Product Liability Defence North and South of the Border:

Is there such thing as Canadian pre-emption?

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Introduction

In Canada, most food products, pharmaceuticals, cosmetic products and medical devices are subject to federal regulation pursuant to the *Food and Drugs Act* (FDA) and other related legislation.[1] Similar to the U.S. regulatory scheme, the Canadian regime is administered and enforced by the federal regulatory authorities – most notably Health Canada – responsible for establishing standards of safety for, and regulating and approving the use of, health-related products sold in Canada.

However, U.S. manufacturers who sell regulated products in Canada may be surprised to learn that compliance with the FDA and associated regulatory frameworks has not historically served as a defence to product liability claims. In particular, the Canadian regulatory regime has traditionally operated as a 'regulatory floor,' rather than a comprehensive code of conduct. Conversely, applicable regulatory frameworks in the United States may prescribe comprehensive codes of conduct that do not leave the regulated entity with any discretion, potentially creating irreconcilable conflicts between the state and federal governments. In such cases, the doctrine of federal pre-emption dictates that compliance with federal rules and regulations serves as a complete defence to conflicting state law claims.

1 RSC 1985, c F-27. See also *Canadian Food Inspection Agency Act*, SC 1997, c 6; *Consumer Packaging and Labelling Act, RSC 1985, c C-38; Consumer Packaging and Labelling Regulations, CRC, c 417; Natural Health Products Regulations, SOR/2003-196; Food and Drug Regulations, CRC, c 870; Safe Food for Canadians Act, SC 2012, c 24; Cosmetic Regulations, CRC, c. 869; Medical Devices Regulations, SOR/98-282*. While the discussion that follows refers to the "FDA regime," the underlying principles discussed herein apply with equal force to parallel federal regulatory schemes, particularly insofar as their interplay with private rights of action is concerned.

The discussion that follows addresses the availability of private rights of action in Canada and the U.S. in the context of regulated products, with a view to illustrating the differing approaches adopted in the respective jurisdictions. In particular, the absence of a formal "pre-emption" defence in Canada – and the implications thereof – will be explored from the perspective of product liability litigation north of the border.

While the doctrine of pre-emption has not been adopted by the Canadian courts to date – and its Canadian constitutional equivalents, including the doctrines of paramountcy and interjurisdictional immunity, have failed to offer defendants to product liability claims any meaningful safe harbour – the recent Canadian jurisprudence indicates that evidence of compliance with the applicable regulatory scheme may nevertheless be highly significant. More specifically, the Canadian courts have recognized that compliance with the FDA regime and related statutory schemes does provide powerful evidence that a defendant met the requisite standard of care in a given case, and is therefore a key consideration when assessing the viability of private law claims. Moreover, recent case law suggests that the Canadian courts may – in very limited circumstances – be willing to adopt a modified form of "pre-emption" where there is clear inconsistency between federal and provincial regimes.

However, while both the United States and Canada allow product manufacturers to refer to compliance with federal regulations in response to product liability claims, the impact of doing so may be substantially different in the respective jurisdictions. In the United States, pre-emption is a complete defence that will foreclose whatever claims plaintiffs may raise. Additionally, if a defendant can prevail on a pre-emption theory prior to trial, the defendant may be spared substantial legal costs. In Canada, by contrast, evidence of regulatory compliance may go a long way towards prevailing in the litigation, but it is not necessarily dispositive.

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An Overview of the U.S. Experience

The Supremacy Clause of the U.S. Constitution requires state law to yield to federal law when they conflict.[2] Such a conflict arises when a federal statute reflects the intent to pre-empt state law claims. Proof of this intention must be sufficient to overcome the court's general presumption against pre-emption.[3] The requisite congressional intent can be manifested in either express or implied pre-emption. Express pre-emption occurs when the statute itself, or case law interpreting that statute, makes it clear that Congress intended to pre-empt state law.[4] Implied pre-emption occurs when state law either conflicts with federal law such that it is impossible to comply with both,[5] when state law runs contrary to federal purposes,[6] or when federal law "occupies the field" such that the addition of state law would disturb the federal regulatory scheme.[7] Any pre-emption analysis begins with an analysis of the applicable regulatory scheme, and the discretion – or lack thereof – that is afforded to the product manufacturer to comply with both federal and state law.

2 U.S. Const., Art. VI, Cl. 2.

3 *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996) *; Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

4 *English v. General Elec. Co.*, 496 U.S. 72, 77 (1990).

5 *See Fidelity Fed. Sav. & Loan Assn. v. de la Cuesta,* 458U.S. 141, 153 (1982).

6 *See Hines v. Davidowitz,* 312 U.S. 52, 66-7 (1941).

7 *English*, 496 U.S. at 79.

A. THE REGULATORY BACKDROP

In the United States the pharmaceutical and medical device industries are highly regulated at the federal level by the U.S. Food and Drug Administration (U.S. FDA). With respect to prescription drugs, the U.S. FDA will approve a drug only after making the determination that it is both safe and effective. The U.S. FDA must also approve the drug's label.[8] Once the label is approved, there are only certain circumstances in which the manufacturer is allowed to change the label without first receiving clearance from the U.S. FDA. The U.S. FDA also oversees the regulatory and approval regime applicable to medical devices. Medical devices are subject to differing levels of scrutiny depending on the level of risk they pose. Class III devices are generally those that pose the greatest level of risk, *e.g.*, replacement heart valves. Such devices are subject to the greatest level of scrutiny.[9] The U.S. FDA enforces its own regulations; plaintiffs do not have a private right of action against pharmaceutical or medical device manufacturers for violations of those regulations.[10]

B. PRE-EMPTION OF CLAIMS AGAINST PHARMACEUTICAL COMPANIES

As the portions of the Food, Drug and Cosmetic Act (FDCA) relating to drug regulation do not expressly pre-empt applicable state laws, implied pre-emption is typically the defence asserted by pharmaceutical companies against product liability claims.[11] In particular, pharmaceutical manufacturers typically argue that "impossibility" pre-emption should apply because they cannot comply with both the applicable federal regulations and the state law theory of liability advanced by the plaintiff. As discussed below, there have been high-profile decisions in recent years regarding when the impossibility defence does and does not apply. The outcome of those decisions has turned on whether the defendant has discretion to do whatever is purportedly required by state law principles, or whether the U.S. FDA's regulatory regime contains mandatory requirements that do not allow for discretion.[12]

The leading U.S. Supreme Court case to address "impossibility" pre-emption with respect to brand name generic devices is *Wyeth v. Levine*. In that case, the plaintiff claimed that the defendant (Wyeth) obtained new information that required it to change the drug's label. Wyeth argued that the claim should have been pre-empted because the U.S. FDA had already approved the label, rendering compliance with both state and federal law "impossible." The Supreme Court disagreed, explaining that the Change Being Effected (CBE) process – which allows for unilateral alteration of the label without U.S. FDA approval – was available to the defendant. As the defendant could change the label, compliance with both federal and state law was possible, meaning that the plaintiff's claim was not pre-empted.[13]

As the portions of the Food, Drug and Cosmetic Act (FDCA) relating to drug regulation do not expressly pre-empt applicable state laws, implied pre-emption is typically the defence asserted by pharmaceutical companies against product liability claims.

8 *See* 21 U.S.C § 355 (detailing the application process for new drugs).

9 *See* 21 U.S.C. § 360c(a)(1)(C)(ii).

10 *See* 21 U.S.C. § 337.

11 *Wyeth v. Levine* 555 U.S. 555, 574 (2009) (noting that Congress did expressly pre-empt medical device tort claims in the 1976 amendment to the FDCA but has not done so for drug claims).

12 *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

13 Wyeth, 555 U.S. at 573, 581.

Wyeth, however, does not categorically prevent defendants from asserting a pre-emption defence to state law claims alleging that the manufacturer should have changed the label. A recent decision of the First Circuit Court of Appeals reached the opposite conclusion. In that case, the CBE process was unavailable because it is applicable only when a manufacturer receives new information after U.S. FDA approval of the label. The purportedly new information identified by the plaintiff, however, was known to the U.S. FDA before approval. The manufacturer thus could not unilaterally alter the label, meaning that the plaintiff's claim was pre-empted because compliance with both federal and state law was "impossible."[14]

While it may be challenging for a branded manufacturer to prevail on an "impossibility" pre-emption defence, it is substantially easier for a generic manufacturer to do so. The Supreme Court has looked more favorably on pre-emption defences raised by generic manufacturers as they are required to use the same chemical composition and label as the branded drug.[15] Unlike a branded manufacturer, a generic manufacturer has essentially no discretion to change the label.[16] The Supreme Court has held that since generic drug manufacturers are unable to change their products' labels to comply with obligations imposed by state law, state law failure-to-warn claims are therefore pre-empted under the impossibility doctrine.[17] The Supreme Court has also held that design-defect claims that turn on the adequacy of a generic drug's warnings are pre-empted, as it was "impossible" for the generic drug manufacturer to comply with state and federal law simultaneously.[18]

The Supreme Court has held that since generic drug manufacturers are unable to change their products' labels to comply with obligations imposed by state law, state law failure-to-warn claims are therefore pre-empted under the impossibility doctrine.

C. MEDICAL DEVICES

Unlike the FDCA provisions relating to drugs, the Medical Device Amendments of 1976 (MDA), which governs the regulation of medical devices, contains an express pre-emption clause. It states that with certain exceptions, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement: (1) which is different from, or in addition to, any requirement applicable ...to the device; and (2) which relates to the safety or effectiveness of the device."[19] This provision, however, does not guarantee pre-emption of all product claims brought against medical device manufacturers. Instead, the Supreme Court only found it applicable to claims regarding certain types of Class III devices, which are subject to the greatest pre-approval scrutiny by U.S. FDA.

The Supreme Court addressed pre-emption of claims against class III devices in *Riegel v. Medtronic Inc.* In that case, the plaintiff alleged that a catheter was designed, labeled and manufactured in a manner that violated state law. The Supreme Court held that this claim was pre-empted because it was "different from, or in addition to," federal standards. It reached this holding because

14 *Marcus v. Forest Labs., Inc.*, 779 F.3d 34, 41 (1st Cir. 2015).

15 *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

16 Ibid.

17 *PLIVA, Inc.*, 131 S. Ct. at 2581.

18 *Mut. Pharm. Co.*, 133 S. Ct. at 2477.

19 21 U.S.C § 360k.

the catheter was subjected to a rigorous pre-market approval process and a manufacturer was not to allowed to deviate from the approved application.[20]

Riegel has not foreclosed other types of product liability claims against medical device manufacturers. Notably, an earlier decision of the Supreme Court in *Medtronic Inc. v. Lohr*,[21] held that class III devices approved under a different regulatory scheme were not pre-empted. The device in question was approved under a "grandfather" provision of the MDA that allows for approval of devices that were "substantially similar" to others in the market in 1976.[22] This form of regulatory review is far less rigorous than the one used by the FDA to approve new class III medical devices. Because the device was subject to limited regulatory scrutiny, the claim against the device manufacturer was not pre-empted. Furthermore, the claim asserted against the device manufacturer alleged state law violations that were "parallel" to the requirements under federal regulations – meaning that there was arguably no conflict between state and federal law claims.[23] The precise circumstances under which claims brought against manufacturers of class III devices will be pre-empted is a matter of ongoing debate and litigation.

20 *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316-317 (2008).

21 518 U.S. 470 (1996).

22 *Id.* at 478.

23 In *Riegel*, the Supreme Court did not address whether "parallel" claims involving Class III devices that were subject to rigorous scrutiny would be pre-empted. 552 U.S. at 330.

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The Canadian Experience

At the outset, it is important to recognize that the doctrine of pre-emption, as it is understood in the United States, does not exist in Canada. Simply put, there is no precedent for a finding that compliance with federal law constitutes a complete defence to a parallel product liability claim. That is not to say that regulatory compliance is irrelevant to the Canadian product liability context. To the contrary, as discussed below, compliance with a regulatory regime does provide, *inter alia*, persuasive evidence that a defendant met a given standard of care and may indeed provide a substantive defence to product liability claims. Nevertheless, the formal pre-emption doctrine has not been adopted by Canadian courts or legislators.

Rather, the provisions of the FDA (and related regulatory schemes) have been interpreted as imposing regulatory floors, such that compliance with such regulatory schemes has not generally been regarded as dispositive of product liability claims. In *Buchan v. Ortho Pharmaceutical (Canada) Ltd*, for example, the FDA regime was deemed to be a regulatory minimum which is not (necessarily) coextensive with the broader common law requirements. Indeed, as the Ontario Court of Appeal expressly observed, a defendant who complies with statutory requirements governing on product warnings may still be held liable at common law:

> Apart from any regulatory scheme under the *Food and Drugs Act*, the general rule at common law is that the manufacturer of such drugs, like the manufacturer of other products, has a duty to provide consumers with adequate warning of the potentially harmful side-effects that the manufacturer knows or has reason to know may be produced by the drug.[24]

Generally speaking, the Canadian courts have – to date – been unwilling to embrace a formal equivalent to the doctrine of pre-emption. In particular, the various Canadian constitutional doctrines which might appear in the abstract

24 *Buchan v. Ortho Pharmaceutical (Canada) Ltd* (1986), 54 OR (2d) 92, 34 ACWS (2d) 328 (Ont CA). The FDA was also interpreted as a regulatory floor in *Wuttunee v. Merck Frosst Canada*, discussed below.

to offer similar protections – most notably the doctrines of paramountcy and interjurisdictional immunity – fall well short of the concept of "pre-emption" as it has developed in the United States.

However, as discussed below, recent jurisprudence suggests that the Canadian courts may be willing – in certain circumstances – to expand the historically "restrictive" judicial approach to regulatory compliance as merely a minimum threshold, particularly in the context of the common law duty of care analysis.

A. FEDERAL PARAMOUNTCY

Federal paramountcy is the Canadian constitutional doctrine that is most readily comparable to the U.S. doctrine of pre-emption.[25] Under the doctrine of paramountcy, where valid federal and provincial laws conflict, the provincial law is inoperative to the extent of that conflict.[26] Though Canadian paramountcy might seem similar to the U.S. pre-emption doctrine, there are three important differences:

1. Canadian paramountcy cannot be asserted vis-à-vis conflicts with the common law. Rather, it only applies to conflicts with provincial legislation.[27] This distinction limits the application of a pre-emption-type defence in Canada, as federal paramountcy cannot operate as a defence to common law claims (although private claims grounded in the provincial consumer protection legislation may be subject to challenge).[28]
2. Canadian courts, to the extent possible, seek to avoid interpretations of federal and provincial laws that result in a finding of conflict. For example, Canadian courts have explicitly rejected the notion that federal law can 'cover the field' of a given subject area in the absence of an express statutory statement to this effect, thereby leaving room for provincial law to buttress or even expand federal law in a given area provided there is no overt inconsistency.[29]

Recent jurisprudence suggests that the Canadian courts may be willing - in certain circumstances - to expand the historically "restrictive" judicial approach to regulatory compliance as merely a minimum threshold, particularly in the context of the common law duty of care analysis.

25 The doctrine is essentially grounded in the "division of powers" between the federal and provincial governments, pursuant to Sections 91 and 92 of the *Constitution Act, 1867*.

26 *Rothmans, Benson & Hedges Inc. v. Saskatchewan*, 2005 SCC 13 at para 11, [2005] 1 SCR 188 (*Rothmans*).

27 *Marine Services International Ltd. v. Ryan Estate*, 2013 SCC 44, [2013] 3 S.C.R. 53, at para 66:Federal paramountcy applies where there is an inconsistency between a valid federal legislative enactment and a valid provincial legislative enactment. The doctrine does not apply to an inconsistency between the common law and a valid legislative enactment. This is unlike interjurisdictional immunity, which protects the core of the "exclusive classes of subject" created by ss. 91 and 92 of the *Constitution Act*, 1867 even if the relevant legislative authority has yet to be exercised: *Canadian Western Bank*, at para. 34. The Chief Justice contrasted the two doctrines in COPA: Unlike interjurisdictional immunity, which is concerned with the scope of the federal power, paramountcy deals with the way in which that power is exercised. Paramountcy is relevant where there is conflicting federal and provincial legislation. [para. 62.]

28 See discussion of *Wakelam*, below.

29 *Bank of Montreal v. Marcotte*, 2014 SCC 55 at para 72, [2014] 2 S.C.R. 725 [*BMO*]. "The fact that Parliament has legislated in respect of a matter does not lead to the presumption that in so doing it intended to rule out any possible provincial action in respect of that subject. As this Court recently stated, "to impute to Parliament such an intention to 'occup[y] the field' in the absence of very clear statutory language to that effect would be to stray from the path of judicial restraint in questions of paramountcy."

3. The Canadian federal legislature is wary of explicitly ousting provincial jurisdiction. Unlike the U.S. FDA regime,[30] the current Canadian landscape does not give rise to any express pre-emption provisions. In particular, the Canadian federal legislature has not expressly signaled an intent to occupy the field in the health or consumer products arenas.

(i) The Requirement of Express Contradiction

In light of the above, any paramountcy defence in Canadian product liability actions would have to be based on a demonstrable conflict between federal and provincial law. Under Canadian law, there are two possible manifestations of such "conflict": impossibility of dual compliance, and frustration of federal purpose.

(a) Impossibility of Dual Compliance

To establish the impossibility of dual compliance, a defendant would need to be able to point to a federal requirement that directly conflicts with a provincial requirement. As stated above, Canadian courts err towards finding that laws do not in fact conflict.[31] Even if one level of government imposes stricter conditions than the other, compliance with the stricter conditions obviates any conflict. Canadian jurisprudence offers very few examples of cases decided on the basis of impossibility of dual compliance, and none that relate to food or drug regulation.

(b) Frustration of Federal Purpose

The frustration of federal purpose doctrine addresses situations where it may be possible to simultaneously comply with both federal and provincial laws, but such compliance would frustrate the purpose of a federal law.[32] To date, the courts have taken a restrictive approach in assessing whether or not provincial legislation has the effect of "frustrating federal purpose." Accordingly, any "frustration of purpose" argument in the regulated products arena will inevitably butt up against the tide of judicial interpretation, which deems the federal provisions to be regulatory floors i.e., minimum standards for the protection of public health, which the provinces are free to exceed.

Any pre-emption-type defence in Canadian product liability actions would have to be based on a demonstrable conflict between federal and provincial laws. Under Canadian law, there are two possible manifestations of such "conflict": impossibility of dual compliance, and frustration of federal purpose.

30 *Supra* note 10.

31 As explained by Hogg, "This is essentially the same presumption of constitutionality that applies in other kinds of federalism cases: where two possible interpretations of a law are possible, and one would make the law unconstitutional, the court should normally choose the one that supports the constitutional validity of the law."(Hogg, Peter W. (2007). *Constitutional Law of Canada (5th ed.)*. Toronto, Ontario: Carswell, at 16-5).

32 For example, *Law Society of British Columbia v. Mangat*, 2001 SCC 67, [2001] 3 SCR 113 dealt with a federal scheme that permitted non-lawyers to appear for a fee before immigration tribunals for the purpose of promoting informal, accessible and expeditious hearings. By contrast, a provincial law prohibited such paid appearances by non-lawyers. Even though forced compliance with the provincial law would not result in a breach of the federal law (as appearances by non-lawyers were not mandatory under the federal scheme), the court held it would nonetheless clearly frustrate the federal purpose.

(ii) Attempts to Invoke Paramountcy in the Product Liability Context

The jurisprudence to date involving attempts by defendants to invoke the paramountcy doctrine – or variations thereof, some of which have closely resembled the pre-emption doctrine – confirms that the Canadian courts are not receptive to such "division of powers" arguments in the context of products claims. For example, in *Rothmans, Benson & Hedges Inc. v. Saskatchewan* (*Rothmans*), the Supreme Court was asked to determine whether provincial legislation relating to tobacco controls[33] was sufficiently inconsistent with federal legislation,[34] so as to be rendered inoperative pursuant to the doctrine of federal legislative paramountcy.[35] In essence, the provincial legislative prohibitions surrounding the promotion and sale of tobacco products were argued to be "stricter" than the federal legislative regime, such that they were alleged to be in "conflict." Ultimately, however, the Supreme Court concluded that the provincial legislation was valid as it was possible for tobacco retailers to comply with both regimes and, accordingly, there was no violation of the paramountcy doctrine.[36]

Similarly, in *Wuttunee v. Merck Frosst Canada*, Merck was faced with a class action alleging that it had designed, manufactured and marketed a defective and dangerous product (Vioxx). Claims were advanced on a number of grounds, including negligence, deceit, assault, battery, breach of fiduciary duty and strict liability, as well as remedies for alleged breaches of the FDA, the *Competition Act* and the Saskatchewan *Consumer Protection Act* (SCPA).[37] In response to the latter statutory claim, Merck argued that because the FDA governs the manufacture, distribution, and sale of prescription drugs, the doctrine of paramountcy rendered the SCPA inapplicable.[38] However, the Saskatchewan Court of Queen's Bench ultimately rejected Merck's argument, holding that the FDA was merely a regulatory floor and thus there was no actual conflict between the SCPA and FDA.[39]

B. INTERJURISDICTIONAL IMMUNITY

Interjurisdictional immunity offers another possible tool for defendants to Canadian proceedings to argue that they are immune from certain legislation, with the effect of shielding them from related liability. The doctrine of interjurisdictional immunity is premised on the idea that the provincial and federal heads of power are 'exclusive,' and therefore each has a 'minimum and unassailable' core of content that is immune from the application of legislation enacted by the other level of government.[40]

Interjurisdictional immunity offers another possible tool for defendants to Canadian proceedings to argue that they are immune from certain legislation, with the effect of shielding them from related liability.

33 *The Tobacco Control Act*, SS 2001, c T-14.1, s 6.

34 *Tobacco Act*, SC 1997, c 13, s 30.

35 *Rothmans*, supra note 26.

36 *Rothmans*, supra note 26 at paras 22–27.

37 *Wuttunee v. Merck Frosst Canada Ltd.*, 2007 SKQB 29, 291 Sask R 161.

38 *Ibid* at para 29.

39 *Ibid* at paras 111–112.

40 *Canadian Western Bank v. Alberta*, 2007 SCC 22 at paras 33–34, [2007] 2 SCR 3 [*CDN Western*]. This argument was recently rejected in the *Carter* case: *Carter v. Canada (Attorney General)*, [2015] 1 SCR 331, 2015 SCC 5.

However, like federal paramountcy, interjurisdictional immunity is very rarely invoked by the courts. The Supreme Court has consistently signaled that the doctrine should be applied with restraint: "A broad application of the doctrine is in tension with the modern cooperative approach to federalism which favours, where possible, the application of statutes enacted by both levels of government."[41] Accordingly, the doctrine will only be applied in situations already covered by existing precedent. Where there is no established precedent, as in the product liability context, the success of a pre-emption type defence on the basis of interjurisdictional immunity seems unlikely.

C. REGULATORY COMPLIANCE AND THE COMMON LAW DUTY OF CARE

The relationship between the common law duty of care and regulatory compliance is by no means straightforward. As a starting point, the Supreme Court of Canada has held that legislative standards are relevant to, but not co-extensive with, the common law standard of care:

> The fact that a statute prescribes or prohibits certain activities may constitute evidence of reasonable conduct in a given situation, but it does not extinguish the underlying obligation of reasonableness. See *R. in right of Canada v. Saskatchewan Wheat Pool,* 1983 CanLII 21 (SCC), [1983] 1 S.C.R. 205. Thus, a statutory breach does not automatically give rise to civil liability; it is merely some evidence of negligence. See, e.g., *Stewart v. Pettie,* 1995 CanLII 147 (SCC), [1995] 1 S.C.R. 131, at para. 36, and *Saskatchewan Wheat Pool,* at p. 225. By the same token, mere compliance with a statute does not, in and of itself, preclude a finding of civil liability.[42]

The above principles emerge from the case of *Ryan v. Victoria (City)*,[43] wherein the Supreme Court of Canada broadly addressed the relationship between statutory standards and the common law standard of care. The Court noted that in determining the standard of care, "one may look to external indicators of reasonable conduct, such as custom, industry practice, and statutory or regulatory standards."[44] Although legislative standards are relevant to determining the standard of care, the two are not co-extensive and "one cannot avoid the underlying obligation of reasonable care simply by discharging statutory duties."[45] The Court also stated that compliance with the statutory standard will be less likely to exhaust the standard of care when the case is unusual (i.e., not clearly within the intended scope of the statute), the statute is general, and the statute allows for discretion in the manner of performance.[46]

Post-*Ryan*, there have been instances where – despite compliance with statutory standards – the defendant was found negligent. In *Zsoldos v. Canadian Pacific Railway*,[47] for example, the plaintiff was driving his motorcycle at night when he collided with a train at a railway crossing. Although Canadian Pacific was found to have complied with the relevant statutory framework, this was not

41 *BMO*, *supra* note 18 at para 63, citing *CDN Western* at paras 66–67.

42 *Ryan v. Victoria (City)*, [1999] 1 SCR 201 at para 29, 85 ACWS (3d) 208.

43 *Ibid*.

44 *Ibid* at para 28.

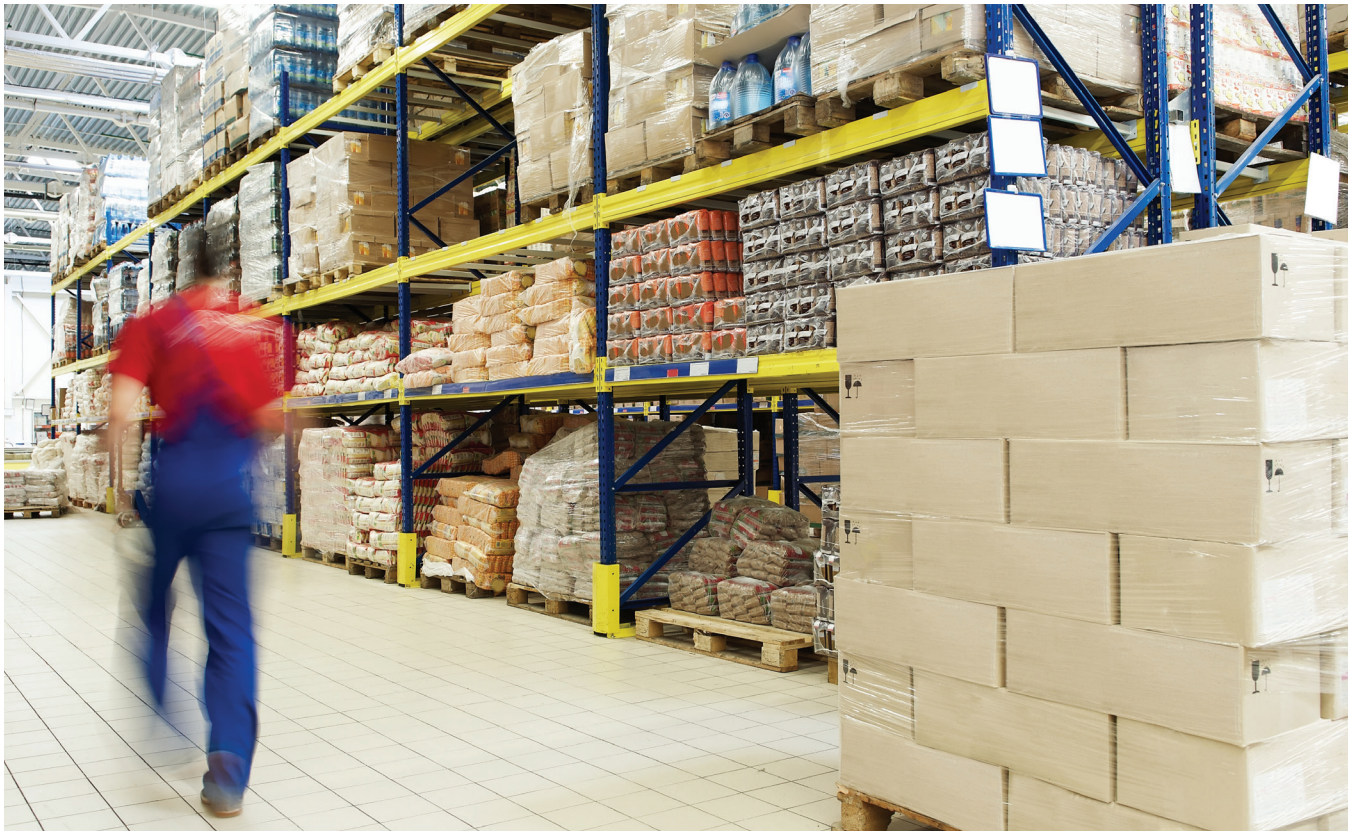
45 *Ibid* at para 29.

46 *Ibid* at paras 39-40.

47 2009 ONCA 55, 93 OR (3d) 321, leave to appeal to SCC refused, 2009 CanLII 36263.

sufficient because the statutory framework afforded the railway significant discretion in determining appropriate safety measures. Thus, Canadian Pacific was found negligent for its failure to take additional steps to address the safety concerns posed by the railway crossing at issue.

Similarly, in *Wos v. Canadian National Railway* – a decision also rendered in the railway context – the defendant was found liable for damages caused by a railway crossing barrier that unexpectedly dropped on a car driving across the tracks, damaging some fishing rods.[48] Despite compliance with the applicable statutory and regulatory standards, CN was found liable for the damages at common law.



48 *Wos v. Canadian National Railway*, 2007 BCPC 166, [2008] BCWLD 1009.

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Recent Developments

However, more recent jurisprudence suggests that the gulf between regulatory and common law duties may not in fact be as broad as some earlier jurisprudence had suggested. In particular, recent decisions in the FDA context demonstrate that while compliance with federal regulations does not preclude a manufacturer's or distributor's liability to consumers as a matter of law, it may do so as a matter of fact or – at the very least – will be materially relevant to the defence of consumer claims.

A. ANDERSEN V. ST. JUDE

Andersen et al. v. St. Jude Medical, Inc. et al. (*Andersen*) was the first Canadian class action involving a pharmaceutical drug or medical device to make its way past certification to a common issues trial, where the claims were ultimately dismissed in their entirety.

At issue in *Andersen* was a prosthetic heart valve with a cuff coated with a proprietary mixture called "Silzone." The Silzone valve was designed to directly reduce the incidence of post-operative infection by inhibiting the growth of bacteria. The plaintiffs alleged that Silzone interfered with tissue healing and impaired the body's ability to incorporate the device into the heart properly, leading to serious medical complications.

Evidence of regulatory compliance was given significant weight by the trial judge with respect to the determination of whether the defendants breached their duty of care. In particular, in relation to the allegation that St. Jude's testing of Silzone was inadequate and that Silzone was rushed onto the market, the trial judge determined that industry standards at the time included FDA standards for pre-market testing,[49] and that those standards were met in this case.[50] The very fact of regulatory approval led the trial judge to conclude that St. Jude conducted appropriate and sufficient testing that met industry and regulatory standards.[51]

49 *Andersen v. St. Jude Medical Inc.*, 2012 ONSC 3660 at para 102, 219 ACWS (3d) 725.

50 *Ibid* at paras 88, 16.

51 *Ibid* at para 181, as corroborated by expert evidence.

Similarly, with respect to the allegation that St. Jude's post-market surveillance and warnings were inadequate, the fact that Health Canada was aware of the asserted underlying risks but did not recommend a change of label or product design again led the trial judge to find that the plaintiffs had not established that St. Jude fell below the requisite standard of care.[52]

Notably, regulatory approval was also relevant to the trial judge's consideration of causation. The plaintiffs had alleged that the silver in Silzone caused significant damage to the heart. However, the trial judge relied on Health Canada's subsequent approval of numerous implantable medical devices containing silver as corroborating evidence that silver was a safe biomaterial to use in an implantable device.[53]

The court's reasoning and conclusions in *Andersen v. St. Jude* suggest that the regulatory standards developed and applied by Health Canada may be the most persuasive evidence of the corresponding common law standard of care. By extension, any plaintiff who seeks to prove that a different or higher standard should apply will be tasked with compiling significant evidence sufficient to displace the evidentiary impact of the regulator's approval. Similarly, with respect to the issue of causation, Health Canada's failure to acknowledge or accept the alleged harm will also prove to be an impediment for a plaintiff seeking to prove otherwise.

The court's reasoning and conclusions in Andersen v. St. Jude suggest that the regulatory standards developed and applied by Health Canada may be the most persuasive evidence of the corresponding common law standard of care.

B. WAKELAM V. WYETH – THE POSSIBILITY OF LIMITED PRE-EMPTION IN CANADA

More recently, the British Columbia Court of Appeal's ruling in *Wakelam v. Wyeth* (*Wakelam*) suggests that there may in fact be a broader role for regulatory compliance (i.e., beyond setting the standard of care) in the context of product liability claims. In particular, the case arguably contemplates the possibility of a pre-emption defence (or a modified version thereof), on the appropriate facts.[54]

The facts in *Wakelam* involved new medicine labeling rules, introduced for the first time in 2008, which required suppliers of children's over-the-counter cough medicine to re-label their medicine to instruct consumers that the product should not be given to children under six. Wyeth complied with the new labeling rules within the time allowed. However, in June 2008, a claim was brought by a class of plaintiffs comprised of "all persons resident in British Columbia who purchased Children's Cough Medicine for use by children under the age of six, that was supplied, offered for sale, advertised or promoted by the Defendants between December 24, 1997, to present."[55] The plaintiffs alleged that

52 *Ibid* at paras 198, 206, 214. Until the decision was made to recall the valves, the information that St. Jude had, and the advice it received, supported a reasonably held belief that there were no additional risks that had not already been communicated or required an additional warning or other action. The plaintiffs have not established that St. Jude fell below the standard of care with respect to its post-market surveillance and duty to warn of a reasonable and prudent heart valve manufacturer in similar circumstances.

53 *Ibid* at para 268.

54 *Wakelam v. Wyeth Consumer Healthcare/Wyeth Soins de Sante Inc.*, 2014 BCCA 36, 54 BCLR (5th) 7.

55 *Ibid* at para 3.

the pre-2008 marketing of medicines to children under age six was a "deceptive act or practice" and therefore contrary to British Columbia's *Business Practices and Consumer Protection Act* (Consumer Protection Act).[56]

At the certification hearing, the defendant advanced a paramountcy argument on two grounds, namely, that it would have been impossible to comply with the FDA requirements without breaching the Consumer Protection Act, as well as the fact that the Consumer Protection Act provision had the effect of frustrating federal purpose. While the BCCA ultimately upheld the certification judge's ruling that no 'real conflict' between the statutory schemes had been demonstrated, the Court was careful to note that an inconsistency between the FDA and Consumer Protection Act could arise "at a future time and on different facts."[57] In so doing, the Court left open the possibility that, on the right facts (i.e., in the event of a direct conflict between federal and provincial legislation), the doctrine of paramountcy may in fact be invoked as a defence to a (statutory) product liability claim.

Arguably, the *Wakelam* decision leaves open the possibility of a modified form of pre-emption defence in the context of claims brought pursuant to consumer protection – or other – provincial legislation, where there is actual conflict with the FDA or related federal regulatory schemes.

C. RECENT POLICY / LEGISLATIVE SHIFTS

As discussed, the provisions of the FDA (and related regulatory schemes) have traditionally been interpreted as imposing regulatory floors.[58] Provided this interpretation of federal food and drug regulatory requirements is maintained by the Canadian courts, it is unlikely that any formal pre-emption-type defence will succeed north of the border. In particular, as a regulatory floor, a provision will not "conflict" in a strict sense with a provincial regulation that adds additional requirements. Moreover, if the purpose of the FDA is interpreted to be "protection of the public," a regulatory floor provision will not be frustrated by a provincial regulation that simply adds layers of protection in furtherance of this purpose.

In recent years, however, Health Canada has focused its attention on streamlining regulation in order to allow innovative products to enter the Canadian market with relative ease. In doing so, the FDA has crafted exemptions to certain requirements. The exemptions arguably have the potential to change the direction of the FDA federal paramountcy rulings, and give rise to a defence akin to pre-emption.

56 *Ibid* at para 5. See also *Business Practices and Consumer Protection Act*, SBC 2004, c 2.

57 *Ibid* at para 43.

58 As was the case in *Buchan*, *supra* note 13, where warnings required by the FDA were interpreted to be regulatory floors.

In 2012, for example, Bill C-38 introduced "Marketing Authorizations" (MA),[59] which are regulations made by the Minister of Health that allow the Minister to exempt products from certain requirements in the FDA and its delegated regulations. Unlike the provisions of the FDA that give rise to regulation, provisions which exempt products from regulation are arguably regulatory ceilings. The federal government, by granting an exemption, is expressly telling a market participant what they do not have to do. For example, a 2012 MA exempts certain food additives from various FDA provisions, including the prohibition against the sale of foods that contain poisonous or harmful substances, as long as certain guidelines are met.[60]

As per the Health Canada website, the purpose of the MA is to "allow more efficient approvals of safe foods that can address emerging safety issues, and better respond to innovation."[61] These purposes would arguably be obstructed by any provincial law that added requirements which the MAs otherwise exempted. Unlike the regulatory floor provisions, therefore, the purpose of the exemptions would arguably be frustrated if any additional provincial law requirements were to be imposed. This argument is supported by Hansard materials, where federal purpose is expressed as 'reducing regulatory oversight'[62] and 'streamlining the regulatory process.'[63]

In the absence of any consideration of this specific issue by the courts, the most that can be said at this stage is that MAs and other exemptions[64] have the potential to breathe life into a more expansive paramountcy defence – on the appropriate facts – which may be in line with certain aspects of the pre-emption doctrine that has developed in the United States.

In 2012, for example, Bill C-38 introduced "Marketing Authorizations," which are regulations made by the Minister of Health that allow the Minister to exempt products from certain requirements in the FDA and its delegated regulations.

59 *FDA*, *supra* note 1 at ss 30.2–30.4.

60 *Marketing Authorization for Food Additives that may be Used as Preservatives*, SOR/2012-212, s 2(1): When a preservative that is set out in column 1 of the List is added to a food that is set out in column 2, the food is exempt from the application of paragraphs 4(1)(a) and (d) and sections 6 and 6.1 of the Food and Drugs Act and sections B.01.042, B.01.043 and B.16.007, as applicable, of the Food and Drug Regulations, in respect of the use or presence of the preservative only, if the amount of the preservative does not exceed the maximum level of use for that food that is set out in column 3 and if any other condition that is set out in that column is met.

61 Health Canada, "Questions and Answers regarding the amendments to the Food and Drugs Act for food (Bill C-38)" (3 May 2012), Food and Nutrition at question 9.

62 Second Reading in the Commons, May 4 2012 at page 1025.

63 Third Reading in the Commons, June 18 2012 at page 2045.

64 For example, the *Marihuana Exemption (Food and Drugs Act) Regulations*, SOR/2013-120, which exempts Marihuana from the Food and Drug Regulations if it is produced by a licensed producer in accordance with the Marihuana for Medical Purposes Regulations; or imported or exported by a licensed producer in accordance with an import or export permit issued under those Regulations.

5

Conclusion

While the U.S. doctrine of pre-emption does not apply in Canada, Canadian courts have become increasingly receptive to evidence of regulatory compliance as being indicative of compliance with the relevant standard of care, thus creating a form of defence to products liability claims. Moreover, recent jurisprudence suggests that claims grounded in provincial statutory rights of action – such as those brought pursuant to the provincial consumer protection legislation – may be "pre-empted" using the Canadian doctrine of paramountcy, although the availability and precise scope of such a defence remains an open question.

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