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MEDICAL DEVICE MANUFACTURER'S DUTY TO WARN

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A recent decision of the Ontario Superior Court of Justice[1] summarized the law in Canada concerning a medical device manufacturer's duty to warn in the context of class action litigation.

Product Liability Class Action

Typically the four steps in a products liability class action are: (1) determining whether the product is defective or whether, although non-defective, the product has a propensity to injure; (2) determining what the manufacturer knew about the dangerousness of its product; (3) given the state of the art and the extent of the risks inherent in the product's use, determining the reasonableness of the warning whether made directly to the consumer or to a learned intermediary; and (4) determining individual causation and damages. The first step, known as the general causation step, determines whether the product is capable of causing harm. The second step is part of determining whether the manufacturer had a duty of care not to sell the product or to sell it only with an appropriate warning. The third step focuses on the adequacy of the warning. The fourth step will determine individual causation and the quantification of the compensation for the consequent harm.

Rationale Behind The Duty To Warn

When manufacturers place products into the flow of commerce, they create a relationship of reliance with consumers who have far less knowledge than the manufacturers concerning the dangers inherent in the use of the products, and are therefore put at risk if the product is not safe. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.

Extent Of The Duty To Warn

A manufacturer of a product has a duty to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge. The warnings must be reasonably communicated and detailed to give the consumer a full indication of each of the specific dangers that arise from the ordinary use of the product.

[1] Batten v. Boehringer Ingelheim (Canada) Ltd. 2017 ONSC 53 (CanLII)

If a product, although suitable for the purpose for which it is manufactured, is at the same time dangerous to use, the manufacturer of the product has a duty of to warn of the attendant dangers in using the product.

Duty Is A Continuing One

The manufacturer's duty to alert consumers about dangers associated with the use of a product is a continuing duty, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered.

High Standard Of Care

In the case of medical products, given their substantial risk of harm from improper use, the standard of care is correspondingly high and there will almost always be a heavy onus on the manufacturer to provide clear, complete and current information concerning the dangers inherent in the ordinary use of its product.

The warning 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 the circumstances relevant to the product in question.

Cases Involving A "Learned Intermediary"

In cases involving highly technical products intended to be used under the supervision of experts or where the nature of the product is such that the consumer will not realistically receive information directly from the manufacturer without the intervention of a learned intermediary, the duty of the manufacturer is discharged if the manufacturer provides the learned intermediary (for example, physicians or surgeons), rather than the consumers, with an adequate warning of the potential dangers associated with the use of its product.

In the context of manufacturers of and medical devices the learned intermediary is the physician that prescribes the medical device. The legal theory here is that where a consumer places primary reliance on the judgment of a learned intermediary, then the manufacturer will satisfy its duty to warn the consumer by adequately warning the learned intermediary of the risks inherent in the use of the product.