

## PRODUCTS LIABILITY - MEDICAL AND PHARMACEUTICAL

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### Introduction

An active area of litigation involves claims relating to faulty medical devices and pharmaceuticals. Such claims often involve alternative theories of liability due to the human element associated with the use of the device or drug. For example, a neuroradiological catheter which ruptures intracranially during surgery seems, at first blush, to point directly at the manufacturer of the catheter. Closer scrutiny reveals not only a potential products liability claim against the manufacturer of the syringe used in the operation, but also against the medical professionals and hospitals involved. Obviously, this sort of lawsuit combines actions in two of the most complex and difficult areas of the law: products liability and medical negligence. Lawsuits are generally based on allegations of a "manufacturing defect", a "negligent design" or a "failure to warn".

A "manufacturing defect" occurs when the product does not comply with the manufacturer's specifications; such defects would include faulty assembly and missing parts, or foreign elements in a product. In short, there is nothing defective about the design of the product; rather, a defect arises as a result of the product not being built in accordance with that design

A "design defect" arises where the product is manufactured as intended, but the design itself is found to present an unreasonable risk of injury when used according to the design.

Allegations of negligent design will generally be combined with allegations of a failure to warn and liability may be imposed for failure to warn even if not for negligent design. Manufacturers of medical products and pharmaceuticals are required to provide clear, complete and current information concerning the dangers associated with use of their products. It may be that the manufacturer will be found liable for failing to disclose risks associated with the use of the product. In fact, there is a "continuous" duty not only to warn of risks known at the time of sale, but also risks subsequently discovered. The courts have indicated that this continuous duty also implies a potential obligation to recall.

### A knowledge imbalance

The Supreme Court of Canada, in *Hollis v. Dow Corning Corporation*,<sup>1</sup> addressed the legal notion of "failure to warn" and has raised the standards of disclosure required of manufacturers.

In this case, the plaintiff received breast implants, manufactured by the defendant corporation and implanted by a surgeon. One of the implants ruptured, requiring removal and further surgery. The literature accompanying the product warned of rupture during surgery, but not of post-surgical rupture, except from abnormal squeezing or trauma. The plaintiff's action against the manufacturer succeeded at trial on the basis of *res ipsa loquitur*; the action against the surgeon was dismissed. The manufacturer's appeal was dismissed, but on the ground that, though not negligent in the manufacture of the product, it was liable for failure to warn, since the evidence showed that it had received reports of about 50 cases of ruptures at the time the plaintiff received her implant. The plaintiff's appeal against the surgeon was allowed and a new trial was ordered. On further appeal to the Supreme Court of Canada, the Court held that the manufacturer had a duty to warn the medical profession of potential dangers, including those coming to its notice after manufacture and distribution of the product.

The Court stated that consumers have far less knowledge than manufacturers concerning the dangers inherent in the use of products, and the duty to warn serves to correct this knowledge imbalance by alerting consumers to such dangers, and allowing them to make informed decisions. The nature of the required warning is that it must be comprehensible to the average consumer. The corollary is that a manufacturer is not liable to a user if it gives a clear warning of, including precautions to be taken against, danger from the use of its product, and the user suffers damage by carelessly disregarding that warning and those instructions.

### **The Learned Intermediary Rule**

The general rule is that the duty to warn is owed directly to the ultimate consumer. In exceptional circumstances, however, a manufacturer may satisfy this duty to the consumer by providing a warning to a "learned intermediary"

In *Buchan v. Ortho Pharmaceutical Corp*<sup>2</sup> it was held that the manufacturers of the drug were negligent for the failure to warn of the danger of stroke from taking the oral contraceptive, even though the warning may have complied with the government mandated text and even though these pills could be obtained only by prescription.

In *Buchan*, the Court of Appeal stated that with oral contraceptives, unlike other prescription drugs, there should also be a duty to warn the consumer directly of the risks involved in addition to warning the physician. Unlike other drugs, oral contraceptives are not medically necessary. Consumers choose to take a certain oral contraceptive over other suitable alternative methods of birth control.

Robins J.A. stated that there is a presumption that a doctor would not ignore a proper warning or fail to disclose a material risk, however, this presumption may be rebutted by the defendant.

Once the breach of duty to warn prescribing physicians has been established, I think it fair and reasonable to presume that the inadequacy of the warning was a contributing cause of the ingestion of the drug. It ought not to be incumbent on a plaintiff to prove as part of her case what her doctor might or might not have done had he been adequately warned. One can assume that a doctor would not ignore a proper warning or fail to disclose a material risk or otherwise act negligently. Even if the evidence were to indicate that the doctor was negligent, the manufacturer would not be shielded from liability if such negligence was a foreseeable consequence of the breach of duty to warn. The presumption may, of course, be rebutted if the defendant comes forth with evidence that despite the inadequacy of the warning the doctor's conduct toward his patient would have been the same whether or not the manufacturer was in breach of the duty...<sup>3</sup>

Although La Forest J. in *Hollis* found favour with most of the comments in the above passage, he took issue with the last sentence.

In the last sentence of this statement, Robins, J.A. refers to the possibility that the manufacturer might be able to adduce evidence that the doctor's conduct might have been the same whether or not the manufacturer was in breach of its duty. I should say that whatever effect this may have regarding the apportionment of liability between the doctor and the manufacturer in the event the doctor is also found to be negligent, it in no way absolves the manufacturer from liability to the plaintiff, except in cases where some extraneous conduct by the doctor would have made the failure to give adequate warning

irrelevant. But that is not this case. In sum, in a case like the present, I see no reason why in establishing the liability of the manufacturer the law should adopt a rule requiring the plaintiff to delve into what the doctor might have done.<sup>4</sup>

In *Hollis*, the Supreme Court applied the "learned intermediary" doctrine, thus making it unnecessary for Dow Corning to directly warn the breast implant recipient. The Court, however, imposed a broad duty of disclosure on the manufacturer to supply appropriate information to medical practitioners. The Supreme Court stated further that where a manufacturer fails to fulfil this duty of disclosure, the plaintiff need only satisfy the "subjective" test in demonstrating a causal link between injuries sustained and the failure to warn. In other words, the Court relied heavily on the evidence of Ms. Hollis herself, as to whether or not she would have undergone the implant surgery even if she had been properly warned of the risks. In adopting a subjective test, the Court noted that the relationship between doctor and patient is different from that of manufacturer and consumer. Bluntly, a physician's role is to protect the patient's health, while breast implant manufacturers exist to sell their medical products. Accordingly, there is an incentive for a manufacturer to accentuate the product's value, while de-emphasizing its risks. This aspect of the relationship, along with the resource and information advantages enjoyed by the manufacturer, were used by the Court to justify a subjective test. The test, therefore, became whether Ms. Hollis would herself have consented to the procedure had she been adequately warned of the risk, and not whether a reasonable person would have consented to the procedure. The point of course, is that the evidence of the consumer would be difficult indeed to rebut, and manufacturers therefore would do well to increase their level of disclosure.

### **Biological Products**

Unlike other manufactured products, biological products carry their own inherent risks. While these inherent risks have rendered findings of strict liability<sup>5</sup> and implied warranty<sup>6</sup> unlikely, claims in negligence have been successful.

In *Walker Estate v. York Finch General Hospital*,<sup>7</sup> two persons received tainted blood products from the Canadian Red Cross Society (CRCS) and eventually developed AIDS. It was held that the CRCS breached its duty to have a proper screening program in place, and that it knew or ought to have known that such a failure could result in the transmission of HIV infected blood.

The Court of Appeal adopted the reasoning of La Forest J. in *Hollis*. Given that the plaintiff bore the onus of proving causation, the necessary causal link was presumptively established once it was shown that the CRCS had failed in its duty to implement adequate donor screening measures. Absent evidence of "extraneous conduct" by the donor that would have made the failure to screen irrelevant, it was not open to the defendant to dislodge the presumptive causal link by showing that proper screening measures would have proved ineffective in deterring the donor from giving blood because of his own negligence.

While mindful of the fact that unlike other manufactured products, blood is a biological substance which carries its own inherent risks the Court, nonetheless, followed *Hollis*. The plaintiff is not required to overcome the additional burden of proving what the HIV infected donor would have done had the CRCS acted in accordance with its duty to the plaintiff. As a matter of policy, it would be unjust to allow the CRCS to escape liability by placing what could amount to an impossible burden on an innocent plaintiff. In *Walker*, claims for strict liability were rejected due to the inherent risks that biological products carry.

In *Robb v. Canadian Red Cross Society*,<sup>8</sup> the plaintiffs were three hemophiliac patients who received HIV contaminated blood products. Among the defendants were the Canadian Red Cross Society (CRCS) who

collected the blood and distributed it to hospitals. The blood fractionators who were under contract with CRCS to extract the required factor concentrates from the blood were also named as defendants.

By the fall of 1984, the informed medical community knew that HIV was a blood borne virus that could be transmitted through factor concentrates, and that hemophiliacs who used these products were at risk of contracting HIV and developing AIDS. By then it was also known that heat-treating the factor concentrates inactivated the virus.

The plaintiffs alleged that the CRCS breached their duties of care because they failed to implement adequate blood donor screening tests in a timely fashion, and failed to implement the heat-treatment of factor concentrates either in 1983, when the process was first commercialized, or in October 1984, when it was announced that heat-treatment inactivated HIV. The plaintiffs also claimed that the CRCS had breached a duty to warn the plaintiffs of the risks associated with use of these products.

The CRCS was found liable for negligence flowing from its delayed transition to heat-treated factor products. Rather than taking steps to make the transition to the heat-treated products as quickly as possible, the CRCS embarked on a course of action which delayed the transition.

On the issue of the CRCS' duty to warn, it was held that the warnings that the plaintiffs received from their physicians about the risk of contracting AIDS from the blood products were adequate, and therefore that claim against the CRCS failed.

The plaintiffs also claimed breach of duty to warn against the blood fractionators. The blood fractionators produced the blood products pursuant to a contract with CRCS. The CRCS collected the blood plasma and sent it to the fractionators to be processed but the CRCS retained ownership of the blood products. The Court found that it was ultimately up to the CRCS to decide whether an AIDS warning should be included on the product. It was held that at most, the fractionators had a duty to warn the CRCS about the risk of AIDS and it was held that they did discharge this duty.

With respect to strict liability, the plaintiffs argued that these cases can be distinguished from other biological product cases where strict liability claims have been denied due to the inherent risks associated with the products. The plaintiffs argued that in these cases, the product is not whole blood but a manufactured product, and it is a product which can be self administered without any medical procedure. The court found that the factor concentrates were still a biological product fraught with inherent risk and, therefore, the doctrine of strict liability could not be imported into these cases. Macdonald J. found that biological products simply cannot be controlled in the same way as manufactured products and as blood products play a crucial role in the health and well being of so many people, the fundamental purpose underlying the theory of strict liability in tort, to drive dangerous product from the market, does not apply.

## **Class Actions**

In addition to actions commenced by individuals or small groups of plaintiffs, manufacturers and the CRCS have also been faced with class proceedings. Several courts in Canada have commented that products liability cases are ideal for certification. Product liability cases dealing with medical devices, biological products and pharmaceuticals have been certified as class proceedings on a number of occasions. In *Nantais v. Teletectonics Proprietary (Canada) Limited*,<sup>9</sup> the plaintiffs alleged a defect in the design and manufacture of heart pacemakers. In *Wilson v. Servier Canada Inc.*,<sup>10</sup> an action was commenced on behalf of persons who ingested a diet drug. In *Endean v. Canadian Red Cross Society*,<sup>11</sup> the members of the plaintiff class

contracted Hepatitis C from tainted blood or blood products. Several cases against the manufacturers of breast implants have also been certified.<sup>12</sup>

## Conclusion

The potential for class proceedings, in combination with the Supreme Court having raised the standard of disclosure required of manufacturers in *Hollis*, should send a clear message to manufacturers whose medical products make their way into the Canadian marketplace.

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

2. *Buchan v. Ortho Pharmaceutical Corp.* (1986), 25 D.L.R. (4<sup>th</sup>) 658 (C.A.).

3. *Buchan v. Ortho Pharmaceutical Corp.* (1986), 25 D.L.R. (4<sup>th</sup>) 658 at 682 (C.A.).

4. *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at 640-41.

5. See *Walker Estate v. York Finch General Hospital* (1997) 39 C.C.L.T. (2d) 1 (Gen. Div.), aff'd and var'd (1999) 169 D.L.R. (4<sup>th</sup>) 689 (Ont. C.A.); *Robb v. Canadian Red Cross Society*, [2000] O.J. No. 2396 (S.C.J.).

6. *ter Newzen v. Korn* [1995] SCC 127 D.L.R. (4<sup>th</sup>) 577; *Pittman Estate v. Bain* (1994), 19 C.C.L.T. (2d) 1 (Gen. Div.). It was held in these two cases that biological products are not manufactured goods in the same sense as commercial goods. Biological products, unlike manufactured products, carry certain inherent risks. No implied warranties applied.

7. *Walker Estate v. York Finch General Hospital* (1997), 39 C.C.L.T. (2d) 1 (Gen. Div.), aff'd and var'd (1999), 169 D.L.R. (4<sup>th</sup>) 689 (Ont. C.A.).

8. *Robb v. Canadian Red Cross Society*, [2000] O.J. No. 2396 (S.C.J.).

9. *Nantais v. Teletectonics Proprietary (Canada) Limited* (1995), 25 O.R. (3d) 331 (Gen. Div.).

10. *Wilson v. Servier Canada Inc.*, [2000] O.J. No. 3392 (S.C.J.).

11. *Endean v. Canadian Red Cross Society* (1997), 148 D.L.R. (4<sup>th</sup>) (B.C.S.C.), rec'd on other grounds 157 D.L.R. (4<sup>th</sup>) 465 (B.C.S.C.).

12. For example: *Bundall v. McGhan Medical Corp.* (1996), 3 C.P.C. (4<sup>th</sup>) 389 (Gen. Div.) and *Harrington v. Dow Corning Corp.* (1996), 22 B.C.L.R. (3d) 97 (S.C.), aff'd [2000] B.C.J. No. 2237 (C.A.).