

Canadian Assistive Devices Association

Product Liability - Developments

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Agenda

- Liabilities of Manufacturers and Distributors
- Bill C-36 – An Act respecting the safety of consumer Products
- Former Bill C-51 – Medical Devices
- Class Action Risks and Prevention

Claims Against Seller

- Terms of contract
 - Promises of performance
 - Warranty protection

- Implied conditions of *Sale of Goods Act* or *International Sale of Goods Act*

Claims Against Seller

- *Sale of Goods Act*, R.S.O. 1990, c.S.1
- S.15.1.
 - The buyer makes known to the seller the particular purpose for which the goods are required
 - The buyer relies on the seller's skill or judgment
 - The goods are of a description that it is in the course of the seller's business to supply
 - There is an implied condition that the goods will be reasonably fit for such purpose

Claims Against Seller

- *Sale of Goods Act*, R.S.O. 1990, c.S.1
- S.15.2.
 - Where goods are bought by description from a seller who deals in goods of that description, there is an implied condition that the goods will be of merchantable quality

Claims against Manufacturer (Who is Not Seller)

- No contract
- Express warranties given by manufacturer
- Negligence in design or manufacture or failure to instruct or warn
- Manufacturer position may be protected by difficulty and expense in proving negligence in design or manufacture
- Economic losses like return of purchase price may not be recoverable by user

Claims Against Manufacturers (Who is Not Seller)

- Foundation principle
 - The courts in this country have long recognized that manufacturers of products that are ingested, consumed or otherwise placed in the body, and thereby have a great capacity to cause injury to consumers, are subject to a correspondingly high standard of care under the law of negligence

***Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634 at 655**

Duty to Warn

- Manufacturers are under a duty to warn consumers of damages inherent in the use of their products of which the manufacturer ought reasonably to be aware
- The duty to warn is extended to manufacturers, distributors, retailer, installers and repairers
- Generally, the duty to warn does not extend to dangers arising from the abuse of the product unless the abuse may reasonably be anticipated

Duty to Warn

- The warning must 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
- The duty to warn does not terminate on the sale of the product. It continues and requires the manufacturer to warn the consumer of risks and dangers that are disclosed after the product is on the market

Claim By Seller Against Manufacturer

- Seller interest to ensure that seller can pass any customer liability to manufacturer
- Parallel terms in both contracts

Retention of Evidence

- Need for independent expert to examine condition and performance before repair
- Opportunity for plaintiff and other proposed defendants to inspect before destruction, repair or modification

Plaintiff Culture

- Accidental injuries deserve compensation
- Accident means a product is defective
- Suspicion of manufacturer delay in recalls
- Suspicion of products manufactured offshore
- Increased damage awards

- *Canadian Consumer Product Safety Act*
- First Reading – June 9, 2010
- Purpose to protect the public by preventing danger to human health or safety posed by consumer products
- Does not apply to Medical Devices

Highlights of Bill C-36

- Manufacturer or importer prohibited from manufacture or sale of consumer product that is a danger to human health or safety
- Manufacturer or importer can be ordered to conduct tests or studies to verify compliance with *Act*

Highlights of Bill C-36

- Mandatory reporting of incidents in Canada or elsewhere that resulted or may reasonably have been expected to result in death or serious adverse effects on health
- Minister may order person to recall product if Minister believes on reasonable grounds that consumer product is a danger to human health or safety

Background on Current *Food and Drugs Act*

- Current Food and Drugs Act (“Canada FDA”) was established in 1952-1953
- Key regulations under Canada FDA: Food and Drugs Regulations, Cosmetic Regulations, Medical Device Regulations and Natural Health Products Regulations

Background on Current *Food and Drugs Act*

- **Blueprint for Renewal**
 - In October 2006, Health Canada’s Health Products and Food Branch released a consultation document, “Blueprint for Renewal: Transforming Canada’s Approach to Regulating Health Products and Food.” (“Blueprint”)
 - Developing a “life cycle” regulatory approach to health products that would “encompass all stages of product development and use” (part of progressive licensing)
 - Moving away from a reactive “waiting for events” regulatory system to a more proactive approach

Bill C-51 Provisions

- “Therapeutic product”
 - Means:
 - (a) a drug
 - (b) a device
 - (c) cells, tissues or organs
 - (d) combination of 2 or more of the above

Bill C-51 Provisions

- No person shall manufacture, process, label, package, sell, import for sale, or advertise a therapeutic product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its benefits, risks, conditions of use, quality, quantity, composition, design, construction, performance, origin or authorization status

Bill C-51 Provisions

- “Sell” includes:
 - (a) a distribution to one or more persons, whether or not made for money or other consideration
[Note—distribution to a single person constitutes a sale]
 - (b) with respect to a device, “lease, offer to lease, expose for lease or have in possession for lease”

Bill C-51 Provisions

- Communication and Sharing of Information
 - Minister may direct a person to provide information that is in the person's control if Minister believes that the information is necessary for Minister to determine whether a food, therapeutic product or cosmetic presents a serious risk to human health

- Recall

- If Minister believes that a therapeutic product or cosmetic presents a serious or imminent risk of injury to health, Minister may direct a person who sells it to recall it and if necessary to have it sent to the place designated by Minister

[Note – currently, only the manufacturer or importer may initiate a recall]

Current Exposure Issues

- Government intervention and consumer protection
- Class Action vehicle to bring Aggregated claims against seller or manufacturer

Class Actions

- Representative plaintiff brings lawsuit on behalf of all purchasers or users
- To provide access to justice and judicial economy
- Decide common issues once – for all class members

Class Actions

- Nine of 10 provinces have class proceeding legislation
- Cost exposure for unsuccessful plaintiffs differs in different provinces making some provinces more attractive
- Breadth of cases certified in Canada surprises U.S. clients and U.S. counsel
- Canadian Hot Spots – Québec, Ontario, Saskatchewan, British Columbia

Class Actions

- Economic issues are similar; products and activities may be identical
- Class action law firms in Canada have established referral relationships with plaintiff firms in the U.S.
- Canadian counsel often follow lead from U.S.
 - Regulatory investigations
 - Expert reports
 - Litigation of conventional or MDL litigation
- Settlement activity in the United States can generate Canadian claims

Current Business Risks & Issues

Commercial Claims

- Claims for overtime pay
- Consumer contracts – fees, interest rates, foreign currency conversion
- Warranty claims for consumer products
- Negligence claims arising from medical procedures
- Claims under Competition legislation
- Claims for injuries suffered due to failure to warn

Claim for Disgorgement of Profit or Revenue

- Impact on business clients
- Plaintiff intent to increase settlement pressure by securing certification, at a minimum
- Defence costs for production of information and expert fees can be of the order of \$750,000 to \$1.5 million
- Courts showing sympathy for defendant position and can order bifurcation of the calculation of the amount of disgorgement until liability decided
- See, “*Waiver of Tort and Non-Injured Claimants in Canadian Class Actions*,” by Barry Glaspell, Lexpert, November 2009

Prevention of Class Actions

- Identify the conventional claim that can explode into class action
- Audit contracts to ensure compliance with consumer protection legislation
- Keep abreast of industry and affiliate lawsuits
- Stay ahead of performance, warranty and recall issues



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Thank you!