Product Liability Law: Recent Developments

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From the first significant amendments to the ***Food and Drugs Act*** in fifty years to Courts exercising their gatekeeping function in proposed class actions, the following is a roundup of notable recent product liability developments.

Amendments to the *Food and Drugs Act*

In 2014, the *Food and Drugs Act* was substantively amended for the first time in fifty years by **Bill C-17**, also known as ***Vanessa's Law***. According to the federal government, the purpose of the amendments is to "strengthen safety oversight of therapeutic products through their life cycle" and "improve reporting by certain health care institutions of serious adverse drug reactions and medical device incidents that involve therapeutic products." The amendments apply to "therapeutic products", which are defined broadly as drugs or devices (which are also defined terms in the Act), and introduce a plethora of new powers for the Minister of Health with respect to the regulation of therapeutic products. These powers include ordering a person to provide information to determine whether a therapeutic product presents a serious risk of injury to human health; disclosing confidential business information about the product, without notifying the company whose information it is, if it poses such a risk; ordering the holder of a therapeutic product authorization to modify the therapeutic product's label or package if necessary to prevent injury to human health; and, critically, ordering a recall of a therapeutic product if it poses a serious or imminent risk of injury to health. The Governor in Council is empowered to make a wide variety of further regulations respecting therapeutic products. By means of an amendment which is not yet in force, prescribed health care institutions will have to provide the Minister with information about serious adverse drug reactions or medical device incidents involving therapeutic products.

The amendments also introduce stiff penalties for breach of the provisions of the Act related to therapeutic products, which can be as severe as a $5 million fine or two years' imprisonment. Penalties for knowing or reckless contraventions of provisions related to therapeutic products can be even more severe, with fines entirely within the sentencing court's discretion.

Amendments to Other Legislation Affecting Products

The ***Hazardous Products Act*** was also amended last year, to bring the Canadian regime into alignment with international standards. These amendments came into force in February 2015. The amendments to the Act add definitions for "suppliers" and "hazardous products", expand the categories of substances that may be subject to the Act and empower the Minister of Health to order testing on products that may be dangerous and to make other orders required to remedy or prevent non-compliance with the Act. The

amendments also replace the current product labelling and safety data sheet elements of **Canada's Workplace Hazardous Materials Information System** (WHMIS) with the **UN's Globally Harmonized System of Classification and Labelling of Chemicals** (GHS). Finally, the changes increase the penalties for non-compliance with the Act.

As with the *Food and Drugs Act*, the amendments to the *Hazardous Products Act* have increased the criminal penalties for contravention of the Act. On conviction on indictment, the court may impose fines of up to $5 million or a maximum of two years' imprisonment, with knowing or reckless contraventions of the Act drawing discretionary fines with no upper limit or imprisonment for a maximum of five years. Penalties for negligent contraventions, and knowing or reckless contraventions, of the Act prosecuted by way of summary conviction have also increased.

The federal government has also recently introduced amendments to the ***Motor Vehicle Safety Act***. The amendments include new notice requirements, specifically the obligation of a company to report to the Minister of Transport any non-compliance of a regulated vehicle or equipment within the regulations to the Act. Current owners of the vehicle or equipment must also be notified of the non-compliance, unless the Minister determines that the non-compliance is inconsequential to safety. This notice requirement is in addition to the continued obligation of companies to report defects in the design, manufacture or functioning of a vehicle or equipment that is likely to affect its safety. It should be noted that these notice requirements are not yet in force. New financial penalties for breach of the Act or its regulations are already in effect, which double the pre-existing fines.

The *Motor Vehicle Safety Act*, the ***Railway Safety Act*** and the ***Transportation of Dangerous Goods Act, 1992***, have been amended to remove interested parties' right to make representations to the Minister of Transport on proposed regulations. Previously, these Acts provided that regulations proposed under the Act would be published in the Canada Gazette, and interested parties would be afforded a reasonable opportunity to make representations about the proposed regulations to the Minister. The amendments remove this opportunity. The government has **stated** that these provisions were made redundant by the ***Cabinet Directive on Regulatory Management***, which sets out the responsibility of departments and agencies to identify interested and affected parties, and provide them with opportunities to take part in consultations at all stages of the regulatory process.

More legislative change is in the pipeline. On February 20, 2015, **Bill C-52**, also known as the ***Safe and Accountable Rail Act***, received its first reading in the House of Commons. The bill proposes amendments to the ***Canada Transportation Act*** and further amendments to the *Railway Safety Act*. In their current form, the amendments to the *Canada Transportation Act* would add the requirement that an operator of a railway that does not relate to passenger rail service have the minimum prescribed liability insurance, including insurance coverage for third-party bodily injury, death, or property damage; for risks associated with leaks, pollution or contamination; and for losses, damages, costs and expenses caused by a railway accident, which would be a new defined term in the Act. The amendments would also create a compensation fund for persons who incur losses as a result of railway accidents. The amendments to the *Railway Safety Act* would grant railway safety inspectors the power to order a person or company to take specified measures to mitigate an immediate threat to the safety or security of railway operations, and give the Minister of Transport the power to order a company to take corrective measures if it is implementing its safety management system in a risky manner.

Regulators May Owe a Duty of Care to Consumers

In recent years, the issue of whether a regulator of products owes a duty of care to end consumers has been considered by a number of Canadian courts.[1] In ***Harrison v. XL Foods Inc.***, the Alberta Court of Queen's Bench refused to rule out that the Canada Food Inspection Agency ("CFIA") owes a duty of care to ultimate consumers of products it regulates. The representative plaintiff sued XL Foods for injury he suffered by eating E. coli-contaminated meat that XL Foods had processed. XL Foods brought a third-party claim against the CFIA, saying that the regulator's inspection processes were tightly integrated

with XL Foods' operation and the CFIA's failure to fulfill its statutory duties contributed to class members' losses. The judge distinguished this case from a **prior B.C. case** that had held the CFIA did not owe a duty of care to upstream food producers, and held that it is not plain and obvious that the CFIA does not owe a duty of care to downstream consumers. If the defendant's pleaded case that the CFIA was systematically involved in its operations proved true, this could establish proximity between the regulator and consumers and it was not plain and obvious that there were countervailing policy considerations that meant such a duty should not be recognized. The court noted that the CFIA would have a number of defences at trial, including policy considerations as to why courts should not recognize such a duty of care on the part of the CFIA. A more in-depth summary of the case can be found **here.** XL Foods has since tentatively settled the economic claims for meat returned as a result of the recall (the largest in Canadian history), but the personal injury claims and the CFIA's duty to consumers both remain to be determined at trial.

Class Actions

Class actions continue to be an active area of product liability law, and defendants continue to make efforts to seek early determination of the merits of plaintiffs' claims through pre-certification dispositive motions.

For instance, in ***Player v. Janssen-Ortho Inc.***, the British Columbia Supreme Court dismissed the plaintiffs' claims after a summary trial held prior to the certification application. The proposed class action was commenced in 2010 against five pharmaceutical companies that manufacture transdermal fentanyl patches for pain management. The claims of the proposed class were founded in negligence, negligent misrepresentation, breaches of warranty and fiduciary duty, as well as breaches of various statutes. Prior to any hearing on certification, two defendants applied for an order directing a summary trial of the claims against them. The proposed representative plaintiffs opposed the use of this summary procedure, arguing that it was inappropriate before the action had been certified as a class proceeding. Bracken J. of the British Columbia Supreme Court concluded that a pre-certification class proceeding is not inherently unsuitable for summary determination. In the case at hand, while his judgment would only bind the named plaintiffs, the case would be practically disposed of by the summary trial because it concerned the two defendants' liability to the proposed class as a whole. Furthermore, despite the voluminous materials and conflicting expert evidence, the Court concluded that the two key issues were straightforward and could be determined by way of a summary trial. Bracken J. then dismissed the plaintiffs' claims against the defendants in their entirety. This decision is under appeal, so there will be more guidance from the B.C. Court of Appeal on the use of the summary trial procedure before certification. A full summary of *Player v. Janssen-Ortho Inc.* is available **here.**

Appellate courts have also indicated that claims with no hope of success should be weeded out early in the process. For example, the British Columbia Court of Appeal decertified a class action brought against manufacturers of a children's cough medicine in ***Wakelam v. Wyeth Consumer Health Care***. The plaintiff alleged that the defendants had engaged in "deceptive acts or practices" contrary to the ***Business Practices and Consumer Protection Act*** (the BPCPA) and made false or misleading representations to the public contrary to the ***Competition Act***. The plaintiff sought not only damages for the cost of cough medicine she had purchased, but also restitutionary remedies, including waiver of tort on the basis of the defendant's alleged statutory breaches. The Court held that the plaintiff's claim did not disclose a cause of action (other than for certain declaratory relief pursuant to the BPCPA) and decertified the action. In particular, the Court held that a claim for restitutionary remedies was not available where the alleged wrongful conduct was a breach of the BPCPA and the *Competition Act*. A summary of *Wakelam v. Wyeth Consumer Health Care Inc.* can be found **here.**

The Courts have carried on with this gatekeeping trend. In January of this year, the British Columbia Court of Appeal released ***Charlton v. Abbott Laboratories, Ltd.***, in which it overturned the certification of a pharmaceutical class action. The plaintiffs alleged that weight-loss drugs with the active agent sibutramine caused or contributed to adverse cardiovascular events such as heart attacks, strokes and arrhythmia. The Court held that the certification judge erred in certifying the class action in the absence of

evidence that the question of general causation (i.e., whether sibutramine increases the risk of adverse cardiovascular events for all class members) was capable of resolution on a class-wide basis. The plaintiffs relied on a study that only concluded that sibutramine increased the risk of cardiovascular events for patients with a history of cardiovascular disease for whom the drug was contraindicated. The plaintiff's own expert admitted there was no study on whether sibutramine increased the risk of cardiovascular events for those without a history of cardiovascular disease or those who are undiagnosed with the disease. The ruling represents an important application of the 2013 Supreme Court of Canada competition class action trilogy's emphasis on the evidentiary requirement for certification and on the role of the certification judge as class action gatekeeper. A full summary of *Charlton v. Abbott Laboratories, Ltd.* is available here.

[1] For example, ***Drady v. Canada (Health), 2008 ONCA 659***; ***Attis v. Canada (Health), 2008 ONCA 660***; ***Taylor v. Canada (Attorney General), 2012 ONCA 479***.