledged as such, requiring both an ethics review and a higher standard of disclosure. In *Halushka v. University of Saskatchewan*,¹¹⁵ the court found that the duty owed to the subject of the experiment was "at least as great, if not greater, than the duty owed by the ordinary physician or surgeon to his patient", without any exception for therapeutic privilege.

The fact that physicians may prescribe drugs for purposes unapproved by the federal government is not widely known. The patient needs to be aware of the technique's status in the medical community and the corresponding degree of reliability for risk-benefit statements. Courts can consider such information essential as part of the appropriate standard of disclosure. The distinction between experimental and merely innovative but therapeutic procedures, is based on the scientific investigatory as opposed to particular therapeutic purpose. In both cases, the novelty and unproven nature of the procedure should support full disclosure to the participant.

In *Zimmer v. Ringrose*,¹¹⁶ the Alberta Court of Appeal applied the therapeutic standard rather than the experimental one to an innovative procedure developed by Dr. Ringrose as a means of sterilization. Although the higher standard of disclosure was not imposed, significantly, the court found that Dr. Ringrose had breached the duty of disclosure by failing to inform the plaintiff of its novelty, of its lack of acceptance by the medical community, and of alternatives. However, the plaintiff lost on causation. The trial judge's finding of negligent after-care was left undisturbed and damages awarded on that basis.

¹¹⁵ (1965), 53 D.L.R. (2d) 436, 52 W.W.R. 608 (Sask. C.A.).

¹¹⁶ (1981), 124 D.L.R. (3d) 215, [1981] 4 W.W.R. 745 (Alta. C.A.), leave to appeal to S.C.C. denied, 28 A.R. 92, 37 N.R. 289 (S.C.C.); see also *Cryderman v. Ringrose* (1977), 89 D.L.R. (3d) 32, [1977] 3 W.W.R. 109 (Alta. Dist. Ct.), aff'd (1978), 89 D.L.R. (3d) 32, [1978] 3 W.W.R. 481 (Alta. App. Div.); Law Reform Commission of Canada, Biomedical Experimentation Involving Human Subjects, Working Paper 61 (1989); Medical Research Council of Canada, Guidelines on Research Involving Human Subjects (1987).

In *Weiss v. Solomon*,¹¹⁷ the Quebec Superior Court was faced with liability issues arising out of the death of Mr. Weiss, a subject in a scientific experiment without therapeutic benefit to Mr. Weiss, to determine the effect of the drug indomethacin in post-operative care for cataract surgery patients. De Blois J. concluded that for purely experimental research the doctor must reveal all known risks, even those which are rare or remote, particularly if the consequence is grave. The case examined as well the role of the research committee which minimized the risks in the consent form and failed to be selective in choosing participants. The hospital failed to create conditions for the experiment in which adequate precautions for cardiac arrest would be taken. This case has important implications for researchers and institutions¹¹⁸ participating in drug trials and other forms of experimental research on human subjects.

In summary, adequacy from a legal standpoint depends on the knowledge of the manufacturer. In practice, knowledge depends, first, on accurate research and testing and secondly, on adequate monitoring and reporting systems. Patient safety and self-protection depend on the availability of accurate information in the system and its presentation in a full and comprehensive manner designed to educate and inform of risks as well as benefits.

III. Causation

Drug liability cases pose some familiar and some unusual causation problems. No less than ten distinct, but interlocking, issues may be identified as requiring analysis.

A. General Scientific Causation

The issue of general scientific causation, the ability of the product to cause the harm, is not usually separated from the particular cause in fact issue because that capability can often be assumed. In the pertussis vaccine cases,¹¹⁹ the causal link between the vaccine and brain damage was at issue. In the Ontario case, *Rothwell v. Raes*,¹²⁰ Osler J. at trial extensively analyzed the possible means of scientific proof in his lengthy decision, examining in detail the British epidemiological study, the National Childhood Encephalopathy Study and the cases included in it, as well as other scientific means of establishing the link. He concluded that, on

¹¹⁷ [1989] R.J.Q. 731, 48 C.C.L.T. 280 (Que. S.C.).

¹¹⁸ Benjamin Freedman and Kathleen Cranley Glass, *Weiss v. Solomon: A Study in Institutional Responsibility for Clinical Research* (1990), 18 Law, Medicine & Health Care 395.

¹¹⁹ See Colin L. Campbell, *Pertussis Vaccine Litigation in Three Countries* (1990), 18 Law, Medicine & Health Care 59-68, discussing the British case, *Loveday v. Renton* (Q.B., Mar. 29, 1988), the trial judgment in *Rothwell v. Raes*, *supra*, footnote 73, and the United States cases.

¹²⁰ *Supra*, footnote 73.

the balance of probabilities, the plaintiff had not proved that the vaccine caused brain damage.¹²¹

B. *Particular Causation*

Even assuming scientific causation had been proved to his satisfaction, Osler J. did not believe that Patrick Rothwell's disability had been caused by the injection of the pertussis vaccine. Patrick Rothwell was one of twins; the other twin was stillborn. The Ontario Court of Appeal, in a judgment by Robins, McKinlay and Osborne J.J.A., found no basis for interfering with the trial judgment. In *Rothwell v. Raes*, both general scientific causation and particular scientific causation were unproved.

C. *Indeterminate Plaintiffs*

If the probability of harm in general has been proved, and particular causation is at issue, then an "indeterminate plaintiff"¹²² situation may exist. In this situation, negligent or intentional acts need to be sorted out from naturally-occurring acts that produce the same kind of harm. In Patrick Rothwell's case, Osler J. decided that the harm was not proved to be attributable to any act of the defendants, and there was a naturally-occurring phenomenon. On appeal, plaintiffs argued that there was only one other possible cause, damage prior to birth, and that this damage had not been proved. The Ontario Court of Appeal rejected this reasoning. The Court of Appeal found that the trial judge was not satisfied either that the vaccine caused the harm or that pre-natal injury caused it, saying that the neurological damage was ideopathic in origin.

Richard Delgado has stated that in United States caselaw no onus-shifting occurs where one agent is non-human.¹²³ In *Cook v. Lewis*,¹²⁴ in *obiter*, the Supreme Court of Canada said that there would be onus-shifting in this situation. Delgado has asked what the result would be if the indeterminate defendants' problem was combined with the indeterminate plaintiff's problem.¹²⁵ Such a situation exists when a group of manufacturers produce a substance causing an injury which also occurs naturally, for instance a synthetic hormone, or a live vaccine that creates the disease it was designed to prevent.

¹²¹ *Sigouin v. Wong* (1991), 4 C.C.L.T. (2d) 129 (B.C.C.A.), is a negligent prescription case that puts at issue general and particular causation also in a situation where the two possible causes are a drug (Cafergot-PB) and genetics. The Court of Appeal overruled the trial judgment and ordered a new trial.

¹²² Richard Delgado, *Beyond Sindell: Relaxation of Cause-in-Fact Rules for Indeterminate Plaintiffs* (1982), 70 Calif. L. Rev. 881.

¹²³ *Ibid.*, at p. 890.

¹²⁴ [1951] S.C.R. 830, [1952] 1 D.L.R. 1.

¹²⁵ *Loc. cit.*, footnote 122, at p. 907.

D. Indeterminate Defendants

Another cause in fact problem is the "indeterminate defendants" problem. In this type of problem, all of the defendants negligently caused harm to members of the class to which plaintiff belongs, but the particular defendant who caused plaintiff's harm cannot be sorted out from other defendants. In *Sindell v. Abbott Laboratories*,¹²⁶ the California court solved this problem by using the device of market share liability to find causation where manufacturers producing a substantial share (90 per cent) of the DES in that market were joined in the action. Liability was apportioned among the defendants on the basis of their market share. The liability then approximated the responsibility for the harm caused by its products among the class of affected persons.

In *Brown v. Superior Court (Abbott Laboratories)*,¹²⁷ an appeal of pre-trial rulings in sixty-nine DES cases, the Supreme Court of California has clarified the seeming ambiguity in *Sindell*, as to whether market share liability was several only or joint and several, holding that liability is several only, and confined to the market share. Similarly, in *Hymowitz v. Eli Lilly & Co.*,¹²⁸ the New York Court of Appeals has held that recovery on a market share basis is several only, recognizing that this prevents some plaintiffs from fully recovering their damages. The court approved of a market share liability approach, based on a national market, where liability corresponds to each defendant's culpability, measured by each defendant's creation of risk to the public. The shift from an attempt to prove causation in a particular case to a concentration on creation of risk, on a nationwide basis, from a notional finding of contribution to the harm to an explicit finding of contribution to the risk, is a significant ruling for plaintiffs. In this case it was the basis for the court's holding that defendants who produced DES for pregnancy use should not be permitted to exculpate themselves by showing that their marketing or the identifiability of their pill undermined the causal link with that particular plaintiff. Wachtler J., for the court, stated that these fortuitous circumstances did not reduce the defendant's culpability for marketing the product, the basis for imposition of liability. *Sindell* finessed the particular causation problem; *Hymowitz*

¹²⁶ *Supra*, footnote 82. See also *Hymowitz v. Eli Lilly & Co.*, *supra*, footnote 82; *Shackil v. Lederle Laboratories*, 116 N.J. 155, 561 A. 2d 511 (N.J., 1989); *Collins v. Lilly & Co.*, 342 N.W. 2d 37 (Wis., 1984), *cert. den.*, 105 S. Ct. 107; *Martin v. Abbott Laboratories*, 689 P. 2d 368 (Wash., 1984). In *Collins*, the Wisconsin court based recovery on the proportion of risk created by each defendant (a question of fact), and permitted defendants to avoid liability by proving that they could not have caused the injury to the particular plaintiff. In *Martin*, the Washington Supreme Court permitted defendants similarly to exculpate themselves. Remaining defendants had 100 per cent of the damage apportioned in equal shares, pending rebuttal on the basis of market share data. Plaintiff's recovery is 100 per cent, after adjustment to the other defendants' shares. Not all jurisdictions which have considered the issue have adopted market share liability.

¹²⁷ 751 P. 2d 470, at pp. 485-487 (Cal., 1988).

¹²⁸ *Supra*, footnote 82.

removes particular causation and cause-in-fact, except in a society-wide sense. As the dissent in *Shackil v. Lederle Laboratories*¹²⁹ noted: "Although perhaps the most controversial of the market-share decisions its [*Hymowitz's*] holding results in the scheme that is most similar to the almost universally-praised federal Vaccine Act."

Consideration was given to resolution through market share liability of a similar cause-in-fact problem in a diphtheria-pertussis-tetanus (DPT) vaccine case where plaintiffs were unable to identify the particular manufacturer of the vaccine administered to the infant plaintiff, who was diagnosed as having chronic encephalopathy and severe retardation. In *Shackil v. Lederle Laboratories*,¹³⁰ an appeal to the New Jersey Supreme Court arising out of a motion for summary judgment, the court in a 4:2 decision rejected the application of market share liability to vaccines. The majority reasoned that the cause-in-fact requirement had as its purpose not only the assignment of blameworthiness but also limitation of the scope of potential liability so as to encourage socially useful activity that would otherwise be deterred. Market share liability would have a "regressive effect" on the "social policy of encouraging vaccine production and research".¹³¹ The relief under the National Childhood Vaccine Injury Act of 1986 that had been available to the plaintiff as an alternative to the tort action also weighed in the majority's opinion and the dissent's criticism. The public policy purpose of encouraging vaccine production and distribution may be sufficient to differentiate DPT from DES, and to discourage the use of the market share liability solution to the indeterminate defendant problem in vaccine cases.

E. Multiple Insufficient Joint Causation

In a case where the defendants are negligent, where each negligent act was insufficient to produce the act but where the combined effect was to produce the act, can the actors be said to have caused the harm? In *Bichler v. Elli Lilly & Co.*,¹³² the concerted action theory formed the basis for the finding of joint action. This finding fits into the category of multiple actors (all negligent) combining to produce plaintiff's harm. The finding of joint tortfeasors fits into this category as well. The sufficiency of the individual actor is glossed over in *Bichler* by this application of the category. Other United States courts have rejected the concerted action

¹²⁹ *Supra*, footnote 126, at p. 533. Numerous *amici curiae* participated in this appeal. It provides a useful summary of the theories of liability and cases in this area. Three previous reported cases considered the applicability of market share liability to vaccines (at pp. 518-519). The Ninth Circuit Court rejected the application of market share liability to DPT vaccine, in *Senn v. Merrell-Dow*, 850 F. 2d 611 (9th Cir., 1988).

¹³⁰ *Ibid.*

¹³¹ *Ibid.*, at p. 528.

¹³² *Supra*, footnote 84.

theory in DES cases,¹³³ as has the New York Court of Appeals itself in its decision in *Hymowitz v. Eli Lilly & Co.*¹³⁴

Enterprise liability has also been used to solve the causation problem in DES cases.

F. Multiple Sufficient Non-Additive Causation

These are cases where each defendant acts negligently in such a way that each act *could* have caused the harm, but where in fact only one act did so. While the *Cook v. Lewis*,¹³⁵ and *Summers v. Tice*¹³⁶ situations are similar to the indeterminate defendants' problem posed by DES, they differ in significant respects, and were not applied in the *Sindell* case. In *Cook v. Lewis*, and its earlier American counterpart, both defendants were negligent but only one caused the harm. All of the approximately 300 manufacturers of DES caused harm to someone. Secondly, in *Cook v. Lewis*, and in *Summers v. Tice*, there were only two negligent actors while in *Sindell* there were many manufacturers. All of the potential defendants were joined in *Cook v. Lewis* but not in *Sindell*, where the tortfeasor who caused the plaintiff's harm might have been missing. In *Cook v. Lewis*, the probability of being wrong in imposing liability on both was only 50 per cent for each defendant while in *Sindell* it was more than 50 per cent for each of the defendants, Eli Lilly and five or six others in that market producing 90 per cent of the DES in that market. As Judith Jarvis Thomson¹³⁷ has suggested, the possibility of this unfairness causes us concern. The cause in fact problem was solved by reversing the onus of proof in *Cook v. Lewis*, and in *Summers v. Tice*, as it was in *Sindell*. The *Cook v. Lewis* situation can be characterized as multiple sufficient non-additive causation: multiple actors each engaged negligently in an act sufficient to produce the harm act independently and not in an additive way so that one act and not the other produces the harm.

G. Multiple Sufficient Additive Causation

In this type of case, where each negligent act was sufficient to create the harm, but where the acts combined to produce the harm, can each defendant be said to have caused the harm? Multiple sufficient additive causation is classically illustrated by the three-house fire. Two fires, each sufficient to cause the harm, combine to set a third house alight. While each can be said to have caused the harm in a factual sense, the but-for test of legal causation fails to attribute cause to either house. The

¹³³ Rymer, *loc. cit.*, footnote 82, at p. 3229, and cases cited.

¹³⁴ *Supra*, footnote 82.

¹³⁵ *Supra*, footnote 124.

¹³⁶ 199 P. 2d 1 (Calif., 1948).

¹³⁷ Judith Jarvis Thomson, in William Parent (ed.), *Rights, Restitution and Risk* (1986), pp. 192-224, esp. pp. 208 *et seq.*

"substantial factor" test of legal causation must be used instead. The case of *Basko v. Sterling Drug, Inc.*¹³⁸ illustrates this problem. Of the drugs used by the plaintiff two contained chloroquine. The plaintiff's vision deteriorated until she went blind, with a condition called chloroquine retinopathy. She took Aralen first, from 1953 to 1957, and then Triquin, from 1959 to 1961. When the drug was first developed and tested, no known or foreseeable risk of idiosyncratic retinal damage existed and there was therefore no duty to warn. If the assumption was made that no knowledge existed until 1959 (after she stopped taking Aralen) and blindness could have been caused by either drug, a three-house fire situation existed, the court said, and the jury should have been instructed on the substantial factor test of causation.¹³⁹ The plaintiff's blindness might have been created by either drug (each was sufficient), and the drug effect combined in an inseparable way, as in the three-house fire. Sorting the causes was important because the duty existed with respect to only one drug. A new trial was ordered. The court also noted that the assumption had been made that the blindness had been caused by one or more of the drugs and that this issue needed to be resolved at trial. In reaching its conclusion, the Second Circuit Court of Appeals cited Learned Hand J.:¹⁴⁰

... the single tortfeasor cannot be allowed to escape through the meshes of a logical net. He is a wrong-doer; let him unravel the casuistries resulting from his wrong.

H. *McGhee v. National Coal Board*¹⁴¹

While other possible combinations of multiplicity, negligence, sufficiency, addition and loss of chance exist, two others are important in this context. *McGhee v. National Coal Board* posed a combination of causation problems. *McGhee* was a multiple cause problem with a single defendant, where the harm was caused in fact by defendant's behaviour but where, because of a lack of scientific evidence, causation could not be attributed to the single cause (the creation of the risk by conditions in the brick kiln) or the additive cause (the brick kilns plus the omission to provide showers). Because of a lack of scientific knowledge about how dermatitis is caused (scientific causation), it was not possible for the court to determine whether this was a single cause situation involving particular causation (did the brick kiln dust cause the dermatitis for this plaintiff?), or whether it was a multiple insufficient additive causation situation in which the brick kiln dust and the shower omission were individually insufficient but additively sufficient to cause the dermatitis. The problem was further

¹³⁸ 416 F. 2d 417 (2nd Cir., 1969). See the discussion of this problem in Joseph H. King Jr., *Causation, Valuation and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences* (1981), 90 Yale L.J. 1353, at p. 1360.

¹³⁹ *Ibid.*, at p. 430.

¹⁴⁰ *Ibid.*, at p. 429, citing Learned Hand J. in *Navigazione Libera T.S.A. v. Newton Creek Towing Co.*, 98 F. 2d 694, at p. 697 (2nd Cir., 1938).

¹⁴¹ [1973] 1 W.L.R. 1, [1972] 3 All E.R. 1008 (H.L.).

complicated by the finding of the court that the brick kiln dust was non-negligently created, while the omission of showers was negligent. The duty to provide the showers, to effect a rescue, arose in the context of participation in the creation of the risk,¹⁴² through creating the conditions in the brick kiln. Therefore the act and the omission were related events. *McGhee* differs from many multiple cause problems in having only one defendant responsible for both acts and in having one independent event and one contingent event. The House of Lords imposed liability in this circumstance.

In *Snell v. Farrell*,¹⁴³ the Supreme Court of Canada considered *McGhee* in the context of a medical case. After a surgeon removed a cataract from a patient's eye, the optic nerve atrophied causing the patient to lose her sight. The expert witnesses could not say whether the operation caused the atrophy. The trial judge followed *McGhee v. National Coal Board*, and reversed the onus of proof. The New Brunswick Court of Appeal upheld the trial judgment. The Supreme Court of Canada dismissed the appeal, but found for the plaintiff on the basis of traditional torts principles, stating that the trial judge had ruled out the naturally occurring cause of the two possible causes and that it was open to him to draw an inference of causation between the defendant's performance of the operation and the harm to the plaintiff.

Sopinka J., writing the unanimous decision, distinguished proof of causation in science from proof of factual causation in law, stating that the legal standard should not attempt to meet the standard acceptable for scientific proof. He considered a more "flexible" use of the traditional tests of causation would solve the problem of difficult cases. In some instances, *Cook v. Lewis* for example, reversing the onus of proof would be acceptable. In other cases, the facts merely gave rise to an inference; in the absence of evidence by the defendant, the plaintiff would win. These were not reverse onus cases. He rejected the application of *McGhee* to this situation, preferring the but-for test or the contribution test of causation.

This judgment seems helpful, so far as it goes, in drawing the distinction between the standards for scientific proof and the legal standard of proof. Steve Gold has argued that:¹⁴⁴

... the use of statistical proof of causation has created confusion between the substantive burden of proof and the standard of persuasion which must be met to satisfy the burden ... The failure to distinguish between the two kinds of probability has led to the collapse of the factual burden and preponderance standard into a single test: does the factual probability of causation exceed 50%?

¹⁴² Ernest Weinrib, *The Case for a Duty to Rescue* (1980), 90 Yale L.J. 247.

¹⁴³ [1990] 2 S.C.R. 311, (1990), 72 D.L.R. (4th) 289.

¹⁴⁴ Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence* (1986), 96 Yale L.J. 376, at p. 378.

Gold has drawn the distinction between "fact probability" and "belief probability", arguing that:¹⁴⁵

The blurring of fact and belief probability conflates the two aspects which describe the plaintiff's task—the definition of the fact or element to be proven ("burden"), and the amount of credence which must be given to that fact in order to support a finding ("standard").

Probability has a "dual nature", measuring strength of belief and indicating quantity statistically.¹⁴⁶ Gold has argued that the collapsing of the two types of probability has had four consequences: (1) loss of meaningful proof standards; (2) invisible substantive changes; (3) fixation on single values; and (4) narrowness in evidentiary rulings. He has illustrated the invisible substantive changes in this way: "where a traditional court would have sought a >50% belief in a yes-or-no fact, a 'collapsing' court seeks a yes-or-no belief in a >50% fact probability".¹⁴⁷

With respect to "fixation on single values", he asserts that undue emphasis is placed on the probability of causation expressed in the epidemiological studies, which must exceed 50% for a "collapsing court" to find that causation is "more likely than not". The scientific evidence is often treated as inherently factual even when confidence intervals are recognized by the court. This point is important to remember when assessing Sopinka J.'s distinction between scientific proof and legal proof. Scientific studies themselves are subject to questions of reliability and validity.

Snell v. Farrell is less helpful in clarifying what *McGhee* now stands for, although Sopinka J. has suggested that confusion about the distinction noted above lay at the heart of Lord Wilberforce's judgment. What should we make of the judgments of Lords Reid, Simon and Salmon, who did not reverse the onus of proof but who equated materially increasing the risk with materially contributing to the harm? Arguably, Lord Wilberforce's judgment was less conceptually radical than the other majority judgments in *McGhee*, permitting the defendant the opportunity to exculpate himself, difficult as that might be on the facts, after cause was inferred. In contrast, the other judges took the step of equating the negligence and causation analyses.

Sopinka J. referred to the test of causation as the but-for test or contribution test, without the qualifiers "substantial" or "material", as the

¹⁴⁵ *Ibid.*, at p. 385.

¹⁴⁶ *Ibid.*, at p. 382.

¹⁴⁷ *Ibid.*, at p. 388. The House of Lords in *Hotson v. East Berkshire Area Health Authority*, [1987] A.C. 750, [1987] 2 All E.R. 809, would be characterized approvingly as a traditional court.

earlier Supreme Court case, *Myers v. Peel County Board of Education*,¹⁴⁸ had also done:¹⁴⁹

The issue, then, in this case is whether the trial judge drew an inference that the appellant's negligence caused or contributed to the respondent's injury, or whether, applying the above principles, he would or ought to have drawn such an inference.

Whether the word "substantial" is to be read in, or whether the standard is to be relaxed in that way too, remains to be seen. Did the court mean to confine the test to multiple cause situations like the three-house fire, or did Sopinka J. mean to use it as a relaxation of but-for in single cause cases? Flexibility is a powerful emotive word suggesting responsiveness and lack of rigidity. It will be a difficult and imprecise concept for trial judges to apply when facing complex causation problems. How would the *McGhee* problem be solved using a flexible approach? Assertion of the traditional approach to causation, with certain acceptable exceptions, is more likely to be the applied version.

Legitimate reverse onus cases like *Cook v. Lewis* and *Summers v. Tice* have been acknowledged, and have been distinguished from inference cases. Sopinka J. had already indicated that medical cases constituted a group where reverse onus might be available because of difficulties of proof. The court also appears to have approved, or at least not disapproved, of the reasoning in *Sindell*. The possibility of further reverse onus situations seems clear, although it is unclear whether it would extend beyond the "indeterminate defendants" problem.

In *Laferrière v. Lawson*,¹⁵⁰ Gonthier J. has provided a summary of causal principles, as follows:

- The rules of civil responsibility require proof of fault, causation and damage.
- Both acts and omissions may amount to fault and both may be analyzed similarly with regard to causation.
- Causation in law is not identical to scientific causation.
- Causation in law must be established on the balance of probabilities, taking into account all the evidence: factual, statistical and that which the judge is entitled to presume.

¹⁴⁸ [1981] 2 S.C.R. 21, (1981), 123 D.L.R. (3d) 1. In *Kersey v. Wellesley Hospital* (1988), 46 C.C.L.T. 271 (Ont. H.C.), Eberle J. cited the relevant passage from *Myers* and said, at p. 317: "Although the Supreme Court framed the test in terms of *contribution* to the injury, I regard it as implicit that the contribution must be *material*." (Emphasis in original). He went on to cite the use of the "material contribution" test in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, *supra*, footnote 1.

¹⁴⁹ *Supra*, footnote 143, at pp. 332 (S.C.R.), 302-303 (D.L.R.).

¹⁵⁰ *Laferrière v. Lawson* (1991), 78 D.L.R. (4th) 609 (S.C.C.), reversing in part (1988), 20 Q.A.C. 52, [1989] R.J.Q. 27, 49 C.C.L.T. 309 (Que. C.A.). Mme Fortier-Dupuis had breast surgery performed by Dr. Lawson in 1971. Although the biopsy showed that cancer was present, her doctor failed to tell her or to treat her. She had no symptoms until 1974. By the time she became aware of her malignancy she had sadly lost any chance of recovery. She died in 1978. Mme Laferrière, bringing action on behalf of the estate, was successful at the Quebec Court of Appeal in a 2:1 decision on a loss of a chance basis under Quebec civil law. In the Supreme Court of Canada, Gonthier J. for the six

- In some cases, where a fault presents a clear danger and where such a danger materializes, it may be reasonable to presume a causal link, unless there is a demonstration or indication to the contrary.
- Statistical evidence may be helpful as indicative but is not determinative. In particular, where statistical evidence does not indicate causation on the balance of probabilities, causation in law may nonetheless exist where evidence in the case supports such a finding.
- Even where statistical and factual evidence do not support a finding of causation on the balance of probabilities with respect to particular damage (e.g., death or sickness), such evidence may still justify a finding of causation with respect to lesser damage (e.g., slightly shorter life, greater pain).
- The evidence must be carefully analyzed to determine the exact nature of the fault or breach of duty and its consequences as well as the particular character of the damage which has been suffered, as experienced by the victim.
- If after consideration of these factors a judge is not satisfied that the fault has, on his or her assessment of the balance of probabilities, caused any real damage, then recovery should be denied.

In *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*,¹⁵¹ the Ontario Court of Appeal upheld the trial judge's conclusion on factual causation, after the defendant argued "that the stroke was caused, not by a combination of MVP and the coagulating effect of oral contraceptives on the blood, but by other causes (vessel wall disease, Depo Provera or MVP) or by unknown causes". Although there was evidence supporting the defendant's position, the Court of Appeal found that the trial judge's conclusion was "supported by substantial competent and convincing evidence".¹⁵² The trial judge had concluded that the oral contraceptive use "probably caused or, at the very least, materially contributed to her stroke".¹⁵³

In *Rothwell v. Raes*,¹⁵⁴ the trial judge held that the onus of proof had not been met and the Ontario Court of Appeal upheld his finding on factual causation.

I. Legal Causation

Legal causation in *Buchan* involved consideration of two issues: (1) What test was to be used to assess causation from the plaintiff's perspective? (2) What role did the doctor play? The Court of Appeal rejected the applicability to products' liability cases of the *Reibl* test. At

majority judges, with La Forest J. dissenting, accepted only the estate's claim for plaintiff's diminished quality of life and psychological harm when she learned that she had gone for four years without treatment, caused directly by the defendant, but disallowing the loss of a chance claim.

¹⁵¹ *Supra*, footnote 1, at pp. 664 (D.L.R.), 98 (O.R.). MVP is mitral valve prolapse, described by the court, at pp. 663 (D.L.R.), 97 (O.R.), as "a heart valve anomaly, fairly common in women, which can increase the possibility of stroke by slowing the circulation of the blood in the area of the mitral valve thus increasing the blood's tendency to clot".

¹⁵² *Ibid.*, at pp. 664 (D.L.R.), 98 (O.R.).

¹⁵³ Cited *ibid.*

¹⁵⁴ *Supra*, footnote 73, at pp. 250-251 (D.L.R.).

trial, Holland J. preferred an examination of the reasonable likelihood that a reasonable person in plaintiff's particular position, if fully informed, would not have taken the drug. The trial judge also used the *Reibl* test and the subjective test, finding causation using all three tests. The Court of Appeal rejected the trial judge's test as well as *Reibl*, using the subjective test instead.¹⁵⁵

So long as the Court is satisfied that the plaintiff herself would not have used the drug if properly informed of the risks, this causation issue should be concluded in her favour regardless of what other women might have done.

Robins J.A. went on to state that it was:¹⁵⁶

... sound in principle and in policy to adopt an approach which facilitates meaningful consumer choice and promotes marketplace honesty by encouraging full disclosure. This is preferable to invoking evidentiary burdens that serve to exonerate negligent manufacturers as well as manufacturers who would rather risk liability than provide information which might prejudicially affect their volume of sales.

In reaching the conclusion that the *Reibl* test should not be applied to products liability cases, the court focused on the manufacturer-consumer relationship, which differs from the doctor-patient relationship. As between the manufacturer and the patient, where the manufacturer has inadequately informed the doctor so as to influence the doctor's non-disclosure of a material risk and patient's taking of the drug, the manufacturer "is not entitled to require" proof of the *Reibl* test.¹⁵⁷

At this juncture, the case stands on no different footing than the usual products liability case in which there is no question of the intervention of an intermediary, and should be treated as such ... Whether the particular consumer would have taken the drug even with a proper warning is a matter to be decided by the trier of fact on all of the relevant evidence.

This passage suggests that once the indirect duty has been breached, the learned intermediary drops out of the causal sequence; the subjective test of causation is used. Where the warning to the learned intermediary is inadequate, the assessment of legal causation should not be the *Reibl* test, which is linked to the doctor-patient relationship, which has been undermined by the inadequate warning. Instead, the plaintiff should have to prove only the subjective test, what the plaintiff would have done. In the passage preceding this analysis, Robins J.A. had elaborated on the significant differences in the relationships. This contextual analysis illustrates the inappropriateness of the doctor-patient test of causation to the manufacturer-consumer relationship.

In *Rothwell v. Raes*,¹⁵⁸ Osler J. applied the *Reibl* test, the reasonable person in the shoes of the patient test, in order to assess causation for the doctors. If advised of the risk, the reasonable patient in the mother's

¹⁵⁵ *Supra*, footnote 1, at pp. 687 (D.L.R.), 121 (O.R.).

¹⁵⁶ *Ibid.*

¹⁵⁷ *Ibid.*, at pp. 686 (D.L.R.), 120 (O.R.).

¹⁵⁸ *Supra*, footnote 73.

shoes would have proceeded with the vaccination. He also concluded that if she had been informed of the risks, Patrick Rothwell's mother would not have refused the vaccination. On the basis of the subjective test, causation was not found.

The trial judge did not reach this part of the analysis for Connaught Laboratories in the *Rothwell* case. After assessing the adequacy of the warnings and concluding that Connaught had breached the duty to warn, he followed *Buchan* in stating that one cannot presume that the doctors would not have warned if they had been adequately informed. He stated:¹⁵⁹

Had a causal relationship been established therefore, I would have found Connaught Laboratories to have been negligent and judgment against them would have followed.

Because factual causation (both scientific and particular) was unproved, the trial judge did not reach the issue of proximate causation. Because he had already determined that the plaintiff's mother would have proceeded with the vaccination, the action would fail on legal causation as well.

In *Davidson v. Connaught Laboratories*,¹⁶⁰ the plaintiff's knowledge, acquired independently of the defendant doctors and the defendant vaccine manufacturer, meant that the plaintiff would not have acted differently if the defendants had given an adequate warning:

Everything that the plaintiff could possibly have wanted to know, was communicated to him in great detail by Dr. Kettyls and was understood by him. Despite this data given to him about side-effects, the plaintiff chose to run the risk. Consequently, the lack of information in the pamphlet was not a cause of this injury.

The but-for test for the subjective plaintiff could not be met.

The contact polio vaccine cases¹⁶¹ pose causation problems of this type. The Sabin oral polio vaccine, a live vaccine, carries with it the risk of causing polio to third persons who come into contact with the bodily fluids of the vaccinated person. If warned, a parent or other caregiver for an infant can take the precaution of having a vaccination, either with the Sabin oral polio vaccine or with the Salk killed vaccine, where available, prior to the child's vaccination. The Salk vaccine does not carry with it the risk of contact polio because it is a killed vaccine. The Sabin-type vaccine is considered more effective though, because it immunizes the inoculated person's intestinal tract, where the virus normally breeds, and

¹⁵⁹ *Ibid.*, at p. 342 (D.L.R.).

¹⁶⁰ *Supra*, footnote 11, at p. 277.

¹⁶¹ The United States oral polio vaccine cases include: *Givens v. Lederle Laboratories*, 556 F. 2d 1341 (5th Cir., 1977); *Reyes v. Wyeth Laboratories*, *supra*, footnote 33; *Davis v. Wyeth Laboratories*, *supra*, footnote 40; *Stahlheber v. America Cyanamid Co.*, 451 S.W. 2d 48 (Mo., 1970); *Williams v. Lederle Laboratories*, 591 F. Supp. 381 (S.D. Ohio, 1984); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P. 2d 1318 (1986); *Dunn v. Lederle Laboratories*, 121 Mich. App. 73, 328 N.W. 2d 576 (1982); *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985).

suppresses the wild virus.¹⁶² Fay F. Spence has argued that the factual causation issue has been proved in the contact polio cases more easily than it should have been, with juries finding causation where medical evidence of scientific causation has been inconclusive.¹⁶³ Proximate causation has been proved using the subjective plaintiff test.

In the vaccine cases, the factor of social benefit is added to the evaluation of risks and benefits. The personal benefit in obtaining a vaccination is great, weighing heavily in consideration of what a plaintiff would do, if adequately informed. The social benefit in having the population immunized, producing "herd immunity", has led governments to make it almost compulsory, required for entry to the school system. In *Lapierre v. Attorney-General of Quebec*,¹⁶⁴ the plaintiffs attempted to argue that this feature could give rise to a necessity argument which, in turn, should lead to the Quebec government paying compensation for the harm created when the risk of the measles-mumps-rubella vaccine arose for their child, causing encephalitis and a severely handicapped condition. This attempt to use necessity affirmatively, under the Quebec Civil Code, to create a claim was ultimately unsuccessful in the Supreme Court of Canada.

J. Intervening Causation

Intervening causation questions are raised by the oral polio vaccine cases as well as by the situation in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*¹⁶⁵ As discussed above, the Ontario Court of Appeal in *Buchan* found that Ortho Canada had promoted the drug's safety to such an extent that the doctor was not an independent cause. Underlying this analysis was the Court of Appeal's awareness of the reliance of doctors on the pharmaceutical industry. In such circumstances, the doctor does not act independently in a manner analogous to *Donoghue v. Stevenson*'s¹⁶⁶ intermediate inspector, breaking the causal sequence, but as a dependent, effectively dropping out of the causal chain.

The role of the doctor in the causal chain was an important element in *Buchan*, *Davidson v. Connaught Laboratories*¹⁶⁷ and other drug/vaccine cases. In *Davidson*, Linden J. found that the case against Connaught Laboratories failed on another causal ground. He found the company's warnings inadequate and stated that the drug companies "cannot rely upon doctors to read all the scientific literature outlining the specific dangers

¹⁶² Fay F. Spence, *Alternatives to Manufacturer Liability for Injuries Caused by the Sabin-Type Oral Polio Vaccines* (1987), 28 William & Mary Law Rev. 711, at p. 713.

¹⁶³ *Ibid.*, at pp. 731-732.

¹⁶⁴ [1985] 1 S.C.R. 241, (1985), 16 D.L.R. (4th) 554.

¹⁶⁵ *Supra*, footnote 1.

¹⁶⁶ *Supra*, footnote 2.

¹⁶⁷ *Supra*, footnote 11.

involved in the many drugs they have to administer each day. . . . They rely on the drug companies to supply them with the necessary data".¹⁶⁸ The doctor then makes the individual decision about what treatment to advise for the patient, based on the information and the patient's best interest. However, in this case there was no evidence that full information would have made any difference to the two defendant doctors. It was not their practice to discuss neurological side-effects with their patients because they were concerned that the patients might refuse the treatment.¹⁶⁹ In other words, the plaintiff had failed to prove that adequate disclosure would have led the learned intermediaries to disclose the information. Although not discussed in these terms, it seems that the independent judgment of the defendant doctors intervened in the chain of causation between the manufacturer and the consumer, causing the plaintiff's action to fail on this basis. In addition, the trial judge found that this determination was "within their range of permissible professional judgment",¹⁷⁰ although he drew no conclusion from this finding. As noted above, Linden J. had concluded, applying *Hopp v. Lepp*,¹⁷¹ that the risk did not have to be disclosed because it was not "probable" and though "unusual" was rare. *Reibl* clarified the duty to disclose risks with a low probability but grave consequences. The causation issue for the doctors was determined by plaintiff's independently acquired knowledge of the risk, as discussed above.

In *Buchan*,¹⁷² Robins J.A. acknowledged that the conduct of a doctor might exempt a manufacturer from liability:

... I do not take issue with the submission that the conduct of a prescribing doctor may exonerate the manufacturer from liability where the evidence establishes that, as a result of what the doctor knew, adequate warnings would have had no effect on whether or not he would have prescribed the drug.

The Court of Appeal found that this was not the situation in *Buchan*. Ortho had argued that the doctor had independent knowledge of the risk of stroke because of the Rx bulletin which the Minister of Health had directed to be sent in 1970 to each physician. This 44-page report prepared by a special advisory committee to the Food and Drug Directorate contained essentially the information made available in the United States.¹⁷³

On the issue of duty, the court stated that the Rx bulletin did not affect the duty to warn which was non-delegable, and was continuous in spite of the availability of information elsewhere. The comments of Linden J. about the relationships, quoted in part above, were agreed with.

¹⁶⁸ *Ibid.*, at p. 276.

¹⁶⁹ *Ibid.*, at pp. 276-277.

¹⁷⁰ *Ibid.*, at p. 277.

¹⁷¹ *Supra*, footnote 13.

¹⁷² *Supra*, footnote 1, at pp. 681-682 (D.L.R.), 116 (O.R.).

¹⁷³ *Ibid.*, at pp. 671, 679-680 (D.L.R.), 106, 113-114 (O.R.).

On the issue of causation, the court stated that the inadequacy of the warning, combined with the promotional sales tactics over time, contributed to the doctor's opinion about safety, as well as to the view that it was not necessary to inform the patients. In essence, the court found that Ortho's activities lulled the doctor into a sense of security about the drug. Therefore, the doctor's failure to warn could not exonerate Ortho from liability for its breach of the duty to warn.

Even if the pharmaceutical companies may not rely on the physicians to conduct independent research and insulate the manufacturer from liability, such independently acquired information must create an intervening actor at some stage. For instance, in *Davidson v. Connaught Laboratories Ltd.*,¹⁷⁴ Dr. Kettys' independently acquired information did not alter the company's duty, but did lead to a finding of no causation since it had been conveyed to the plaintiff. Consider the situation where the doctor is aware of the risks because of the doctor's own reading and research in reputable medical journals, but has been given inadequate risk information by the negligent pharmaceutical company. Does the doctor's failure to disclose information to the patient act as a break in the causal chain? If only the manufacturer is sued, is the company liable in these circumstances? Liability may be imposed to the extent that the doctor is dependent on or lulled by the promotion of the company. Similarly, the heavier the barrage of promotional materials the more foreseeable is the doctor's failure to disclose. In most cases the volume of marketing would swamp the trickle of risk information.

Robins J.A. considered foreseeability in a different context and stated that it was not foreseeable that the doctor would be negligent. Instead, it should be presumed that the doctor would disclose if adequately warned; this issue should not be a matter for the patient to prove in order to reach the subjective test of causation. In a key passage in this section of the judgment, Robins J.A. spoke of a presumption arising on proof of the breach of the duty to warn—a presumption that the inadequate warning was a contributing cause of the ingestion of drug. He went on to state that the presumption would arise that the doctor would disclose the risk, acting non-negligently; the plaintiff should not be required to prove this element. The defendant could rebut this presumption through evidence that a warning would have made no difference to the doctor's conduct.¹⁷⁵ This presumption is a significant protection for plaintiffs.

In light of *Snell v. Farrell*,¹⁷⁶ we might want to think of these comments as a matter of inference rather than as a shifting of the onus of proof to the defendant. The passage is saying that the plaintiff need not prove that the doctor would act non-negligently, if properly informed. Given

¹⁷⁴ *Supra*, footnote 11.

¹⁷⁵ *Supra*, footnote 1, at pp. 682 (D.L.R.), 116 (O.R.). He cited three United States cases, including *Reyes*, but not *Davidson v. Connaught Laboratories*.

¹⁷⁶ *Supra*, footnote 143.

the context of the remarks, it seems unlikely that the court intended to do more than establish this point about intervening causation, and did not mean to reach a *McGhee*-like conclusion, equating material contribution to the risk with materially increasing the risk. Furthermore, Robins J.A. was not considering foreseeability in the situation where both the company and the doctor are sued and where intervening causation is an issue. It is possible to imagine a court concluding that physician failure to disclose is foreseeable.¹⁷⁷

The presumption was applied in *Rothwell v. Raes*,¹⁷⁸ in a situation where both the company and the doctors were sued. The trial judge found that it was not customary to inform parents of the risk of brain damage and that it was not a material risk in 1979. Even so, Osler J. followed *Buchan* in presuming that the physician would have warned of the risk if the pharmaceutical company had warned physicians adequately. On the evidence, he concluded that the presumption was not overcome.

The Ontario Government has imposed on doctors a statutory reporting obligation for "reportable events" after vaccination.¹⁷⁹ The creation of a statutory duty to disclose "the benefits and material risks" to the patient or substitute decision-maker, and to report the presence of a reportable event possibly linked to the vaccination to the Medical Officer of Health in these circumstances, may heighten the doctor's role as an independent actor in the administration of vaccines. From the patient's point of view, it seems likely to increase the available information and enhance the ability of parents, doctors and governments to monitor adverse effects.

Conclusion

The learned intermediary rule, adopted by the Ontario Court of Appeal, imposes an indirect duty on pharmaceutical companies, even for oral contraceptive prescriptions. As a result, once the company has been found to have breached its duty of disclosure the patient can lose on the issue of causation if (1) the doctor already knows of the risks and/or (2) the doctor would not tell the patient of the risks. The presumption set out in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*,¹⁸⁰ that the doctor would behave non-negligently in disclosing the risks, improves the plaintiff's prospects considerably, but still leaves room for proof of the physician's situational or habitual non-disclosure. As a result, a plaintiff may lose an action against a drug company because the patient's doctor makes a practice of not disclosing risks. While the possibility of suing the non-disclosing

¹⁷⁷ *Price v. Milawski* (1977), 82 D.L.R. (3d) 130, 18 O.R. (2d) 113 (Ont. C.A.); *Dunn v. Lederle Laboratories*, 121 Mich. App. 73, 328 N.W. 2d 576 (1982).

¹⁷⁸ *Supra*, footnote 73, at p. 339 (D.L.R.).

¹⁷⁹ Section 37a of the Health Protection and Promotion Act, S.O. 1983, as amended S.O. 1987, c. 18, s. 2, and S.O. 1987, c. 18, s. 2.

¹⁸⁰ *Supra*, footnote 1.

doctor remains open to the plaintiff, the non-disclosing pharmaceutical company is free of liability because of the non-disclosure practices of the doctor. The possibility of harm-avoidance has been minimized and whatever deterrent effect tort law has is lost. The patient is denied compensation from the company that created the harm. While the possibility of compensation from the doctor remains, the plaintiff will only be successful if the materiality of the risk can be demonstrated, seemingly according to the higher standard of informed consent rather than according to the very low probabilities in the drug/vaccine products liability cases, and if causation can be demonstrated under the *Reibl v. Hughes*¹⁸¹ contextual reasonable person standard.

The plaintiff may also lose the action against the company if the doctor possessed independently acquired knowledge of the drug/vaccine risks, but this situation is more ambiguous. The promotional efforts of the company, the degree of reliance by the doctor on the company, and the nature of the independent source of information are all factors to be taken into account in assessing the impact of the company's non-disclosure on the doctor's behaviour. For instance, Ortho's barrage of promotional activities clearly overshadowed the lengthy warnings in the Rx bulletin. In the earlier case of *Davidson v. Connaught Laboratories*,¹⁸² one physician's independent expertise effectively insulated Connaught from liability.

In contrast, where a pharmaceutical company has a direct duty to warn, the likelihood of recovery from the company is improved. In an action against the company, where the company has failed to disclose the risk and the doctor, also knowing, has failed to disclose, the patient wins, instead of losing, on the basis of physician non-disclosure. In addition, direct transmission of information significantly improves access to information, unmediated by the medical profession, and heightens patient control of decision-making. The direct duty increases the sources of information available to patient consumers. The physician's duty to disclose treatment information still operates in this situation. Whether a court would be satisfied that a physician's reliance on drug company sources, as a customary practice of the profession, would be sufficient to meet the standard of care, or whether the physician might be required to seek out independent information, is a matter of speculation at this stage.

The causation test for the behaviour of the plaintiff is more stringent in the informed consent action against the doctor than in the products liability action against the pharmaceutical company. If the patient sues the doctor, the "reasonable patient in the shoes of the patient" test is used to assess the causal link between the physician's non-disclosure and the harm that occurred. If the patient sues the pharmaceutical company, the subjective patient test is used to assess the causal link between the company's

¹⁸¹ *Supra*, footnote 14.

¹⁸² *Supra*, footnote 11.

non-disclosure and the harm. The patient who would have made an unreasonable choice, in full exercise of her or his autonomy, could win against the non-disclosing pharmaceutical company but lose against the non-disclosing physician. The products liability action provides better protection for the autonomy of the patient than the informed consent action.

Perhaps this irony, as well as the undermining effect the reasonable patient test has on doctor-patient disclosure, will lead to judicial adoption of the subjective patient test in informed consent cases. In itself, the acceptance of the subjective patient test in *Buchan* is a significant recognition of patient autonomy in the drug situation.

The imbalance in the power relationship is only partially remedied by the requirements of tort law. In many ways dependency is increased because there is a single source for information and the system is relatively closed. Mandatory direct warnings to consumers through patient package inserts would provide greater consumer control of information, as well as a basis for asking questions of doctors.

The adequacy of the adverse effects information itself and both its compilation and diffusion are questionable. The adequacy of the warning is contingent on such factors as the reporting of adverse effects, company testing practices, and the promotional techniques of the pharmaceutical industry. These problems, seen in the context of the hierarchical relationship between company and doctor and patient, need to continue to be factored into the assessment of the standard of care. Full information on innovative treatment needs to be given to prospective patients. Consumers need to become better aware of the need for risk information, more sceptical of drugs and vaccines, and less trusting of organizations, pharmaceutical companies, in particular, that cannot be assumed to be acting in the public interest.

Causation in drug/vaccine cases is complex, providing instances of many causation dilemmas, sometimes in combination. Legal causation is easier to prove in the manufacturer's duty to warn action than in a doctor's duty to disclose action, making compensation for harm more readily accessible. Many factual causation problems arise in this area, making manufacturers' liability difficult to impose, but not impossible. Causation analysis needs to be carried out with creativity, bearing in mind the power dynamics, in order to serve the underlying purposes of harm prevention and patient control of decision-making.