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Erin Fowler

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VACCINE-RELATED INJURIES: WHY CANADA NEEDS TO ADOPT A NO-FAULT COMPENSATION SCHEME IN LIGHT OF THE NEW H1N1 VACCINE

Erin Fowler*

INTRODUCTION

On June 11, 2009, the World Health Organization (“WHO”) declared the H1N1 influenza a pandemic. H1N1 is a strain of the influenza virus that, in the past, usually only affected pigs. In the spring of 2009, it emerged in people in North America. This is a new strain of influenza, and because humans have little to no natural immunity to this virus, it can cause serious and widespread illness.¹ As of November 1, 2009, there were more than 440 000 laboratory-confirmed worldwide cases of pandemic influenza H1N1 and over 6000 deaths reported to WHO.² In late October, the H1N1 vaccine was approved for rollout across Canada. Since then, Canadians lined up *en masse* across the provinces and territories to receive the vaccine. This was in part due to the strong urging by the Government of Canada for every Canadian to receive the vaccine. Despite the advantages of wide-scale immunization, there is a significant drawback – many people who receive vaccines each year suffer adverse effects.³ Despite this fact, Quebec is the only province in Canada that currently has a plan to compensate people who may be injured by vaccinations. For the majority of Canadians, the only recourse when injured by a vaccine is to go through the tort system.

By requiring individuals to proceed through the tort system (i.e.: having to prove someone was at fault for causing the injury), many people who have a severe reaction from a vaccine are left with no remedy. This article urges more jurisdictions in Canada

* Erin Fowler, B.A. (McMaster), is a law student at Dalhousie University’s Schulich School of Law, and expects to graduate in May 2011. Subsequent to this article being accepted for publication in *InfraRead*, Erin was appointed as one of three Editors-in-Chief of Volume 20 of *Dalhousie Journal of Legal Studies* for the upcoming year (2010-2011).

¹ Public Health Agency of Canada, *Frequently Asked Questions – H1N1 Flu Virus*, online: Public Health Agency of Canada <http://www.phac-aspc.gc.ca/alert-alerte/h1n1/faq_rg_h1n1-eng.php>.

² World Health Organization, *Pandemic H1N1 (2009) – Update 72*, online: World Health Organization <http://www.who.int/csr/don/2009_10_30/en/index.html>.

³ Nicole J. Kutlesa, “Creating a Sustainable Immunization System in Canada – The Case for a Vaccine-Related Injury Compensation Scheme” (2004) 12 *Health L.J.* at 201.

to adopt a no-fault compensation scheme for vaccine-related injuries. It will explore how vaccine-related injuries are currently covered under medical malpractice and manufacturer liability schemes, and the reasons why many believe that medical malpractice approaches should be retained in their entirety. In contrast to these beliefs, this article will address how a no-fault system would prove to be an adequate and efficient means of compensating individuals who have been injured by vaccines. This argument will be advanced by looking at how other jurisdictions have implemented no-fault compensation for vaccine-related injuries. Finally, this article will address why it is essential for Canada to adopt this new compensation system as soon as possible in order to address the needs of citizens who may be injured by the new H1N1 vaccine.

I. IMMUNIZATION IN CANADA

The Public Health Agency of Canada describes immunization as an important, cost-effective, and successful public health intervention. Vaccination effectively prevents disease, improves the health of Canadians, and reduces pressures on the Canadian health care system.⁴ Although immunization recommendations are made at the national level, with the exception of two provinces, immunization is not mandatory in Canada. This is in contrast to the United States, where almost all states require that children receive vaccination as a condition of attending school, and reprisals range from denying poor pregnant mothers the right to get food or welfare unless all their children are immunized, charges for child abuse for failure to have your child immunized, imprisonment of a teenager for failure to show proof of a second MMR (measles-mumps-rubella) shot, and denying children the right to attend school.⁵ Although there is no explicit mandatory immunization scheme throughout most of Canada, the current immunization system in place creates enough pressure so as to have almost the effect of a mandatory scheme.

⁴ Public Health Agency of Canada, *Immunization: The Most Successful Public Health Measure*, online: Public Health Agency of Canada <<http://www.phac-aspc.gc.ca/im/measure-intervention-eng.php>>.

⁵ *Supra* note 3 at 204.

In Canada, immunization is a shared responsibility between the federal, provincial, and territorial governments.⁶ Despite this arrangement, the large majority of costs are borne by the provinces and territories, as each province and territory is responsible for the structure and implementation of the system of immunization.⁷ The public health branch of each province determines which vaccines should be administered and to whom they should be administered.⁸ In planning their immunization programs, provinces and territories adjust their recommended schedules and selection of vaccines based on the National Advisory Committee on Immunization (“NACI”) or other expert advisory committee recommendations, as well as on local epidemiological, program, and financial considerations.⁹

Manufacturers of vaccines must secure from the federal government a license to market any vaccine in Canada. Vaccines used in Canada are approved and licensed by the Bureau of Biologics and Radiopharmaceuticals of the Health Protection Branch, Health Canada. In addition, vaccines continue to be monitored after approval. The Canadian Adverse Events Following Immunization Surveillance System (“CAEFISS”) is a national monitoring system for reporting adverse events and suspected adverse events following immunization.¹⁰

Currently, only two provinces, Ontario and New Brunswick, ensure wide-scale immunization through legislation that directly targets children in school.¹¹ In Ontario, the *Immunization of School Pupils Act* places a statutory duty on parents to have their children immunized according to the prescribed program of immunization.¹² Failure to comply with the legislation is a summary conviction offence and is grounds for suspension of an unvaccinated pupil from school. In practice, school and public health authorities periodically require proof of vaccination of pupils whose vaccination records are not on file. Parents of unvaccinated students are then given an opportunity

⁶ Public Health Agency of Canada, *National Immunization Strategy*, online: Public Health Agency of Canada <http://www.phac-aspc.gc.ca/publicat/nis-sni-03/pdf/nat_imm_strat_e.pdf>.

⁷ *Ibid.*

⁸ Manitoba Law Reform Commission, *Compensation of Vaccine-Damaged Children (Report # 104)* (Winnipeg: Law Reform Commission, 2000) at 4.

⁹ *Supra* note 6 at 4.

¹⁰ Law Reform Commission of Saskatchewan, *Consultation Paper: Vaccination and the Law* (Saskatoon: Law Reform Commission, 2007) at 5.

¹¹ *Supra* note 3 at 204.

¹² *Immunization of School Pupils Act*, R.S.O. 1990, c. I.1.

to either vaccinate their children, or file an exemption for philosophical reasons, before further action is taken.¹³ In other provinces that do not make routine vaccination mandatory, public health legislation permits mandatory vaccination to be ordered during an epidemic.¹⁴

In addition to direct legal enforcement of vaccination recommendations, most provincial and territorial governments have adopted a proactive approach to ensuring all children in the province are fully immunized. Thus, in cooperation with local school boards, programs are established that provide for routine vaccinations to be administered in schools. As well, governments engage in mass promotional campaigns that utilize all manner of print and broadcast media to reach the broader public.¹⁵

Seasonal flu vaccines are administered in Canada in the same manner as routine childhood vaccines. Decisions on vaccine delivery and the administration of flu clinics is a provincial and territorial responsibility. Each province and territory must assess its capacity to delivery immunization clinics and then make decisions considering the cost of the vaccine. About 10 million doses of influenza vaccine are distributed annually during the flu season in Canada.¹⁶

Even in provinces and territories that do not make vaccination compulsory, there is considerable governmental and social pressure to participate in the immunization process. The government promotes, encourages, and facilitates the complete vaccination of all children in each province and territory. Parents are persuaded to place great reliance in the integrity and safety of the routine childhood immunization system and to expose their healthy children to it.¹⁷ Furthermore, both WHO and the Canadian Public Health Association (“CPHA”) have strongly urged people to receive the new H1N1 vaccine. CPHA urges all Canadians to be immunized against H1N1,

¹³ *Supra* note 10 at 28.

¹⁴ See for instance, *The Public Health Act, 1994*, S.S. 1994, c. P-37.1, s. 45(1).

¹⁵ *Supra* note 3 at 204.

¹⁶ Health Canada, *Influenza (“The Flu”)*, online: Health Canada <www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/flu-grippe-eng.php>.

¹⁷ *Supra* note 8 at 15.

declaring that “the important health benefits the vaccine offers far outweigh any potential risks.”¹⁸

II. BENEFITS OF VACCINES AND IMMUNIZATION PROGRAMS

Immunization, the process by which the body’s own protective mechanisms are primed to thwart the invasion or multiplication of pathogens, has been described as effective and relatively inexpensive, simple, and easy to deliver.¹⁹ Childhood immunization was one of the foremost public health measures of the twentieth century. It allowed control and prevention of many diseases from which morbidity and mortality were staggering.²⁰ There is undoubtedly a great benefit to having vaccinations available on a wide scale. In the United States, prior to the availability of a vaccine, deaths resulting from pertussis were seventy per million in the 1920’s. Vaccine use reduced this figure to seven per million by the mid 1950’s. It has been estimated that use of the DTP vaccine prevents approximately 322 000 cases of pertussis per year in the United States.²¹

High vaccination rates, particularly among school-age children, are necessary to maintain sufficient immunity in the population to prevent outbreaks of infectious diseases. Outbreaks can be prevented only when immunity rates are high enough that it is unlikely that infected and susceptible individuals will come into contact. Even in an immunized population, an outbreak can occur if clusters of susceptible individuals remain. Since school-aged children usually have the highest susceptibility to vaccine-preventable diseases, childhood immunization has been identified as a particularly effective public health measure. Accordingly, vaccination protects not only the children who receive the vaccination and develop immunity, but also children who have been

¹⁸ “Canadian Public Health Association urges Canadians to get vaccinated against H1N1: Making complex decisions on immunization simpler with credible information” *Canadian Business* (29 October 2009), online: Canadian Business <http://www.canadianbusiness.com/markets/cnw/article.jsp?content=20091029_094502_4_cnw_cnw>.

¹⁹ Kathleen R. Stratton, Cynthia J. Howe & Richard B. Johnson Jr., eds., *Adverse events associated with Childhood Vaccines: Evidence bearing on causality* (Washington, D.C.: National Academy Press, 1994) at 310.

²⁰ *Ibid.*

²¹ Patricia Carmen Murray, “DTP Vaccine Related Injury: An examination of proposed Vaccine Injury Compensation Legislation” (1997) 3 J. Contemp. Health L. & Pol’y 233 at 233.

vaccinated but fail to develop immunity, children who are unvaccinated, and susceptible adults in the community.²²

Public health officials point out that high rates of vaccination coverage are required to prevent outbreaks. This is a result of what is sometimes called the “herd effect.” When most of the population that is most at risk is immunized, an infectious disease will not be able to spread in the population to those who lack immunization. But when vaccination rates are too low to produce the herd effect, then those who lack immunization are at risk. Health Canada regards the optimum coverage to be 95% of the target population.²³

Each province/territory and its people benefit greatly from immunization. The process not only provides personal protection to the recipient from disease, but also provides protection for the whole community by reducing the incidence of communicable disease. This phenomenon results in a significant savings to government via reduced health care costs and to businesses by avoidance of a loss of productivity arising from the parental care of sick children. Estimates of savings due to immunizations have been in the billions of medical and health-related dollars.²⁴ Furthermore, there is an increase in work productivity when fewer individuals are suffering from illnesses that may keep them away from school or work for extended periods of time. From an economics-based approach, sick leave translates into less productivity, which impedes the growth, capital, and competitiveness of a nation. Childhood vaccination is, therefore, not merely a selfish act; it is an altruistic act to the advantage of the whole community.²⁵

The wide-spread benefit of immunization programs is apparent. The Canadian National Report on Immunization (1996) describes vaccination as “a cornerstone of improving the health of people worldwide,” and as “the most cost-beneficial of all prevention strategies, resulting in huge savings to society and to health-care systems.”²⁶

²² *Supra* note 10 at 31.

²³ *Ibid.* at 5.

²⁴ *Supra* note 8 at 15.

²⁵ *Ibid.*

²⁶ Canada, Public Health Agency of Canada, *Canadian National Report on Immunization, 1996*, vol. 23S4 (Ottawa: Canada Communicable Disease Report).

Next to clean water, no single intervention has had so profound an effect on reducing mortality from childhood diseases as has the widespread introduction of vaccines.²⁷

III. RISKS OF VACCINES AND IMMUNIZATION PROGRAMS

Whereas the benefits of national immunization programs are obvious, the drawbacks are not as apparent and indeed may be hidden from the public gaze. One of the major concerns is the serious adverse consequences of routine vaccinations that occur in a significant number of children each year.²⁸ The term *adverse event following immunization* (“AEFI”) is defined by WHO as a medical incident that takes place after an immunization, that causes concern, and that is believed to be caused by the immunization.²⁹ The majority of adverse effects suffered from vaccines are minor and short term. Some tenderness and redness may be experienced at the site of the vaccination and the individual may have a low fever. In exceptional circumstances, the consequences may be serious, such as high fever, systemic joint or muscle pain, seizures or anaphylactic shock. In rare situations, an individual may suffer permanent disability such as neurological damage, or may even die.³⁰

According to the Public Health Agency of Canada, a total of 3,625 adverse events following immunization reports were received for vaccines given in 2004. The three most commonly reported adverse events were local reactions (32.4%), allergic reactions (31.7%), and fever (23%).³¹ Although more serious reactions are rare, they obviously are of greater concern to both parents and public health officials. Some of the more serious reactions include: encephalitis in about .06% of reported adverse effects, infection with live virus, Guillain-Barre Syndrome in about 0.07% of reported adverse effects, and anaphylactic shock in about 0.37% of reported adverse effects.³²

²⁷ *Supra* note 19 at 310.

²⁸ *Supra* note 3 at 206.

²⁹ World Health Organization, *Vaccine Safety and Adverse Events Following Immunization*, online: World Health Organization <http://www.who.int/immunization_monitoring/routine/immunization_adverse/en/index.html>.

³⁰ *Supra* note 8 at 1.

³¹ Canada, Public Health Agency of Canada, *Canadian National Report on Immunization*, 2006, vol. 32S3 (Ottawa: Canada Communicable Disease Report) at 31.

³² *Supra* note 10 at 14.

Much speculation surrounds discussions of the risk of contracting Guillain-Barre Syndrome (“GBS”), an autoimmune disorder that affects the peripheral nervous system, from the flu vaccine. Since 1997, during 12 annual seasonal influenza vaccine campaigns, a total of 79 cases of GBS have been reported following influenza vaccine. This is an average of 7 cases per year, with a yearly range of 1 to 14 cases.³³ According to WHO, data is conflicting as to whether a causal relationship exists between modern influenza vaccines and GBS. They claim that if one exists, the risk is estimated to be very low (no more than 1 to 2 cases per million doses).³⁴ With regard to the H1N1 vaccine, the Public Health Agency of Canada claims that since GBS is so rare, it is usually not seen as an adverse event following immunization in the clinical trial stage. In order to assess the potential risk, if any, of GBS following H1N1 flu vaccine, a larger population would need to be observed.³⁵

Some studies have also attributed the dramatic increases of autoimmune disorders such as asthma and diabetes in the last two decades, as well as the significant rise in autism and sudden infant death syndrome, to the widespread use of vaccines.³⁶ Much of this concern has arisen due to the use of thimerosal additives in vaccines. Thimerosal is a mercury-containing organized compound that is widely used as a preservative in biological and drug products to prevent life-threatening contamination of harmful microbes.³⁷ Most influenza vaccines available in Canada contain minute amounts of thimerosal. However, despite the concern over the use of mercury, a number of studies indicate that the evidence does not support a causal link between vaccination and neurological disorders or death.³⁸

With regards to the new H1N1 vaccine, although WHO claims that it has been thoroughly tested, is safe, and does not create harmful effects, they have admitted that even very large clinical studies will not be able to identify possible rare events that can become evident when pandemic vaccines are administered to many millions of people.

³³ *Supra* note 1.

³⁴ World Health Organization, *Safety of Pandemic (H1N1) 2009 Vaccines*, online: World Health Organization <http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/safety_approval/en/>.

³⁵ *Supra* note 1.

³⁶ *Supra* note 3 at 207.

³⁷ Regina Moreland, “National Vaccine Injury Compensation Program: The Potential Impact of Cedillo for Vaccine Related Autism Cases” (2008) 29 J. Legal Med. 363 at 370.

³⁸ *Ibid.*

They have noted that these can only be assessed when a vaccine is in widespread use.³⁹ Therefore, although extensive clinical and non-clinical testing has been performed on the new vaccine to assess its safety, severe adverse effects may still present when the vaccine is delivered to Canadians *en masse*.

Vaccine injuries can be the result of various factors. Many times, vaccine-related injuries are not due to the fault of any one party. Usually, the vaccine is manufactured by a drug company and administered by health officials in strict compliance with federal and local laws. Vaccines represent a special class of health products in that they can cause harm despite proper manufacture, distribution, and administration. Injuries may be as a result of a genetic predisposition or as a result of the very nature of the vaccine itself.⁴⁰ The vaccine may further be contraindicated because of allergy, pre-existing illness, immunosuppression, or age.⁴¹

Vaccine injuries can, however, also be caused by the negligence of one or more persons. Contamination, adulteration, improper configuration, or other errors in the manufacturing process, inadequate testing, or improper labeling can result in defective vaccines. Even if the vaccine is not defective, injury may occur if the vaccine is administered improperly or in an improper dosage.⁴²

Furthermore, lack of informed consent may cause injuries due to the fact that an individual may have declined to receive the vaccine if they had been properly informed of all of the material risks. The Supreme Court of Canada in *Reibl v. Hughes* held that doctors have a duty to disclose all material risks of a proposed procedure, which includes those risks that may have a low probability but grave results.⁴³ It is therefore imperative that individuals be provided with full disclosure of all risks and benefits when making the decision to vaccinate either themselves or their children. However, both empirical studies and anecdotal evidence indicate that individuals are rarely

³⁹ *Supra* note 34.

⁴⁰ *Supra* note 3 at 208.

⁴¹ Wendy K. Mariner, "Compensation programs for vaccine-related injury abroad: a comparative analysis" (1987) 31 Saint Louis U.L.J. 599 at 599.

⁴² *Ibid.*

⁴³ *Reibl v. Hughes*, [1980] 2 S.C.R. 880, 33 N.R. 361.

guided through a full informed consent process with respect to vaccines.⁴⁴ This discrepancy may be attributed to a number of factors. It may be a result of continued acceptance by the public and those who administer vaccines of the status quo of routine vaccine administration systems. Many parents or patients themselves may follow their doctor's advice without engaging in independent decision-making. Furthermore, due to time constraints, disclosure when it does exist may consist only of a pamphlet or fact sheet, which is arguably insufficient to meet the standard as prescribed by the common law.⁴⁵ Finally, disclosure may not be occurring because many physicians themselves may not be aware of all the risks and contraindications of vaccination.⁴⁶

It is therefore apparent that there are serious risks involved with vaccination, both from vaccines themselves and through the system of immunization. Although serious adverse events following immunization are rare, when they do occur they can have severe, sometimes permanent damaging effects, and in some cases can even cause death. As will be discussed below, the current system for addressing the needs of those who have suffered from the risks of vaccines is inadequate. It may be impossible to eliminate all risks from vaccinations. However, Canada can create a system that fairly and efficiently compensates those who have been injured in an act that benefits not only those who have suffered harm, but society in general.

IV. VACCINE INJURIES AND THE TORT SYSTEM

In Canada, with the exception of Quebec, compensation for adverse reactions to vaccination is mediated under principles of tort law. Entitlement to compensation depends upon whether a manufacturer or some other person, such as the administering physician, is legally liable for causing the injury.⁴⁷ The medical malpractice system assumes that a patient should be compensated if, and only if, he or she is injured by the fault of a physician or another health care provider.⁴⁸ In the absence of conduct amounting to fault, there is no basis for imposing liability, and consequently, no

⁴⁴ *Supra* note 3 at 210.

⁴⁵ *Ibid.* at 211.

⁴⁶ *Davidson v. Connaught Laboratories*, [1980] O.J. No. 153, 14 C.C.L.T. 251.

⁴⁷ *Supra* note 41 at 600.

⁴⁸ Robert E. Astroff, "Show me the money!: Making the case for no-fault medical malpractice insurance" (1996) 5 Health L. Rev. 9 at 10.

entitlement to compensation.⁴⁹ If an action is successful, then the remedy is an award of damages which is designed to place the victim in the position that he or she was in before the accident occurred, insofar as money can achieve that goal.⁵⁰

With respect to vaccine injuries, there are two relevant torts that may apply: negligence and battery. The tort of battery in medical procedures exists when a plaintiff has not consented to a procedure and is consequently injured by the actions of a physician, regardless of the good intent or lack of negligence on the part of the physician.⁵¹ Thus, proof of a lack of consent for the administration of the vaccine or proof of invalid consent (i.e. as when obtained through fraud or misrepresentation), is required, as well as proof that the defendant touched the plaintiff.⁵²

The tort of negligence imposes liability for damage caused by the failure of one person (the defendant) to take reasonable care for the safety of another person (the plaintiff). The plaintiff must prove that the defendant owed the plaintiff a legal duty of care and failed to exercise reasonable care causing foreseeable damage to the plaintiff. The plaintiff must establish that “but for” the negligent action of the defendant, the plaintiff would not have sustained the injury.⁵³ If the plaintiff is able to prove negligence, the defendant may then be able to assert one or more of the defences of voluntary assumption of risk (a complete defence), or contributory negligence (which reduces damages in proportion to the plaintiff’s responsibility for the damage or the loss). Those who suffer vaccine-related disabilities may have a negligence claim against the person who administered the vaccine, such as a physician or public health care worker.⁵⁴

Those who administer a vaccine owe a duty of care to vaccine recipients. This duty has two components. First, there is a duty to give the vaccination with reasonable care and skill and in accordance with standard medical practice. Negligence can arise in a number of ways: the vaccine may be improperly stored or prepared; the vaccination

⁴⁹ *Supra* note 41 at 601.

⁵⁰ *Supra* note 8 at 8.

⁵¹ *Supra* note 3 at 213.

⁵² *Ibid.* at 214.

⁵³ *Ibid.*

⁵⁴ *Supra* note 8 at 8.

may be contraindicated because of the health of the individual; or, possibly, a course of vaccinations may be negligently continued in spite of adverse reactions exhibited by an individual to each of the preceding doses.⁵⁵

Second, there is a duty to provide the recipient, or the parent or guardian if the recipient is a child, with sufficient information about the material risks and side effects of the vaccine to secure an informed consent to the procedure. Material risks are those which a reasonable person in the position of the patient would want to know about when deciding whether or not to consent to the medical procedure at issue. The health care professional is obliged to see that the requisite information has been communicated and understood.⁵⁶

A plaintiff has a difficult hurdle to overcome with respect to causation in informed consent cases. The plaintiff must first establish that, on a balance of probabilities, the injuries were caused by the vaccine. The plaintiff then has to show that the decision-maker would have refused to consent to the vaccination if the required information of material risks had been given. This decision is resolved based on what a reasonable person in the particular circumstances of the decision-maker would have done. If the same decision would have been made, then the plaintiff has failed to prove that the lack of information caused the injury or illness.⁵⁷

A plaintiff who suffers an injury by a vaccine may also have a cause of action against the manufacturer. The manufacturer of a vaccine owes a duty of care to the consumers of its products. Negligence may be found in the manufacture of defective vaccines, in the failure to provide information about the inherent risks of the vaccine, and in the faulty design of vaccines.⁵⁸ Although a manufacturer has a duty to warn consumers of the material risks associated with the use of its product, it can discharge its obligation to inform the patient by providing it to a “learned intermediary” such as a physician.⁵⁹ Yet, if a product is inherently unsafe due to negligence in developing and testing it,

⁵⁵ *Ibid.* at 9.

⁵⁶ *Ibid.*

⁵⁷ *Ibid.* at 10.

⁵⁸ *Ibid.*

⁵⁹ *Supra* note 3 at 213.

then the manufacturer is liable for harm caused by the product. The plaintiff would then have to show that the adverse effects of the vaccine rendered it unsuitable for use.⁶⁰

There have been very few, if any, doctrinal changes of any real significance in health care liability over the last 50 years.⁶¹ A plaintiff, in proceeding with a negligence claim against a medical professional, must overcome many difficult hurdles in order to receive compensation. It is questionable whether the tort system is the adequate forum to provide proper redress for vaccine-related injuries. The next section of this article will discuss the pros and cons of tort law in general, and the reasons why, in the context of vaccine-related injuries, tort law needs to be replaced or supplemented by a no-fault compensation system.

V. THE PROS AND CONS OF THE TORT SYSTEM

The ideological premise behind tort law is clear. The tort notion that individuals should be held personally responsible and accountable for the injuries which they cause to themselves or to others, when these injuries were reasonably preventable, reflects our deep-seated beliefs in morality and justice.⁶² Advocates of the present tort system assert that requiring wrongdoers to pay for the results of their wrongful acts results in a number of beneficial consequences: justice, deterrence, education, and compensation.⁶³ Arguments that tort law should be abolished and replaced by no-fault schemes generally focus on tort law's ineffectiveness and economic inefficiencies in delivering these consequences.⁶⁴ The next section will enquire whether tort law alone is sufficient to provide redress for victims of medical errors.

1. Justice

Many would argue that the most persuasive reason for retaining tort law is that it expresses an important principle of justice.⁶⁵ Lewis Klar argues that "the idea that a wrongdoer who injures another ought to be required, both as a moral and a legal

⁶⁰ *Supra* note 10 at 17.

⁶¹ Gerald B. Robertson, "A View of the Future: Emerging Developments in Health Care Liability" (2008) *Health L.J.* 1 at 1.

⁶² Lewis N. Klar, "Tort and no-fault" (1997) 5 *Health L. Rev.* 2 at 3.

⁶³ *Supra* note 48 at 10.

⁶⁴ *Supra* note 62 at 3.

⁶⁵ *Ibid.*

obligation, to repair the damage caused by restoring the victim to his or her pre-accident state, is undeniably a fundamental feature of our system of beliefs.”⁶⁶ The idea of personal responsibility for one’s wrongful conduct is so deeply ingrained in our society that, for some, this alone justifies tort law’s continued existence, since tort law is the mechanism by which accountability is assessed and, hence, how this imperative is realized.⁶⁷ In sum, to ignore wrongdoing would simply be unacceptable.

A common response to this view is that, in a medical malpractice claim, even if a doctor were found to be negligent, liability insurance would cover most losses.⁶⁸ The argument for bringing the wrongdoer to justice becomes less convincing when an insurance company, instead of the individual medical professional, pays for the tort claim.

While this reasoning is valid, it is important to note that a tort action still holds the medical professional accountable to answer to the victim. A finding of liability can seriously hurt one’s reputation and goodwill. Additionally, insurance premiums will go up for those with bad claims records.⁶⁹ Furthermore, for the victim who was injured by the negligent conduct of the health professional, the source of compensation may not be as important as the ability to place fault and accountability.⁷⁰

2. Deterrence

The deterrent effect of tort liability is also commonly cited as a goal of tort law. The threat of tort liability and the imposition of financial sanctions on those who fail to take reasonable care will, at least in theory, encourage careful behaviour.⁷¹ Some studies have indicated that tort liability does, in fact, deter unreasonable behaviour and that when no-fault schemes are implemented, accident rates and accident costs increase.⁷² On a theoretical level, however, it has been argued that people’s conduct and concern for others is more likely a reflection of human psychological traits, attitudes, habits, and

⁶⁶ *Ibid.* at 4.

⁶⁷ Andrew Brine, “Medical malpractice and the goals of tort law” (2003) 11 Health L.J. 241 at 251.

⁶⁸ *Ibid.*

⁶⁹ *Supra* note 62 at 5.

⁷⁰ *Supra* note 67 at 251.

⁷¹ *Ibid.* at 245.

⁷² *Supra* note 62 at 6.

personal codes of conduct rather than a desire to avoid tort liability.⁷³ Despite this possibility, in some settings and for some defendants, such as health-care professionals (where there is a hypersensitivity to findings of liability), general deterrence may have a powerful effect.⁷⁴

The problem with this concern by health professionals for incurring liability is the resulting phenomenon of defensive medicine. The concept behind defensive medicine is that doctors act defensively in order to avoid law suits.⁷⁵ Due to a fear of accusations and liability, litigation induces health care providers to practice inefficient medicine, unnecessarily using medical resources to protect against law suits and also refusing to provide care or adopt new methods of treatment for fear of increased liability exposure.⁷⁶ Notwithstanding these apparent negative effects, defensive medicine can also arguably create situations wherein doctors are more careful and meticulous in their dealings with patients, despite the cost it has on the medical system, and that therefore fewer cases of negligence and failure to inform will arise.⁷⁷

3. Education

Tort law is also said to provide education. This is so because activities regulated by tort law tend to arise through ignorance more than intentional departures from accepted norms and standards of behaviour.⁷⁸ In the medical malpractice context, this function of tort law is thought to be very important, since standards of care are continually changing. In tort litigation, current standards of care are reviewed, tested, and advanced. It would seem, therefore, that without tort law, practice standards would remain relatively static.⁷⁹ The current system, it is argued, achieves the important functions of enhancing practice standards and educating doctors about the current minimum standards of care and other legal issues through the publication and publicity of important court decisions.⁸⁰

⁷³ *Supra* note 67 at 246.

⁷⁴ *Ibid.*

⁷⁵ *Supra* note 62 at 6.

⁷⁶ *Supra* note 67 at 247.

⁷⁷ *Ibid.* at 248.

⁷⁸ *Ibid.* at 249.

⁷⁹ *Ibid.* at 250.

⁸⁰ *Ibid.*

4. Compensation

Finally, compensation is also a generally accepted goal of tort law. It is thought to be just that the defendant must compensate the person who he or she has wronged and that this amount be measured by the loss suffered by the plaintiff.⁸¹ The idea behind compensation is that the victim will be fully restored by the wrongdoer to his or her pre-accident position. The idea of full compensation is a fundamental part of tort law, so much so that victims are compensated for even intangible losses.⁸² In cases where fault is proven, compensation includes, but is not limited to, recovery for pain and suffering, replacement of lost past and future income, costs of future care, gross-up for income tax, and pre-judgment interest.⁸³

One commonly cited flaw of the current system, however, is that it does not actually achieve its goal of compensating victims of iatrogenic injuries, since only a small percentage of those injured during their stays in the hospital actually receive any form of compensation.⁸⁴ Under the current system, the means of compensating have been called subjective, intuitive, and unequal.⁸⁵ It heavily overpays some claimants, while underpaying or denying others who are equally or more deserving.⁸⁶ As a result, the tort system has been characterized as a “lottery” because of its unpredictability and tendency to award disproportionate compensation to similarly situated plaintiffs.⁸⁷

In 2008, 884 lawsuits were commenced against Canadian doctors. Of the actions that have proceeded to trial, only 13 judgments have been rendered in favour of the plaintiffs.⁸⁸ It is believed that only approximately one-third of medical malpractice claimants per year are likely to receive any compensation.⁸⁹ Some reports go as far as to

⁸¹ *Ibid.* at 243.

⁸² *Supra* note 62 at 5.

⁸³ Jocelyn Downie *et al.*, *Patient Safety Law: From Silos to Systems. Appendix 2: Country Reports CANADA*, online: Patient Safety Law <http://www.patientsafetylaw.ca/documents/Appendix_2_Canada.pdf>.

⁸⁴ *Supra* note 67 at 243.

⁸⁵ *Supra* note 48 at 13.

⁸⁶ S. A. Sturges, “Vaccine-Related Injuries: Alternatives to the Tort Compensation System” (1986) 30 *Saint Louis U.L.J.* 919 at 920.

⁸⁷ *Supra* note 48 at 13.

⁸⁸ Canadian Medical Protective Association, *2008 Annual Report* (Ottawa: C.M.P.A., 2008).

⁸⁹ *Supra* note 61 at 4.

say that perhaps as few as 2% of the people who suffer injury as a result of medical negligence actually receive any compensation.⁹⁰

Furthermore, many victims choose not to litigate, and therefore receive no compensation for their injuries. In the United States, the Harvard Medical Practice Study physician review concluded that only one negligence claim is made for every 7.5 injuries caused by negligence.⁹¹ There are many reasons why victims choose not to litigate. Often patients are unaware that they have suffered an iatrogenic injury; the plaintiff must prove a breach of the medical standard of care; it is very difficult for a lawyer to prove even a meritorious malpractice case;⁹² the plaintiff must prove causation, which can be very difficult in a complex medical malpractice claim; and, cases can be lengthy and expensive. In sum, the expense, time, and difficulty of initiating and maintaining a malpractice action limit plaintiff access to tort compensation.⁹³ In fact, a number of respected judges over the last 20 years have expressed regret that patients deserving of compensation are precluded from it by the present requirements of tort law.⁹⁴

It appears that tort law does offer several beneficial effects. Although there may be severe drawbacks and inadequacies of the current system, it may end up causing more harm than good to abandon the entire medical malpractice system for no-fault compensation. Despite this possibility, however, in the isolated context of vaccine injury, tort law, as will be discussed below, is not well-equipped to provide adequate and sufficient redress.

VI. PROBLEMS WITH THE TORT SYSTEM FOR VACCINE-RELATED INJURIES

Very few vaccine injury claims have been litigated in Canada. Those that have been have not been favourable to the plaintiffs.⁹⁵ Specifically, plaintiffs in vaccine injury

⁹⁰ *Ibid.*

⁹¹ Robert G. Elgie, Timothy A. Cauffield & Michael L. Christie, "Medical injuries and malpractice: Is it time for "no fault"?" (1993) 1 Health L.J. 97 at 98.

⁹² Michael Ganley, "Hard-nosed medical protective association has a winning record" (2003) 23:7 Lawyers Wkly 9(2).

⁹³ *Supra* note 91 at 99.

⁹⁴ Ellen Picard & Gerald Robertson, *The Future in Legal Liability of Doctors and Hospitals in Canada*, 3d ed., (Toronto: Carswell, 1996) at 534.

⁹⁵ *Supra* note 10 at 18.

claims have a significant hurdle in proving causation. Because of this problem, there is a general lack of success of vaccine-damaged plaintiffs in Canada to date.⁹⁶

To be successful in a negligence claim, the plaintiff must prove on a balance of probabilities that the injury was caused by the defendant's acts or omissions. This is especially difficult in many vaccine injury cases. The first element of causation in a vaccine liability case is general scientific causation – the ability of the product to cause the harm.⁹⁷ Unfortunately, the mechanisms of vaccine damage are not well understood.⁹⁸ Adverse effects of vaccination are reported when there is a temporal link between vaccination and symptoms. However, further research is still needed in many cases in order to actually establish a causal link.⁹⁹ For example, a link between Guillain-Barre syndrome and vaccination has not been satisfactorily demonstrated in the twenty years since it was first suspected.¹⁰⁰

If a plaintiff is successful in establishing general scientific causation, then the plaintiff next has to prove legal causation. As was set out in *Barnett v. Chelsea & Kensington Hospital Management Committee*, the plaintiff must show that “but for” the negligent action of the defendant, the plaintiff would not have been injured.¹⁰¹ In order to do this, the plaintiff must prove that the vaccine indeed caused the particular plaintiff's injury. As with general scientific causation, this is also a scientific enquiry that is difficult to prove. It is often difficult to determine whether the harm was incidentally related to the vaccine or whether the vaccine directly caused it.¹⁰²

In an action for lack of informed consent, the plaintiff must prove that he or she would have declined to consent had the risks been disclosed.¹⁰³ As discussed above, the doctrine of informed consent creates several problems for the plaintiff in a vaccine injury claim. Ideally, when a parent decides to vaccinate a child, he or she should be informed of all of the material risks of vaccination and of a refusal to vaccinate. The

⁹⁶ *Supra* note 8 at 12.

⁹⁷ *Supra* note 3 at 215.

⁹⁸ *Ibid.*

⁹⁹ *Supra* note 10 at 17.

¹⁰⁰ *Ibid.*

¹⁰¹ *Barnett v. Chelsea and Kensington Hospital Management Committee*, [1969] 1 Q.B. 428.

¹⁰² *Supra* note 3 at 215.

¹⁰³ *Ibid.* at 216.

extent and degree of disclosure of the risks of vaccines is high because the recipient is not ill.¹⁰⁴ The practice of providing information about vaccination appears to vary, however, from providing a pamphlet or information sheet with general information about vaccination, to more detailed discussion with the patient or parent; some parents do not believe that they are given adequate information¹⁰⁵

Furthermore, the role of consent is somewhat different if vaccination is mandatory. Parents are still able to refuse vaccination for their children in jurisdictions such as Ontario and New Brunswick where vaccination is compulsory, but the vaccination may be administered without positive consent if the parent has not filed a statement in the approved form to claim an exemption.¹⁰⁶ This requirement may contribute to a sense that vaccination programs have not been fully justified to the public.¹⁰⁷

Creating further difficulty with informed consent is the problem that the question asking what the decision-maker would have decided if the required information on material risks had been given is not based on what that particular decision-maker would have decided, but instead on what a reasonable person in the particular circumstances of the decision maker would have decided. This is what is known as a modified objective standard for legal causation. In almost all situations, a full explanation of the risks and benefits of vaccination and the risks and consequences of the disease the vaccination is meant to prevent will lead reasonable persons to proceed with the vaccination.¹⁰⁸ Considering the alternatives to vaccination, namely a higher probability of contracting a serious disease, balanced with the comparatively insignificant associated risks, in a situation where the risks and benefits have been disclosed, it is inevitable that a reasonable person would choose vaccination. Where the benefits clearly outweigh the risks, the plaintiff is placed in the almost impossible situation of having to establish that he or she would have refused vaccination.

¹⁰⁴ *Supra* note 8 at 10.

¹⁰⁵ *Supra* note 10 at 8.

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*

¹⁰⁸ *Supra* note 8 at 10.

The situation is a little different, however, in product liability cases where the claim for negligence for failure to warn is against the manufacturer. The standard applied in these cases is the subjective standard, asking what that particular plaintiff would have decided if he or she had been properly informed.¹⁰⁹ This different analysis of causation is thought to reflect the distinction between the manufacturer-consumer relationship and the doctor-patient relationship.¹¹⁰ However, the manufacturer may discharge its duty to warn the consumer through the learned intermediary rule, which dictates that the manufacturer must take adequate steps to ensure that the intermediary, usually a doctor, is provided with the relevant information on the product. If it has provided this information to the learned intermediary, then it cannot be held liable for a failure to warn.

Finally, the plaintiff in vaccine injury cases faces the problem of indeterminate defendants. This occurs when the plaintiff is unable to point to one particular defendant among a group of negligent defendants as having actually caused the plaintiff's injury.¹¹¹ For a vaccine injury case, there may be more than one manufacturer of a type of vaccine that have all been negligent, but the plaintiff cannot establish which of the negligent manufacturers supplied the vaccine that caused the plaintiff's injury. If a plaintiff cannot prove that it was more likely than not that one particular manufacturer supplied the vaccine that caused the injury, then the claim must fail.

Because of the difficulties that plaintiffs face in the context of vaccine injuries, there has been much judicial suggestion that the normal process of litigation is inadequate to deal with claims of this nature. Some examples to this effect are discussed below.

VII. EXAMPLES FROM CASE LAW

The difficulty a plaintiff faces in establishing scientific causation is illustrated in the case *Rothwell v. Raes*.¹¹² The plaintiff, Patrick Rothwell, alleged that the pertussis vaccine

¹⁰⁹ *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634, S.C.J. No. 104.

¹¹⁰ *Supra* note 3 at 217.

¹¹¹ *Ibid.* at 218.

¹¹² *Rothwell v. Raes*, [1988] 54 D.L.R. (4th) 193, O.J. No. 1847 [*Rothwell*].

caused severe physical and mental disability. About one month after receiving his third shot of the vaccine at the age of five months, Patrick began to show signs of developmental abnormality. The plaintiff sued the manufacturer, Connaught Laboratories, the physicians who administered the vaccine, and the Crown, who had distributed the vaccine. A broad range of expert testimony and medical research was canvassed by the trial judge. The court ultimately held that the plaintiff had not established on a balance of probabilities either that the pertussis vaccine was capable of causing injury of the kind suffered by the plaintiff, or if it was capable of causing such injuries, that it had done so in the case under consideration. In concluding, Justice Osler commented on how “the normal process of litigation is an utterly inappropriate procedure for dealing with claims of this nature.”¹¹³ He went on to quote Justice Krever from *Ferguson v. Hamilton Civic Hospitals*, who stated:

I confess to a feeling of discomfort over a state of affairs, in an enlightened and compassionate society, in which a patient, who undergoes a necessary procedure and who cannot afford to bear the entire loss, through no fault of his and reposing full confidence in our system of medical care, suffers catastrophic disability but is not entitled to be compensated because of the absence of fault on the part of those involved in his care. While it may be that there is no remedy for this unfortunate and brave plaintiff and that this shortcoming should not be corrected judicially, there is, in my view, an urgent need for correction.¹¹⁴

He and many other judges have noted how the current tort process holds out very little promise for an efficient and fair remedy for those children who suffer vaccine-related injury and illness. In *Rothwell*, the trial judgment in favour of the defendants was not rendered until nine years after the vaccine in question was given. An appeal to the Ontario Court of Appeal was dismissed two years later. It has been estimated that the legal costs of the litigation exceeded \$1 000 000.¹¹⁵ This type of uncertainty, delay, and expense is unfortunately a common phenomenon in the tort process.

¹¹³ *Ibid.* at para. 291.

¹¹⁴ *Ferguson v. Hamilton Civic Hospitals* (1983), 40 O.R. (2d) 577 at pp. 618-19, 144 D.L.R. (3d) 214 at 258-9, 23 C.C.L.T. 254.

¹¹⁵ *Supra* note 8 at 12.

The inability of the tort system to provide redress to vaccine-injured plaintiffs is further illustrated in the recent Ontario case, *Morgan v. Metropolitan Toronto (Municipality)*.¹¹⁶ The plaintiff, Lucia Morgan, sued the City of Toronto for negligently administering the hepatitis B vaccine. She allegedly developed chronic fatigue syndrome as a result, which dramatically and permanently affected her quality of life. The plaintiff was a social worker who got the vaccine after being urged to do so by her employer. The plaintiff argued that the City breached the standard of care in failing to adequately disclose the risks of the vaccine. The trial judge, however, concluded that the information provided adequately reflected the state of knowledge of the known risks of the vaccine at the time. Furthermore, the trial judge ultimately concluded that even if all the risks had been adequately disclosed, Lucia would nevertheless have opted to receive the shots.

In her concluding remarks, the trial judge, Mary Anne Sanderson, commented on how “the road to protecting public health should not be paved with individual victims. Fair, meaningful, no-fault compensation should be made available to individuals suffering from serious adverse side effects of vaccines.”¹¹⁷ She went on to note that:

At present, as this case illustrates, even when it can be credibly postulated that a vaccine has caused serious adverse consequences, the barriers standing in the way of recovery are formidable. A tort claimant who suspects a vaccine has caused her damage will not likely be working and able to afford the costs of litigation. Complex and protracted litigation such as this is notoriously costly, given the need for expert scientific evidence and medical proof. Even those able to afford such costs would likely be met (as here) with experts stridently touting vaccine safety.¹¹⁸

It took 12 years between Ms. Morgan falling ill and a judgment being rendered. Her case is yet another example of how our system is failing victims who are injured by vaccines that yield widespread public benefits.

¹¹⁶ *Morgan v. Metropolitan Toronto (Municipality)*, [2006] O.J. No. 4951, 44 C.C.L.T. (3d) 198.

¹¹⁷ *Ibid.* at para. 437.

¹¹⁸ *Ibid.* at para. 441.

A final example of how the tort system has failed plaintiffs injured by vaccines is the Supreme Court of Canada case, *Lapierre v. Québec (Attorney General)*.¹¹⁹ The unsuccessful litigation of the plaintiff, Nathalie Lapierre, was what prompted the Quebec government to implement a no-fault vaccine injury compensation plan. One week after being vaccinated for measles, Nathalie suffered acute viral encephalitis which left her in a state of permanent and almost total disability. An action was brought against the government of Quebec, which in turn joined the manufacturer and the distributor of the vaccine. The trial judge found a causal link between the vaccine and the disability, but found that none of the defendants were negligent. The case reached the Supreme Court of Canada on the issue of whether the government can be held strictly liable for the adverse consequences of vaccination programs funded and supported by it. The Court declined to impose liability. In concluding, the Court quoted Justice McCarthy: “In my opinion, an obligation independent of any fault in circumstances such as those of the case at bar would be an excellent thing, but it does not exist in our law at present.”¹²⁰ The message from this case is that proof of negligence is an essential component of tort liability, and that there is little likelihood of negligence and causation being established against government, vaccine manufacturers, or health care professionals for vaccine injuries.¹²¹

VIII. NO-FAULT COMPENSATION PROPOSALS

The concern over the inadequacies of the current tort system has led many to push for the implementation of no-fault compensation schemes. The basic premise behind no-fault is simple: those persons who have been injured in an accident and who have become disabled as a result should receive compensation for their injuries and losses without regard to the cause of their accidents.¹²² The principle is that “fault” should play no role either in the eligibility for compensation or level of compensation decisions.¹²³ There are innumerable variations of these systems, ranging from partial to full compensation and from “pure” no-fault to a mixed tort/no-fault system.¹²⁴ One

¹¹⁹ *Lapierre v. Québec (Attorney General)*, [1985] 1 S.C.R. 241, S.C.J. No. 13.

¹²⁰ *Ibid.* at para. 121.

¹²¹ *Supra* note 8 at 18.

¹²² *Supra* note 62 at 3.

¹²³ *Ibid.*

¹²⁴ *Supra* note 91 at 98.

alternative to a fault system is to implement limited no-fault plans utilizing specified events. A no-fault vaccine-related injury compensation scheme to specifically address vaccine-related injury and illness has been recommended to supplement the tort scheme. A no-fault system would provide compensation for those who can establish that they suffered harm from a vaccination, regardless of fault.

Many jurisdictions throughout the world have introduced special compensatory initiatives to address vaccine-related injury and illness. A similar rationale underlies most of the existing programs: where individuals receive vaccinations required or recommended by government in the public interest, and they are injured as a consequence, government has a special responsibility to provide compensatory support regardless of whether or not negligence can be proven.¹²⁵

There are many advantages proposed for no-fault schemes. Under a no-fault plan, more victims will recover their economic losses, with much less delay than under the present scheme. Health care providers may be more likely to reveal the nature of the injury to the patient because the provider would no longer be held financially liable. Under a no-fault system, all patients would have the security of a prompt award equal to their economic loss, without incurring significant legal or expert fees. In addition, patients would be able to avoid the uncertainty of a long and costly litigation process, with potentially no recovery. Finally, a no-fault system would eliminate the unfairness of the current tort system against plaintiffs who cannot afford the best lawyers and expert witnesses.¹²⁶

Furthermore, a no-fault compensation plan for vaccine-related injuries would reflect the reciprocal relationship between the individual receiving the vaccine and society in general. As previously stated, the general population as well as the individual recipient benefit from vaccination. Michelle Mello argues that, “among vaccinees, the injured and the uninjured pay unequal shares of the social cost of producing the shared good of herd immunity. In other words, the uninjured are (unintentionally) free-riding on the

¹²⁵ J. Robert S. Prichard, *Liability and Compensation in Health Care: A Report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care. Appendix A: Health Care Liability and Compensation Review – Working Paper* (Toronto: University of Toronto Press, 1990) at 296.

¹²⁶ *Supra* note 48 at 15.

injured.”¹²⁷ To balance this inequality, Mello argues that fairness and solidarity both militate in favour of a safety net for those who bear the burden of injury.¹²⁸ The argument in favour of compensating those who are injured is even stronger in provinces that require mandatory childhood vaccination. Individuals who are harmed by the exercise of coercive power should be offered restitution, to the extent that the government can reasonably provide it.¹²⁹

Although the adoption of a no-fault scheme would appear to create an efficient and relatively uncomplicated means for compensating victims of vaccine injuries, there are certain factors that are cause for some concern. First, as was pointed out by the Manitoba Law Reform Commission, such a scheme would differentiate unfairly between those who suffer a childhood vaccine accident and those who suffer some other kind of medical accident.¹³⁰ The former would receive guaranteed benefits and the latter would need to rely on the tort system, with uneven results. The distinction may, however, be justified on the grounds that the former participate in a public health campaign that benefits not only the receiver of the vaccine but the population in general, and they have received treatment unrelated to any personal current illness.¹³¹

Second, the establishment of a compensation plan for victims of vaccine accidents may undermine the public confidence in an important public health initiative, and may lead to a lowering of vaccination rates among the general disadvantaged public.¹³² However, it is unlikely that any governmental initiative which depends on public support and confidence will prosper by unduly discounting risks and disadvantages. The open discussion of all material risks is essential for a successful immunization program.¹³³

Third, the development of a no-fault plan may diminish the power of tort law to positively influence the conduct of health care professionals and manufacturers. It is argued that with a no-fault scheme, there will be no effective deterrent against wrongful

¹²⁷ Michelle M. Mello, “Rationalizing vaccine injury compensation” (2007) 22 *Bioethics* 32 at 39.

¹²⁸ *Ibid.* at 40.

¹²⁹ *Ibid.* at 36.

¹³⁰ *Supra* note 8 at 15.

¹³¹ *Ibid.*

¹³² *Ibid.*

¹³³ *Ibid.* at 16.

behaviour, and therefore risky conduct will increase.¹³⁴ In theory, this may be correct, but the experience of health care professionals and manufacturers in relation to vaccine injuries is one in which there is no reported Canadian case where anyone has been held liable. Since it is already almost impossible to find liability in vaccine-injury cases, moving to a no-fault scheme will likely not create a great loss in deterrence. Furthermore, by supplementing the tort system with a no-fault scheme, a plaintiff would still be able to bring a tort claim, thereby retaining the deterrent effect of tort law.

Fourth, critics of no-fault proposals argue that they are more expensive to finance and administer than the current tort system.¹³⁵ For example, the costs of the ambitious and comprehensive no-fault system in New Zealand escalated substantially from what was predicted, and has led to a major revamping of the scheme.¹³⁶ However, whether a no-fault scheme would cost more depends on the design of the compensation program.¹³⁷

Fifth, the elimination of compensation for pain and suffering is seen as a controversial aspect of no-fault systems. No-fault systems generally do not offer victims any compensation for non-pecuniary losses, such as pain and suffering, or loss of enjoyment of life, and have ceilings on pecuniary losses, such as loss of earning capacity. There may also be restrictions on what can be claimed as loss of earnings, because (generally) potential earnings for those not currently employed are not compensated for by no-fault schemes.¹³⁸ However, given the fact that few victims receive compensation even for pecuniary loss within the tort system, it might be more fair to offset the elimination of pain and suffering by guaranteeing economic loss compensation to a greater number of victims.¹³⁹

A final problem with no-fault systems is the difficulty in proving causation. The victim under a no-fault system faces the same hurdles that he or she would face under the tort system in having to prove that the vaccine caused the injury or illness. In order to receive compensation, the claimant must establish a causal link between the vaccine and

¹³⁴ *Ibid.*

¹³⁵ *Supra* note 48 at 15.

¹³⁶ *Supra* note 62 at 8.

¹³⁷ *Supra* note 91 at 106.

¹³⁸ *Supra* note 62 at 5.

¹³⁹ *Supra* note 48 at 17.

the disability or death on a balance of probabilities. Under the Quebec no-fault vaccination scheme, the causation requirement has led to the same result as in the tort system – very few victims are able to meet the burden of proof when it comes to vaccine injuries.¹⁴⁰ From its inception until the year 2000, there have been only 117 claims under the Quebec scheme. Of these claims, only 20 have been compensated, with the average pay out being \$135 000. It is thought that the low number probably reflects the difficulty in establishing causation.¹⁴¹ However, this criticism applies to all medical compensation arrangements, not just to no-fault systems. Although no compensation scheme is perfect, it is suggested that, on balance, some version of a no-fault scheme will provide a better option than the current tort/ fault-based system.

IX. NO-FAULT VACCINE COMPENSATION SCHEMES IN OTHER JURISDICTIONS

Public compensation programs for vaccine injury have been established in numerous jurisdictions, including Germany (1961), France (1964), Japan (1970), Switzerland (1970), Denmark (1972), New Zealand (1974), Sweden (1978), United Kingdom (1979), Québec (1987), United States (1988), Taiwan (1988), Italy (1992) and Norway (1995).¹⁴² This section will describe the programs that have been established in Quebec and the United States. A combination of elements from these two schemes would arguably be ideal for the creation of compensation plans for the rest of Canada.

1. Quebec

Quebec's no-fault system for vaccination was enacted in 1985 after the unsuccessful litigation of Nathalie Lapierre.¹⁴³ The plan provides compensation to any person, adult or child, who suffers "grave and permanent mental or physical damage" caused by a designated vaccination, or by a disease contracted from an immunized person, or as a result of being a fetus of an immunized person. If causation is proved and the claimant meets other necessary criteria, then compensation is paid in accordance with the benefits outlined in the *Automobile Insurance Act*.

¹⁴⁰ *Supra* note 3 at 222.

¹⁴¹ *Supra* note 8 at 21.

¹⁴² *Ibid.* at 17.

¹⁴³ *Public Health Act*, R.S.Q. c. S-2.2, ss. 70-78; *Regulation Under the Public Health Act*, R.Q. 2009, c. S-2.2, r. 1.

The vaccines covered by the plan are listed in a regulation, which is intended to include all vaccines approved for use in the province. The claimant must make a written application to a three-member medical assessment committee in the Department of Health and Social Services. The committee is composed of a physician nominated by the Minister of Health, a physician nominated by the claimant, and a physician nominated by the other two members.¹⁴⁴ Compensation is awarded on a no-fault basis; negligence need not be proved. However, a causal relationship between the vaccination and the injury must be established on a balance of probabilities.

The decision of the Minister of Health and Social Services may be appealed both on the merits of the decision and as to the quantum of compensation to the Commission des Affaires Sociales.¹⁴⁵ The funding for the plan comes from the consolidated revenue fund of the province of Quebec. A limitation is placed on the claimants in that they must bring their claims within three years of the date of the vaccination, or in the case of death, three years from the death.¹⁴⁶ The no-fault plan does not limit any tort claims that may be available to the claimant; however, in the event of the recovery of tort damages, there must be reimbursement of any indemnities received under the no-fault plan.

2. The United States

The United States' plan is somewhat different from Quebec's. In 1986, the U.S. Congress passed the *National Childhood Vaccine Injury Act*¹⁴⁷ in response to worries about the safety of currently licensed childhood vaccines and in response to the economic pressures that were threatening the integrity of childhood immunization programs. The litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines.¹⁴⁸ The development of this scheme was also

¹⁴⁴ *Ibid.*, s. 12.

¹⁴⁵ *Supra* note 8 at 20.

¹⁴⁶ *Ibid.* at 21.

¹⁴⁷ *National Childhood Vaccine Injury Act*, 42 U.S.C. ss. 300aa-1 to 34 (1986).

¹⁴⁸ *Supra* note 19 at 2.

prompted by the idea that those who suffer the adverse consequences of a vaccination program designed for the public benefit should not bear the loss alone.¹⁴⁹

The National Vaccine Injury Compensation Program (“NVICP”) is a federal no-fault plan which was originally designed to provide compensation for injuries arising from vaccines recommended by the Centers of Disease Control and Prevention for routine administration to children.¹⁵⁰ The NVICP has recently been expanded to cover the smallpox vaccine and the trivalent influenza vaccine, including injuries to adults from these vaccines.¹⁵¹ Although the scheme is narrower than Quebec’s plan in that it is mostly restricted to children, it is more broad with respect to compensable injuries in that it covers all injuries, illnesses, and death that arise from a vaccination.¹⁵²

To be eligible for compensation, the effects of any injury must have continued for at least six months and, until very recently, at least \$1000 in non-reimbursable medical costs must have been incurred.¹⁵³ Further, a claim must be made within 36 months of the appearance of the claimant’s first symptoms. The program has somewhat reduced the causation problem by using a “Table of Injuries” that specifies known adverse reactions associated with specific vaccines within a given time period.¹⁵⁴ If the claimant’s injury is recognized in the Table within a prescribed amount of time, the presumption of causation is in the complainant’s favour. The government may attempt to rebut this presumption by presenting evidence of a definitive alternative cause such as an infection or trauma.¹⁵⁵ If the claimant’s injury is not found in the Table, or it did not arise within the prescribed time period, he or she may independently of the Table prove that the injury is vaccine-related.¹⁵⁶

The amount of compensation payable to a claimant is assessed on tort principles. There are certain limitations in respect to certain heads of damage. Claims for pain and suffering are limited to \$250 000. Funding for the program comes from an excise tax

¹⁴⁹ *Supra* note 8 at 22.

¹⁵⁰ *Ibid.*

¹⁵¹ *Supra* note 127 at 34.

¹⁵² *Supra* note 3 at 222.

¹⁵³ *Supra* note 8 at 23.

¹⁵⁴ *Supra* note 10 at 25.

¹⁵⁵ *Supra* note 8 at 23.

¹⁵⁶ *Ibid.*

paid by the manufacturer on the sale of every dose of childhood vaccine. The tax is accumulated in the Vaccine Injury Compensation Fund. As of August 5, 1997, the excise tax has been set at a flat rate of 75¢ per dose of vaccine.¹⁵⁷ In roughly a 15-year period since its inception, there have been 5,335 claims and 1,390 successful claimants, thus resulting in a success rate of approximately 25%. In 2003, the average award was \$1 427 169.¹⁵⁸

Tort actions for vaccine injuries have been severely limited by the NVICP. No tort litigation may be commenced against a manufacturer or a health care provider in respect of a vaccine injury until a claim has been pursued through the NVICP and the claimant has either refused the offered compensation or has failed to establish his or her case.¹⁵⁹

Overall, the compensation scheme in the U.S. for vaccine-related injuries represents a more complex scheme but one that is arguably more comprehensive than the scheme in Quebec.

X. RECOMMENDATIONS FOR CANADA

As stated above, the only province in Canada which currently has a compensation plan in place is Quebec. The Law Reform Commissions of Saskatchewan and Manitoba have considered implementing such a plan, but as of yet, none are in place. Drawing from the experience in other jurisdictions will be useful in developing a comprehensive vaccine-related injury compensation scheme throughout the rest of Canada. In general, a no-fault vaccine compensation program should include the following elements: (1) the vaccines to be covered, (2) the compensable injuries, (3) the kinds of compensation, (4) the administrative mechanisms, and, (5) the relationship with existing compensation programs including civil legal avenues and social programs.¹⁶⁰ The following is a discussion of some of the suggestions for implementing a no-fault scheme in the rest of Canada.

¹⁵⁷ *Ibid.* at 25.

¹⁵⁸ *Supra* note 3 at 223.

¹⁵⁹ *Supra* note 8 at 25.

¹⁶⁰ *Supra* note 3 at 23.

1. Vaccines Covered

As in Quebec, the plan should cover all children who are immunized as part of a routine immunization program as well as adults who are injured from vaccination.¹⁶¹ Although the circumstances surrounding vaccines given to children might justify giving them priority over adults, namely their age, vulnerability, dependence on substitute decision-makers, the social pressures on vaccinating children, and the importance of childhood immunization,¹⁶² the present situation in Canada regarding the crisis surrounding the H1N1 vaccine demands that adults be included in any compensation plan. When Canada faces a pandemic, it is essential to encourage all members of society to be vaccinated in order to foster herd immunity. By restricting compensation to children if a vaccine injury occurs, there may not be sufficient incentives for adults to risk receiving a vaccine. Therefore, it is important to also provide compensation to adults who may be injured in an act that serves to benefit society on the whole.

It is clear that some types of vaccinations are sought primarily out of self-interest and confer substantial benefit on the recipient of the vaccine. Vaccinations obtained in advance of travel to regions where infectious diseases are endemic are one such example.¹⁶³ One possible compensation policy, then, would be to offer compensation where the circumstances of the injured person's vaccination fit the description of a collective-action problem: where there is an outcome that makes all members of a group better off, but which they cannot achieve because they cannot agree on how to share the costs or cannot enforce all members to share the cost.¹⁶⁴ In the context of vaccination programs, the relevant public good is herd immunity against the disease. Therefore, compensation should be available when the person accepted vaccination, notwithstanding a personal risk/benefit calculation suggesting that he should refuse it, but not where vaccination was clearly in the person's self-interest.¹⁶⁵

2. Compensable Injuries

¹⁶¹ *Ibid.*

¹⁶² *Supra* note 8 at 34.

¹⁶³ *Supra* note 127 at 38.

¹⁶⁴ *Ibid.* at 34.

¹⁶⁵ *Ibid.* at 38.

Compensable injuries should not be restricted to “grave and permanent mental or physical damage” as is covered under the Quebec plan. Instead, the plan should cover any disability, illness, or death that was caused by vaccination. A table of injuries, qualifications, and aids for interpretation, such as that which is used in the United States, would be an ideal mechanism to determine compensable injuries. A table and other aids would list all of the compensable injuries and respective time frames for their occurrence for each vaccine approved for use in the province or territory. This would function so as to alleviate the burden of proof on a claimant, to ensure consistency and predictability of claims, and to confine the scope of claims within a reasonable range of injuries.¹⁶⁶ The table of injuries should be carefully designed in consultation with medical experts and manufacturers and after a careful review of the scientific evidence.¹⁶⁷ The table should be reviewed and updated regularly to reflect scientific advancements. If the development and continual update of a province-specific table would be beyond the financial and medical resources of that particular jurisdiction, then the United States’ table could be adopted by reference.¹⁶⁸

A presumption of causation should arise if an injury falls within the table. The onus of proof would then shift to the government to show that there is another likely cause of the injury other than the vaccine. If the injury does not fall within the scope of the table, then the claimant would have to prove on a balance of probabilities that the vaccine caused the injuries.

Finally, a generous limitation period is warranted by possible medical uncertainty as to the cause of the death or injury. Reasonable limitation periods are important to ensure that a claim is assessed at a time when the best evidence is most readily available. The time limitation to bring the claim should commence no sooner than the date of diagnosis, or in the case of fatalities, the date of death.¹⁶⁹

3. Compensation

¹⁶⁶ *Supra* note 3 at 225.

¹⁶⁷ *Ibid.*

¹⁶⁸ *Supra* note 8 at 35.

¹⁶⁹ *Ibid.* at 39.

There are various possibilities for calculating compensation to claimants. Comprehensive awards may be calculated based on tort principles. This would include future care and loss of income, as well as limited non-pecuniary damages. This would be the most generous measure of compensation but it has some disadvantages, including the difficulty, time, and expense of personalized assessments as required in the tort process and its inconsistency with other no-fault schemes which do not use tort principles.¹⁷⁰

Instead, it may be more beneficial for other provinces to follow the model of Quebec. The assessment of benefits could be made in accordance with the rules of another provincial no-fault scheme if one is available. This procedure would avoid the many administrative barriers that would arise in establishing a completely new system. Compensation would include income replacement, compensation for physical disability, future care costs, rehabilitation expenses and death benefits to family.

4. Administrative Mechanisms

In establishing an institution to administer the program, provinces could create a discrete administrative tribunal such as the United States' Childhood Vaccination Injury Compensation Board with its own staff and procedures. However, based on the number of claims brought in Quebec, it is unlikely that there would be a sufficient number of claims to warrant the expense of an independent institution. Instead, other provinces should follow the lead of Quebec where compensation to vaccine-injured individuals can "piggy-back" on an already existing no-fault scheme if one is available.¹⁷¹

The government department most suited to administer a vaccination injury compensation scheme is that of Health. The Minister could appoint an employee who would handle vaccine injury claims and determine the eligibility of the claimants under the Act. Those who have their claims rejected should be able to bring appeals to an independent administrative tribunal.¹⁷²

¹⁷⁰ *Ibid.* at 36.

¹⁷¹ *Ibid.* at 37.

¹⁷² *Ibid.*

The system could possibly be set up nationally or by each province and territory. Provinces have primary constitutional jurisdiction over compensation and the delivery of immunization is a provincial and territorial responsibility.¹⁷³ However, Canada has a national health care system within which funding is a federal initiative under the *Canada Health Act*.¹⁷⁴ Plus, the organization of physicians and other health care providers is set up nationally (C.M.P.A., CMA, etc.). Although Canada would be well served by the implementation of a national plan, provincial/territorial plans specifically tailored to reflect differing circumstances and constitutional jurisdiction may be the best route.¹⁷⁵

Finally, funding options would also most likely have to follow the Quebec model. A charge on each vaccine sold, as is levied through the United States' system, would probably be impermissible as a user charge on health care under the *Canada Health Act*.¹⁷⁶ The realistic option would be to make the cost of the scheme a charge on general tax revenues. This option has the added advantage of spreading the cost in the widest manner throughout society, which, as a whole, receives the benefits of immunization programs.¹⁷⁷

5. The Relationship with Existing Compensation Programs

To the extent that a claimant may be compensated through other programs, the scheme should be entitled to reimbursement.¹⁷⁸ As well, there does not appear to be any pressing reason to remove a claimant's ability to proceed through tort actions. The scheme should not limit a claimant's right to sue a manufacturer, physician, or any other defendant for negligence, lack of informed consent, or breach of a duty to warn. The history of tort litigation in the field of vaccines suggests that litigation in respect of vaccine injuries will be infrequent.¹⁷⁹ If a tort action is successful, the monies received through the no-fault scheme should be reimbursed so as to avoid double compensation.

¹⁷³ *Supra* note 125 at 315.

¹⁷⁴ *Canada Health Act*, R.S.C. 1985, c. C-6, s. 19(1).

¹⁷⁵ *Supra* note 125 at 316.

¹⁷⁶ *Supra* note 174, s. 19(1).

¹⁷⁷ *Supra* note 8 at 38.

¹⁷⁸ *Supra* note 3 at 226.

¹⁷⁹ *Supra* note 8 at 39.

XI. IMPACT OF THE NEW H1N1 VACCINE

Canada recently faced a crisis that it was unprepared to handle: the H1N1 pandemic. H1N1 is a new strain of influenza, and because humans have little to no natural immunity to this virus, it can cause serious and widespread illness.¹⁸⁰ As of April 3, 2010, 428 people had died in Canada from the H1N1 flu virus.¹⁸¹ Since the H1N1 flu virus first appeared in Canada in the spring of 2009, manufacturers scrambled to produce and deliver an effective vaccine. Ottawa purchased 50.4 million doses of the vaccine from the manufacturer GlaxoSmithKline PLC, and as of late October 2009, the vaccine had been approved for rollout across Canada.¹⁸²

Despite the fact that H1N1 has been a particularly deadly form of influenza, targeting not only vulnerable populations, but healthy young people, many Canadians have expressed concern that the H1N1 vaccine is unsafe, and an unwillingness to receive the vaccine. The most common complaint is that the vaccine has been newly formed and quickly distributed without the benefit of clinical trials.¹⁸³ Public Health Agency of Canada officials acknowledged in July that there would not be time for a swine flu vaccine to go through standard safety testing before immunizations began.¹⁸⁴ Despite these concerns, Health Canada assured Canadians that the new vaccine was safe. It was manufactured in the same way as the regular flu vaccine and was subject to the same scrutiny and regulatory oversight. In order to be approved and sold in Canada, the benefits of the vaccine needed to outweigh the risks.¹⁸⁵ Therefore, the system of approval in fact acknowledges that some persons may suffer adverse effects from the vaccine.

The fears over the new vaccine are not entirely unfounded. The last time there was an outbreak of swine flu in the U.S., more people were harmed by the vaccine than by the

¹⁸⁰ *Supra* note 1.

¹⁸¹ Public Health Agency of Canada, *FluWatch: March 28 – April 3, 2010 (Week 13)*, online: Public Health Agency of Canada <http://198.103.98.171/fluwatch/09-10/w13_10/index-eng.php>.

¹⁸² “Fed’s vaccine purchase a concern” *The Toronto Star* (1 September 2009) A18 (QL).

¹⁸³ Jennifer Steinhauer, “Swine flu shots revive a debate about vaccines” *The New York Times* (16 October 2009) A1.

¹⁸⁴ Sharon Kirkey, “Swine flu vaccine will need compensation program: expert” *Canwest News Service* (21 July 2009), online: <<http://www.pandemicfluonline.com/?p=677>>.

¹⁸⁵ *Supra* note 1.

actual flu. In 1976, an outbreak of swine flu at the Fort Dix army base in New Jersey spawned a nationwide emergency vaccination program. About 45 million Americans were vaccinated. In the end, the deadly pandemic that officials feared never materialized. Instead, thousands of Americans suffered side effects from the vaccine – including about 500 people who developed a paralyzing neurological disorder called Guillain-Barre Syndrome. Many U.S. citizens believed that officials were trying to hide serious complications when they insisted the vaccine was safe. More than 5,000 people sued the federal government for vaccine-related injuries, resulting in payouts totaling \$73 million.¹⁸⁶

Furthermore, many Canadians are fearful of the adjuvants added to the new H1N1 vaccine. Adjuvants are sometimes added to vaccines to boost the immune system and to increase an individual's response to a vaccine. Unlike in the U.S., where no adjuvant is used in any H1N1 vaccines, Canada has approved the use of adjuvants even though they have not previously been approved for use with influenza vaccines in Canada.¹⁸⁷ Both Health Canada and WHO have declared that there are no significant safety concerns regarding the use of the adjuvanted vaccine. Yet, the adjuvanted H1N1 flu vaccine is not recommended for everyone. Only the unadjuvanted vaccine is recommended for pregnant women. The reason cited for this is that there is no clinical data on the safety of the adjuvanted vaccine in this group.¹⁸⁸ Although some Canadians on the front lines of health care have expressed concerns about taking the H1N1 vaccine until more is known about it and the adjuvant it contains, federal health officials have noted that “the risks from the vaccine are only theoretical while the risk of severe disease and even death from H1N1 are too real to ignore.”¹⁸⁹

As of late October, 2009, according to clinical trials and adverse event monitoring during deployment of vaccines in early introducer countries, there were no indications that unusual adverse events had been observed after H1N1 immunization. However, WHO reports that the need for continued vigilance and regular evaluation by health

¹⁸⁶ Steve Rennie, “Ottawa to cover vaccine damages” *London Free Press* (1 October 2009) B10.

¹⁸⁷ *Supra* note 1.

¹⁸⁸ *Ibid.*

¹⁸⁹ “Taxpayers on hook for any H1N1 vaccine damages” *CBC News* (30 September 2009) online: <<http://www.cbc.ca/health/story/2009/09/30/h1n1-vaccine-canada.html#socialcomments>>.

authorities is ongoing.¹⁹⁰ In Canada, as of November 7, 2009, out of 6.6 million H1N1 vaccinations given, there were 36 reported serious adverse reactions to the vaccine and one suspected death. An 80-year-old man from Quebec died after being vaccinated against the H1N1 flu, although officials say that it is too soon to determine whether the vaccine played a role in the death of the man who had underlying health issues.¹⁹¹

Recently, the federal government announced that it had agreed to shield drug companies from lawsuits over the H1N1 pandemic vaccine. Canadians who suffer harmful effects from the new vaccine can still take the vaccine maker to court, but the federal government will be responsible for any damages. The chief public health officer, Dr. David Butler-Jones, stated that “we’re not obviously anticipating problems with it, but having indemnification for a vaccine is important.”¹⁹² The provision does not apply, however, in the case of malpractice, where the manufacturer will still be liable for any negligence during the manufacturing process.

Although the government has taken the steps to protect the H1N1 vaccine manufacturer, with the exception of Quebec, provinces and territories have not yet made any plans to compensate people who have been injured after conceptually buying into the immunization program for the benefit of all Canadians. A leading public health expert, Kumanan Wilson, has been calling on Canada to create a no-fault compensation program for people who may be harmed by a swine flu vaccine that millions of Canadians are being urged by the government to receive. In an interview with Canwest News Service, he stated:

I’m not saying that we shouldn’t roll out this vaccine. I don’t know how confident we will be in its efficacy and safety at the outset, but I don’t think we’ll have any choice but to roll it out, because, at this point, the only way to control the spread is going to be a vaccine. But, there are going to be concerns about people not wanting to take the vaccine, health-care workers in particular. We have been arguing that it needs to be

¹⁹⁰ *Supra* note 34.

¹⁹¹ “Possible H1N1 vaccine-related death in Quebec” *CBC News* (17 November 2009), online: <<http://www.cbc.ca>>.

¹⁹² *Supra* note 182.

complemented with a no-fault compensation program, just like in 1976, and we need to develop systems to pick up these adverse events.¹⁹³

Currently, those who are harmed by vaccines are treated as collateral damage in the war against vaccine-preventable illness. The only just, ethical, and sensible thing to do is for Canada to compensate people who have been exposed to a potential harm while undergoing an intervention that is in the greater public good. In the words of Judge Sanderson from *Morgan v. Metropolitan Toronto (Municipality)*, it is necessary “for the sake of the health of citizens and fairness to individuals.”¹⁹⁴

¹⁹³ *Supra* note 285.

¹⁹⁴ *Supra* note 116 at para. 446.