

Subjective Tests and Implied Warranties: Prescriptions for *Hollis* v. *Dow Corning* and *ter Neutzen* v. *Korn*

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I. INTRODUCTION

Medical products have a therapeutic potential that can substantially improve the quality of life. Nevertheless, technological progress in the field of medicine is consistently met with guarded optimism. The benefits to be gained are often accompanied by unexpected risks. If injury occurs within the confines of ordinary commercial transactions, then a remedy might be swift and familiar. However, when medical products are distributed by medical professionals themselves, the legal relations prescribed by the Canadian authorities are altered to the patient's detriment. The general protection afforded to consumers may shift to shield from liability not only medical professionals, but may also inadvertently allow the manufacturer to avoid responsibility. The result is that the injured party may incur inordinate expense to initiate an action that may never yield compensation.

This paper will examine the complex nature of the legal instruments commonly used to secure compensation for victims of dangerous medical products administered by doctors. The recent Supreme Court of Canada decisions in *Hollis v. Dow Corning*¹ and *ter Neutzen v. Korn*² will be used to illustrate the ambiguities and inconsistencies that plague this area of jurisprudence. The discussion will focus on two instruments that are frequently engaged in actions involving dangerous medical products: the duty to warn and the implied warranty of fitness for purpose.

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Hollis v. Dow Corning Corp., [1995] 4 S.C.R. 634 [hereinafter Hollis].

ter Neutzen v. Korn, [1995] 3 S.C.R. 674 [hereinafter ter Neutzen].

II. THE DUTY TO WARN

A. THE NATURE OF THE DUTY

A manufacturer's duty to warn is the primary issue addressed by the Supreme Court in *Hollis*. The plaintiff was a young woman who sought medical treatment to ameliorate a congenital breast deformity. The physician, Dr. Birch, suggested that silicone breast implants would remedy her condition. One of the breast implants ruptured subsequent to the operation. Ultimately, the damage caused by the rupture forced the plaintiff to undergo a double mastectomy.³

In his judgment delivered for the majority, Justice La Forest held that the manufacturer of the implants, Dow Corning, breached its duty to warn Ms. Hollis of the risks inherent in the use of the product.⁴ Justice La Forest further held that, although Dow could have discharged its duty to Ms. Hollis if it had communicated its knowledge of the risks to the attending physician, it could not avoid liability by arguing that, even if the doctor had been warned, he would not have related that information to the plaintiff.⁵

The Supreme Court judgment reaffirmed a manufacturer's duty to warn consumers of dangers that are inherent in the use of a product.⁶ The court justified this position by stating that "the duty to warn serves to correct the knowledge imbalance between manufacturers and consumers...."⁷ The manufacturer is clearly in the best position to research the attributes of the product it sells. If there are any problems or dangers associated with the use of the product, that knowledge will filter back to the manufacturer in the form of consumer complaints.⁸ It follows that the manufacturer should be held responsible for warning consumers of inherent dangers that exist at the time of sale or become manifest at a later date.⁹ This duty to warn encourages the dissemination of product information by imposing responsibility on the party in the best position to acquire and distribute knowledge that can prevent the occurrence of harm.

The corollary of the duty to warn is the individual's right to make informed choices and to avoid harm.¹⁰ This right should be protected by

Hollis, supra note 1 at 644-48 (facts taken from the judgment of La Forest J.).

⁴ *Ibid.* at 686.

³ Ibid. at 685: "Simply put, I do not think a manufacturer should be able to escape liability for failing to give a warning it was under a duty to give, by simply presenting evidence tending to establish that even if the doctor had been given the warning, he or she would not have passed it on to the patient, let alone putting an onus on the plaintiff to do so."

⁶ *Ibid.* at 652.

⁷ *Ibid.* at 653.

^o Hollis v. Birch, [1993] 81 B.C.L.R. 1 at 20-21 (B.C.C.A.) [hereinafter Hollis (B.C.C.A.)].

Rivtow Marine Ltd. v. Washington Iron Works, [1974] S.C.R. 1189 at 1200.

P. Peppin, "Feminism, Law, and the Pharmaceutical Industry" in F. Pearce and L. Snider, eds., Corporate Crime: Contemporary Debates, (Toronto: University of Toronto Press Inc., 1995) 87 at 91.

principles of tort law. The freedom of the individual to make choices of personal preference can be impaired when knowledge is withheld from the market.

Information is central to the increasing of consumer's autonomy. Unless consumers are warned of product risks, they are unable to assess the detriments and benefits.... The ability to protect one's bodily integrity is contingent on adequate information.¹¹

If consumers are denied access to information that can prevent a loss from occurring, they are vulnerable to misrepresentations that are characteristic of a free market economy.¹² Whether such misrepresentations are characterized as negligent or intentional, their ultimate consequence deprives consumers of knowledge that may have an immediate impact on their lives.

The need for protection becomes even more pronounced in cases involving medical products. The Supreme Court of Canada recognized the intimacy of the relationship between consumer and product in *Hollis* and raised the standard of care accordingly:

In the case of medical products such as the breast implants...the standard of care to be met by manufacturers...is necessarily high. Medical products are often designed for bodily ingestion or implantation, and the risks created by their improper use are obviously substantial.¹³

The court appropriately drew an analogy between the duty to warn and what is commonly referred to as the doctrine of "informed consent" in Canadian tort law.¹⁴ Justice La Forest recognized that the principles underlying both doctrines are almost identical.¹⁵

¹¹ Ibid.

¹² Buchan v. Ortho Pharmaceutical (Canada) Ltd. (1986), 25 D.L.R. (4th) 658 at 686 (Ont. C.A.) [hereinafter Buchan]. "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 underemphasizing risks."

¹³ Hollis, supra note 1 at 654-55.

¹⁴ Ibid. at 655. Note: The duty to warn and the doctrine of informed consent, as referred to by Justice La Forest, are the same concept. See *Reibl* v. *Hughes* (1980), 114 D.L.R. (3d) 1 at 8-9 (S.C.C.) [hereinafter *Reibfl*.

¹⁵ Hollis, ibid. at 656.

The high standard of care articulated by the Supreme Court in *Hollis* is illustrative of the "Learned Hand Formula",¹⁶ a moral cost-benefit equation that has become a popular tool for the assessment of unreasonable risk in tort. The serious risks attendant on dangerous medical (as opposed to purely commercial) products dictate that the manufacturer must take greater care in communicating medical (as opposed to non-medical) risks to consumers.¹⁷ A vague or general warning will not discharge the duty where there is a specific risk with serious consequences.¹⁸

If the Learned Hand Formula were strictly adhered to in the context of medical products, it would be difficult to conceive of situations in which the duty could be discharged. The intimate physical relationship between the product and the consumer harbours a hazardous potential that differs in both nature and degree from ordinary commercial transactions. It would be appropriate for tort law to provide at least as much protection to consumers in the hospital as it does in the hardware store or restaurant. Nevertheless, Canadian courts recognize the advantages of technological progress and medical research. Social utility is injected into the analysis:

In the present state of human knowledge, many drugs are incapable of being made totally safe for their intended or ordinary use, even though they have been properly manufactured and are not impure or defective. Notwithstanding a medically recognizable risk, their marketing may be justified by their utility.¹⁹

The essence of this proposition is that, if a medical product proves beneficial to the majority of users and harmful to only a few, then the court should sanction technological progress by allowing manufacturers to pass the risk of injury onto the consumer.

B. RISK UNCERTAINTY

Although it adopts this methodology, the court retained the discretion to delineate the scope of the duty, which was defined by ambiguous parameters.

¹⁶ United States v. Carroll Towing Co., 159 F.2d 169 at 173 (2d Cir. 1947). "[T]he...duty, as in other similar situations, to provide against resulting injuries is a function of three variables: (1) The probability [of injury]; (2) the gravity of the resulting injury...; (3) the burden of adequate precautions.... [1]f the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P : *i.e.*, whether B<PL."</p>

¹⁷ Buchan, supra note 12 at 667.

¹⁸ Lambert v. Lastoplex Chemicals Co., [1972] S.C.R. 569 at 575 [hereinafter Lambert].

¹⁹ Buchan, supra note 12 at 668-69.

General warnings are insufficient; they must be precise²⁰ and "commensurate with the gravity of the potential hazard."²¹ The state of knowledge of the manufacturer is a crucial factor that the court can manipulate to find a breach of the duty. The scope of the duty is, in effect, often determined by knowledge attributed to the manufacturer post facto. In Hollis, the Supreme Court insisted that the manufacturer should not be held to a standard of knowledge obtained subsequent to the occurrence of the tortious breach,²² but held that Dow had access to the same information in 1983 as it had in 1985²³ even though the reports were of "unexplained ruptures".²⁴ This reasoning invites conjecture as to what type of warning would have absolved Dow of liability under the circumstances. A general warning to the medical community that unexplained ruptures were occurring in .001% of the procedures²⁵ would bring the state of knowledge between the parties to equilibrium²⁶ (assuming that knowledge is communicated to the consumer) yet it would not have offered any meaningful assumption of risk.²⁷ If the product is marketed before all quantifiable effects are known, then the evidence intended to establish a breach of the duty to warn could be confusing. Hence, as long as the *theoretical* ability to justify the distribution of dangerous medical products remains as a practical feature of the tort action, there exists an uncertainty that results in costly litigation and deprives the plaintiff of compensation for the duration of the court battle.²⁸ Although this potential is minute (arguably non-existent), it remains a burden on the plaintiff that makes the tort action inefficient. The corporate defendant would be well advised to contest claims like Hollis because it can absorb litigation costs.

C. LEARNED INTERMEDIARIES AND CAUSAL PREJUDICE

This strategy is made even more attractive by the "learned intermediary" defence, which allows manufacturers to discharge their ultimate duty to the consumer by providing an adequate warning to an interposing physician.²⁹

²⁶ *Ibid.* at 660.

²⁰ *Lambert, supra* note 18 at 575.

Buchan, supra note 12 at 667.

Hollis, supra note 1 at 666.

²³ *Ibid.* at 667.

²⁴ *Ibid.* 25

²⁵ *Ibid.* at 670.

K. Cooper-Stephenson, "Economic Analysis, Substantive Equality and Tort Law" in K. Cooper-Stephenson and E. Gibson, eds., *Tort Theory* (North York: Captus Press Inc., 1993) 131 at 144.
Stephenson and E. Gibson, eds., *Control Theory* (North York: Captus Press Inc., 1993) 131 at 144.

S.M. Wexler, "Hollis v. Dow Corning and Buchan v. Ortho Pharmaceuticals" (1994) 22 Man. L.J.
426 at 427.
426 at 427.

²⁹ Hollis, supra note 1 at 660.

The rationale of the defence is that the duty to warn should be distributed throughout "the tripartite informational relationship between drug manufacturers, physicians and patients...."³⁰ The importance of information in the medical context demands the participation of professionals who can assess the physical idiosyncracies of the specific consumer involved. Ideally, product knowledge possessed by the manufacturer will be passed on to the medical community, which can correlate the risks to consumers.

Although the Supreme Court found the facts in *Hollis* receptive to the concept of learned intermediaries, it held that Dow's warning to Dr. Birch did not eliminate the knowledge gap between manufacturer and physician. It is on this basis that Dow was held liable. However, in order to evaluate the full potential of the learned intermediary defence, one must analyze the influential Supreme Court decision *Reibl* v. *Hughes*,³¹ because it delineates the test for causation that is used when the defendant is a doctor. Should a manufacturer adequately communicate knowledge to a physician, the test for causation will shift and offer less protection to the victim.

D. REIBL v. HUGHES: A MISSING LINK

In *Reibl*, a doctor performed a surgery to remove an occlusion from an artery in the plaintiff's neck. Although the operation was not performed negligently, the plaintiff suffered a massive stroke subsequent to the operation that left the right side of his body paralyzed. The plaintiff brought action claiming that the doctor did not discharge his duty to disclose all relevant risks to the plaintiff before he consented to the procedure.³²

In his judgment for the court, Chief Justice Laskin repeated a refrain that is uniform throughout the jurisprudence canvassed so far: "What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment."³³

Throughout his judgment, Chief Justice Laskin referred to the patient in a specific³⁴ (not a general) sense, yet he adopted an objective test for causation.³⁵ In other words, the doctor would be held liable only if the plaintiff could prove that a reasonable person would have refused the treatment if informed of the material risks. The personal right is watered

³⁰ *Ibid.* at 659.

³¹ *Reibl, supra* note 14.

³² *Ibid.* at 4.

³³ *Ibid.* at 13.

Ibid. at 12. "What the doctor knows or should know that the *particular patient* deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge." [emphasis added].
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³⁵ *Ibid.* at 16.

down by this objective standard. The justification for the objective test is the concern that a subjective test for causation would "put a premium on hindsight."³⁶

The judgment in *Reibl* adopted an approach that betrays the underlying principles of the duty to inform. The content of the individual right of physical autonomy cannot be adequately represented by an objective standard:

In a medical negligence case where the issue is as to the advice and information given to the patient as to the treatment proposed, the available options and the risk, the court is concerned primarily with a patient's right. The doctor's duty arises from his patient's rights.³⁷

The factors that a reasonable person finds material may differ entirely from what the particular patient values. Inevitably, the objective test will exclude those personal values that, although important to the victim, would not be characteristic of the reasonable person.³⁸

E. CRITIQUE

The most paralyzing feature of the objective test for causation is that it presumes, in many instances, that victims would have trusted their doctors' advice.³⁹ The plaintiff must prove causation by calling other doctors as witnesses, a task that is expensive and difficult considering that most doctors share the same perspective of the doctor-patient relationship.⁴⁰ Doctor witnesses will "reasonably" defer to the judgment of their defendant colleague because they share the same experience. Dow attempted to exploit this reality in *Hollis* by asserting that, even if Dr. Birch had warned Ms. Hollis of the risks involved, she still would have consented to the procedure and use of the implants.⁴¹

Although Justice La Forest rejected the objective test in products liability cases,⁴² he reaffirms the use of that same test in cases where the defendant

³⁶ Ibid.

³⁷ Sidaway v. Bethlem Royal Hospital Governors, [1985] 1 All E.R. 643 at 654 (H.L.).

See, for example, Videto v. Kennedy (1981), 17 C.C.L.T. 307 at 317 (Ont. C.A.) where the plaintiff was Catholic.
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G. Robertson, "Informed Consent Ten Years Later: The Impact of *Reibl v. Hughes*" (1991) 70
Can. Bar Rev. 423 at 435.
The Informed Consent Ten Years Later: The Impact of *Reibl v. Hughes*" (1991) 70

E. Picard, Legal Liability of Doctors and Hospitals in Canada, 2d ed. (Toronto: Carswell, 1984)
270-73.
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Hollis, supra note 1 at 675.

⁴² Ibid. at 674. Justice La Forest adopts the Buchan test for causation where the defendant is a manufacturer. "In my view, the rationale given by Robins J.A. [in Buchan] for a subjective test is compelling and justifies the adoption of the subjective test in cases of this nature."

involved happens to be a doctor.⁴³ When this reasoning is combined with the existence of the learned intermediary rule, it creates the potential for anomalous results. The existence of an identical amount of information could engage or exclude liability, depending upon the party possessing it. Had Dow given all the relevant information to Dr. Birch, Ms. Hollis' action may have failed because it would have been easier to convince the trier of fact that a reasonable person would defer to the judgment of a doctor. This possibility could be rationalized if the victim actively assumed the risk, but in reality we have only altered one variable: the character of the defendant. Justice Sopinka recognized this potential in his dissenting judgment:

I see no reason why the test for determining the same issue should be different for the physician and the manufacturer. With respect to both, the question for the plaintiff is the same.... [T]his could conceivably result in a finding that, vis-à-vis the physician, the patient would have consented, and vis-à-vis the manufacturer, she would not.⁴⁴

Justice Sopinka would remedy this discrepancy by adopting the *Reibl* objective test in the manufacturer-consumer relationship.⁴⁵ However, the nature of the right involved makes the subjective test more appropriate. If the purpose of the duty is to allow the patient to make informed choices, then it would be inappropriate to apply a standard based on what other people may consider to be material risks. This is especially important where the procedure involved is elective.⁴⁶ The *plaintiff* is the most qualified person to articulate her own preferences with respect to her own body.⁴⁷

The use of the objective test in the doctor-patient relationship is traditionally justified on the basis that the plaintiff's testimony would be tainted by hindsight.⁴⁸ This argument would be more convincing if the

⁴³ *Ibid.* at 675.

⁴⁴ *Ibid.* at 690.

⁴⁵ Ibid.

⁴⁶ Hankins v. Papillon (1980), 14 C.C.L.T. 198 at 203 (C.S. Que.).

⁴⁷ There have been recent Canadian cases that suggest a willingness to reexamine the subjective test in a doctor-patient relationship. See *Drolet v. Parenteau* (1994), 61 Q.A.C. 1 at 28 (Que. C.A.), Baudoin J.A. "[I]I faut alors appliquer un test qui, à mon avis, est essentiellement un test subjectif et consiste à évaluer si la patiente, dans les circonstances particulières, aurait accepté l'intervention quand même, si elle avait été convenablement informée.... [S]ouvent les tribuneaux se posent aussi la question de savoir ce qu'une personne normalement prudente et diligente aurait décidé en l'espèce, test dit "objectif" mais qui, à mon avis, s'attache essentiellement à la crédibilité [du] témoignage [de la patiente]. Ce test objectif ne se substitue donc pas au test subjectif. Il ne fait que le compléter."

⁴⁸ Reibl, supra note 14 at 16.

Supreme Court of Canada employed a consistent approach on this issue. The nature of the testimony does not change when the defendant is a doctor (as opposed to a manufacturer), yet Justice La Forest clings to an artificial distinction:

Although the concern raised by Laskin C.J. [in *Reibl*] is valid and should continue in the doctor-patient relationship, in a suit against a manufacturer for failure to warn this concern can be adequately addressed at the trial level through cross-examination and through a proper weighing by the trial judge of the relevant testimony.⁴⁹

The nature of the testimony remains static, yet the test varies depending upon the character of the defendant. The trial judge is competent to weigh the plaintiff's testimony in actions against a manufacturer, but the objective test for causation precludes this discretion in actions where a doctor is the defendant.

The true motivation behind the distinction is an anachronistic allegiance to a paternalistic interpretation of the doctor-patient relationship. The judgments in Reibl and Hollis protect the professional autonomy of the medical professional at the expense of the patient's right to be informed. There is a tendency to lend a therapeutic privilege to doctors because it is presumed that the majority of patients will act irrationally or contrary to their own health interest. The plaintiff's testimony is openly suspect after the injury, but the ability of the individual to act rationally is questioned even before the patient receives the treatment. The courts habitually defer to the opinions of medical professionals because they assume that patients cannot identify what is in their best interest. This judicial reflex is the antithesis of personal autonomy and informed choice because it presumes that doctors make the best choices for patients and are competent to weigh the relevant risks against the potential benefits of the procedure. The personal preferences of the patient, whatever they may be, are subordinate to medical opinion when they should be paramount.

The distinction drawn between defendants who are manufacturers and those who are doctors is illustrative of judicial deference to medical professionals. In *Hollis*, Justice La Forest recognized a distinction between cases involving products liability and cases involving medical treatment,⁵⁰ yet he treated the

⁴⁹ Hollis, supra note 1 at 675.

⁵⁰ *Ibid.* at 672-75.

scenarios as mutually exclusive.⁵¹ The person injured by the product is a "consumer" when discussing the liability of the manufacturer,⁵² but is referred to as a "patient" when the duty of the doctor is involved.⁵³ This characterization of the doctor-patient relationship obscures the role that doctors play in distributing medical products in the market. More importantly, it subordinates the rights of the plaintiff when the analysis shifts from the market to the doctor's office. The connotation of the words used to designate the plaintiff has a profound impact on how the court will prioritize the interests of the parties involved.

The internal inconsistencies and vague application of principles in duty to warn actions make the tort a cumbersome tool for obtaining compensation for people injured by medical products. The application of the objective test for causation could have disastrous results where the manufacturer has become insolvent or cannot be identified. In these situations, the plaintiff is restricted to an action initiated against the attending physician.⁵⁴ The complexity of the objective test espoused by Canadian courts in these circumstances has proved fatal to the majority of claims brought against physicians.⁵⁵

Adopting a consistent subjective test for causation in duty to warn actions would reconcile the mechanics of the tort with the underlying principles of physical autonomy and informed choice. The anomaly created by the learned intermediary defence would dissolve. Where the manufacturer does provide the physician with adequate information, the plaintiff would not be vulnerable to the prejudice of the objective test.⁵⁶ This would clarify the onus imposed on the plaintiff and would allow for a simpler resolution of disputes similar to *Hollis*.

The subjective standard for causation in the medical context should approximate the consent necessary to invoke the defence of *volenti non fit injuria* or voluntary assumption of risk. Oddly enough, it was Justice Laskin (as he then was) who proposed such a standard in the commercial context:

I do not think that the duty resting on the respondent [manufacturer] in this case can be excluded as against the male

56 Ibid.

⁵¹ Ibid.

⁵² *Ibid.* at 654-55.

⁵³ *Ibid.* at 655.

⁵⁴ The plaintiff may also attempt to extend the principles of market share liability, but this action would also be very difficult to sustain. See *Sindell v. Abbot Laboratories*, 607 P.2d 924 (Cal. S.C.).

⁵⁵ Robertson, *supra* note 39 at 435.

appellant, or anyone else injured in like circumstances, unless it can be shown that there was a voluntary assumption of the risk of injury. That can only be in this case if there was proof that the male appellant appreciated the risk involved...and willingly took it.⁵⁷

If the purpose of the duty to warn is to protect the individual right to make informed choices, then the appropriate standard would be one that insured that the plaintiff, in fact, appreciated the nature and extent of the risk.⁵⁸ This approach would have a profound effect on the duty to warn action, one that would be closely related to the purpose of the duty. Under these circumstances, the doctor or manufacturer would bear the onus of proof. The defendant (whoever it may be) is the party with access to the pertinent information, so they should bear both the antecedent duty to communicate risk and the subsequent responsibility of proving that the plaintiff received the knowledge necessary to assume the risk. A subjective test that is consistent with the purpose of the duty will have a concrete effect on how plaintiffs organize their argument and present their case. This would give the necessary protection to consumers of medical products.

III. IMPLIED WARRANTIES: THE ALTERNATIVE A. CONTRACTS AND CONSIDERATION

Although the duty to warn provides the basis for the decision in *Hollis*, the problem posed by dangerous medical products can be approached from the perspective of contract, a perspective that was also argued in *ter Neutzen* v. *Korn.*⁵⁹ There are a number of important advantages that can be gained by framing the action in contract rather than tort. The first is that an action in contract will not be subject to the same ambiguities and inconsistencies now present in the duty to warn action in Canadian law. If the subjective test for causation were applied in a fashion similar to voluntary assumption of risk, then the tort would be effective; however, the most recent Canadian authority, *Hollis*, clearly falls short of the mark. It would seem that reform within the law of tort may be difficult at the present time. Second, the limitation period for an action in contract is more forgiving than if the action were framed in negligence.⁶⁰ This means that the consumer would

⁵⁷ *Lambert, supra* note 18 at 576.

See, for example, *Kelliher* v. *Smith*, [1931] S.C.R. 672 at 679.

ter Neutzen, supra note 2.

⁶⁰ The Limitation of Actions Act, R.S.S. 1978, c. L-15, ss. 3(1)(d),(f). This is, of course, subject to the new rules regarding the discoverability of damage. See M.(K.) v. M.(H.), [1992] 3 S.C.R. 3 at 33-35.

have six years to claim for breach of contract; if the action were for negligence, the limitation period would shrink to two years.⁶¹ Finally, breach of a contractual warranty involves strict liability;⁶² in tort, the plaintiff must prove negligence. As we have seen, many of the attributes of the duty to warn action make it a difficult means of securing compensation in what could be characterized as a consumer-retailer relationship.

At trial, Ms. Hollis argued that her doctor failed to provide her with implants that were reasonably fit for their intended purpose.⁶³ The trial judge in *Hollis* found that no contract existed between Ms. Hollis and Dr. Birch. He based this decision on the findings that there was no intent to enter contractual relations and no consideration to form the contract.⁶⁴ In effect, he found that the absence of consideration precluded any contractual intent.⁶⁵

The issue of offer and acceptance should not pose much difficulty in the medical context. In *Hollis*, the doctor diagnosed the plaintiff as having a congenital breast deformity and suggested that surgical implants would serve as a remedy.⁶⁶ This could constitute an offer to supply goods and services.⁶⁷ Ms. Hollis consented to the procedure,⁶⁸ an act that could serve as acceptance.⁶⁹

The element of consideration in the relationship between Ms. Hollis and her doctor is more problematic. The breast implant procedure was covered by the provincial medical insurance program and the trial judge denied the claim for breach of contractual warranty.⁷⁰ The absence of money consideration flowing from patient to physician in *Hollis* is exceptional because cosmetic procedures like breast implantation are normally not covered by provincial insurance. Had Dr. Birch not arranged⁷¹ for the procedure to be paid for by the provincial insurance plan, the formality of consideration would have been satisfied, because Ms. Hollis would have paid for the procedure.

Nevertheless, the prerequisite of consideration in the medical context may be satisfied even where the procedure is covered by medicare. Consideration can be found within the doctor-patient relationship.⁷² In the

⁶¹ Ibid.

⁶² G.H.L. Fridman, *The Law of Contract in Canada*, 3d ed. (Scarborough: Carswell, 1994) at 694. "Liability is strict, in the sense that the aggrieved party does not have to show that the breach was committed deliberately or negligently." See also *ter Neutzen*, *supra* note 2 at 717.

Hollis v. Birch, [1990] B.C.J. No. 1059 at 8 (QL) (B.C.S.C.) [hereinafter Hollis (B.C.S.C.)].

⁶⁴ Hollis (B.C.S.C.), supra note 63 at 46-48.

⁶⁵ *Ibid.* at 35-36.

⁶⁶ Hollis, supra note 1 at 645.

⁶⁷ Picard, *supra* note 40 at 2.

Hollis, supra note 1 at 646.

Picard, supra note 40 at 2.

⁷⁰ Hollis (B.C.S.C.), supra note 63 at 44.

⁷¹ *Ibid.*

⁷² Picard, *supra* note 40 at 32.

case of *Goldthorpe* v. *Logan*, the Ontario Court of Appeal found that submission to treatment can constitute adequate consideration to support a contract.⁷³ The plaintiff had consented to electrolysis treatments advertised by the defendant. Although the court denied liability in negligence, it awarded damages in contract, saying:

These parties had a common intention, and there was good consideration present. It was constituted by the detriment or inconvenience sustained by the female plaintiff. Her submission to the treatments, in accordance with the advertisements, was a benefit sought by the advertiser.⁷⁴

Submission to treatment does confer a benefit on the doctor. Without the patient's consent to the treatment, the doctor cannot apply for payment from the provincial health program. The act of consent is a necessary occurrence if the doctor is to claim recompense.⁷⁵ The patient is entitled to refuse treatment and withhold a benefit from the physician. If direct money consideration were required to ground liability in contract in the medical context, then there would be a patchwork scheme of contractual relations based on which procedures are covered by provincial medicare and which are excluded. The result is that those products that have the greatest potential to cause harm would be excluded from the realm of statutory and common law warranties.

B. STATUTORY WARRANTIES

If consideration for a contract can be found, then the statutory warranties set forth in *The Sale of Goods Act*⁷⁶ may arguably apply. Unfortunately, most of the scenarios involving dangerous medical products will involve a significant component of professional services. In *ter Neutzen* v. *Korn*, the plaintiff was infected with HIV after participating in an artificial insemination (AI) program.⁷⁷ The Supreme Court of Canada held that the transaction did not fall within the purview of the statute because the contract was primarily for the provision of medical services and not the sale of semen:⁷⁸

⁷³ Goldthorpe v. Logan, [1943] 2 D.L.R. 519 at 524 (Ont. C.A.).

⁷⁴ Ibid.

This argument is analogous to the "collateral contract" analysis in contract law. See, for example, *Murray v. Sperry Rand Corp.* (1979), 96 D.L.R. (3d) 113 (Ont. H.C.).
The field contract is a second second

The Sale of Goods Act, R.S.S. 1978, c. S-1, s. 16.

ter Neutzen, supra note 2 at 681.

⁷⁸ Ibid. at 709.

[T]he primary reason that the appellant went to a gynaecologist was for professional medical services and expertise. As the respondent argued, he provided medical services to the appellant in order to assist her to become pregnant....

The appellant...relied on the respondent's expertise in the screening process for donors, the collection of the semen, the insemination procedure itself, and the provision of medical advice and information concerning any risks and the possibility of success of the AI procedure.⁷⁹

Although the sale of semen was a necessary element of the contract, the sale was deemed to be incidental to the provision of medical services. Since the contract was not primarily for the sale of goods, the statutory warranties are not engaged.

C. IMPLIED WARRANTIES

The fact that a contract is primarily for the provision of medical services does not end the analysis. The products used in the procedure remain a substantial component of the transaction and may be subject to an implied common law warranty of fitness for purpose. In *ter Neutzen*, the Supreme Court rejected the submission that contaminated semen is subject to such a warranty. Justice Sopinka held that the common law warranty is inapplicable to biological products used in medical procedures because they carry inherent risks that cannot be detected through the exercise of reasonable care.⁸⁰ The court did not imply the common law warranty because there was no medical evidence that linked the transmission of the virus to body fluids at the time of the transaction.⁸¹ The court was reluctant to attach liability where the defendant could not have detected the presence of HIV, the "defect", or pass liability for that defect back to the "manufacturer" responsible for distributing it.⁸²

The reasons given by Justice Sopinka are another example of how Canadian courts draw artificial distinctions between doctors and manufacturers based on some unarticulated policy argument. The inability of a seller or supplier to detect flaws or hidden dangers in a product does not justify a blanket application of *caveat emptor* in sales/service transactions nor does it exclude implied warranties of fitness for purpose:

⁷⁹ Ibid.

⁸⁰ *Ibid.* at 716-17. "This would have the effect of making physicians insurers of the biological substances that are used in medical procedures."

⁸¹ *Ibid.* at 683, 717-18.

⁸² *Ibid.* at 717.

If the article or commodity offered or delivered does not *in fact* answer the description of it in the contract, it does not do so more or less because the defect in it is patent, latent, or discoverable.⁸³

For example, if a restaurant sells a meal that makes a patron sick, then the restaurant is strictly liable.⁸⁴ There is no question of fault; the plaintiff need only prove that the product was the source of the damage.⁸⁵ Any question of whether the supplier could detect the danger is, under ordinary principles of contract law, irrelevant.⁸⁶

Justice Sopinka later qualified the exclusion of an implied warranty in *ter Neutzen* by saying:

even if I am wrong in my conclusion that a warranty should not be implied in the circumstances of this case, I would hold...that any warranty would simply be to take reasonable care.⁸⁷

This comment treats these transactions as being exclusively for the provision of services. The warranties normally associated with the goods component of the transaction are displaced by the standards applied to services. What is properly characterized as a sales/service hybrid contract has a remedy limited in scope and content by the service component. In the commercial context, the authorities apply the warranty of fitness to the materials used notwithstanding the concomitant service element.⁸⁸ The formal classification of the contract applied by the Supreme Court ignores the subtle components of the relationship and the appropriate standards applicable to goods and services that remain exclusive of each other. This definition of the contract into a question of duty that is replete with the inefficiency of actionable negligence discussed earlier under the duty to warn.

The courts refuse to hold medical products to the same standards as commercial products in a breach of contract action for the same reasons that

^{Randall v. Newson (1877), 2 Q.B. 102 at 109 (C.A.) [emphasis added]; aff'd in Murray Harbour Seafoods Inc. v. Ocean Flo Seafood Ltd. (1989), [1990] 79 Nfld. & P.E.I.R. 188. (P.E.I.S.C.).}

⁸⁴ Gee v. White Spot Ltd. (1986), 7 B.C.L.R. (2d) 235 (B.C.S.C.). 85 Hitta - 242

⁶⁵ *Ibid.* at 242.

ter Neutzen, supra note 2 at 721.

⁸⁷ Ibid. 88 o.u

³⁸ G.H. Myers & Co. v. Brent Cross Service Co. (1933), [1934] 1 K.B. 46 at 55; aff'd in Young & Marten Ltd. v. McManus Childs Ltd. (1968), [1969] A.C. 454 (H.L.); see also S.M. Waddams, "Strict Liability, Warranties, and the Sale of Goods" (1969) 19 Univ. Tor. L.J. 157 at 166-67.

they hold doctors and manufacturers to different standards in the duty to warn action. The courts vary their application of the principles depending upon who is the defendant to the action. Justice Sopinka shielded the doctor from the implied warranty by arguing that the product is of a different nature because it is associated with a medical procedure:

Whether a doctor is trying to save a patient's life via a blood transfusion, or is simply attempting to assist a patient to become pregnant by AI, the physician cannot control the safety of these products beyond exhibiting the reasonable care expected.... By contrast, in the commercial world, the manufacturer has control over the goods. If they cannot be manufactured to be safe, then the products ought to be removed from the market. In medicine blood is essential to a variety of procedures in order to save lives. While arguably, AI is not in the same category as other life saving techniques, it is nonetheless a very important medical procedure. As long as the procedure does not amount to an unreasonable risk such that it should not be offered at all, the patient is entitled to weigh those risks and elect to proceed.⁸⁹

The analogy drawn between life-saving blood transfusions and a procedure such as AI that is not essential to preserve the life of the plaintiff amounts to a questionable generalization about all medical products. Some biological products used in medical procedures save lives. Saving lives is good. Therefore, all products used in medical procedures are good. The effect of this type of reasoning is that those products that have the greatest potential to do harm (as well as good) are likely to fall outside of the protection normally afforded by common law because the products are associated with an activity that is immune from implied warranties. This generalization is particularly prejudicial where the product cannot be obtained except through a physician. In Hollis, the plaintiff could only acquire breast implants through her surgeon.⁹⁰ If Ms. Hollis had been able to purchase the implants herself from a retailer, separate from the services provided by Dr. Birch, then they would have been subject to the warranties under The Sale of Goods Act; however, because she acquired the implants in conjunction with medical services, she was limited to the tort action, with all of its infirmities.

⁸⁹ *ter Neutzen, supra* note 2 at 717-18. This comment presumes, of course, that the duty to warn has been satisfied.

⁹⁰ Hollis, supra note 1 at 661.

The therapeutic potential of many medical products invites the court to adopt a general exclusion from implied warranties. The hope of improved health care remains a strong influence. Nevertheless, the court should be prepared to articulate the basis of that exclusion and openly decide whether a distinction can be drawn between the various categories of medical products. Biological products such as blood differ substantially from prosthetic implants and must be treated as such. At present, however, the lowest common denominator (the medical profession) blurs that distinction and it appears that most medical products are innocent by association.

There are many possible explanations for the tendency to avoid contractual analysis within the doctor-patient relationship. The courts may be concerned about the feasibility of quality control (especially when biological products like blood are involved), loss distribution where the manufacturer is not readily identifiable, or the special status of hospitals in the chain of distribution. Any or all of these considerations may be relevant to the discussion of implied warranties, but unless they are openly addressed there is no meaningful way of testing the efficacy of the distinction drawn between medical products like breast implants and products distributed outside of the confines of the medical community.

The question of what is required to prove breach of an implied warranty has also proven difficult for courts when considering the issue within the medical context. The British Columbia Court of Appeal dealt with the issue in *Hollis* and concluded that where the evidence is insufficient to support a finding of negligent manufacture, an action for breach of implied warranty is preempted.⁹¹ As in the duty to warn, the evidentiary burden ascribed to the plaintiff differs depending on whether the defendant is a doctor or an "ordinary" commercial retailer. Justice Prowse avoided detailed analysis of the issue but recognized the distinction she drew between products used in the provision of medical services and commercial products:

Can a [breast implant] be found not to be reasonably fit for the purpose for which it is intended because, from some unidentified cause, it breaks down more than a year after its insertion?

I think not. The failure of a thing does not establish, as a matter of law, that it is not reasonably fit for the purpose, *although the failure of an ordinary article of commerce often leads, as a matter of fact, to such a conclusion.*

On the evidence in this case, it would be sheer speculation to conclude that these prostheses were not reasonably fit for the purpose intended.⁹²

Had there been privity of contract between Ms. Hollis and Dow, the action may have succeeded, but because the chain of distribution was interrupted by a doctor, the plaintiff was confined to the tort, which has a different onus of proof and offers less protection. This analysis leaves us wondering why it is not possible to infer, in the absence of evidence to the contrary, that the plaintiff's symptoms alone were sufficient proof of the absence of fitness. The onus could then shift to the defendant to establish that the symptoms were due to some other cause.⁹³

If the British Columbia Court of Appeal granted recovery based on the implied warranty, Dr. Birch would have been free to sue Dow in a like manner because there was privity of contract between them. Ultimately, Dow would still have borne the loss:

[O]ne can always proceed up the chain of production and ultimately recover from the one who should bear responsibility for the production of faulty goods. From time to time, the supplier will be unable to recover from the manufacturer, for example, owing to insolvency or limitation periods. However, arguably it is better that the purchaser be compensated and the supplier occasionally bear the cost of defects than leaving the consumer without a remedy.⁹⁴

This approach to attaching liability clearly does not require a finding of fault. Nevertheless, the party ultimately responsible for producing the product will

⁹² Ibid. [emphasis added]. It is worth noting that the British Columbia Court of Appeal, in disposing of Ms. Hollis' contractual claim against Dr. Birch, reasons that there was no defect and therefore, no breach of implied warranty. The court skips over the issue of antecedent consideration, which may suggest that the issue of consideration did not preempt Ms. Hollis' claim in contract.

⁹³ Ashington Piggeries v. Christopher Hill, [1971] 1 All E.R. 847 at 874-5 (H.L.). "[The plaintiff] must, I think, carry his proof to the point of showing that the guilty ingredient has some generally (as opposed to specifically) toxic quality. But once he has done this, has he not shown, at least with strong prima facie force, that a feeding stuff which contained it was unsuitable?

Is he not entitled to throw on to the seller the burden of showing, if he can, that the damage to the [plaintiff]...was due to some factor within the field of responsibility reserved to the buyer? I would answer yes to these questions."

⁹⁴ ter Neutzen, supra note 2 at 714.

usually bear the loss. The difference is that this method is more efficient and favourable for the plaintiff than an action in negligence.

IV. CONCLUSION

The changes proposed in this paper would assign responsibility for unfit medical products to the party responsible for distributing them in the market. To the present, Canadian courts have shielded doctors from common law principles that normally provide protection for the consumer. Under both forms of action, the Supreme Court's decisions operate against the plaintiff on both dimensions of substantive liability and onus of proof. This approach is founded on policy considerations that are based on generalizations about the doctor-patient relationship and the practice of medicine that may or may not be relevant in specific circumstances, such as elective surgery. It is time for the courts to reexamine the basis for these distinctions and reformulate a principled approach that can effectively protect the rights of informed choice and personal autonomy. It is time for doctors to share accountability for the role they play in distributing dangerous medical products such as breast implants. It is time to change the way the law protects the consumer, when the consumer is a patient.