#### CITATION: ADAM, ABUDU v. LEDESMA-CADHIT ET AL, 2014 ONSC 5726 COURT FILE NO.: CV-11-440375 And COURT FILE NO.: CV-12-447333 DATE: 20141015

#### **SUPERIOR COURT OF JUSTICE - ONTARIO**

**RE:** ABUDU IBN ADAM, MAY HYACENTH ABUDU, IBRAHIM A.C. ABUDU, THE ESTATE OF AMINATAWALLA NAPOGA CHIDINMA ABUDU, Plaintiffs

#### AND:

CHRISTINE J. LEDESMA-CADHIT, GLAXOSMITHKLINE INC., ATTORNEY GENERAL OF CANADA, ATTORNEY GENERAL OF ONTARIO, Defendants

#### **BEFORE:** CHIAPPETTA J.

**COUNSEL:** *Ms. Ghosn* for the Plaintiffs

Ms. Yankou for Attorney General of Canada

Ms. Laeeque and Ms. Smith for Attorney General of Ontario

Mr. Sutton and Ms. Edwards for GlaxoSmithKline Inc.

Ms. Jones for Dr. Ledesma-Cadhit

**HEARD:** August 18, 2014

#### **ENDORSEMENT**

#### **Overview**

[1] The facts of this case are tragic. Aminatawalla Napoga Chidinma Abudu ("Aminatawalla"), the daughter of the Plaintiffs, Abudu Ibn Adam and May Hyacenth Abudu died on November 28, 2009 at the age of 5 years old. The Plaintiffs allege that her death was the result of an H1N1 influenza vaccination that was administered by her family physician five days earlier, on November 23, 2009.

[2] The Plaintiffs commenced two actions in negligence, naming as defendants the doctor who administered the vaccination, Dr. Christine J. Ledesma-Cadhit ("Ledesma-Cadhit"), the manufacturer of the vaccination, GlaxoSmithKline Inc. ("GlaxoSmith"), the Attorney General of Canada/Her Majesty the Queen in Right of Canada ("federal Crown") and the Attorney General of Ontario/Her Majesty the Queen in Right of Ontario ("provincial Crown") (collectively "the Crowns").

[3] In June and October 2012 the federal Crown and the provincial Crown brought motions seeking to strike the Statement of Claim and dismissing the actions in court file Nos. CV-11-440375 and CV-12-447333 as disclosing no reasonable cause of action against them. The motions were heard on August 18, 2014. The critical issue for the Court is whether the respective Crowns owed a private law duty of care to the Plaintiffs.

[4] For reasons set out below, I have concluded that a private law duty of care has not been established. The relevant statutes do not demonstrate a legislative intent to provide a private remedy to individuals. Rather, the purpose of the relevant legislative schemes is to facilitate the public authority to act in its discretion in the interest of public health. Further, the factual allegations do not distinguish the relationship that exists between the public health regulators and the members of the public sufficiently to create a relationship of proximity between the Plaintiffs and the public health regulator.

[5] At the relevant time in 2009, a pandemic health risk was facing the entire country. The Crowns developed a course of action in anticipation of the pandemic situation, designed to address the health and safety of the Canadian population. The decisions made necessarily involved the consideration and balancing of a myriad of competing interests blanketed by the ultimate goal of public health protection. The Crowns decisions were identifiable policy decisions and cannot therefore ground an action in tort.

[6] Despite the tragic circumstances, therefore, I have concluded that the Plaintiffs were not owed a private law duty of care by the federal Crown or the provincial Crown such that it is plain and obvious that the Plaintiffs' claim in negligence as against them will fail. The motions are allowed, the Statements of Claim struck and the actions dismissed as against the federal Crown and the provincial Crown.

# **Preliminary Matters**

(i) Plaintiffs legal representation

[7] At the commencement of the hearing Ms. Ghosn, barrister and solicitor confirmed that she has been retained to represent and is representing the Plaintiffs in this matter. She advised that the minor plaintiff, Ibrahim A.C. Abudu, is represented by his litigation guardian and father, Abudu Ibn Adam. She undertook, on behalf of the Plaintiffs to have the pleadings amended forthwith to address representation and identification of the litigation guardian.

(ii) The Plaintiffs' motion

[8] The original return date for the motions was October 29, 2012. The motions were adjourned several times at the request of the Plaintiffs, as they were self-represented at the time. In September 2013, a further return date of May 30, 2014 was scheduled peremptory to the Plaintiffs. On May 30, 2014, the Plaintiffs attended with Ms. Ghosn, and a further adjournment was requested. The motions were adjourned to August 18, 2014, peremptory to the Plaintiffs.

[9] On July 18, 2014, Ms. Ghosn, served a Motion Record on behalf of the Plaintiffs seeking the following relief:

- (b) An Order permitting the amendment of the pleadings to consolidate the relief sought in both court file no. CV-11-440375 and court file no. CV- 12- 447333; and,
- (c) An Order permitting the amendment of the pleadings into a Fresh as Amended Statement of Claim to be issued in court file No. CV-11- 440375.

[10] The Plaintiffs' motion record contained a proposed Amended Notice of Action and Statement of Claim and a proposed Fresh as Amended Notice of Action and Statement of Claim ("proposed amended claim"). The proposed amended claim seeks not only to consolidate the allegations and relief in the existing two court files but also seeks to add new allegations and new causes of action as against the Defendants. The Defendants oppose the Plaintiffs' motion.

[11] Upon hearing submissions from counsel, I ordered that the Plaintiffs' motion served on July 18, 2014 be stayed as against the provincial Crown and the federal Crown pending the resolution of the motions brought by the Crowns almost 2 years earlier. The 2012 motions seek to strike both Statements of Claim, without leave to amend. Without agreement by the parties, it would be unfair to consider the Plaintiffs' motion to amend their pleading prior to considering whether the original claims disclose a reasonable cause of action and if not, whether leave to amend is appropriate.

[12] The Plaintiffs' motion as served on July 18, 2014 is proceeding therefore only as against Ledesma-Cadhit and GlaxoSmith. The motion is returnable on November 18, 2014.

(iii) Claim against the Provincial Crown is a nullity, CV-11-440375

[13] Counsel for the provincial Crown and counsel for the Plaintiffs advised the Court at the outset of the motion that the Crown had recently received documentation that confirmed that notice had been provided to the Crown and therefore the portion of the Crown's motion to strike that dealt with the nullity issue was to be withdrawn without costs, on consent of all the parties. The parties also agreed that the plaintiff's allegation against the provincial Crown found at paragraph 18 of the affidavit of Abudu Ibn Adam dated July 18, 2014 was to be struck.

(iv) Interim Order of the Minister of Health

[14] During her submissions in response to the motion, Ms. Ghosn on behalf of the Plaintiffs, sought to file with the court and rely on an interim order of the Federal Minister of Health, respecting the sale of the vaccine for HINI dated October 13, 2009 and made pursuant to s. 30.1 (1) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (the "FDA") ("interim order"). I heard submissions from the Plaintiffs in this regard. As counsel for the federal and provincial Crowns were not aware of the Plaintiffs' intention to attempt to rely on the interim order, I invited their submissions in writing within 7 days of the hearing. The Plaintiffs were invited to respond to the Crowns' position within 7 days thereafter.

[15] The interim order is not admissible on this motion in accordance with Rule 21.01(2)(b) of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194, r. 21.01(2)(b). I will nonetheless admit the

document and consider it herein as it is referenced in the Plaintiffs' Proposed Amended Claim and neither the provincial nor the federal Crown object to the admissibility of the interim order.

[16] As will be discussed further below, s. 30.1 of the FDA authorizes the making of interim orders under certain specified circumstances. In the present case the Minister made the interim order pursuant to s. 30.1(1) which permits such an order when "the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment". The explanatory note at the end of the interim order demonstrates the time sensitive nature of addressing the HINI virus with timely access to the vaccine for Canadians.

[17] Consideration of the interim order does not change my conclusions as detailed below. The language of the interim order clearly demonstrates its intention to protect the health and safety of Canadians as a whole, and not to individuals in particular. There is nothing in the interim order that creates a "close and direct" relationship between the parties to justify the imposition of a *prima facie* duty of care.

# <u>The Claims</u>

[18] As noted above, the Plaintiffs have issued two Statements of Claim. The first claim was issued on December 20, 2011 and the second claim was issued on February 27, 2012. The claims both plead in negligence against the federal Crown and the provincial Crown. The second claim repeats the facts as alleged and the allegations of negligence included in the first claim.

- [19] The claims read:
  - In or about the year 2009, the defendants the Federal and Provincial governments acting through the Federal Ministry of Health, Health Canada, and the Ministry of Health and Long Term Care in the province of Ontario, notified the Canadian population using all means of communication that there was a pandemic of catastrophic consequences known as the swine flu about to infect the Canadian population.
  - The said Governments brought intense pressure on the medical and health care professions to encourage everyone in Canada to be vaccinated with the H1N1 flu vaccine.
  - The said Governments individually and jointly embarked on a project to immunize each member of the Canadian population including the plaintiffs and Aminatawalla by vaccinating them with the H1N1flu shot.
  - In or around the middle of November 2009, the defendant Dr. Ledesma-Cadhit solicited the plaintiff May Hyacenth, legal guardian and biological mother of Aminatawalla requesting that she and her family come to her office to be vaccinated with the said flu shot.
  - In response to the said request and also influenced by the advertising by the said defendants Government of Canada and Government of Ontario, the

plaintiff May Hyacenth attended at the office of the defendant, Dr. Ledesma-Cadhit on or about November 23, 2009.

- The defendant, Dr. Ledesma-Cadhit administered an injection to Aminatawalla that caused her untimely, sudden death.
- Aminatawalla was at the time of the said injection about five years of age, was in good health and lived with the Plaintiffs in an apartment home at 3161 Eglinton Avenue East, Toronto.
- On or about November 28, 2009, the said Aminatawall collapsed and died suddenly and unexpectedly as a result of the injection that Dr. Ledesma-Cadhit gave her.
- The Plaintiffs allege that the said death of Aminatawalla was caused by all of the Defendants individually and jointly.

[20] The particulars of the negligence of the provincial Crown and federal Crown are as follows:

- They invited the public, Aminatawalla and her family to take the H1N1 virus vaccination without advising of the risks of adverse effects of taking the said vaccination (19.1);
- They failed to caution the medical profession or the public that there were additional higher risks of death or injury when the H1N1 vaccine is used on specific populations such as the age group of Aminatawalla (19.2);
- They failed to call an inquiry to investigate the circumstances of Aminatawalla's death even after several requests were made to all appropriate governmental departments by the Plaintiffs (19.3).
- [21] The following two particulars are only alleged in court file no: CV-11-440375:
  - They failed to undertake a clinical study of the said injected substance to determine its safety for all classes of the population including that of Aminatawalla (19.4);
  - They concealed from the public knowledge that they had that there were cases of death and injury because of the said vaccine in Canada and worldwide (19.5).
- [22] The claims do not reference any federal or provincial legislation.

#### Test on Rule 21 Motion

[23] Rule 21, relates to the determination of an issue before trial and is available to any party on a question of law. It states:

21.01 (1) A party may move before a judge,

(a) for the determination, before trial, of a question of law raised by a pleading in an action where the determination of the question may dispose of all or part of the action, substantially shorten the trial or result in a substantial saving of costs; or,

(b) to strike out a pleading on the ground that it discloses no reasonable cause of action or defence;

and the judge may make an order or grant judgment accordingly.

[24] The test for Rule 21 was articulated by the Supreme Court of Canada in *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959, at para. 33. Wilson J. writes:

[T]he test in Canada [...] assuming that the facts as stated in the statement of claim can be proved, is it "plain and obvious" that the plaintiff's statement of claim discloses no reasonable cause of action? [...][I]f there is a chance that the plaintiff might succeed, then the plaintiff should not be "driven from the judgment seat". Neither the length and complexity of the issues, the novelty of the cause of action, nor the potential for the defendant to present a strong defence should prevent the plaintiff from proceeding with his or her case. Only if the action is certain to fail because it contains a radical defect [...] should the relevant portions of a plaintiff's statement of claim be struck out [...]

[25] Similarly, in *R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42, at para. 17, McLachlin C.J. writes:

This Court has reiterated the test on many occasions. A claim will only be struck if it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action [...].

Another way of putting the test is that the claim has no reasonable prospect of success. Where a reasonable prospect of success exists, the matter should be allowed to proceed to trial [...].

#### A Claim in Negligence

[26] A cause of action for negligence arises if all of the following elements are present:

1. The claimant must suffer some damage.

2. The damage suffered must be caused by the conduct of the defendant.

3. The defendant's conduct must be negligent, that is, in breach of the standard of care set by the law.

4. There must be a duty recognized by the law to avoid this damage.

5. The conduct of the defendant must be a proximate or legal cause of the loss or, stated in another way, the damage should not be too remote a result of the defendant's conduct.

6. The conduct of the plaintiff should not be such as to bar or reduce recovery, that is, the plaintiff must not be guilty of contributory negligence and must not voluntarily assume the risk.

[27] A claim in negligence can only succeed against a public authority in circumstances where a private law duty of care exists between the public authority and the plaintiff. The case must be one in which the law imposes an obligation to take reasonable care, in the circumstances, to avoid conduct that entails an unreasonable risk of harm to the plaintiff, as opposed to a situation where a public authority has a duty to the public collectively, to act in the public interest: *Cooper v. Hobart*, 2001 SCC 79, [2001] 3 S.C.R. 537, at paras. 42 and 43.

[28] The federal and provincial Crowns can only be liable in tort vicariously for the negligence of Crown servants or agents whose acts or omissions have caused injury in circumstances where a private law duty of care is owed to the Plaintiffs, the servants or agents have breached the applicable standard of care, and the Plaintiffs' damages result from that breach.

[29] In the present case, the constituent elements of the tort have not been pleaded.

[30] With respect to the allegation at paragraph 19.3, there is no statutory requirement for the federal or provincial Crowns to call an inquiry into the circumstances of this sad case and no causal nexus exists between the failure complained of and the damages claimed. Further, there is no statutory requirement concerning the allegation at paragraph 19.4 to undertake clinical studies. With regard to the allegation at paragraph 19.5 of the claim, that the parties concealed knowledge from the public, no material facts are pleaded and no causal nexus is alleged.

[31] Most significantly, however, no private law duty of care is owed to the Plaintiffs. Without such duty there can be no cause of action in negligence and it is plain and obvious therefore that the claim in negligence will fail.

# **Private Law Duty of Care**

[32] In order to maintain a claim in negligence against the federal and provincial Crowns the Plaintiffs must establish that the Crowns owed a private law duty of care arising from proximity with the federal and provincial Crown and the reasonable foreseeability of harm arising from the Crowns respective actions or inactions. The Supreme Court of Canada has recently affirmed the analysis determining whether a duty of care exists.

[33] In companion cases *Cooper* and *Edwards v. Law Society of Upper Canada*, 2001 SCC 80, [2001] 3 S.C.R. 562, the Supreme Court of Canada discussed the approach to be taken to determine whether a public authority owes a private law duty of care to an individual or to a

class. The Court held that the analysis is the two-part test first announced by the House of Lords in *Anns v. Merton London Borough Council*, [1978] A.C. 728, [1977] 2 All E.R. 492 (H.L.). In *Edwards*, at paras. 9 and 10, McLachlin C.J. and Major J. write:

At the first stage of the *Anns* test, the question is whether the circumstances disclose reasonably foreseeable harm and proximity sufficient to establish a *prima facie* duty of care. The focus at this stage is on factors arising from the relationship between the plaintiff and the defendant, including broad considerations of policy. The starting point for this analysis is to determine whether there are analogous categories of cases in which proximity has previously been recognized. If no such cases exist, the question then becomes whether a new duty of care should be recognized in the circumstances. Mere foreseeability is not enough to establish a *prima facie* duty of care. The plaintiff must also show proximity -- that the defendant was in a close and direct relationship to him or her such that it is just to impose a duty of care in the circumstances. Factors giving rise to proximity must be grounded in the governing statute when there is one, as in the present case.

If the plaintiff is successful at the first stage of *Anns* such that a *prima facie* duty of care has been established (despite the fact that the proposed duty does not fall within an already recognized category of recovery), the second stage of the *Anns* test must be addressed. That question is whether there exist residual policy considerations which justify denying liability. Residual policy considerations include, among other things, the effect of recognizing that duty of care on other legal obligations, its impact on the legal system and, in a less precise but important consideration, the effect of imposing liability on society in general.

[34] In *Cooper*, at para. 30, McLachlin C.J. and Major J. explained the proximity analysis:

[...] The proximity analysis involved at the first stage of the *Anns* test focuses on factors arising from the relationship between the plaintiff and the defendant. These factors include questions of policy, in the broad sense of that word. If foreseeability and proximity are established at the first stage, a *prima facie* duty of care arises. At the second stage of the *Anns* test, the question still remains whether there are residual policy considerations outside the relationship of the parties that may negative the imposition of a duty of care...

On the first branch of the *Anns* test, reasonable foreseeability of the harm must be supplemented by proximity. The question is what is meant by proximity. Two things may be said. The first is that "proximity" is generally used in the authorities to characterize the type of relationship in which a duty of care may arise. The second is that sufficiently proximate relationships are identified through the use of categories. The categories are not closed and new categories of negligence may be introduced. But generally, proximity is established by reference to these categories. This provides certainty to the law of negligence, while still permitting it to evolve to meet the needs of new circumstances.

[35] The two part test, known as the *Anns/Cooper* analysis, was again affirmed by the Court in *Odhavji Estate v. Woodhouse*, 2003 SCC 69, [2003] 3 S.C.R. 263, at para. 46. Iacobucci J. writes:

It is now well established in Canada that the existence of such a duty is to be determined in accordance with the two-step analysis first enunciated by the House of Lords in *Anns v. Merton London Borough Council*, [1978] A.C. 728, at pp. 751-52: First one has to ask whether, as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity or neighbourhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause damage to the latter -- in which case a *prima facie* duty of care arises. Secondly, if the first question is answered affirmatively, it is necessary to consider whether there are any considerations which ought to negative, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of it may give rise.

[36] Similarly, in *Imperial Tobacco*, at paras. 37-38, McLachlin C.J. stated:

To determine whether such a cause of action has a reasonable prospect of success, we must therefore consider whether the general requirements for liability in tort are met, on the test set out by the House of Lords in *Anns v*. *Merton London Borough Council*, [1978] A.C. 728, and somewhat reformulated but consistently applied by this Court, most notably in *Cooper*.

[37] McLachlin C.J. explained that there are two types of situations where proximity would arise, the first being when a duty of care is said to arise explicitly from the statutory scheme. McLachlin C.J., at para. 45, explained the second situation:

The second situation is where the proximity essential to the private duty of care is alleged to arise from a series of specific interactions between the government and the claimant. The argument in these cases is that the government has, through its conduct, entered into a special relationship with the plaintiff sufficient to establish the necessary proximity for a duty of care. In these cases, the governing statutes are still relevant to the analysis. For instance, if a finding of proximity would conflict with the state's general public duty established by the statute, the court may hold that no proximity arises: *Syl Apps*; see also *Heaslip Estate v. Mansfield Ski Club Inc.*, 2009 ONCA 594, 96 O.R. (3d) 401. However, the factor that gives rise to a duty of care in these types of cases is the specific interactions between the government actor and the claimant.

[38] The Court then examined what constitutes a policy decision that is generally protected from negligence liability and explained that this is often a difficult distinction to make. Only "true" policy decisions are protected from judicial scrutiny, as opposed to operational decisions. McLachlin C.J., at para. 87, writes:

[...] Generally, policy decisions are made by legislators or officers whose official responsibility requires them to assess and balance public policy considerations. The decision is a considered decision that represents a "policy" in the sense of a general rule or approach, applied to a particular situation. It represents "a course or principle of action adopted or proposed by a government": New Oxford Dictionary of English (1998), at p. 1434. When judges are faced with such a course or principle of action adopted by a government, they generally will find the matter to be a policy decision. The weighing of social, economic, and political considerations to arrive at a course or principle of action is the proper role of government, not the courts. For this reason, decisions and conduct based on these considerations cannot ground an action in tort.

[39] McLachlin C.J., at para. 90, continued:

I conclude that "core policy" government decisions protected from suit are decisions as to a course or principle of action that are based on public policy considerations, such as economic, social and political factors, provided they are neither irrational nor taken in bad faith. This approach is consistent with the basic thrust of Canadian cases on the issue, although it emphasizes positive features of policy decisions, instead of relying exclusively on the quality of being "non-operational". It is also supported by the insights of emerging jurisprudence here and elsewhere. This said, it does not purport to be a litmus test. Difficult cases may be expected to arise from time to time where it is not easy to decide whether the degree of "policy" involved suffices for protection from negligence liability. A black and white test that will provide a ready and irrefutable answer for every decision in the infinite variety of decisions that government actors may produce is likely chimerical. Nevertheless, most government decisions that represent a course or principle of action based on a balancing of economic, social and political considerations will be readily identifiable.

[40] The federal Crown admits that the claim neither falls within nor is analogous to a category of duty of care that has been previously recognized such that a *prima facie* duty is not established and an *Anns/Cooper* analysis is necessary.

[41] The provincial Crown submits however that an *Anns/Cooper* analysis is not required as the case law is clear that there is no private law duty of care between Ontario and individual members of the public in the promotion and protection of health. The relationship at issue, it is submitted, has therefore been recognized as one that attracts immunity from liability such that the *Anns/Cooper* analysis is not required. I disagree. The Courts have considered other examples

of claims in negligence against the Ontario Ministry of Health with respect to the protection and promotion of health when dealing with communicable diseases and vaccination. In my view, however, these broad considerations are not sufficient to deter liability without further analysis.

[42] While the allegations herein can generally be described to be about the protection and promotion of health, the claim specifically alleges that the Crown notified the public of a pandemic of catastrophic consequences, pressured health professionals to encourage vaccination and failed to warn of the risks associated with a vaccination. The allegations of negligence at issue are not sufficiently analogous to those considered previously in *Abarquez v. Ontario*, 2009 ONCA 374, 95 O.R. (3d) 414 or *Williams v. Canada (Attorney-General)*, 2009 ONCA 378, 95 O.R. (3d) 401, where the Court held that plaintiffs who contracted SARS failed to establish a proximate relationship with the Province of Ontario so as to establish a public law duty of care.

[43] In my view, unless the facts at issue specifically attach to a settled category where a duty of care has been previously denied, it would be unwise to forgo the *Anns/Cooper* analysis as important considerations of proximity and assessments of foreseeability are ultimately grounded in legislative context and specific interactions as may be pleaded. I am therefore loath to dismiss the Plaintiffs' claims at this stage of the analysis. Rather, I will consider whether a new duty of care should be recognized by applying the two stage *Anns/Cooper* analysis.

[44] Prior to doing so, however, in a case such as this, wherein a family is seeking to establish liability and damages for a daughter's death, I think it is appropriate, if not incumbent on the Court, to comprehensively review our court's previous findings in the area of private law duty of care and public health. While the concept is legally complex, our Courts have provided useful clarifications for its application.

[45] Put simply, if the statutory scheme establishes only general duties to the public, the relationship between the parties must be of sufficient proximity to prioritize the interest of the individual over the general public interest. If sufficient proximity is established, tort liability may nonetheless be negated because of important policy considerations.

i) Cooper

[46] In *Cooper*, the appellant was an investor who alleged that the Registrar of Mortgage Brokers, a statutory regulator, was liable in negligence for failing to oversee the conduct of an investment company which the Registrar licensed.

[47] At step one of the *Anns/Cooper* analysis the Court held there was insufficient proximity between the Registrar and the investors to ground a *prima facie* duty of care. The Court examined the *Mortgage Brokers Act*, R.S.B.C. 1996, c. 313 ("the Act") and the Regulations. The Registrar had broad regulatory and investigatory powers with respect to the operation of mortgage brokers, with the goal of ensuring that the public had access to capital through mortgage financing while at the same time instilling public confidence in the system. Even though to some degree the provisions of the Act served to protect the interests of investors, the overall scheme of the Act mandated that the Registrar's duty of care was not owed to investors exclusively but to the public as a whole.

[48] The Court further held that even if a *prima facie* duty of care had been established under the first branch of the *Anns/Cooper* analysis, it would have been negated at the second stage for overriding policy reasons. For policy reasons the Court looked to the quasi-judicial nature of the Registrar. The Registrar must act fairly or judicially in removing a broker's licence and those requirements would be inconsistent with a duty of care to investors. The Court also looked at the distinction between government policy and the execution of policy as a reason to negate the duty of care. McLachlin C.J. and Major J., at para. 53, stated:

[T]he Registrar must make difficult discretionary decisions in the area of public policy, decisions which command deference. As Huddart J.A. (concurring in the result) found, the decisions made by the Registrar were made within the limits of the powers conferred upon him in the public interest.

[49] The Court found that it was plain and obvious that pleadings did not disclose a cause of action against the Registrar and dismissed the appeal.

*ii)* Edwards

[50] In *Edwards*, the appellants brought a claim in negligence against the Law Society of Upper Canada ("Law Society"), the governing body of the self-regulated legal profession in Ontario, for failing to properly monitor the trust accounts of the defendant solicitor after they were allegedly victimized in a gold delivery fraud. The Court examined the governing statute, the *Law Society Act* (the "Act") and found that it did not reveal any legislative intent to expressly or by implication impose a private law duty on the Law Society.

[51] The Act is geared for the protection of clients and thereby the public as a whole, it does not mean that the Law Society owes a private law duty of care to a member of the public who deposits money into a solicitor's trust account. Decisions made by the Law Society require the exercise of legislatively delegated discretion and involve pursuing a myriad of objectives consistent with public rather than private law duties.

[52] The Court held it was unnecessary to examine the second stage of the *Anns/Cooper* Analysis.

*iii)* Eliopoulos (Litigation Trustee of) v. Ontario (Minister of Health and Long-Term Care), 82 O.R. (3D) 321, 276 D.L.R. (4th) 411, (ONCA)

[53] In *Eliopoulos*, George Eliopoulos was bitten by a mosquito and became infected with West Nile Virus ("WNV"). He was treated in hospital but later died from complications following a fall. His estate and family members brought an action in negligence against the Minister of Health and Long-Term Care, alleging that Ontario could and should have prevented the outbreak of WNV. Sharpe J.A. held it was plain and obvious that Ontario did not owe a private law duty of care to individuals to prevent the spread of WNV.

[54] Sharpe J.A. examined Ontario's statutory duties under the *Health Protection and Promotion Act*, R.S.O. 1990, c. H-7 ("HPPA"). In particular, Sharpe J.A. examined the purpose

of the legislation and the broad discretion conferred to the Minister under the legislation. Sharpe J.A. held that the overall scheme of the HPPA created a general public law duty, but did not give rise to a private law duty sufficient to ground an action in negligence. Sharpe J.A., at para. 17, held:

In my view, these important and extensive statutory provisions create discretionary powers that are not capable of creating a private law duty. The discretionary powers created by the HPPA are to be exercised, if the Minister chooses to exercise them, in the general public interest. They are not aimed at or geared to the protection of the private interests of specific individuals. From the statement of purpose in s. 2 and by implication from the overall scheme of the HPPA, no doubt there is a general public law duty that requires the Minister to endeavour to promote, safeguard and protect the health of Ontario residents and prevent the spread of infectious diseases. However, a general public law duty of that nature does not give rise to a private law duty sufficient to ground an action in negligence. I fail to see how it could be possible to convert any of the Minister's public law discretionary powers, to be exercised in the general public interest, into private law duties owed to specific individuals.

[55] Sharpe J.A. then examined whether there was sufficient interactions between the parties to trigger a special relationship. Sharpe J.A., at para. 23, writes:

I turn to the issue of whether the Plan amounted to the adoption of a policy that engaged Ontario at the operational level. The Plan was prepared by the Public Health Branch of the Ministry in cooperation with a number of nongovernmental agencies. Its purpose, as described at p. 5 of the Plan, was "to describe the Surveillance Plan for WNV in the Province of Ontario" and "the Prevention and Public Education measures aimed at reducing the risk of WNV disease for the population of Ontario". [...] As I read it, the Plan represented an attempt by the Ministry to encourage and coordinate appropriate measures to reduce the risk of WNV by providing information to local authorities and the public. The Ministry undertook to do very little, if anything at all, beyond providing information and encouraging coordination. The implementation of specific measures was essentially left to the discretion of members of the public, local authorities and local boards of health.

[...] In this regard, the Plan mirrors the scheme of the HPPA, ss. 4 and 5: responsibility for the implementation of health policy, including superintending and carrying out health promotion, health protection, disease prevention, community health protection, and control of infectious diseases and reportable diseases, rests with local boards of health, not the Ministry. Local boards of health are subject to direction from the Minister (s. 83(1)), and in the event the local board of health fails to follow such direction, the Minister can act in its stead (s. 84(1)). However, this serves only to

emphasize that under the HPPA, local boards of health, constituted as independent non-share capital corporations, bear primary operational responsibility for the implementation of health promotion and disease prevention policies.

[56] Sharpe J.A. held that the Plan did not amount to an operational plan, with commensurate duties, on which the respondents could base a claim in negligence and therefore no proximity had been established.

[57] Sharpe J.A., at paras. 32 and 33, then examined the residual policy concerns at stage two of the *Anns/Cooper* analysis:

[...] In deciding how to protect its citizens from risks of this kind that do not arise from Ontario's actions and that pose an undifferentiated threat to the entire public, Ontario must weigh and balance the many competing claims for the scarce resources available to promote and protect the health of its citizens.

I agree with Ontario's submission that to impose a private law duty of care on the facts that have been pleaded here would create an unreasonable and undesirable burden on Ontario that would interfere with sound decisionmaking in the realm of public health. Public health priorities should be based on the general public interest. Public health authorities should be left to decide where to focus their attention and resources without the fear or threat of lawsuits.

[58] The action was dismissed on the ground that the facts pleaded by the respondents disclosed no cause of action.

iv) *Klein v. American Medical Systems, Inc.* [2006] 84 O.R. (3d) 217, 2006 CanLII 42799, (Div. Ct.)

[59] In *Klein*, the plaintiff brought an action against the manufacturer and distributor of a medical device designed to alleviate or cure female incontinence and against the federal government, through Health Canada, who regulates the sale and marketing of medical devices. The device in question was authorized to be imported or sold in Canada in accordance with a licence issued by Health Canada to the manufacturer pursuant to the FDA and the *Medical Devices Regulations*, S.O.R./1998-282 (the "Regulations"). The plaintiff claimed that Health Canada was negligent in its regulation of the device. At the Divisional Court, Chapnik J. held that it was plain and obvious that a sufficient relationship of proximity between the federal government and the plaintiff did not exist.

[60] The Court examined the legislative scheme, particularly ss. 22-29 of the FDA, which dealt with the administration, and enforcement of the Act with respect to inspections and ss. 11-20 of the Regulations, which set out details stipulating that a medical device shall not adversely affect the health or safety of an individual. The Court also examined the provisions that set out the application process for a medical device license, the power of the Minister to issue a medical

license and attach conditions and the discretion of the Minister to refuse to issue a medical device license or to suspend licenses.

[61] At the first stage of the *Anns/Cooper* analysis the Court considered the proximity between the parties. Chapnik J. explained that it did not follow that a legislative scheme created to regulate an activity, product, or industry was intended to protect individual users and consumers.

[62] Chapnik J., at para. 25, continued:

Thus, a statute must demonstrate a legislative intent to provide a private remedy to individuals. There can be no private law duty of care where the purpose of the legislative scheme is to facilitate a public authority to act in its discretion in the public interest.

[63] Further, at para. 33:

[...] Health Canada is only one player in the complex regulatory and delivery scheme governing medical devices in Canada. It has no direct role in the commercial transaction or the medical decision-making that leads to individual use. The duties of care toward the patient or consumer are qualitatively different from any public duty owed by Health Canada as the government regulator.

[64] Chapnik J. held that it was plain and obvious that a sufficient relationship of proximity between the federal government and the plaintiff did not exist. Regarding the second stage of the *Anns/Cooper* analysis the Court held, had a duty of care been established, it would have been negated for policy reasons. Chapnik J., at para. 37, stated:

First, recognizing a duty of care would create a spectrum of unlimited liability to an unlimited class. At the time the device was available in Canada, it was not possible for Health Canada to control its manufacture or sale, and the spectrum of unlimited liability would therefore loom large. Second, recognizing a duty of care would effectively create an insurance scheme for medical devices funded by taxpayers, which, according to the legislation, its content and emphasis, was not the intention of Parliament. Third, recognizing a duty of care may have a negative impact on the government's ability to balance all relevant interests when making regulatory decisions regarding medical devices. The regulatory scheme focuses on the requirements of manufacturers, distributors and importers, among other things, to demonstrate the safety and effectiveness of the products they seek to introduce in the marketplace. Fourth, recognition of a duty of care is not consistent with the societal interest to promote advances in medical science and technology.

v) Wuttunee v. Merck Frosst Canada Ltd., 2007 SKQB 29, [2007] 4 W.W.R. 309

[65] In W*uttunee*, the plaintiff commenced an action to recover damages for injuries and losses he suffered by ingesting a prescription drug manufactured and distributed by the defendant with the approval of Health Canada. The plaintiff sought certification for a class action. The plaintiff also made claims against Canada, based on Health Canada having failed to discharge its statutory duty pursuant to the FDA and its common law duty of care to the Plaintiffs.

[66] Klebuc J. sought to determine if the pleadings disclosed the various causes of action alleged against both the manufacturer and the government. Klebuc J. determined that the foreseeability aspect of stage one of the *Anns/Cooper* analysis was met, but then turned to the statute to examine proximity:

Section 4(1) of the *Department of Health Act* gives the Minister of Health responsibility for administering all legislation and regulations related to "the health of the people of Canada" that are not specifically assigned to another department and includes the regulation of pharmaceutical manufacturers through the registration and enforcement provisions of the FDA. (at para. 80)

[67] Klebuc J., at para. 83, held that proximity had not been established based on the pleadings and Canada did not owe the Plaintiffs a duty of care:

In my view, the Minister in the instant case made, and was only required to make, policy decisions having regard to the public at large when it licensed Vioxx for use in Canada. In this respect, the licensing and related regulatory functions of Health Canada did not create any rights in favour of the Plaintiffs or a direct relationship between Canada and the Plaintiffs for the reasons canvassed in *Cooper, supra* and *Edwards, supra*. In the result, no private duty of care on the part of Canada exists upon which the Plaintiffs' negligence claim can be sustained, unless Health Canada undertook or otherwise was obligated to undertake an operational duty.

[68] Regarding stage two of the *Anns/Cooper* analysis Klebuc J. held that the potential for indeterminate liability was similar to that discussed in *Cooper*. Klebuc J., at para. 88, stated that Health Canada's actions are "a policy decision in relation to public health and represents an implementation of social and economic policy and not the application of rules to individual cases". The negligence claim against Canada was struck.

vi) Attis v. Canada (Minister of Health), 2008 ONCA 660, 93 O.R (3d) 35

[69] In *Attis*, the plaintiffs alleged that the FDA imposed a duty on Health Canada to protect the Canadian public from devices that might cause them harm. The plaintiffs alleged that the government breached its duty to properly regulate medical devices, namely, silicone breast implants. At the first stage of the *Anns/Cooper* analysis, Lang J.A. held that foreseeability was

met, but that the plaintiff failed to establish a relationship of proximity, which must be found in the governing statute. Lang J.A., at para. 55, began by examining the legislative framework:

[T]he umbrella statute of the *Department of Health Act*, at s. 4, provides that the Minister's obligations are to the people of Canada for the promotion of their health and the prevention of risk generally. Thus, under this statute, the Minister's duty is to the people of Canada as a whole, not to individual residents.

[...]

Since an examination of the legislative scheme reveals that no duty is placed on Health Canada, and all obligations are on the industry, I conclude that the statute signals an intention that the government's duty is owed to the public as a whole, not to the individual consumer.

Finally, I am not persuaded that the absence of an immunity clause in the legislation is indicative of a relationship of proximity between the appellants and Health Canada. Given the plain language of the legislative scheme, no intention to impose a private law duty of care can be inferred.

[70] Lang J.A. then considered the appellants argument that a relationship of proximity can be established by operational conduct outside the statutory framework based on the interaction between the parties. Lang J.A., at para. 64, rejected this argument:

In my view, there is no allegation of such representations by Health Canada in this case that are capable of supporting a relationship of proximity. Accepting the pleading that Health Canada knew the implants were dangerous for all consumers, knowledge alone is insufficient to found a private law duty of care. In this case, it is not pleaded that Health Canada knew, or ought to have known, that the appellants - as opposed to unknown members of the general public - were relying on it to ensure product safety: see *Rivtow Marine Ltd. v. Washington Iron Works*, [1974] S.C.R. 1189 at 1196-7. In other words, a relationship of proximity is still necessary to support a duty of care.

Apart from a bald pleading that the appellants relied on Health Canada for the safety of the breast implants, no facts are pled to support any reliance. Moreover, there is no suggestion of any direct reliance. Even if the appellants could be said to have placed general reliance on Health Canada based on its role as regulator, that reliance was not evidenced by any pleaded communication and was not pled to be within the reasonable expectations of the parties. Health Canada provided no direct service to the appellants and had no contact with them. This lack of a relationship is evident from the fact that Health Canada did not keep, and was not mandated to keep, any record of individuals who received implants. It had no mechanism to notify such individuals about product defects or recalls. Those responsibilities were placed on the manufacturer. Moreover, the fact that Health Canada's only method of notification to the public would be by public notice supports the conclusion that the duty was public, rather than private, in nature. In addition, as I have observed, the statutory framework included no complaints mechanism such as those often provided for professional regulatory bodies. Thus, the appellants never raised and had no procedure for registering a complaint with Health Canada.

In this case, the legislation put the duty on the medical device industry to ensure the safety of its products, to track product complaints, to recall dangerous products, and to warn consumers. Moreover, there was no interaction with Health Canada that could have led the appellants to believe Health Canada had assumed a private law duty of care for product safety. Nothing in the relationship between the parties would lead an individual to assume a government product guarantee. Rather, the appellants' expectations and reliance would have been on their medical advisors, the hospital, the manufacturer and the distributor of the device. I would conclude that the pleaded facts in this case do not support a finding of proximity through interaction.

[71] Lang J.A. went on to stage two of the analysis and held that in the event she was wrong about the proximate relationship, a duty of care would be negated because of policy considerations. Lang J.A., at para. 74, stated:

[...] The appellants argue that indeterminate liability is not a concern because the number of affected consumers in this proceeding is relatively contained. However, Health Canada's responsibilities extend far beyond the regulation of the specific devices at issue in this case to the regulation of thousands of other devices. In addition, potential liability could extend from medical devices to other products regulated under the FDA, such as food, drugs and cosmetics, as well as to many other regulatory regimes. It follows that the imposition of liability on the public purse would place an indeterminate strain on available resources. Accordingly, in my view, the prospect of indeterminate liability weighs against the imposition of liability in this case.

[72] Lang J.A. held that the motions judge was correct in concluding that it was plain and obvious that the appellants failed to frame a cause of action capable of establishing a duty of care.

vii) Drady v. Canada (Minister of Health), 2008 ONCA 659, 270 O.A.C. 1

[73] In *Drady*, the appellant received a temporomandibular joint implant ("TMJ implant") which he alleged was unsafe and caused irreversible consequences that left him disabled and in pain. Since the device implanted in the appellant was unlabeled, he was unable to identify its

manufacturer and he sued Health Canada, as implants are medical devices regulated by Health Canada under the FDA. Lang J.A. dismissed the appeal holding that it was plain and obvious that the appellant's pleadings did not establish that Health Canada owed him a private law duty of care.

[74] At the first stage of the *Anns/Cooper* analysis Lang J.A. determined that the legislative scheme did not support a finding of proximity. The scheme was aimed at regulating devices with the cooperation of the industry. It required manufacturers, distributors and importers to take responsibility for product safety and to comply with certain requirements. It was not mandatory for Health Canada to enforce compliance, the legislative scheme envisaged no relationship between Health Canada and the consumer of the medical devices.

[75] Next, Lang J.A., at para. 53, considered whether Health Canada assumed a proximate relationship with the appellant rooted in the interactions between the parties:

[...] [T]he pleadings include three allegations that distinguish the claim from that in *Attis*. The first is that "Health Canada represented that it monitored the effectiveness of recalls by manufacturers and took a lead role in alerting the public of recalls and safety concerns". The second is that, in 1983, Health Canada issued an information letter explaining that the issuance of a Notice of Compliance "meant that Health Canada was satisfied that the manufacturer had carried out tests and had submitted appropriate results to Health Canada to demonstrate a reasonable probability of safety of the devices and effectiveness of the devices in humans". The third is that Health Canada failed "to respond to requests for information made by members of the public concerning devices".

The pleadings do not allege that any of the three communications came to the appellant's attention or to the attention of any specific member of the public. Nowhere does the appellant plead a specific representation made to him by Health Canada. Moreover, nowhere does the appellant assert reliance, other than by pleading that members of the public generally relied on Health Canada to implement its public law duties. In the absence of a specific representation or reliance on Health Canada regarding the safety of the implant, in my view, it is plain and obvious that the appellant cannot establish a direct and close relationship of proximity that makes it just and fair to impose a private law duty of care on Health Canada.

[76] Lang J.A. concluded that it was unnecessary to consider the second stage of the analysis given the finding on proximity.

viii) Williams v. Canada (Attorney-General), 2009 ONCA 378, 95 O.R. (3d) 401

[77] In *Williams*, the plaintiff sued the province of Ontario in a class action for damages suffered by individuals who contracted SARS in 2003. In late April 2003 Ontario began to relax the infection control procedures imposed on hospitals and the plaintiff claimed this was done

prematurely and negligently. Sharpe J.A. held that it was plain and obvious on the facts pleaded in the claim that Ontario did not owe a private law duty of care to the plaintiff and that the claim had no prospect of success.

[78] At stage one of the *Anns/Cooper* analysis, Sharpe J.A., at para. 25, examined the statutory scheme at issue, the *Health Protection and Promotion Act*, R.S.O. 1990, c. H.7, ("HPPA") and explained that the nature of this legislative scheme was considered at length in *Eliopoulos*:

[...] After considering the *Cooper-Anns* test, this court held, at paras. 17-19, that the exercise of the extensive discretionary powers to take measures to protect the public from the spread of infectious disease did not create a private law duty in that case. The powers "are to be exercised...in the general public interest" and they "are not aimed at or geared to the protection of the private interests of specific individuals". While the Minister of Health is under a general public law duty "to promote, safeguard and protect the health of Ontario residents and prevent the spread of infectious diseases...a general public law duty of that nature does not give rise to a private law duty sufficient to ground an action in negligence". Rather, the Minister is required to act in the general public interest, and in so doing must balance "a myriad of competing interests", the nature of which are inconsistent with the imposition of a private law duty of care.

[79] Sharpe J.A., at para. 31, stated:

When assessing how best to deal with the SARS outbreak, Ontario was required to address the interests of the public at large rather than focus on the particular interests of the plaintiff or other individuals in her situation. Decisions relating to the imposition, lifting or re-introduction of measures to combat SARS are clear examples of decisions that must be made on the basis of the general public interest rather than on the basis of the interests of a narrow class of individuals. Restrictions limiting access to hospitals or parts of hospitals may help combat the spread of disease, but such restrictions will also have an impact upon the interests of those who require access to the hospital for other health care needs or those of relatives and friends. Similarly, a decision to lift restrictions may increase the risk of the disease spreading but may offer other advantages to the public at large including enhanced access to health care facilities. The public officials charged with the responsibility for imposing and lifting such measures must weigh and balance the advantages and disadvantages and strive to act in a manner that best meets the overall interests of the public at large.

[80] Sharpe J.A. held that the plaintiff failed to satisfy the first stage of the *Anns/Cooper* analysis. Sharpe J.A. found it was unnecessary to go on to stage two, but observed that it was difficult to see any meaningful distinction between this case and *Eliopoulos*, where the Court found that residual policy concerns would negate imposing a duty of care.

## *ix) Abarquez*

[81] In *Abarquez*, 53 registered nurses and a number of their family members, alleged that they suffered serious injury to their health from SARS. The plaintiffs alleged that the Ministry of Health and Long Term Care and Provincial Operations Centre failed to provide nurses with timely information about SARS.

[82] Sharpe J.A. examined the relationship of proximity between the parties. The plaintiffs argued that when Ontario intervened in the day-to-day operations of the hospitals by issuing Directives to mandate the specific procedures the plaintiff nurses were to employ regarding the SARS outbreak, Ontario was under an obligation to be mindful of their interests. Sharpe J.A., at para. 20, rejected this argument for similar reasons to *Eliopoulos* and *Williams*, while Ontario is obliged to protect the public at large from the spread of communicable diseases such as West Nile Virus and SARS, "Ontario does not owe individual residents of the province who contract such diseases a private law duty of care giving rise claims for damages".

[83] Sharpe J.A., at para. 28, explained:

In the present case, the potential for conflict is obvious. Health care workers are already significantly at risk when it comes to containing an infectious disease. As the plaintiff nurses point out, they were legally required to treat SARS patients and, given the nature of that disease, they were thereby exposed to the risk of contracting the disease. To impose a private law duty of care upon Ontario to safeguard the health of the nurses would conflict with the overriding public law duty to pronounce standards that are in the interest of the public at large. Simply put, the interests of nurses, like the interest of investors in *Cooper*, the clients in *Edwards* and the parents in *Syl Apps*, cannot be prioritized over the general public interest, yet that would be the effect of finding that they were owed the special consideration in the formulation of health care policy that a private law duty of care would entail.

[84] Sharpe J.A. held that the relationship between the parties was not sufficiently proximate to give rise to a private law duty of care, and it was not necessary to consider stage two of the *Anns/Cooper* analysis.

*x)* Heaslip Estate v. Mansfield Ski Club Inc., 2009 ONCA 594, 96 O.R. (3d) 401

[85] In *Heaslip*, 17 year old Patrick Heaslip died as a result of injuries sustained in a tobogganing accident. Patrick was taken by land ambulance to Stevenson Memorial Hospital in Alliston where one of the defendant physicians assessed his injuries and requested an air ambulance to take Patrick to St. Michael's Hospital in Toronto. The Medical Air Transport Centre, which is operated by Ontario, advised that an air ambulance would not be available for 2 hours. The doctor thereupon cancelled the request for an air ambulance and ordered a land ambulance to transfer Patrick to St. Michael's Hospital. Patrick died during the transfer.

[86] Sharpe J.A. examined the legislation and the motions judge's decision that a private law duty of care was not owed in this case. *The Ambulance Act*, R.S.O. 1990, c. A.19, s. 4(1) (the "Act"), sets out the duties and powers given to the Minister of Health in regard to ambulances. Sharpe J.A., at para. 18, found:

[T]he facts alleged bring Patrick Heaslip into a direct relationship with Ontario that is sufficiently proximate to satisfy the *Cooper-Anns* test for recognizing a new category of duty of care. As it is not "plain and obvious" that no duty of care arises, the claim against Ontario should not be dismissed at the pleading stage.

[87] Sharpe J.A., at paras. 19 and 20, continued:

This case is distinguishable from cases like *Cooper* and *Attis*. In those cases, the plaintiffs suffered harm at the hands of a party involved in an activity subject to regulatory authority, and then alleged negligence on the part of the governmental authority charged with the duty of regulating the activity that gave rise to the plaintiff's loss. *Cooper* and *Attis* hold that such plaintiffs have no direct relationship with the governmental authority and can assert no higher claim to a duty of care than any other member of the public.

The claim asserted here does not rest solely upon a statute conferring regulatory powers, as in *Cooper* and *Attis*, but is focused instead on the specific interaction that took place between Patrick Heaslip and Ontario when the request for an air ambulance was made. In this case, the relationship between Patrick Heaslip and the governmental authority is direct, rather than being mediated by a party subject to the regulatory control of the governmental authority.

[88] Sharpe J.A. held that the motions judge erred by concluding that this case did not fall within an established category of negligence and that had an *Anns/Cooper* analysis been conducted, it was arguable that proximity would have been established. Further, Sharpe J.A. held that should a full *Anns* analysis be required, the motions judge erred with respect to the second stage by concluding that any duty of care was negated by residual policy concerns. Sharpe J.A., at paras. 33 and 34, stated:

The motion judge's concerns regarding the risk of indeterminate liability suffers from the same difficulty as his duty of care analysis, namely, he failed to take into account the very specific nature of the claim. As I have indicated, I would strike the broad allegations complaining of the failure to provide an adequate system of air ambulance services. When stripped to its essentials, the allegation of specific acts of negligence in response to a specific request for air ambulance services, any risk of indeterminate liability evaporates. Likewise, the motion judge erred in characterizing the claim as implicating a policy decision as opposed to an operational decision. The facts pleaded bring this case within the category of operational negligence identified in *Just*, in which the Supreme Court held that where the government has made a policy decision to provide a service, a negligent failure to implement that policy at the operational level may be actionable when an individual member of the public suffers loss.

xi) Imperial Tobacco

[89] In *Imperial Tobacco*, the Government of British Columbia sought to recover from tobacco companies the cost of paying for the medical treatment of individuals suffering from tobacco-related illnesses. This case also involved a second matter, a class action brought against Imperial Tobacco on behalf of class members who purchased "light" or "mild" cigarettes. In both cases the tobacco companies issued third-party notices to the Government of Canada alleging that Canada made negligent misrepresentations to tobacco companies and negligently represented the health attributes of low-tar cigarettes to consumers and failed to warn of the harms of these products. Canada brought motions to strike the third party notices alleging that it was plain and obvious that the third-party claims failed to disclose a reasonable cause of action. McLachlin C.J. held that all the claims of Imperial and the other tobacco companies brought against the Government of Canada were bound to fail, and should be struck.

[90] At the first stage of the *Anns/Cooper* analysis McLachlin C.J., at para. 48, examined the relationships at issue:

As mentioned above, there are two relationships at issue in these claims: the relationship between Canada and consumers (the *Knight* case), and the relationship between Canada and tobacco companies (both cases). The question at this stage is whether there is a *prima facie* duty of care in either or both these relationships. In my view, on the facts pleaded, Canada did not owe a *prima facie* duty of care to consumers, but did owe a *prima facie* duty to the tobacco companies.

[91] She continued, at paras. 49 and 50:

The facts pleaded in Imperial's third-party notice in the *Knight* case establish no direct relationship between Canada and the consumers of light cigarettes. The relationship between the two was limited to Canada's statements to the general public that low-tar cigarettes are less hazardous. There were no specific interactions between Canada and the class members. Consequently, a finding of proximity in this relationship must arise from the governing statutes: *Cooper*, at para. 43.

The relevant statutes establish only general duties to the public, and no private law duties to consumers. The *Department of Health Act*, S.C. 1996, c. 8, establishes that the duties of the Minister of Health relate to "the promotion and preservation of the health of the people of Canada": s. 4(1).

Similarly, the Department of Agriculture and Agri-Food Act, R.S.C. 1985, c. A-9, s. 4, the Tobacco Act, S.C. 1997, c. 13, s. 4, and the Tobacco Products Control Act, R.S.C. 1985, c. 14 (4th Supp.), s. 3 [rep. 1997, c. 13, s. 64], only establish duties to the general public. These general duties to the public do not give rise to a private law duty of care to particular individuals. To borrow the words of Sharpe J.A. of the Ontario Court of Appeal in Eliopoulos Estate v. Ontario (Minister of Health and Long-Term Care) (2006), 276 D.L.R. (4th) 411, "I fail to see how it could be possible to convert any of the Minister's public law discretionary powers, to be exercised in the general public interest, into private law duties owed to specific individuals": para. 17. At the same time, the governing statutes do not foreclose the possibility of recognizing a duty of care to the tobacco companies. Recognizing a duty of care on the government when it makes representations to the tobacco companies about the health attributes of tobacco strains would not conflict with its general duty to protect the health of the public.

[92] McLachlin C.J. found that the pleadings disclosed a *prima facie* duty of care in negligent misrepresentation between Canada and the tobacco companies because of the special relationship that existed between the parties. However, the claims between Canada and the consumers should have been struck because they did not disclose a duty of care.

[93] The Court went on to stage two of the *Anns/Cooper* analysis and held that Canada's alleged negligent misrepresentations to the tobacco industry should not give rise to tort liability because of important policy considerations, including the prospect of indeterminate liability.

[94] McLachlin C.J., at para. 95, held that it was plain and obvious that the alleged representations were matters of government policy, with the result that the tobacco companies' claims against Canada for negligent misrepresentation must be struck out:

In short, the representations on which the third-party claims rely were part and parcel of a government policy to encourage people who continued to smoke to switch to low-tar cigarettes. This was a "true" or "core" policy, in the sense of a course or principle of action that the government adopted. The government's alleged course of action was adopted at the highest level in the Canadian government, and involved social and economic considerations. Canada, on the pleadings, developed this policy out of concern for the health of Canadians and the individual and institutional costs associated with tobacco-related disease.

[95] Regarding indeterminate liability, McLachlin C.J., at para. 99, stated:

I agree with Canada that the prospect of indeterminate liability is fatal to the tobacco companies' claims of negligent misrepresentation. Insofar as the claims are based on representations to consumers, Canada had no control over the number of people who smoked light cigarettes. This situation is analogous to *Cooper*, where this Court held that it would have declined to

apply a duty of care to the Registrar of Mortgage Brokers in respect of economic losses suffered by investors because "[t]he Act itself imposes no limit and the Registrar has no means of controlling the number of investors or the amount of money invested in the mortgage brokerage system" (para. 54). While this statement was made in *obiter*, the argument is persuasive.

[96] The Court then turned to an argument made by the tobacco companies alleging that Canada had a duty to warn the tobacco companies about the dangers posed by the strains of tobacco designed and licensed by Canada and it failed to fulfill this duty. McLachlin C.J., at para. 105, stated:

The crux of this failure to warn claim is essentially the same as the negligent misrepresentation claim, and should be rejected for the same policy reasons. The Minister of Health's recommendations on warning labels were integral to the government's policy of encouraging smokers to switch to low-tar cigarettes. As such, they cannot ground a claim in failure to warn.

[97] The Court rejected all of the arguments made by the tobacco companies and held that it was plain and obvious that the claims against Canada should be struck out as having no reasonable chance of success.

xii) Taylor v. Canada (Attorney-General), 2012 ONCA 479, 111 O.R. (3d) 161

[98] In *Taylor*, the plaintiff was a representative of a class of persons who claimed to have suffered injury as a result of the implantation of temporomandibular joint implants in their jaws. The implants were manufactured by an American company, however, the plaintiff alleged that Health Canada was negligent in the exercise of its responsibilities under the FDA and the regulations proclaimed under the Act, particularly the *Medical Devices Regulations*, R.R.C. 1978, c. 871, as amended by S.O.R./82-914 (the "Regulations"). The plaintiff alleged that Health Canada owed a duty of care to protect her and other class members from unsafe medical devices and that it negligently failed to perform that duty in relation to the implants. The motion judge originally held that the claim disclosed a reasonable cause of action, but was asked to reconsider following the decisions of *Drady* and *Attis* and determined that this case could not be distinguished from *Drady*. This case proceeded to the Court of Appeal under a special procedural rule.

[99] At stage one of the *Anns/Cooper* analysis the Court asked if proximity was established. Doherty J.A., at para. 104, stated:

Where the relationship of proximity is said to arise out of the interaction between a plaintiff and the regulator, the question must be - what is there in the factual allegations that distinguishes the relationship between this plaintiff and the regulator from the relationship that exists between the regulator and all those affected by the regulator's actions? In the amendments to her claim found in the Fresh Statement of Claim, Ms. Taylor tries to establish a direct and close relationship with the regulator by reference to the regulator's public statements concerning its general powers and practices under the legislative scheme and her reliance on them. For example, in para. 25, she refers to the RIAS as representations of Health Canada's "habitual practice to monitor and assure the safety of medical devices used by Class Members". Ms. Taylor further alleged that these broad public representations "were intended to be and were, reasonably relied on by the public, including the representative plaintiff and Class Members".

[100] The Court held that a regulator's public statements acknowledging its public duties and obligations and its commitment to the performance of those duties, combined with the reliance on those public statements by members of the public affected by the performance of those duties, cannot, standing alone, create a relationship of proximity between individual plaintiffs and the regulator.

[101] The Court, at para. 110, continued with the proximity analysis:

Reading Ms. Taylor's pleadings generously, they allege that between 1988 and 1990 Health Canada repeatedly misrepresented the safety of the implants Ms. Taylor and others received by wrongly representing that those implants had received a notice of compliance. The pleadings further allege that when Health Canada became aware of its misrepresentation in 1990, it failed to correct that misrepresentation despite the knowledge that the implants were being improperly imported and sold in Canada and that there was strong and growing evidence that the implants were unsafe and caused serious harm to users. These allegations, taken in combination, in my view, describe a relationship between Health Canada and the users of those implants that is different from the relationship that exists between Health Canada and consumers of medical devices at large. The more difficult question is whether the allegations create a sufficiently close relationship to give rise to a private law duty of care.

[102] The Court, at para. 114, continued:

Acknowledging, however, the factual differences among the cases, one should not ignore the similarities. In *Fullowka*, *Doe* and this case, the regulator failed to act to protect the life and safety of individuals when the regulator was fixed with knowledge of a clear, present and significant danger posed to a discrete and identifiable segment of the community. On these pleadings, there are the added features of a material misstatement by the regulator, a failure to correct that misstatement, a decision to refrain from notifying at least some of those individuals whom the regulator knew to be at risk as a result of the use of the implants, and a failure to adequately warn those whom Health Canada did notify of potential problems with the implants. It is arguable that those features of the case enhance Ms. Taylor's proximity argument.

[103] The Court held that it was not plain and obvious that the claim as pleaded is bound to fail for want of a private law duty of care.

xiii) Swarath v. Canada, 2014 FC 75

[104] In *Swarath*, the plaintiffs marketed and distributed a product called "Libidus", a natural health product intended to increase blood circulation and address symptoms of erectile dysfunction. In 2006, Health Canada issued a direction to the plaintiffs under the *Natural Health Products Regulations*, SOR/2003-196 to stop the sale of Libidus in Canada and to issue a recall on the product. The plaintiffs complied with the direction; however, they attempted for six years to persuade Health Canada that its analysis was incorrect. Health Canada declined to revoke the direction and re-issue a license.

[105] Mosley J. engaged in the two step *Anns/Cooper* analysis and examined the applicable legislation including the FDA, the *Department of Health Act*, S.C. 1996, c. 8 s. 4, and *Natural Health Products Regulations*.

[106] The Court, at para. 28, held that there was no proximity in the relationship of the parties:

The clear purpose of the relevant legislative and regulatory scheme in this matter is to protect the health of Canadians by preventing the sale of contaminated natural health products in Canada. To recognize a private duty of care to the importers and distributors of those products would conflict with that purpose. I am unable to agree with the argument of the plaintiffs that the duty to promote and preserve the health of the people of Canada encompasses a duty to the distributors of products such as Libidus.

[107] Regarding stage two of the analysis, Mosley J. held that for reasons of indeterminate liability, had a duty of care been established, the imposition of the duty would have been negated.

xiv) Paradis Honey Ltd. v. Canada (Attorney-General), 2014 FC 215

[108] In *Paradis*, the plaintiffs alleged the defendant imposed a *de facto* prohibition on the imports of US packaged honeybees without lawful authority and that in doing so the defendant has breached their duty of care.

[109] At stage one of the *Anns/Cooper* analysis, the Court examined the *Health of Animals Act*, S.C. 1990, c. 21 ("the HAA") and the *Health of Animals Regulations*, C.R.C., c. 296 ("the HAR"). The Court looked at s. 14 of the HAA which provides that the Minister may make regulations prohibiting the importation of any animal into Canada for the purpose of preventing a disease from being introduced into or spread within the Country. The Court held that the legislative scheme was aimed primarily at entrusting the Canadian Food Inspection Agency with broad regulatory authority to protect animal health for the public good and excluded any duty to safeguard the economic interests of individuals who wanted to use imported animals in the exploitation of their commercial ventures. Scott J., at para. 103, stated:

[...] It is apparent from these general provisions that the objective is to protect animal health and public safety. The Minister is entrusted with the authority to take measures in order to remedy or mitigate any danger to life, health, property or the environment. Therefore, the Minister's duty is to the people of Canada as a whole, not to individual industry participants like the Plaintiffs. To recognize a private duty of care to the beekeeping industry and its economic interests would conflict with that purpose.

[110] The Court held that there was not sufficient proximity arising from the governing statutes in this case. At stage two of the analysis the Court held that a finding of a duty of care in this case would lead to an exposure of indeterminate liability, which would negate the imposition of the duty.

## Application to the Facts Herein

[111] The cases demonstrate that our courts have found sufficient proximity by exception, in limited and strict circumstances such as those established in *Taylor* and *Heaslip*. The facts of this claim are distinguished from that of *Taylor* and *Heaslip*.

[112] The pleadings in *Taylor* contained detailed allegations regarding the safety of the devices that was made known to Health Canada. The representations were made to a discrete and identifiable segment of the community; users of TMJ implants. The Court in *Taylor* highlighted that based on the pleading, the government regulator had knowledge of the clearly definable and relatively small group of consumers of the implants: at para. 114. Health Canada made misrepresentations to Ms. Taylor, as a member of that discrete group, about the notice of compliance, failed to correct the misrepresentation when they became aware of it, and had knowledge of the serious and ongoing risk posed to the clearly definable and small group of consumers. The Court held that all of this taken in combination could ground sufficient proximity to warrant the imposition of a private law duty of care.

[113] In the current case, on the facts as pleaded, there is no combination of interactions between the parties sufficient to ground proximity: *Taylor*, para. 111. The pleading in terms of knowledge is bald and speculative, representations are alleged to have been made to the Canadian public, the group to which Aminatawalla is alleged to have belonged was neither discrete nor identifiable and there are no allegations of a similar type of material misstatement.

[114] In *Heaslip*, the Court held that the relationship that existed between Patrick Heaslip and Ontario was direct; when a request was made for an air ambulance, this involved a specific and direct interaction between the parties. The facts alleged therein established direct interactions between the parties. It was the specific interactions between the plaintiff and the Province that created a direct relationship between them, which arguably created a duty of care: at paras. 18-21.

[115] No such interactions or direct relationship exists in this case. This case involved a pandemic health risk facing the entire country. The Crowns' course of action was developed out of concern for the health of Canadians and involved high level decisions and social and economic considerations.

[116] The facts herein are analogous to *Williams* and *Eliopoulos* where the Courts struck claims of proximity in the public health context on the basis that those cases involved a risk faced by the public at large. By its very nature, the H1N1 pandemic posed a health risk to the Canadian public at large. The facts herein are further analogous to *Attis* given the lack of direct communications in this case between the plaintiffs and the government regulators: at para. 69. Finally, the facts herein are analogous to *Imperial Tobacco* in that a relationship of proximity cannot arise from public representations and public reliance and that similar representations constitute core policy decisions: at paras. 49 and 95.

# Application of the Anns/Cooper Test

## **Stage 1 – Forseeability and Proximity**

[117] Consideration of foreseeability and proximity are two aspects of one inquiry into whether the facts disclose a relationship that gives rise to a *prima facie* duty of care. Foreseeability must be grounded in a relationship of sufficient closeness or proximity to make it just and reasonable to impose an obligation on one party to take reasonable care not to injure the other: *Imperial Tobacco* at para. 41. When the claim is advanced against a regulator, the proximity inquiry will focus initially on the legislative scheme and secondly on interactions, if any, between the government authority and the plaintiff: *Taylor* at para. 75.

1. Legislative Scheme

[118] No private law duty of care can arise where the purpose of the legislative scheme is to facilitate whatever the public authority thinks best in the interests of the public in general. The Court must consider the governing statute in order to determine whether the scheme of the Act mandates that the public authority owes a duty of care to specific individuals in a particular segment of the public or to the public as a whole: *Attis* at para. 58, *Imperial Tobacco* at paras. 43-50, *Cooper* at paras. 43-50.

[119] The Plaintiffs' claims fail to plead or reference any Provincial or Federal legislation they rely upon in furtherance of their claim in negligence.

[120] I accept the submissions of the federal Crown and the provincial Crown, with respect to the potentially relevant statutes. The submission is consistent with the case law as reviewed above:

- (a) With respect to the federal Crown: the *Department of Health Act*, S.C. 1996, c.8 ("DHA"); the *Public Health Agency of Canada Act*, S.C. 2006, c.5 ("PHACA"); the *Food and Drug Act*, R.S.C. 1985, c. F-27 ("FDA");
- (b) With respect to the provincial Crown: the *Ministry of Health and Long Term Care Act*, R.S.O. 1990, c. M-26 ("MHLTCA"); the *Health Protection and Promotion Act*, R.S.O. 1990, c. H-7 ("HPPA").

[121] The respective governing statutes are reviewed below. I have concluded that the governing statues cannot properly be construed as giving rise to a relationship of proximity that

could ground a civil action because the duty under the respective statutes is owed not to any one individual but to the public at large: *Cooper*, *Edwards*.

[122] The government mandate in each governing statute is to promote and protect the health of the entire population in the context of the spread of communicable diseases generally and the regulation of vaccinations distributed for sale in Canada. The regulators necessarily have broad discretionary powers to balance a multitude of competing interests while identifying and responding to widespread threats to public health. The risk assessment is population-based, rather than individual. The legislative functions are exercised for the benefit of the public as a whole and do not give rise to a private law duty of care to particular individuals or sub-groups of the public: *Williams, Eliopoulos, Attis,* and *Wuttunee*.

## Department of Health Act (DHA)

[123] Health Canada is a federal department that is presided over by the Minister of Health. The minister's responsibilities under the DHA include the protection of the public against risks to health and the spread of diseases as well as investigation and research into public health. The powers and functions of the Minister are set out in s. 4 of the DHA and include the following:

(*a*) the administration of such Acts of Parliament and of orders or regulations of the Government of Canada as are not by law assigned to any other department of the Government of Canada or any minister of that Government relating in any way to the health of the people of Canada;

(a.1) the promotion and preservation of the physical, mental and social wellbeing of the people of Canada;

(b) the protection of the people of Canada against risks to health and the spreading of diseases;

(c) investigation and research into public health, including the monitoring of diseases;

[...]

(*h*) subject to the *Statistics Act*, the collection, analysis, interpretation, publication and distribution of information relating to public health; and

(*i*) co-operation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.

[124] This Court in *Williams*, the Court of Appeal in *Attis*, and the Supreme Court in *Imperial Tobacco* have all found that the DHA did not create a duty of care to individuals in claims analogous to those made by the Plaintiffs in this action. I accept those decisions as applicable and determinative herein with respect to the DHA: *Attis* at para. 54, and *Imperial Tobacco* at para. 50.

Public Health Agency of Canada Act (PHACA)

[125] The Public Health Agency of Canada (the "PHA") is a statutory federal agency established pursuant to the PHACA. The PHA is also presided over by the Minister of Health. The preamble to the PHACA reads:

WHEREAS the Government of Canada wishes to take public health measures, including measures relating to health protection and promotion, population health assessment, health surveillance, disease and injury prevention, and public health emergency preparedness and response;

WHEREAS the Government of Canada wishes to foster collaboration within the field of public health and to coordinate federal policies and programs in the area of public health;

WHEREAS the Government of Canada wishes to promote cooperation and consultation in the field of public health with provincial and territorial governments;

WHEREAS the Government of Canada also wishes to foster cooperation in that field with foreign governments and international organizations, as well as other interested persons or organizations;

AND WHEREAS the Government of Canada considers that the creation of a public health agency for Canada and the appointment of a Chief Public Health Officer will contribute to federal efforts to identify and reduce public health risk factors and to support national readiness for public health threats;

[126] Section 3 of the PHACA sets out the purpose of the PHA:

The Public Health Agency of Canada is established for the purpose of assisting the Minister in exercising or performing the Minister's powers, duties and functions in relation to public health.

[127] Section 5 of the PHACA states:

(1) The Minister may, subject to any terms and conditions that the Minister specifies, delegate to an officer or employee of the Agency any of the powers, duties and functions that the Minister is authorized to exercise or perform under any Act of Parliament or any order made by the Governor in Council in respect of public health.

2) Subsection (1) does not authorize the Minister to delegate a power to make regulations nor a power to delegate under that subsection.

[128] The legislation indicates an obligation to protect Canadians against infectious diseases on a national level. The duty is to all Canadians not to an individual recipient of a vaccine.

# Food and Drug Act (FDA)

[129] A vaccine is a drug within the meaning of the FDA and is normally authorized for sale in Canada under the new drug submission process. The weighing of risks and benefits forms part of the normal process to determine whether to grant market authorization for a drug. The *Food and Drug Regulations*, C.R.C., c. 870 ("FDRs") are replete with references to the fact that the Minister of Health must assess safety and effectiveness information, or side effects or risks and benefits, as decisions are made to authorize a drug for sale, to stop or suspend the sale of a drug, or to issue or suspend an establishment licence relating to the manufacture of a drug.

[130] There is no provision under the aforementioned legislation that requires Health Canada to conduct clinical studies or clinical trials on drugs, including vaccines.

[131] The new drug submission must contain sufficient information and material for the Minister to assess the safety and effectiveness of the new drug pursuant to ss. C.08.002 (2)(a) to (n) of the FDRs. The new drug submission information is provided by the manufacturer.

[132] If the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment, he or she may make an interim order pursuant to s. 30.1 of the FDA. In the present case, although not pleaded, as noted above, we know that the Minister made the interim order. As is evident from a review, the Minister made the interim order as she had reason to believe that immediate action was required to deal with the H1N1 pandemic risk to health, safety, or the environment. The explanatory note at the end of the interim order demonstrates the time sensitive nature of addressing the H1N1 virus with timely access to the vaccine for Canadians.

[133] The interim order highlights the policy decision made by the federal government in addressing the H1N1 pandemic in consideration of a population-based assessment of risk.

[134] The Divisional Court in *Klein* and the Ontario Court of Appeal in *Attis, Taylor* and *Drady* have held that analogous provisions of the FDA regulatory scheme, governing the approval for sale in Canada of medical devices, did not give rise to a relationship of proximity between the federal government and the plaintiffs who allegedly had suffered harm as a result of use of those devices. I accept those decisions as applicable and determinative herein with respect to the FDA: *Klein* at para. 32, *Attis* at para. 59, *Taylor* at para. 61, and *Drady* at para. 38.

[135] I have therefore concluded that the regulatory powers and functions of Health Canada under the FDA and regulations in relation to licensing of vaccines for use in Canada do not give rise to proximity between the regulator and individual users of a vaccine sufficient to create a relationship of proximity.

# Ministry of Health and Long Term Care Act (MHLTCA)

[136] The MHLTCA establishes that the Minister of Health shall preside over and have charge of the Ministry and all its functions. It sets out the functions and the power of the Minister in broad terms. Section 6 confers powers on the Minister in relation to the health of "the people of Ontario":

6(1) It is the function of the Minister and he or she has power to carry out the following duties:

1. To advise the Government in respect of the health of the people of Ontario.

2. To oversee and promote the health and the physical and mental wellbeing of the people of Ontario.

3. To be responsible for the development, co-ordination and maintenance of comprehensive health services and a balanced and integrated system of hospitals, long-term care homes, laboratories, ambulances and other health facilities in Ontario.

4. To enter into agreements for the provision of health services and equipment required therefor and for the payment of remuneration for such health services on a basis other than fee for service.

5. To institute a system for payment of amounts payable under the *Health Insurance Act* in the form of payment by the Province of all or any part of the annual expenditures of hospitals and health facilities.

6. To establish and operate, alone or in co-operation with one or more persons or organizations, institutes and centres for the training of hospital and health service personnel.

7. To govern the care, treatment and services and facilities therefor provided by hospitals and health facilities and assess the revenues required to provide such care, treatment and services.

8. To control charges made to all patients by hospitals and health facilities.

9. To authorize and provide financial support, alone or in co-operation with one or more persons or organizations, on a periodic basis or otherwise, for the establishment and operation of corporations to supply centralized services and commodities to hospitals, long-term care homes and health facilities and to others associated with health workers and the health field generally and enter into agreements necessary therefor, and enter into agreements with hospitals, long-term care homes and other health facilities and other persons on such terms and conditions and for such periods as the Minister considers advisable to assist in financing all or any part of the cost of such centralized services and commodities or for any other purpose incidental to the foregoing.

10. To convene conferences and conduct seminars and educational programs respecting health matters.

(2) The Minister in exercising his or her powers and carrying out his or her duties and functions under this Act,

(a) shall inquire into and determine the hospital and health facilities, services and personnel required to meet the health needs of the people of Ontario;

(b) shall promote and assist in the development of adequate health resources, both human and material, in Ontario;

(c) may initiate, promote, conduct and maintain surveys, scientific and administrative research programs and planning studies into any matters relating to the health needs of Ontario and obtain statistics for purposes of the Ministry;

(d) may collect such information and statistics respecting the state of health of members of the public, health resources, facilities and services and any other matters relating to the health needs or conditions affecting the public as are considered necessary or advisable, and publish any information so collected; and

(e) may recommend to the Government the methods and programs by which the health needs of the people of Ontario can be met.

[137] Section 6 of the MHLTCA provides for discretionary decision-making: *Re Metropolitan General Hospital and Minister of Health*, [1979] 25 O.R. (2d), 101 D.L.R. (3d) 530 (H.C.J.) at paras. 7-12 and *Robb Estate v. Canadian Red Cross Society*, [2000] O.T.C. 23, 98 A.C.W.S. (3d) 237, at paras. 149-161. The statutory scheme both by its nature and plain language is intended to facilitate the public authority to act in its discretion in the public interest. There is no legislative intent to expressly or by implication impose a private law duty of care.

#### Health Protection and Promotion Act (HPPA)

[138] The HPPA establishes a comprehensive legislative scheme to address public health concerns in Ontario. The purpose of the Act is set out in s. 2 as follows:

The purpose of this Act is to provide for the organization and delivery of public health programs and services, the prevention of the spread of disease and the promotion and protection of the health of the people of Ontario.

[139] The Minister is empowered to take steps in a variety of areas but is under no statutory duty to take any specific step in any specific circumstances.

[140] Section 78(1) states:

The Minister has power to make investigations respecting the causes of disease and mortality in any part of Ontario.

#### [141] Sections 83-84 state:

83. (1) The Minister may give a board of health a written direction described in subsection (2) if he or she is of the opinion, based on an assessment under section 82, that the board of health has,

(a) failed to provide or ensure the provision of a health program or service in accordance with section 5, 6 or 7, the regulations or the guidelines;

(b) failed to comply in any other respect with this Act or the regulations; or

(c) failed to ensure the adequacy of the quality of the administration or management of its affairs.

Same

(2) In a direction under this section, the Minister may require a board of health,

(a) to do anything that the Minister considers necessary or advisable to correct the failure identified in the direction; or

(b) to cease to do anything that the Minister believes may have caused or contributed to the failure identified in the direction.

Compliance with direction

(3) A board of health that is given a direction under this section shall comply with the direction,

(a) within the period of time specified in the direction; or

(b) if no period of time is specified in the direction, within 30 days from the day the direction is given.

Power to take steps to ensure direction is carried out

84. (1) If, in the opinion of the Minister, a board of health has failed to comply with a direction under section 83 within the period of time required under subsection 83 (3), the Minister may do whatever is necessary to ensure that the direction is carried out, including but not limited to,

(a) providing or ensuring the provision of any health program or service in accordance with sections 5, 6 and 7, of the regulations and the guidelines; (b) exercising any of the powers of the board of health or the medical officer of health of the board of health;

(c) appointing a person to act as the medical officer of health of the board of health in the place of the medical officer of health appointed by the board;

(d) providing advice and guidance to the board of health, the medical officer of health of the board of health, and any person whose services are engaged by the board of health;

(e) approving, revoking or amending any decision of the board of health, the medical officer of health of the board of health, or any person whose services are engaged by the board of health; and

(f) accessing any record or document that is in the custody or under the control of the board of health, the medical officer of health of the board of health, or any person whose services are engaged by the board of health.

[142] The HPPA and regulations clarify that the responsibility for superintending and carrying out health promotion, health protection, disease prevention, community health protection and control of diseases rest primarily with local boards of health, rather than with the province.

[143] Sections 4 and 5 state:

4. Every board of health,

(a) shall superintend, provide or ensure the provision of the health programs and services required by this Act and the regulations to the persons who reside in the health unit served by the board; and

(b) shall perform such other functions as are required by or under this or any other Act.

5. Every board of health shall superintend, provide or ensure the provision of health programs and services in the following areas:

1. Community sanitation, to ensure the maintenance of sanitary conditions and the prevention or elimination of health hazards.

1.1 The provision of safe drinking water by small drinking water systems.

2. Control of infectious diseases and reportable diseases, including provision of immunization services to children and adults.

3. Health promotion, health protection and disease and injury prevention, including the prevention and control of cardiovascular disease, cancer, AIDS and other diseases.

4. Family health, including,

i. counselling services,

ii. family planning services,

iii. health services to infants, pregnant women in high risk health categories and the elderly,

iv. preschool and school health services, including dental services,

v. screening programs to reduce the morbidity and mortality of disease,

vi. tobacco use prevention programs, and

vii. nutrition services.

[144] The Ontario Court of Appeal has held that the duties arising out of the HPPA are owed to the general public and not a specific individual or a particular group. I find this jurisprudence applicable and determinative of this issue: *Williams* at para. 25. It is for these reasons that I have concluded that the legislative scheme does not support a relationship of proximity.

2. Specific Interactions

[145] In a case like this where the governing legislation is not determinative, the courts will examine the pleadings for specific interactions between a regulator and the plaintiff to assess whether these create a sufficiently "close and direct" relationship to justify the imposition of a *prima facie* duty of care: *Taylor* at para. 70, and *Imperial Tobacco* at para. 50.

[146] While the Plaintiffs make allegations of negligence against the Crowns, they do not assert that a duty of care is owed to them. Reading the pleading broadly and accepting the allegations therein as true, however, the following interactions should properly be assessed to determine whether taken together these create proximity sufficient to impose a *prima facie* duty of care:

- i) The relationship between the regulator of vaccines and the consumer;
- ii) The public pronouncement made by the regulator;
- iii) The failure to warn consumers of the knowledge of adverse risks of the vaccination; and,
- iv) That the plaintiff belonged to a specific identifiable vulnerable group.

i) The relationship between the regulator of vaccines and the consumer

[147] On the facts as pleaded, the Plaintiffs did not have direct contact with anyone on whose behalf the federal or provincial Crowns could be vicariously liable. There is no allegation that the Crowns or their representatives made any specific representations to the Plaintiffs, provided any direct service to the Plaintiffs or had any specific interactions with them in relation to any of these matters prior to Aminatawalla's death: *Attis* at paras. 68-70.

ii) The public pronouncement made by the regulator

[148] The Plaintiffs' claim is that the Crowns recommended and encouraged a vaccination to the public at large. Public representations by a regulator as to its public duties and obligations, however, do not establish a relationship of proximity between the regulator and an individual plaintiff.

[149] In *Imperial Tobacco*, at para. 49, the Supreme Court of Canada specifically rejected the argument that the regulator's assertions to the general smoking public that low tar cigarettes were less hazardous could create a relationship of proximity.

[150] The relationship herein is limited to the Crowns' statements to the general public and there were no specific interactions between the Crowns and the Plaintiffs. General representations made by the regulators to the public and relied on by the Plaintiffs as members of the public do not, standing alone, create a proximate relationship or duty of care: *Taylor* at para. 38, and *Drady* at paras. 53-54.

iii) The failure to warn consumers of the knowledge of adverse risks of the vaccination

[151] The Plaintiffs allege that the Crowns failed to caution the medical profession and the public at large with respect to the risks of the vaccination. Again, no proximity exists between the Plaintiffs and the Crowns as the allegation itself is grounded in the duty to the public at large. Further, no material facts are pleaded to substantiate that the Crowns had knowledge and concealed the knowledge from the public and no causal nexus is alleged.

iv) That the Plaintiffs belonged to a specific identifiable group

[152] Read broadly the pleadings allege that Aminatawalla was part of a group with hypersensitivities particularly vulnerable to vaccine-related injuries. The Plaintiffs claim that the Crowns failed to caution the medical profession and the public with respect to additional risks associated with specific age groups, concealed from the public the knowledge of cases of death and injury because of the vaccine, and failed to undertake a clinical study of the vaccination to determine its safety for all classes of the population.

[153] But for a bald pleading, however, no facts are pled to support these allegations.

[154] Even if the Plaintiffs could be said to have pled sufficient facts demonstrating Aminatawalla as one with hypersensitivities to the HINI vaccination, this would not, in my view, be sufficient on its own to distinguish the relationship between her and the public regulators from the relationship that exists between the public regulators and all those affected by their core policy decision to take immediate action to deal with the H1N1 pandemic risk to public health.

[155] When a claimant establishes that they belong to a specific identifiable group, this may be sufficient to establish a special relationship of proximity. The group, however, must be sufficiently discrete and identifiable. The standard is a high one.

[156] In *Doe v. Metropolitan Toronto (Municipality) Commissioners of Police*, (1990) 74 O.R. (2d) 225, 40 O.A.C. 161 (Div. Ct.), aff'g (1989), 58 D.L.R. (4<sup>th</sup>) 396 (H. Ct. J.), Moldaver J., accepting the facts as pleaded in *Doe* (1989), held that the claimant's group was sufficiently discrete and recognizable such that the public authority, in that case the police, had the requisite knowledge sufficient to establish a private law duty of care. The pleading in *Doe* (1989) included the following particulars which were determinative of the issue of sufficient proximity at p. 400:

- (i) The police identified the apartments that the serial rapist would likely target, namely second and third floor apartments with balcony access occupied by single women in the Church-Wellesley area.
- (ii) The plaintiff was readily identifiable by the police as a likely target of the serial rapist because of her distinguishing characteristics, including the fact that she was a white, single woman residing in a second or third floor apartment with a balcony in the Church-Wellesley area.
- (iii) Although the police identified the plaintiff as a likely target, they specifically decided not to warn her because they believed it would cause hysteria among the women and would alert the suspect to flee and not engage in further criminal activity.
- iv) The Defendants admitted that they should have issued a warning in the circumstances.

[157] Similarly, in *Taylor*, the representations were made to a discrete and identifiable segment of the community; users of TMJ implants. The pleadings in *Taylor* alleged knowledge of repeated misrepresentations to this discrete group of consumers and a decision to refrain from notifying the identifiable members therein after becoming aware of alleged safety risks.

[158] No such particulars exist in the relationship in this case sufficient to create the proximity required to reasonably expect and legally impose a private law duty of care.

[159] Aminatawalla may belong to a populate group with hypersensitivities to vaccinations. Such a group is not readily identifiable or sufficiently discrete in the circumstances as pled to warrant proximity and duty different from that to the public at large. Hypersensitivity, side effects or reactions are inherent in any vaccination. The size of the affected group is indeterminate and the identity of its members is unknown by the public regulators. There can be no reasonable expectation of duty to such a vast unquantified, anonymous group. The duty of care to those with hypersensitivities or reactions is a duty to the patient and the consumer. This is necessarily different from the public duty owed by the government regulators developing a public vaccination strategy to address a decided threat to public health.

## Stage 2 – Policy Reasons Negating Liability

[160] I have concluded that the pleadings read broadly and deemed true do not establish a sufficient relationship of proximity between the Plaintiffs and the federal and provincial Crowns to warrant imposing a private law duty of care. I will nonetheless consider below whether there are any policy considerations that would have negated a finding of a private law duty, if that duty was indeed established. Upon consideration, I have concluded that I would negate the imposition of the duty, if established, for policy reasons.

i) Core public policy decisions immune from suit

[161] The H1N1 public vaccination program was a national strategy developed to address the threat of a pandemic. Urgent action was taken in the face of a decided threat to public health. An interim order was made. The interim order highlights the high level policy decisions that were made by the Federal Government in addressing the pandemic. In my view, these are core policy decisions as defined by the Supreme Court in *Imperial Tobacco* and are not actionable in tort: *Imperial Tobacco* at para. 95.

[162] In *Eliopoulos*, at paras. 32-33, the Ontario Court of Appeal held that the Province must weigh and balance competing claims for scarce resources available to promote and protect the health of citizens and agreed that imposing a private law duty of care on those facts would create an unreasonable burden that would interfere with decision making in the realm of public health.

[163] In my view, the same reasoning applies to the facts of this case. The Crown's actions were aimed at mitigating the health impact on the public of a potential influenza pandemic. Urgent action was deemed necessary in the form of a public sponsored immunization program. Inherent in such a program is potential for some individuals to suffer harm – either from contracting the disease or through adverse effects associated with immunization. The Minister exercised his discretion to issue a notice of compliance allowing a manufacturer to sell a prescription drug in Canada. Such actions were aimed at mitigating the health impact on the public of a potential influenza pandemic and cannot attract a private law duty of care. To do so would interfere with sound decision-making in the realm of public health and risk the displacement of public health priorities from the general public interest to the fear or threat of lawsuits.

ii) Creation of indeterminate liability

[164] A further policy reason why the duty of care ought not to be recognized in this circumstance is the potential for the creation of unlimited liability to an indeterminate class: *Cooper* at para. 54, *Wuttunee* at para. 90, and *Attis* at para. 74.

[165] The Crowns have no control over the number of Canadians who received the H1N1 vaccination. Nor do they have means to control the number of individuals impacted by vaccinations to combat H1N1 or any other disease or illness. There is no principled reason why compensation would be recoverable in relation to H1N1 vaccinations as opposed to any other vaccination recommended or made available by government to prevent or control infectious diseases. The Crowns would face potential liability in relation to adverse effects experienced by individuals in relation to any vaccinations recommended or made available to prevent the spread of disease in the population. The potential number of Plaintiffs and the amount of liability would be indeterminate.

[166] As referenced in *Klein*, at para. 37:

[...] Finally, recognizing a duty of care in these circumstances may open the door potentially to innumerable claims in any number of similar type cases. The nature of drug and device pre-approval testing is such that it is not possible to predict the emergence of long-term adverse events before such products come to market. If Health Canada were held liable for every adverse effect that became apparent during post-marketing surveillance, the courts would be inundated with lawsuits. The proper defendant in such cases is clearly the manufacturer who is responsible for the careful monitoring and long term safety of the drug or device.

## **Disposition**

[167] I have concluded that it is plain and obvious that the Plaintiffs cannot succeed in their claims against the federal Crown and the provincial Crown as the necessary requirements of a cause of action in negligence are not present. Specifically, no private law duty of care is owed by the federal Crown or the provincial Crown to the Plaintiffs and policy considerations mitigate against the finding of such a duty.

[168] An Order is granted dismissing the action in court file no. CV-11-440375 as against the Attornty Gneral of Canada and the Attornty Gneral of Ontario and in the action court file no. CV-12-447333 as against Her Majesty the Queen in Right of Canada and Her Majesty the Queen in Right of Ontario.

#### Leave To Amend

[169] In my view, it would not be appropriate or wise to grant the Plaintiffs leave to amend. Having regard to the original pleadings, hearing submissions from counsel for the Plaintiffs on the motion and upon review the Proposed Fresh as Amended Statement of Claim, I have concluded that no amendment can establish proximity sufficient to impose a private law duty of care.

# <u>Costs</u>

[170] I exercise my discretion and award no costs on this motion. I acknowledge the many hours of work and excellent argument and materials put before the Court by counsel for the

moving parties. In my view however, the concept of a private law duty of care is not readily available to those who live outside of the legal world. It is a difficult concept to comprehend, particularly while mourning the loss of a beloved family member. It is apparent to me that either the law in this area was not sufficiently explained to the Plaintiffs or that given their loss they were not prepared to accept it. In either case, I am not prepared to make a costs award against them.

CHIAPPETTA J.

**Date:** October 15, 2014