

Creating a Sustainable Immunization System in Canada — The Case for a Vaccine-Related Injury Compensation Scheme

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I. Introduction

The introduction of vaccines to Canada in the early 1960s marked a radical advancement in public health and one that has conferred immense benefits to Canadian society. Before that time, childhood diseases such as polio, diphtheria, whooping cough, mumps and measles were present in epidemic proportions resulting in massive hospitalizations, permanent disability, and often death. For example, prior to the measles vaccine, almost every child contracted the disease, which resulted in 5,000 hospitalizations each year and an annual death toll of 50 to 75.¹ In contrast, as a result of widespread vaccination, today the disease has been virtually eradicated in all of North and South America.² As a result, immunization programs in Canada have traditionally received generous support from the government, the medical profession and the general public to the extent that the concept of routine vaccinations has become entrenched in public health practice.

Despite the obvious advantages of wide-scale immunization programs, there is a significant drawback — many children who are vaccinated each year suffer adverse effects ranging from common minor reactions to serious injuries that in some cases result in permanent disability or even death. Historically, the government and indeed society in general has adopted a utilitarian approach in explaining these rare occurrences by labelling them as “collateral damage,” an unavoidable yet necessary risk that serves the interests of the public at large.

This paper argues that the propagation and support by the Canadian government of wide-scale immunization has in effect created a scheme of compulsory vaccination that over-emphasizes the benefits while under-emphasizing the potential harms. It will become clear that the importance of a sustainable immunization program is paramount in the government’s view. However, in order to ensure a sustainable system whereby the benefit to the public is as valuable as it is to the

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¹ Canada, Ministry of Health, *Canadian Immunization Guide*, 6th ed. (Ottawa: Canadian Medical Association, 2002) at 50.

² *Ibid.*

individual, there must be a mechanism in place to compensate those individuals who, although selfishly motivated, nonetheless place themselves at risk of harm. Through this scheme the public will benefit from herd immunity, and the government incurs the necessary responsibility for what is, in effect, a mandatory vaccination system.

Unfortunately, the unique nature of vaccines and the difficulties that are inherent in obtaining compensation through the traditional tort system have left the majority of vaccine victims without reparation. Furthermore, existing government compensation schemes have been inadequate. In the alternative, this paper will argue that Canada has a social responsibility and a moral obligation to implement a no-fault vaccine-related injury compensation scheme similar to those that exist in numerous jurisdictions worldwide. Suggestions and considerations for a workable and fair system will be discussed through a comparison and critique of existing schemes in Quebec and the US. The development of such a scheme will further the government's directive of ensuring the health and well-being of Canadians through reduced death and suffering and will function to re-build the trust of Canadians in a rapidly disintegrating but essential immunization system.

II. The Benefits of Vaccines and Immunization Programs

In the early 20th century, the leading cause of death worldwide was infectious diseases. Since then, the implementation of health protection measures such as immunization, sanitation, public health education and better living conditions have drastically improved the state of public health such that currently, infectious diseases account for less than 5% of all deaths in Canada.³ Indeed, immunizations have been described as the single most effective health intervention after clean water and sewage disposal.⁴ To this end, wide-scale immunization has proven effective in eradicating most of the early 20th century childhood diseases including polio, diphtheria, tetanus, measles and smallpox, diseases which spread through cities in epidemic proportions and wiped out entire families. For example in Canada, reported cases of diphtheria dropped from 9000 in 1924 to five in 1994;⁵ in the US, measles immunization programs implemented between 1963 and 1965

³ Canada, *Reforming Health Protection and Promotion in Canada: Time To Act* (Ottawa: Standing Senate Committee on Social Affairs, Science And Technology, 2003) (Chair: M.J.L. Kirby), online: Canadian Parliament <<http://www.parl.gc.ca/37/2/parlbus/commbus/senate/com-e/soci-e/rep-e/repfinnov03-e.htm>> (date accessed: 24 August 2004).

⁴ S.L. Plotkin & S.A. Plotkin, "A Short History of Vaccinations" in S.A. Plotkin & E.A. Mortimer, eds., *Vaccines*, 2nd ed. (Philadelphia: W.B. Saunders Co., 1994) 1-11.

⁵ B.L. Fisher, "Shots in the Dark: Attempts at eradicating infectious diseases are putting our children at risk" (2000) [unpublished], online: National Vaccine Information Centre <<http://www.nextcity.com/contents/summer99/16shots.html>> (date accessed: 15 November 2003).

reduced the number of measles cases from 400,000 annually to 309 in 1995.⁶ Tetanus cases are virtually non-existent in Europe and North America.⁷

Furthermore, the World Health Organization (WHO) estimates that whereas vaccines save millions of lives each year, the lack of vaccination kills two million children worldwide, mostly in the developing world.⁸ For example, paralysis due to the polio virus has not occurred in the US since 1979 nor in the Western Hemisphere since 1991,⁹ yet the WHO estimates that 90,000 children are victimized by the virus each year in the developing world.¹⁰ Despite these numbers, polio had been eradicated in 146 countries by the year 2000, and the WHO claims that the prevalence of polio in the remaining areas is “low-incidence”.¹¹

In addition, vaccine manufacturers and medical researchers continue efforts to expand the vaccine arsenal by developing new vaccines and introducing more effective and safer versions of those that exist currently. The Haemophilus influenza type b (Hib) vaccine is one recent example of a new vaccine that, within a relatively short period of time has significantly reduced the frequency of Hib disease in children, a disease that resulted in 100 infants dying each year and which left many suffering from brain damage or deafness. Within less than a decade, the number of cases went from 2,000 each year to less than four in the year 2000.¹² Other new vaccine developments include those that prevent hepatitis A and B, influenza, pneumococcal and meningococcal infection and varicella.

Through wide-scale immunization, whole populations can be immunized which will result in expeditious elimination of the disease. This fast turnaround is also related to the concept of “herd immunity”, a phenomenon whereby protection is conferred to non-immunized individuals through a greatly reduced chance of an outbreak among an immunized population.¹³ This effect, however, can only be realized if at least 95% of the population is vaccinated, otherwise outbreaks may recur.¹⁴ For example, although only two cases of measles were reported in British Columbia in 1999, an outbreak in 2000 in a north eastern community that had a

⁶ *Ibid.*

⁷ *Ibid.*

⁸ “Vaccination: A Grant of Immunity” *CBC News Online* (27 April 2004), online: CBC News <<http://www.cbc.ca/news/background/flu/vaccination.html>> (date accessed: 11 August 2004).

⁹ A.R. Hinman, “How Should Physicians and Nurses Deal With People Who Do Not Want Immunizations?” (2000) 91:4 *Canadian Journal of Public Health* 248 at 248.

¹⁰ *Supra* note 8.

¹¹ *Ibid.*

¹² *Supra* note 1.

¹³ Congress of the United States: Office of Technology Assessment, *Compensation for Vaccine-Related Injuries — A Technical Memorandum* (1980) at 2, online: The Woodrow Wilson School of Public and International Affairs at Princeton University <<http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota/disk3/1980/8005/8005.PDF>> (date accessed: 24 January 2005).

¹⁴ Editorial, “A Patchwork Policy: Vaccination in Canada” (2003) 168:5 *Journal of the Canadian Medical Association* 533.

low acceptance rate of immunization occurred almost exclusively in underimmunized or unimmunized persons.¹⁵

Apart from the public health benefits, wide-scale immunization carries other social benefits including benefits to the public health care purse. Estimates of savings due to immunizations have been in the billions of medical and health-related dollars. Compared to the amounts a government will spend on vaccines,¹⁶ the economic benefits are obvious. The cost effectiveness of vaccines is evident when one compares the cost of vaccines to the cumulative costs of treatment, hospitalization, and working days lost.¹⁷ For example, the MMR vaccine saves \$16.34 in direct medical costs for every \$1 spent and the diphtheria/tetanus/pertussis (DTP) vaccine saves \$6.21 for every \$1 spent.¹⁸ Moreover, some authors suggest that these figures may underestimate the value contribution of vaccines by a factor between 10 and 100 if one also takes into account factors for avoiding disease altogether.¹⁹

A related social benefit of immunization is the increase in work productivity that is achieved when fewer individuals are at risk of infection from diseases that may keep them away from school or work for extended periods of time.²⁰ From an economics-based approach, this translates to less productivity, which according to contemporary Western ideology, impedes the growth, capital and competitiveness of a nation. This ideology has been reflected by the World Bank who has stated that the absence of health is a major obstacle to the economic development of poor nations and further, that an important step to improving the health and thus the economies of such nations would be through vaccination.²¹ Indeed, insofar as wide-scale immunization enables government to fulfill its mandate to ensure the health and well being of Canadians through reduced death and suffering, this ideology can be seen as yet another underlying rationale for creating a sustainable immunization scheme.

Finally, despite the relatively low cost of vaccines, wide-scale immunization schemes have spurred the growth of the global vaccine industry so that today close to \$10 billion is generated each year.²² Arguably, this creates a necessary market

¹⁵ *Ibid.*

¹⁶ For example, the Canadian federal government in the 1996/97 fiscal year spent \$40 million on vaccine purchases (Ontario, Office of the Provincial Auditor of Ontario, *Annual Report* (Toronto: Queen's Printer for Ontario, 1997), online: Office of the Provincial Auditor of Ontario homepage <<http://www.gov.on.ca/opa/english/e97/ch1.pdf>>.

¹⁷ R. Rappuoli, H.I. Miller & S. Falkow, "The Intangible Value of Vaccination" (2002) 297:5583 *Science* 937 at 938.

¹⁸ Centre for Disease Control, *An Ounce of Prevention...What are the Returns?*, 2nd rev. ed., (Atlanta: Centre for Disease Control, 1999). Note these figures showing cost-effectiveness are in U.S. currency but the cost-effectiveness of vaccines was noted in a report by the Canadian federal government's Standing Senate Committee on Social Affairs, Science and Technology (*Supra* note 3).

¹⁹ *Supra* note 17 at 938.

²⁰ As quoted by R. Johnston, Jr., M.D., medical director of the March of Dimes in *supra* note 5.

²¹ *Supra* note 17 at 937.

²² *Supra* note 5.

incentive for manufacturers to develop and produce much needed vaccines.²³ However, when compared to the revenue generated from pharmaceutical sales, vaccine sales represent only about 2% of the global pharmaceutical market.²⁴ This comparatively low economic incentive coupled with exposure to legal liability has created a situation in North America where vaccine production is dependent on relatively few manufacturers.²⁵ Furthermore, policy-makers complain that the cost of vaccines is prohibitive, and argue that low price is the solution to ensuring vaccines are available to everyone.²⁶ The end result is a constant shortage of vaccines in North America and an absence of vaccine development for diseases with low investment returns, such as malaria and tuberculosis that predominantly plague developing nations.²⁷

In the end, a virtual vaccine monopoly exists that places government in a precarious situation since the decision of a major supplier to pull out of the market will have an alarming effect on the vaccine stockpile. The challenge governments face is in seeking to promote the production of vaccines by making it economically attractive to manufacturers while ensuring affordability in an effort to achieve national immunization. In this sense, government and the vaccine manufacturing industry come dangerously close to a conflict of interest if the goal of ensuring cheaper prices and a steady supply of vaccines becomes the guiding factor behind government promotion of wide-scale immunization, rather than ensuring that the safest and most effective vaccines are available.

III. Immunization in Canada

Clearly, the substantial benefits of wide-scale immunization are convincing, yet mandatory vaccination of children is not directly legally enforced in Canada. Health Canada has stated that immunization is not mandatory in Canada because of the Canadian Constitution and has emphasized that although some provincial legislation in Canada requires proof of immunization for school entrance, such legislation must not be interpreted to imply compulsory immunization.²⁸ In con-

²³ Periodic shortages have occurred in the U.S. as a result of a decrease in vaccine manufacture. As recently as June 6, 2002 supply shortages were reported for the varicella, Hib and pneumococcal conjugate vaccines: Minutes of 51st Meeting of the Advisory Commission on Childhood Vaccines (ACCV) and Conference Call (June 6, 2002), online: U.S. Department of Health and Human Services <<http://www.hrsa.gov/osp/vicp/ACCVmin6-6-2002.htm>> (last modified: 2 December 2002) ["ACCV Minutes"].

²⁴ *Supra* note 17 at 937.

²⁵ The number of companies producing vaccines in the U.S. has dropped from 37 to 10 since 1967, *ibid.*

²⁶ *Ibid.*

²⁷ *Ibid.*

²⁸ Canada, *Immunization in Canada*, Volume 23S4 (Ottawa: Canadian National Report on Immunization, 1996), online: Health Canada <<http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/97vol23/23s4/>> (date accessed: 24 August 2004).

trast, in the U.S., almost all states require that children receive vaccination as a condition of attending school²⁹ 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 shot and denying children the right to go to school.³⁰ Notwithstanding that in Canada there is no mandatory immunization scheme, it is arguable that the system in place is so institutionalized and the pressures so great as to create in effect a mandatory scheme.

In Canada, immunization is the responsibility of each province³¹ and thus immunization is achieved on a national level through the establishment of provincial programs. This has led to what many critics deem a “patchwork of policies” in which there is little consistency from province to province. For example, in Quebec meningococcal vaccine is part of the routine childhood vaccination schedule, but in Ontario it is not.³² The implication of this inconsistency is sadly demonstrated by the fact that recently, a child in Ottawa died from meningococcal meningitis — had she lived a few kilometres away, this tragedy may have been avoided.³³ Similarly, there are glaring inequities in immunization rates among First Nations communities in Canada with infectious disease rates up to nine times higher than in the general Canadian population,³⁴ and continuous outbreaks of vaccine-preventable diseases occurring due to low immunization rates.³⁵

Currently only two provinces, Ontario and New Brunswick, ensure wide-scale immunization through legislation that directly targets children in school.³⁶ For example, in Ontario the *Immunization of School Pupils Act*³⁷ places a statutory duty on parents to have their children immunized according to the prescribed program of immunization, requiring proof for diphtheria, tetanus, polio, measles, mumps and rubella vaccination. Failure to do so can result in a fine of up to \$1,000 and

²⁹ *Supra* note 13.

³⁰ B.L. Fisher, “The Moral Right to Conscientious, Personal Belief or Philosophical Exemption to Mandatory Vaccination Laws” (National Vaccine Advisory Committee, 2 May 1997) [unpublished], online: National Vaccine Information Centre <<http://www.909shot.com/>> (last modified: 2 December 2002).

³¹ See *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, s. 92, reprinted in R.S.C. 1985, App. II, No. 5. Immunization relates either to property and civil rights (s. 92 (13)) or is a matter of local or private nature (s. 92 (16)).

³² *Supra* note 14.

³³ *Ibid.*

³⁴ H.L. MacMillan *et al.*, “Aboriginal Health” (1996) 155 *Canadian Medical Association Journal* 1569.

³⁵ The most recent data indicates that only 51% of children less than a year old were age-appropriately vaccinated: M. Tarrant & D. Gregory, “Mothers’ Perceptions of Childhood Immunizations in First Nations Communities of the Sioux Lookout Zone” (2001) 92:1 *Canadian Journal of Public Health* 42 at 42.

³⁶ Manitoba recently repealed a similar provision that existed in *The Public Schools Act*, R.S.M. 1987, c. P250, s. 261(1) (*The Public Schools Amendment Act*, S.M. 1999, c. 14, s. 5). See also, Manitoba Law Reform Commission, *Compensation of Vaccine-Damaged Children* (Report #104) (Manitoba: Manitoba Law Reform Commission, 2000) at 5 [“Manitoba Law Reform Commission”].

³⁷ *Immunization of School Pupils Act*, R.S.O. 1990, c. I.1.

suspension of the student for a period of 20 days. Thus, indirectly, a parent is forced to have their child immunized if the child is to stay in school. However, exceptions are granted if the parent submits by affidavit a statement of conscience or religious belief or a physician's statement that the child be exempt for medical reasons. Similarly, the regulations under the *Ontario Day Nurseries Act*³⁸ requires a day nursery operator to ensure that a child is immunized before that child is permitted to attend a day nursery. Again, a parent may object to immunization in writing and will be exempted based on medical grounds or on the person's religion or conscience.

In addition to direct legal enforcement of vaccinations, most provincial governments have adopted a pro-active approach in ensuring all children in the province are fully immunized. Thus, in co-operation with local school boards, programs are established that provide for routine vaccinations to be administered in schools. Some provinces have created centralized monitoring systems to keep track of the immunization history of each child.³⁹ As well, governments engage in mass promotional campaigns that utilize all manner of print and broadcast media to reach the broader public. For example, in August 1995, the Canadian government recommended the implementation of a special measles vaccination "catch-up" program to prevent large outbreaks of measles that had been occurring in some provinces at the time. In order to promote this initiative a range of materials were developed at the local, provincial and federal level, including TV advertisements, information pamphlets for parents and newspaper articles. A study that looked at the impact of this particular mass campaign in two provinces found that these materials were extremely successful in promoting immunization to parents of school-aged children and caused many parents to revise their opinions regarding the importance of measles immunization.⁴⁰

Finally, professional organizations and industry play a significant role in helping to sustain a pro-vaccination environment in Canada. One example is the Canadian Immunization Awareness Program (CIAP). The program was developed in 1996 by the Canadian Paediatric Society (CPS) and is made up of numerous key Canadian health and health professional organizations, including Health Canada. What is interesting is that despite its name, CIAP's self-explained objective is "to help parents and health providers in Canada work together to make sure children get all the shots they need at the right times."⁴¹ Notwithstanding that there may be some risk information provided by CIAP, their stated objective clearly does not contemplate raising "awareness" to the public of the associated risks, or benefits for that matter, of vaccines.

³⁸ *Day Nurseries Act*, R.R.O. 1990, Reg. 262, s. 33.

³⁹ For example, the Manitoba Immunization Monitoring System (MIMS).

⁴⁰ L. Pelletier *et al.*, "Evaluation of the Promotional Materials Used During the Measles Mass Immunization Campaign in Ontario and British Columbia" (1998) 89:5 *Canadian Journal of Public Health* 329-332.

⁴¹ See in general CIAP website <<http://www.immunize.cpha.ca>> (date accessed: 15 November 2003).

Two issues are immediately apparent from both the direct and indirect pro-vaccination methods provinces employ in ensuring immunization. First, single mothers, immigrants, low-income families and other marginalized groups are most at risk of the coercive effects of these methods. Thus, for those whose first language is not English, who have limited education, who are illiterate, who depend on day care or who could not afford to risk a fine, the administrative procedures quickly become insurmountable and realistically, a parent in those circumstances is left with no alternative but to vaccinate their child. Research reveals the role that such socioeconomic factors may play in the context of the coercive methods utilized in public vaccination schemes. One study that assessed parent comprehension of a polio immunization pamphlet written at a grade six level and with the input of parents who helped to develop it found that parents reading at a sixth grade level understood less than half of the basic vaccine information and those reading on a seventh to eighth grade level understood only about half.⁴² Another U.S.-based study revealed the insecurity prevalent among low-income mothers (in this case mothers of children participating in Medicaid) who reported that they wanted a trusted physician to initiate discussions about child development because they did not always know what to ask.⁴³ A similar lack of knowledge was cited as a major barrier to immunization uptake in a First Nations community.⁴⁴

Secondly, these methods assume the general awareness of the public of the possibility for exemption, but the statutes themselves do not require a medical officer or day care operator to describe the options to parents. Notably, for all of the efforts the government puts into promotion and marketing of immunization programs, there is comparatively little mention of a parent's right to refuse on religious or conscientious grounds. The Vaccination Risk Awareness Network (VRAN), a Canadian organization whose mandate is to provide parents with full disclosure of vaccine-associated risks before the decision to vaccinate is made, reports that it receives hundreds of calls from parents each year whose children have been threatened with expulsion from school because their vaccine records are not up to date or because they have chosen to discontinue vaccinating their children.⁴⁵ VRAN further reports that many school boards and school administrators, including school principals, are unaware of the availability of legal exemptions in Ontario and argues that the public health units take advantage of the wide-spread perception that vaccination is mandatory in order to carry out vaccination mandates.⁴⁶ Furthermore, this perception exists to some extent within the medical

⁴²T.C. Davis *et al.*, "Parent Comprehension of Polio Vaccine Information Pamphlets" (1996) 97 *Pediatrics* 804.

⁴³D.R. Fredrickson *et al.*, "Childhood Immunization Refusal: Provider and Parent Perception" (2004) 36:6 *Family Medicine Journal* 431 at 437.

⁴⁴*Supra* note 35.

⁴⁵*Health Officials violate the Public Trust: Parents-Students Kept in the Dark About Vaccine Exemptions* (2001), online: Vaccine Risk Awareness Network Legal Homepage <http://64.41.99.118/vran/legal/legal_ont.htm> (date accessed: 20 August 2004).

⁴⁶*Ibid.*

profession as parents report that often they are told by their physicians that their child will not be allowed into school without vaccination.⁴⁷

In 1999, VRAN wrote to Ontario's Chief Medical Officer of Health demanding that the Ministry of Health ensure that, as part of its pro-vaccination policy, it take steps to ensure that physicians and patients are fully informed of the availability of vaccination requirements in Ontario.⁴⁸ In the letter, VRAN's lawyers argue that the Ministry has a public duty to do so and cites numerous omissions in Ministry immunization policy papers, publications and guidelines that violate this duty and which contravene certain aspects of the *Health Protection and Promotion Act* (HPPA)⁴⁹ and the *Health Care Consent Act* (HCCA).⁵⁰

Despite the decentralized control of immunization, the Federal government plays a significant role in the support, consistency and integrity of each provincial system. First, as a signatory to the Declaration of the 1990 World Summit for Children, Canada must endorse the objective of the Declaration to eradicate and reduce diseases in children worldwide. To this end, national immunization targets and regulatory policies have been established through the Population and Public Health Branch (PPHB) of Health Canada, specifically through the Division of Immunization & Respiratory Diseases, and the Health Products and Food Branch (HPFB) of Health Canada.

Second, the manufacture of human vaccines is regulated by the Biologics and Genetic Therapies Directorate (BGTD) of the HPFB. The BGTD is responsible for ensuring the safety, efficacy and quality of all vaccines for human use marketed in Canada, which includes evaluating the safety of Clinical Trial Applications.⁵¹ This extends to the review of clinical protocols used to study new vaccines, the pre-market and post-market assessment of the safety, efficacy and quality of vaccines, and participation in the development of risk management strategies, including risk-benefit assessments, for these products. Furthermore, manufacturers must obtain a Drug Establishment Licence⁵² issued through the HPFB Inspectorate in order to fabricate, package/label, import, distribute, wholesale, or test a vaccine in Canada. A province is only able to purchase a licensed vaccine which it administers free of charge to its residents.

⁴⁷ *Ibid.*

⁴⁸ Letter from L. Stoltz, lawyer representing VRAN, to Dr. Colin O. D'Cunha, Chief Medical Officer of Ontario Health (10 September 1999), available online: <http://64.41.99.118/vran/legal/leg_ont_itr.htm> (date accessed: 20 August 2004).

⁴⁹ *Health Protection and Promotion Act*, R.S.O. 1990, c. H-7 [HPPA].

⁵⁰ *Health Care Consent Act*, S.O. 1996, c. 2, Schedule A [HCCA].

⁵¹ Regulations for clinical trials involving human subjects are found in Division 5 of the *Food and Drug Regulations*, C.R.C., c. 870 of the *Food and Drugs Act*, R.S. 1985, c. F-27.

⁵² The definition of "drug" in the *Food and Drugs Act*, R.S. 1985, c. F-27, s.2 under which a vaccine would fall under includes any substance for use in the prevention of a disease.

Third, through the Vaccine Associated Adverse Events Surveillance System (VAAESS), the federal government is responsible for monitoring provincial immunization programs for adverse vaccine effects temporally associated with immunization. The system is a passive one in that reports from health care providers are voluntary.⁵³ The reports which are directed to local, provincial and/or territorial public health authorities are forwarded to the Division of Immunization of the Bureau of Infectious Diseases at the Laboratory Centre for Disease Control in Health Canada.⁵⁴ Moreover, the Immunization Division of Health Canada provides funding to the CPS to administer IMPACT (Immunization Monitoring Program ACTive), a paediatric hospital-based national surveillance network for Vaccine Associated Adverse Events (VAAEs), vaccine failures and selected infectious diseases in children.⁵⁵

Last and most significant is the role that the National Advisory Committee on Immunization plays in the functioning of local immunization programs. This committee, comprised of experts in public health, infectious diseases and paediatrics, provides regular recommendations for the administration of these programs that in practice have essentially become pseudo-regulatory since the recommendations are rarely rejected.⁵⁶ Consequently, laws and policies have developed which effectively coerce the vast majority of parents to continue their children's participation in immunization programs.

Notwithstanding this Federal oversight, critics have called for a comprehensive and consistent national policy that does more than merely recommend vaccines to one that also supports their delivery.⁵⁷ In 2002, Roy Romanow of the Commission on the Future of Health Care in Canada recommended the implementation of a national vaccination strategy.⁵⁸ Since then, there have been several proposals urging the implementation of a national vaccination strategy. In 2003, the National Advisory Committee on SARS and Public Health ("Naylor Advisory Committee") conducted an extensive review of immunization practices across Canada and found substantial variation in publicly-funded programs and legislation relating to vaccination and further noted concerns with respect to rising costs of vaccines, safety,

⁵³ However, in Ontario for example under s. 38(3) of the *HPPA*, *supra* note 49, anyone administering a vaccine has a positive duty to report the presence of a reportable event (as defined) believed to be associated with a vaccine. Furthermore, s. 38(2) requires the health care professional to inform the patient receiving the vaccine of the importance of reporting any adverse event.

⁵⁴ Vaccine Associated Adverse Events Surveillance System (VAAESS), online: Population and Public Health Branch <http://www.hc-sc.gc.ca/pphb-dgsp/dird-dimr/vs-sv/vaaess_e.html> (date accessed: 20 August 2004).

⁵⁵ The national network involves 12 centres across Canada which account for about 90,000 admissions annually and representing 90% of all tertiary care paediatric beds (online: CPS Homepage <<http://www.cps.ca/english/proadv/IMPACT/IMPACT.htm>> (date accessed: 20 August 2004)).

⁵⁶ Manitoba Law Reform Commission, *supra* note 36.

⁵⁷ *Supra* note 14.

⁵⁸ Canada, *Building On Values: The Future of Health Care in Canada* (Saskatoon: Commission on the Future of Health Care in Canada, 2002) (Chair: R.J. Romanow).

and accessibility.⁵⁹ Similarly, the Standing Senate Committee on Social Affairs, Science and Technology endorsed the recommendations of the Naylor Advisory Committee and in November 2003 recommended that the federal government, through the Health Protection and Promotion Agency, invest \$100 million annually for the development of a National Immunization Program.⁶⁰ This national strategy would include the purchase by the federal government of new vaccines to meet the needs of the provinces and territories, increased funding to support a national tracking system of immunization coverage, and surveillance and mandatory reporting of VAAEs and funding for research on possible long-term adverse effects of vaccines.⁶¹ In response, the Federal government recently announced a decision to invest \$300 million over the next three years to fund a national immunization strategy.⁶²

When considering all of these factors collectively, the convenient and accessible administration of vaccines combined with a constant barrage of advertisements, personal reminders and notices sent home with children, legislative enforcement and government endorsement have created an immunization regime that is coercive and, for all intents and purposes, compulsory.

IV. Inherent Risks of Immunization — Risks in Product and System

1. Risks in Product

Whereas the benefits of national immunization programs are obvious — the savings to the health care system that are afforded by preventing disease and the improvement of public health — 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. The Canadian Immunization Guide⁶³ lists some of the more common side effects to vaccines which range from minor short-term tenderness and redness to more serious symptoms including high fever, systemic joint or muscle pain, seizures and, in some rare cases, permanent neurological damage or death.

A recent Canadian study reviewing data on over 1500 cases of drug reactions from 1985 to 1995 revealed that among children, antibiotics and vaccines cause

⁵⁹ Canada, *Learning from SARS: Renewal of Public Health in Canada — Report of the National Advisory Committee on SARS and Public Health* (Ottawa: Health Canada Publications, 2003) (Chair: Dr. D. Naylor), online: Health Canada <<http://www.hc-sc.gc.ca/english/pdf/sars/sars-e.pdf>> (date accessed: 24 January 2005).

⁶⁰ *Supra* note 3.

⁶¹ *Ibid.*

⁶² A. Picard, “Vaccines to Be Nationally Available” *The National Post* (24 March 2004).

⁶³ See *supra* note 1.

more adverse reactions than any other prescribed medicines.⁶⁴ Many studies have also attributed the dramatic increases of autoimmune disorders such as asthma and diabetes in the last two decades,⁶⁵ as well as the significant rise in autism and sudden infant death syndrome (SIDS), to the widespread use of vaccines.⁶⁶

With respect to SIDS, this belief has been described as a “myth” by the WHO, who argues that the belief stems from the observation that a moderate proportion of children who die of SIDS have recently been vaccinated with the DTP vaccine; the WHO rightly points out that it is an illogical leap of faith to conclude that this proves a causal connection.⁶⁷ In fact, a number of studies conducted by the U.S. National Academy of Sciences, Institute of Medicine (IOM) in the 1980s demonstrated that the number of SIDS deaths temporally related to DTP vaccination was similar to that expected to occur by chance alone and further, some of these studies indicated that the likelihood of a child getting SIDS was reduced following DTP vaccination.⁶⁸ In the U.S., the Immunization Safety Review Committee (ISRC)⁶⁹ was established to review some of the perceived safety concerns about immunization. In particular, the ISRC concluded that the evidence does not support a causal link between the MMR vaccine and autism, but that there nonetheless exists a possibility that the MMR vaccine could contribute to autistic spectrum disorders in a small number of children.⁷⁰ The committee concluded that further researched was warranted.

Notwithstanding the conflicting scientific data, one must consider the risks in combination with the benefits. Even assuming, as some of the data suggests, that there exists potential severe harm through vaccination, the actual probability of risk is considered negligible in medical terms. For example, convulsions following DTP vaccination occur with a frequency of 1 in 5,000, and the risk of developing an immediate severe allergic reaction resulting in death following a vaccination has

⁶⁴ *Supra* note 5. For example, the Global Advisory Committee on Vaccine Safety (GACVS) established by the WHO to provide reliable and independent scientific assessment of vaccine safety issues recently concluded that there is a real risk of serious adverse events following immunization with smallpox vaccine: World Health Organization, “Statement on Safety of Smallpox Vaccines”, online: <http://www.who.int/vaccine_safety/topics/smallpox/statement/en>

⁶⁵ For example, an article in Science News entitled “The Dark Side of Immunizations?” reviewed several studies demonstrating that vaccinated children have a higher incidence of asthma and diabetes than unvaccinated children. See in general the National Vaccine Information Centre’s website for several references to studies of this type published in scientific journals <<http://www.909shot.com>>.

⁶⁶ *Supra* note 5.

⁶⁷ World Health Organization, “Six common misconceptions about immunization”, online: World Health Organization <<http://www.who.int/vaccines-diseases/safety/prof/misconcept.shtml>>.

⁶⁸ *Ibid.*

⁶⁹ This independent committee was set up by the IOM and is comprised of 15 experts in the fields of pediatrics, neurology, immunology, internal medicine, infectious diseases, genetics, epidemiology, biostatistics, risk perceptions and communications, decision analysis, public health, nursing, and ethics.

⁷⁰ K. Stratton et al., eds., *Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism* (Washington: National Academy Press, 2001), online: <<http://www.nap.edu/openbook/0309074479/html>> (date accessed: 18 November 2003).

an estimated risk of 1 in 10 million.⁷¹ In terms of actual numbers, U.S. data cites that out of the 20 million children vaccinated each year, an estimated 500 suffer serious reactions and 75 die.⁷² Health Canada reports that serious side effects such as allergic reactions occur in Canada less than once in one million doses of vaccines.⁷³ Compared to the probability of contracting a disease in the absence of a vaccination that protects against the disease, the risk assumed is arguably insignificant. For example, without the MMR vaccine, there is a 1 in 20 risk of contracting pneumonia and a 1 in 2000 risk of contracting encephalitis versus a 1 in 1,000,000 chance of severe allergic reaction from the vaccine.⁷⁴

Vaccines represent a special class of health products in that they can cause harm despite proper manufacture, distribution or administration. This may be as a result of a genetic predisposition or as a result of the very nature of the vaccine itself, which in the majority of cases, will consist of a milder or killed version of the infectious agent that acts to induce the bodies' natural immune response. The DTP vaccine, which has been responsible for the majority of vaccine-related injuries,⁷⁵ was originally composed of whole-cell dead pertussis cells that consisted of the valuable antigen. Moreover, many vaccines contain harmful toxins including, *inter alia*, formaldehyde, thimerosal, which is comprised of almost 50% mercury,⁷⁶ aluminum phosphate, antibiotics, and phenols.⁷⁷ Thus, vaccines can be characterized as "inherently dangerous" products that, as will be discussed below, carry significant legal implications for users.

As a result of the public's growing awareness and concern over vaccine-related adverse events, immunization rates have fallen in various countries, resulting in a quick return of diseases. For example, Ireland experienced a dramatic increase in measles cases when immunization rates fell to 76% with more than 1,200 cases in the year 2000 as compared to only 148 cases in 1999.⁷⁸ Therefore, in assessing the safety of vaccines, both risks and benefits must be considered. As stated in Health Canada's Canadian Immunization Guide, "If there were no benefit from a vaccine, even one serious side effect in a million doses could not

⁷¹ *Supra* note 13 at 1.

⁷² See note 25 in E.C. Scott, "The National Childhood Vaccine Injury Act Turns Fifteen" (2001) 56 Food Drug L.J. 351.

⁷³ Health Canada website <http://www.hc-sc.gc.ca/English/iyh/medical/childhood_immu.html> (date accessed: 11 November 2003).

⁷⁴ *Supra* note 67.

⁷⁵ *Supra* note 72 at 353.

⁷⁶ A recent study published in the Journal of American Physicians and Surgeons presents strong epidemiological evidence for a link between neurodevelopmental disorders, such as autism, and mercury exposure from thimerosal-containing vaccines: M. Geier, "Thimerosal in Childhood Vaccines, Neurodevelopmental Disorders, and Heart Disease in the United States" (2003) 8(1) Journal of American Physicians and Surgeons 6.

⁷⁷ K.P. O'Meara, "Vaccines fueling autism epidemic? Report: U.S. infants exposed to mercury beyond EPA, FDA limits" *WorldNetDaily* (9 June 2003), online: <www.worldnetdaily.com/news/article.asp?ARTICLE_ID=32988> (date accessed: 18 November 2003).

⁷⁸ *Supra* note 1 at 47.

be justified.”⁷⁹ Applying a cost-benefit analysis then, wide-scale immunization is clearly favoured. This reasoning also implies an underlying utilitarian philosophy in that it suggests that if there are benefits to be gained from a vaccine, a one in a million chance of a serious side effect will be justified. Under this moral argument, immunization is justified since it results in the greatest benefit for the greatest number of people.

Under Kantian principles, however, treating a fellow human being as a means to an end, no matter how desirable that end, is never justified. Interestingly, both the Nuremberg Code and the 1964 Helsinki Declarations on which contemporary medical ethics is based, implicitly reject utilitarian principles in medical treatment and research, instead emphasizing individual autonomy and the human right to voluntary, informed consent. As bioethicist Arthur Caplan wrote: “Every experiment, no matter how important or valuable, requires the express voluntary consent of the individual. The right of individuals to control their bodies trumps the interest of others in obtaining knowledge or benefits from them.”⁸⁰

Contemporary Western medical models now recognize the fundamental guiding principles that individual autonomy and self-determination, as well as one’s right to bodily integrity and control over that, are inviolable rights essential to human dignity.⁸¹ Thus, in rejecting the more traditional paternalistic model of the early 20th century, concepts such as informed consent and full disclosure of risks have become integral to medicine and health policy today. As a result, legislation has developed that codifies these principles. For example, in Ontario the HCCA creates a presumption of capacity in all persons with respect to treatment;⁸² therefore, children are not automatically excluded. It is only after it can be shown that a person does not have such capacity that a decision may be made by another on behalf of the incapable person.⁸³ Thus, the law permits parents to make treatment decisions on behalf of their child as a person who is not capable with respect to treatment. Furthermore, the Act codifies the concept of informed consent by requiring that a health practitioner shall not administer a proposed treatment without the consent of the person or, if incapable, without the consent of a substitute decision-maker.⁸⁴

⁷⁹ *Ibid.*

⁸⁰ A.L. Caplan, “The Doctor’s Trial and Analogies to the Holocaust in Contemporary Bioethical Debates” in G.J. Annas & M.A. Grodin, eds., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (New York, NY: Oxford University Press, 1992) 258 at 269.

⁸¹ As an interesting historical note, the first vaccine-related discovery occurred in 1796 when Edward Jenner injected an 8-year old boy with cowpox and later smallpox, only to discover that the boy had acquired immunity and did not get the disease (*supra* note 8). Ironically, this “experiment” would not survive ethical scrutiny today.

⁸² HCCA, *supra* note 50, s. 4(2).

⁸³ *Ibid.*, ss. 4(1), 4(3), 20(1).

⁸⁴ *Ibid.*, s. 10(1).

Notwithstanding the high value modern society places on the concept of autonomy, it nonetheless permits the violation of a child's autonomy in various circumstances provided it is in the child's "best interests".⁸⁵ Clearly, decisions made on behalf of a minor should always be fully informed and only made after careful consideration of a variety of factors. In the context of vaccination today, however, it is questionable whether the decision to vaccinate is in the child's best interest since routine vaccinations are non-urgent, some are not directly beneficial, and many of the diseases against which vaccines protect are non-existent.⁸⁶ In this sense, vaccination has slowly made the shift from being a self-interested act that coincidentally benefits society, to an act of altruism.⁸⁷

Additionally from a legal perspective, the decision to vaccinate a child may contravene substitute-decision making legislation.⁸⁸ For example, the HCCA requires that a substitute decision-maker act in the incapable person's best interests⁸⁹ and outlines the factors that a person making a decision on behalf of an incapable person must take into account when deciding what those best interests are.⁹⁰ Among the listed factors is a consideration of whether the treatment is likely to: (i) improve the person's condition or well-being, (ii) prevent their condition or well-being from deteriorating, or (iii) reduce the extent to which or rate at which the person's condition or well-being is likely to deteriorate, and a consideration of whether their condition or well-being is likely to improve, remain the same, or deteriorate without the treatment, whether the benefits of the treatment outweigh the risks, and whether a less restrictive or less intrusive treatment would be as beneficial as the treatment proposed. Arguably then, the choice to vaccinate one's child against polio, a disease which has not existed in the Western world since 1991, may not be in that child's best interest even considering the slight risk of a serious VAAE. One author points out that 19 of 25 cases of polio reported in the U.K. between 1985 and 1995 were due to unimmunized individuals coming into contact with the feces of recently vaccinated infant, and notes that the vaccine is thought to lead to the vaccinee contracting polio in one in two million cases.⁹¹ Despite this risk and the negligible benefit, children in the U.K. receive four doses of polio vaccine before the age of five.⁹²

How a parent may consider what is in their child's best interest with respect to vaccination will vary according to the parent's understanding and awareness of

⁸⁵ This concept of "best interests" is a common yardstick for decision-making employed in child welfare legislation in Canada.

⁸⁶ S. Pywell, "Vaccination and Other Altruistic Medical Treatments: Should Autonomy or Communitarianism Prevail?" (2000) 4 *Medical Law International* 223 at 232.

⁸⁷ *Ibid.* at 225.

⁸⁸ The *Substitute Decisions Act*, S.O. 1992, c. 30. S. 66(4) also refers to the best interests of a person who is under a Power of Attorney for Personal Care or a Guardian of the Person.

⁸⁹ HCCA, *supra* note 50, s. 21(1).

⁹⁰ *Ibid.*, s. 21(2).

⁹¹ *Supra* note 86 at 225.

⁹² *Ibid.*

both the benefits and risks of vaccination. As discussed above, the law in Ontario requires a health practitioner to ensure informed consent is obtained before administering treatment.⁹³ Informed consent includes the disclosure of information that a reasonable person in the same circumstances would require in order to make the decision with respect to the treatment including the expected benefits of the treatment, the material risks and side effects of the treatment, alternative courses of action and the likely consequences of not having the treatment.⁹⁴ Despite this statutory guidance, however, what the standard of disclosure is in the context of vaccinations is unclear.

There has been some debate that since the risks of injury from vaccines are statistically insignificant, that to disclose such remote risks to a parent may act to deter immunization without warrant. Again, this paternalistic attitude is no longer acceptable in determining medical decisions today. Further, the Supreme Court of Canada in *Reibl v. Hughes*⁹⁵ held that a doctor's duty to disclose all material risks of a proposed procedure includes those risks with low probability of occurrence but grave results. This continues to be the standard for disclosure in the informed consent process for medical procedures including the prescribing of drugs and the use of human subjects in research. A study published in the Canadian Bar Review in 1991 by Gerald Robertson examined developments in the law of informed consent in Canada following the Supreme Court of Canada's decision in *Reibl*.⁹⁶ The study reported, *inter alia*, that the duty to disclose has been interpreted expansively by Courts and has become increasingly onerous for physicians. Moreover, the case law since 1991 demonstrates the continuance of this trend; disclosure now further requires all material information including available alternative treatment, as well as a duty to take reasonable steps to ensure that the patient actually understands the information provided, which may be applicable if the patient's first language is not English or if the physician uses overly technical terminology.⁹⁷

Applied to an immunization program, this requires that consent be obtained from the child's parent but only after all of the risks have been disclosed. The rationale is simple: if the government wants to ask someone to sacrifice themselves for the greater good, they must ensure that the decision to do so is based on an understanding of the risks and benefits associated with the act. In theory, Health Canada supports the informed consent process for the administration of vaccines. The most recent version of the Canadian Immunization Guide has included a section entitled "Talking with Patients about Immunization"⁹⁸ that appears to embody these principles and marks a departure from the remainder of the Guide. However, despite

⁹³ *HCCA*, *supra* note 50, ss. 10(1), 11(1).

⁹⁴ *Ibid.*, ss. 11(2), 11(3).

⁹⁵ *Reibl v. Hughes*, [1980] 2 S.C.R. 880.

⁹⁶ See generally G. Robertson, "Informed Consent Ten Years Later: The Impact of *Reibl v. Hughes*" (1991) 70 Can. Bar Rev. 423.

⁹⁷ G.B. Robertson, "Informed Consent Twenty Years Later" (2003) 11 Health L.J. 153.

⁹⁸ *Supra* note 1 at 42.

this rather noble gesture, not much else is being done to ensure that informed consent is being obtained prior to vaccination. The government needs to recognize how the system works in practice, evaluate its shortcomings and develop ways to improve the integrity of a very necessary and valuable system. It is because of traditional paternalistic attitudes, secrecy regarding risks and lack of education that a climate of distrust over vaccines has evolved, threatening the viability of the system and overall rates of immunization.

2. Risks in System — Informed Consent in Practice

From the foregoing analysis, most will agree that immunization despite its inherent risks still serves a vital purpose, both for the individual as well as the public who benefits from herd immunity. However, in order to maintain a sustainable immunization system, efforts must focus on those aspects that are most capable of disintegrating the system. Where the system is most at danger of eroding is through the informed consent process.

In the Quebec decision of *Charbonneau c. Poupart*, the judge established that a person has the right to decide whether she wants to be vaccinated or not pursuant to the Charters and the inviolability of the human being.⁹⁹ Although there is legislation in Canada that enables a minor to consent or at least assent to medical treatment,¹⁰⁰ the reality is that most children will invariably receive their first vaccination through a substitute decision maker (the parent) so consent is never directly achieved. This is a necessary element though, since immunization occurs in infancy. The child therefore lacks the legal capacity to consent and the parent has the legal authority to consent on their child's behalf.¹⁰¹

As discussed in the previous section, it is imperative that parents be provided with full disclosure of all risks and benefits when making the decision to vaccinate their child.¹⁰² However, both empirical studies¹⁰³ and anecdotal evidence¹⁰⁴ indicate that parents are rarely guided through a full informed consent process with respect to vaccines. For example, in 2001 a national U.S.-based study found that in about 70% of immunization visits, physicians and nurses reported initiating discussion

⁹⁹ *Charbonneau c. Poupart*, [1990] R.J.Q. 1136.

¹⁰⁰ *Medical Consent of Minors Act*, R.S.N.B. 1973, c. M-6.1, s.2; *Infants Act*, R.S.B.C. 1996 c. 223, s.17.

¹⁰¹ See for example the *HCCA*, *supra* note 50, s. 20.

¹⁰² The *HCCA* lists some factors to consider when making the decision to refuse consent on behalf of another person; they cannot possibly be achieved unless *all* benefits and risks of the procedure are disclosed (*ibid.*, s. 21).

¹⁰³ The literature, although mostly U.S.-based, reports that physicians say little to parents about immunizations. For a review of this literature, see generally T.C. Davis *et al.*, "Childhood Vaccine Risk/Benefit Communication in Private Practice Office Settings: A National Survey" (2001) 107:2 *Pediatrics*, online: *Pediatrics* Homepage <<http://www.pediatrics.org/cgi/content/full/107/2/e17>> (date accessed: 20 August 2004) [*National Survey*].

¹⁰⁴ One author reports that parents in her study believed vaccination to be compulsory, making comments such as, "I just did what I was told" or "I felt I had no choice": *Supra* note 86 at 232.

of common side effects, when to call the clinic and the immunization schedule.¹⁰⁵ However, less than 50% of physicians reported initiating discussions of contraindications, notwithstanding that 69% believed that parents needed to know contraindications.¹⁰⁶ Although this study illustrates the situation in the U.S., inferences can reasonably be drawn since physicians in the U.S. are similarly required to disclose the risks of vaccination to patients.¹⁰⁷ Furthermore, a Canadian study of nurses at a paediatric tertiary care centre indicates that nurses are more likely to be asked for immunization information, which mirrors the situation in the U.S.¹⁰⁸ Fewer than half felt adequately prepared to answer questions.¹⁰⁹ In comparison, although public health nurses' in the U.S. self-reported compliance with the law greatly exceeded that reported by physicians and nurses in private clinics,¹¹⁰ they nonetheless reported that they rarely discussed risks because they felt unskilled and were unsure of what to say.¹¹¹

The observation that in reality, the informed consent process is not occurring in the context of vaccination can be attributed to a complexity of intervening factors. First, it may partially be as a result of continued acceptance by the public and those who administer vaccines of the status quo of routine vaccine administration system, a system that has existed in our society for decades. In some cases, physicians may adopt a more traditional but outdated paternalistic approach to dictating vaccine choices to their patients.¹¹² Indeed, almost 25% of physicians in one study were concerned that parents would be unnecessarily alarmed by disclosure of vaccine risks, and a significant number believed that parents did not want to know about risks.¹¹³ Because paediatricians are viewed as a credible source of vaccine recommendations,¹¹⁴ the majority of parents may tend to follow their paediatrician's advice without engaging in independent decision-making.¹¹⁵ Moreover, parents often experience pressure from health care professionals to vaccinate their children,

¹⁰⁵ *National Survey*, *supra* note 103.

¹⁰⁶ *Ibid.*

¹⁰⁷ Vaccine risk/benefit communication is legally required under the *National Childhood Vaccine Injury Act*, *infra* note 214.

¹⁰⁸ The study conducted by T.C. Davis *et al.* found that nurses play the major role in vaccination dose delivery: *National Survey*, *supra* note 103.

¹⁰⁹ D. Manning *et al.*, "How Knowledgeable Are We? Parents Are Asking Pediatric Nurses Questions About Routine Vaccinations, But Do Nurses Know the Answers?" (2003) 99:4 *The Canadian Nurse* 27.

¹¹⁰ *National Survey*, *supra* note 103.

¹¹¹ T.C. Davis *et al.*, "Childhood Vaccine Risk/Benefit Communication Among Public Health Clinics: A Time Motion Study" (2004) 21:3 *Public Health Nursing* 228 at 230.

¹¹² L.K. Ball, G. Evans & A. Bostrom, "Risky Business: Challenges in Vaccine Risk Communication" (1998) 101:3 *Pediatrics* 453.

¹¹³ *National Survey*, *supra* note 103.

¹¹⁴ J.A. Taylor *et al.*, "The Influence of Provider Behaviour, Parental Characteristics, and a Public Policy Initiative on the Immunization Status Followed by Private Pediatricians: A Study from Pediatric Research in Office Settings" (1997) 99 *Pediatrics* 209. Another study indicated that in both vaccinating and non-vaccinating parents, the trust worthiness of the media, the Internet, and word of mouth was small in comparison to a trusted provider: *Supra* note 43.

¹¹⁵ *Supra* note 112.

and in some cases report that they were told by such professionals that vaccination was a social duty.¹¹⁶ This power imbalance between doctor and patient may further undermine the informed consent process since where it does not take place, vaccination is thereby not presented as a choice to parents. Since most parents may not be aware of the risks¹¹⁷ or their rights,¹¹⁸ they undoubtedly comply without questioning.¹¹⁹

Second, even assuming a health care professional is not intentionally avoiding the informed consent process, the process as required by law may nonetheless be prohibitive for busy physicians. Nurses self-reported spending more time discussing vaccines with parents than physicians and both indicated an additional 60 to 90 seconds was needed to optimally discuss immunization with parents under current conditions.¹²⁰ Third, given these 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.¹²¹ This is a particularly crucial issue for the illiterate or for those whose first language is not English or French, since comprehension of the material may not be present. In a study of clinics in Rochester, New York, results indicated that although Vaccine Information Statements¹²² (VISs) were given to family members 98% of the time, only 5% read any materials during the visits.¹²³ Other studies indicate that many parents visiting clinics have limited literacy skills and do not understand written vaccine information.¹²⁴ Finally, the literature indicates that parents who are given written vaccine information material still desire verbal information from their primary provider.¹²⁵

Further complicating the issue of disclosure is the fact that many physicians themselves may not be aware of all of the risks and contraindications of vaccination.¹²⁶ This issue is further exacerbated by the nature of the relationship between patient-physician-manufacturer. Every link in this chain can be characterized as a relationship of dependency and inequality in that the patient relies on the advice and opinion of the physician, who in turn relies on the information and scientific

¹¹⁶ *Supra* note 86 at 232-233.

¹¹⁷ Parents in a focus group study reported that they were unaware of any associated vaccine risks and had not been told of such risks: *Supra* note 111 at 229.

¹¹⁸ Less than 10% of physicians in a national U.S. study reported initiating discussion regarding the National Vaccine Injury Compensation Fund with their patients: *National Survey*, *supra* note 103.

¹¹⁹ *Supra* note 5.

¹²⁰ *National Survey*, *supra* note 103.

¹²¹ *Supra* note 95.

¹²² In the U.S. the use of Vaccine Information Sheets is required by law: see *infra* note 171.

¹²³ *Supra* note 111 at 229.

¹²⁴ *Supra* note 42.

¹²⁵ E.W. Clayton, G.B. Hickson & C.S. Miller, "Parents' Responses to Vaccine Information Pamphlets" (1994) 93:3 *Pediatrics* 369.

¹²⁶ *Supra* 9 at 249.

evidence supplied by the manufacturer.¹²⁷ Similarly, the aggressive promotional sales tactics of vaccine manufacturers¹²⁸ contributes to the physician's opinion regarding safety of a product and to the view that it is not necessary to fully inform a patient.¹²⁹ The foreseeability of a physician's failure to disclose is also directly proportional to the extent of promotional materials that a physician receives; consequently, the volume of marketing tends to stifle the trickle of risk information.¹³⁰

Finally, as outlined above, the social mechanisms in place to administer and promote wide-scale immunization further undermine the informed consent process by introducing an element of coercion that encourages complacency and ignorance thereby reducing the likelihood of refusal to consent. These mechanisms include, *inter alia*, legislation that mandates compulsory vaccinations in specific circumstances, availability and access of free vaccines, government supported immunization programs through the educational system, direct pressure from family physicians and indirect pressure from the manufacturers (whose marketing techniques prompt physicians to prescribe their products), and lack of a statutory requirement in many provinces of a strict process of informed consent.

Thus, in order to maintain a sustainable immunization system, the focus of government should be to reduce the risks associated with vaccines, to increase public awareness through education in order to dispel myths and to maximize immunization, to recognize individual autonomy by promoting full and frank disclosure and informed consent (this must include an understanding not only of risks but also legal rights and obligations), and to maintain transparency in the system. Finally, the government should undertake to compensate those individuals injured by a vaccine as a result of an immunization program that ultimately benefits society.

V. The Lack of Compensation for Vaccine-related Injuries

The lack of a feasible mode of compensation for a child injured by a vaccine further disintegrates the immunization system since parents may be less apt to comply if there is no recompense in the slight chance an injury occurs. Currently, Quebec is the only Canadian jurisdiction in which a child injured through vaccination has an effective recourse to obtain compensation. In the discussion that follows, the available compensation options and associated problems will be discussed.

¹²⁷ P. Peppin, "Drug/Vaccine Risks: Patient Decision-Making and Harm Reduction in the Pharmaceutical Company Duty to Warn" (1991) 70 Can. Bar Rev. 473 at 474 ["Peppin"]. See also Robins J.A. in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 12 O.A.C. 361 at 380-381 ["Ortho"].

¹²⁸ Promotional activities are extensive and include sponsorship of lectures and conferences, travel expenses, advertising in physician's magazines, visits by drug sales reps, free samples, and free computer hardware and software (Peppin, *ibid.* at 494).

¹²⁹ *Ortho*, *supra* note 127.

¹³⁰ Peppin, *supra* note 127 at 513.

1. Options in Tort for Vaccine-Related Injuries

The first option is to seek compensation through the tort system. Immediately, however, the plaintiff encounters a problem — who is to be held liable for the harm incurred, the vaccine administrator, the prescribing physician, the manufacturer or the government that regulates the system? In theory, all may be held partly or jointly liable if the circumstances warrant; however, Canadian jurisprudence to date indicates that a plaintiff is most likely to be unsuccessful on all counts.

In tort, liability is incurred through the fault of one person (including a corporate or government entity) that results in harm to another. Damages in tort are based on the principle of *restitutio in integrum* whereby the victim is restored to the position she enjoyed prior to the harm. With respect to vaccine injuries, there are two relevant torts that may apply, negligence and battery. In negligence, liability is imposed on an individual for failing to take reasonable care for the safety of another person, and includes failure to obtain informed consent. Proof will consist first of establishing that a duty of care was owed and secondly, that the defendant failed to exercise reasonable care, causing foreseeable harm to the plaintiff.¹³¹ The tort of battery in medical procedures exists when the plaintiff has not consented to the procedure and is consequently injured by the actions of the physician, regardless of the good intent or lack of negligence on the part of the physician. Thus, proof of a lack of consent for the specific procedure or proof of invalid consent (i.e. as when obtained through fraud, misrepresentation or absence of information), is required as well as proof that the defendant touched the plaintiff.¹³² Clearly, a person administering a vaccine will have satisfied the latter of the two criteria.

Negligence and battery may be appropriate in a vaccine-related injury claim as outlined in the following chart:¹³³

NEGLIGENCE			BATTERY
Failure to warn of material risks	Defective manufacture	Negligent administration	Failure to obtain informed consent
Possible Defendants			
Manufacturer Physician Person administering i.e. public health nurse Government	Manufacturer Government	Physician Person administering i.e. public health nurse Hospital	Physician Person administering i.e. public health nurse Hospital

¹³¹ Manitoba Law Reform Commission, *supra* note 36 at 8.

¹³² *Supra* note 95 at 888-892.

¹³³ None of these are exclusive so each claim could potentially be brought.

In a negligence action generally, the plaintiff must establish that “but for” the negligent action of the defendant, the plaintiff would not have sustained the injury (See “Legal Causation”, below). However, it must first be established that the defendant owes a duty of care and that the duty of care has been breached. The content of the duty of care is what may give rise to the negligence actions outlined above. For example, it is a well-established principle in Canadian products liability law that a manufacturer has a duty to warn the consumer of the material risks associated with the use of the product.¹³⁴ Similarly, where a patient relies on a “learned intermediary” for such information rather than on the manufacturer, the manufacturer can discharge its obligation to inform the patient of material risks by providing it to the learned intermediary.¹³⁵ Thus, a physician or other person administering a vaccine may act as a learned intermediary charged with the burden of providing disclosure. Both physician and vaccine administrator are also required to exercise reasonable care in accordance with accepted medical practice, standards and customs and may be held liable if negligent in the administration of vaccines. A hospital may similarly be liable for failure to ensure the competency of its employees.

The possible negligence of the government in vaccine-related injuries raises interesting issues regarding the standard of care a court may impose in such cases. In establishing whether a duty of care exists for a public authority, the court will apply the two-part test as set out in *Anns v. Merton London Borough Council*¹³⁶ and adopted by the Supreme Court of Canada in *Kamloops v. Neilsen*.¹³⁷ In the first part of the test, the court must determine whether there is a sufficient relationship of proximity between the plaintiff and the alleged wrongdoer such that any carelessness on the part of the wrongdoer may reasonably be foreseen to result in the plaintiff’s harm. If so, a *prima facie* duty of care arises and the court must next consider whether there are any policy factors which may negate the duty. Several cases since¹³⁸ have imposed a duty of care on public authorities for “regulatory negligence” and indicate that the necessary standard of care required to fulfil this duty is high. In the context of a government authority’s inspection and enforcement programs, where such programs are negligently administered, the authority may be found liable for failing to meet its enforcement responsibilities where damage arises as a result of its omissions. For example, it is estimated that the federal government is currently exposed to claims for regulatory negligence to the order of \$12 billion for tainted blood and faulty medical devices.¹³⁹ Notwithstanding this increasingly risky regulatory environment, it is not clear whether liability may be imposed on

¹³⁴ *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569.

¹³⁵ *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634.

¹³⁶ *Anns v. Merton London Borough Council*, [1978] A.C. 728, [1977] 2 All E.R. 492 (H.L.).

¹³⁷ *Kamloops (City) v. Neilsen*, [1984] 2 S.C.R. 2.

¹³⁸ *Just v. British Columbia*, [1989] 2 S.C.R. 1228; *Lewis (Guardian ad litem of) v. British Columbia*, [1997] 3 S.C.R. 1145.

¹³⁹ M. McBane, “Risk First, Safety Last: A Citizen’s Guide to Health Canada’s Health & Safety First! A Proposal to Renew Federal Health Protection Legislation” (2003), online: Canadian Health Coalition Homepage <<http://www.healthcoalition.ca/index.html>> (date accessed: 20 August 2004).

government in the context of vaccine-related injuries. In *Rothwell v. Raes*,¹⁴⁰ the Court found that the province reasonably relied on the federal government to license and monitor vaccines and held that the province's decision not to exercise the authority it had to regulate and monitor did not subject it to liability. Since no other province had issued warnings at the time, no negligence could be found on the part of the ministry.

Finally, the failure to obtain informed consent before administering a vaccine may constitute battery. In one recent case, a nurse and her public health employer were held liable for battery as a result of vaccinating the 11-year old plaintiff against her will.¹⁴¹ The child had informed the nurse that her mother did not want to have her vaccinated, but the nurse administered the Hepatitis B vaccine anyway. Notwithstanding that the court found the nurse was under an honest belief that she had obtained verbal consent from the child's mother days before, her failure to confirm consent in the face of the child's remarks constituted a violation of an individual's right to control access to her own body. The court ordered damages in the amount of \$1000.

(i) Problems With the Tort System in Canada

Despite the rather promising appearance of the chart above, the situation in Canada is surprisingly bleak and seems to be a direct result of both the nature of vaccine injuries and the standard of proof that is required for the tort to succeed. Furthermore, the historical rejection of vaccine-related claims in Canada and the UK has had a chilling effect on the initiation of other similar claims in these jurisdictions. A major Canadian case in point is *Rothwell*.¹⁴² In that case, it was alleged that the pertussis vaccine caused the severe mental and physical disability of the plaintiff. About one month after receiving his third shot of the vaccine at the age of five months, Patrick Rothwell began to show signs of developmental abnormality. His family sued the manufacturer Connaught Laboratories, the physicians who administered the vaccine and the Crown, who had distributed the vaccine. The Court ultimately rejected the claim for inability to prove causation (see below). Subsequently, a number of claims that were pending against physicians, the government and the manufacturer were abandoned.¹⁴³ Similarly, the UK case of *Loveday v. Renton*,¹⁴⁴ which exceeded 40 days, quashed the hopes of over 200 plaintiffs who had claims pending and were awaiting the determination of that trial.¹⁴⁵

¹⁴⁰ *Rothwell v. Raes* (1988), 54 D.L.R. (4th) 193 (Ont.H.C.), aff'd (1990), 76 D.L.R. (4th) 280 (Ont.C.A.), leave to appeal to SCC refused, [1991] 1 S.C.R. xiii.

¹⁴¹ *Toews (Guardian ad litem of) v. Weisner*, [2001] B.C.J. No. 30 (B.C.S.C.), (2001) 3 C.C.L.T. (3d) 293.

¹⁴² *Supra* note 140.

¹⁴³ Manitoba Law Reform Commission, *supra* note 36 at 10.

¹⁴⁴ *Loveday v. Renton*, (1989) 66 O.R. (2nd) 449.

¹⁴⁵ C.L. Campbell, "Pertussis Vaccine Litigation in Three Countries" (1990) 18 Law, Medicine & Health Care 59 at 60-62.

(ii) The Challenge in Establishing Causation for Vaccine-Injury Liability

a) General Scientific Causation

One of the most significant hurdles that a plaintiff claiming vaccine-related injury must overcome is proof of causation. The first element of causation in a vaccine liability case is general scientific causation, the ability of the product to cause the harm.¹⁴⁶ In tort, the plaintiff must prove that the negligence of the defendant was a proximate cause of the injury. Vaccine-related injuries are a unique class, since often it is difficult to determine whether the harm was incidentally related to the vaccine or whether the vaccine directly caused it.¹⁴⁷ The legal problem is further confounded by disagreement in the scientific community concerning the effects of vaccines. The trier of fact in such cases is thus faced with conflicting expert testimony that can be either accepted or rejected solely on the basis of credibility alone.¹⁴⁸

In the pertussis vaccine (DTP) cases,¹⁴⁹ the causal link between the vaccine and brain damage was at issue. Similarly, in the Canadian case of *Rothwell*,¹⁵⁰ Osler J. concluded that the plaintiff had not discharged the onus of showing that it is more likely than not that the pertussis component of the DTP vaccine can cause serious permanent brain damage in young children.¹⁵¹ This conclusion was made notwithstanding the existence of a British epidemiological study, the National Childhood Encephalopathy Study and associated cases, as well as other scientific evidence pointing to a causal link.¹⁵² Finally in 1991, an Irish court in *Best v. Wellcome Foundation Ltd.* made an unprecedented statement when it acknowledged that the DTP vaccine could cause encephalopathy.¹⁵³ In any event, the question of a vaccine's ability to cause a particular type of injury is a scientific question, and there are many who argue that the courtroom is not an appropriate place to attempt to answer it.¹⁵⁴

¹⁴⁶ Peppin, *supra* note 127 at 499.

¹⁴⁷ This problem was recognized by the U.S. Vaccine Injury Compensation Program (discussed *infra*). To avoid the scientific causation issue, a temporal association between a vaccine and a "listed injury" is sufficient to create a presumption of causation.

¹⁴⁸ The trial judge in the *Loveday* trial accepted the testimony of the defendant's experts over that of the plaintiff's on the basis that he was more impressed by the cogency and quality of the evidence and reasoning of defendant's experts: *Supra* note 144. Interestingly, these same witnesses were held not credible by the trial judge in *Graham v. Wyeth Industries Inc.*, 666 F. Supp. 1483 (Kan. Dist. Ct. 1987) [*Graham*]: *Supra* note 145 at 63.

¹⁴⁹ See *supra* note 145 at 59-68.

¹⁵⁰ *Supra* note 140.

¹⁵¹ Osler J. affirmed the approach taken by Lord Justice Stuart-Smith in the *Loveday* case (*supra* note 144) that the onus is on the plaintiff to demonstrate, as a matter of fact, that it is more likely than not that the particular vaccine can cause permanent brain damage in children: *Supra* note 140.

¹⁵² Peppin, *supra* note 127 at 499-500.

¹⁵³ *Best v. Wellcome Foundation Ltd.*, [1995] 2 IR 393.

¹⁵⁴ *Supra* note 145 at 66.

Note that in these earlier cases, the vaccine at issue was a “whole cell vaccine” meaning that the pertussis portion of the DTP vaccine was comprised of the whole pertussis bacteria. In the U.S. case of *White v. Wyeth Laboratories Inc.*,¹⁵⁵ the court found that although the whole cell vaccine was considered more potent than non-whole cell vaccines, the earlier DTP vaccine was neurotoxic and could cause adverse reactions on occasion. Today, however, safer acellular versions of the vaccine are employed, thus proof of scientific causation may be even more difficult.

b) Particular Causation

Assuming the plaintiff is able to establish general scientific causation, the next element of proof is equally challenging and consists of proving particular causation¹⁵⁶ or “cause in fact”. At this stage of the analysis, the question is not whether a vaccine can cause a particular injury but rather, whether it did indeed cause the particular plaintiff’s injury. The standard of proof is on a balance of probabilities.¹⁵⁷ The same problems of proof arise, as this is also a scientific enquiry that is difficult to prove as illustrated again by the *Rothwell* case. The Court held that even assuming scientific causation had been proved, the plaintiff had failed to prove that the vaccine was the cause in fact of his disability.¹⁵⁸

c) Legal Causation

The last hurdle of proof in the causation analysis is arguably the hardest to overcome if not impossible with respect to vaccine injuries, especially if the plaintiff is alleging lack of adequate informed consent. The test for legal causation as set out in *Reibl*¹⁵⁹ requires that the plaintiff must establish a causal link between the negligent act of the defendant and the injury. In other words, the plaintiff must show that “but for” the negligent action of the defendant, the plaintiff would not have been injured. In an action for lack of informed consent, the plaintiff must prove that she would have declined to consent had she been aware of the risks.¹⁶⁰

Robertson’s earlier study that examined developments in the law of informed consent in Canada following the Supreme Court of Canada’s decision in *Reibl* revealed that 82% of patients in informed consent cases were unsuccessful, and the author contributed this to the problem of causation.¹⁶¹ A follow-up study that examined whether this trend still currently exists found that it does, with informed consent cases in 2001 and 2002 showing a failure rate of patients of 86% and 80% respectively.¹⁶² The author notes, however, that the reason for the failure of patients

¹⁵⁵ *White v. Wyeth Laboratories Inc.*, 533 N.E.2d 748 (Ohio 1988).

¹⁵⁶ Peppin, *supra* note 127 at 500.

¹⁵⁷ Manitoba Law Reform Commission, *supra* note 36 at 10.

¹⁵⁸ *Supra* note 140.

¹⁵⁹ *Supra* note 95.

¹⁶⁰ Manitoba Law Reform Commission, *supra* note 36 at 10.

¹⁶¹ *Supra* note 96.

¹⁶² *Supra* note 97 at 154-157.

in informed consent cases has shifted from one of causation to the fact that doctors appear to be disclosing the required information much more often than before.¹⁶³ Arguably though, causation is still problematic in vaccine-related cases since those cases may not only turn on lack of informed consent.

There are several inherent problems that exist for vaccines. First, legal causation is based on a modified objective standard that asks whether a reasonable person in the particular circumstances of the plaintiff would have declined the treatment if she had known all of the material risks.¹⁶⁴ Considering the alternatives to immunization, namely a higher probability of contracting a serious disease, balanced with the comparatively insignificant associated risks, in almost all situations in which a full explanation of the risks and benefits have been disclosed, a reasonable person will choose vaccination.¹⁶⁵ This was the result in the *Rothwell* case¹⁶⁶ in which Osler J. held that the reasonable patient in the same position of the plaintiff's mother would have proceeded with the vaccination. Recent trends in informed consent case law, however, indicate that Courts are increasingly looking at the test of causation subjectively. Ironically, as Robertson's recent study reveals,¹⁶⁷ this shift has made it even more difficult for patients to establish causation in informed consent cases. For vaccines specifically, even if the court applies the lesser subjective standard, the test is nonetheless prohibitive since in many cases, the benefits will outweigh the risks so the plaintiff is faced with an insurmountable hurdle of establishing that she would have refused vaccination.

Second, in applying this subjective test, the court will necessarily engage in an assessment of the plaintiff's credibility.¹⁶⁸ Indeed, in the *Rothwell* case,¹⁶⁹ Osler J. went on after applying the modified objective test to find on the basis of the subjective test that the plaintiff's mother herself would not have refused vaccination had she been informed of the risks, notwithstanding that she testified that she would have. The courts' concern that such testimony is disingenuous and motivated by the "hindsight and bitterness"¹⁷⁰ of patients can be seen as the impetus for the development of the modified objective standard. However, whether assessed on this standard or on the basis of credibility, the legal test for causation is but one more hurdle that the plaintiff must overcome. Finally, this reasonableness test, which requires both proof of a hypothetical and a negative, carries a heavy persuasive burden with the onus placed exclusively on the plaintiff.¹⁷¹

¹⁶³ *Ibid.*

¹⁶⁴ *Supra* note 95.

¹⁶⁵ Manitoba Law Reform Commission, *supra* note 36 at 10.

¹⁶⁶ *Supra* note 140.

¹⁶⁷ *Supra* note 97 at 156-158.

¹⁶⁸ Peppin, *supra* note 127 at 478.

¹⁶⁹ *Supra* note 140.

¹⁷⁰ Comment, "Informed Consent — A Proposed Standard for Medical Disclosure" (1973) 48 N.Y.U.L. Rev. 548 at 550.

¹⁷¹ Peppin, *supra* note 127 at 478.

In contrast to the principles applied in the informed consent cases, the courts have adopted a different analysis of causation in products liability cases where the claim for negligence is against the manufacturer. The standard applied in these cases is the subjective standard. The rationale for this differing analysis was expressed by Robins J.A in *Ortho*,¹⁷² who rejected the modified objective test in *Reibl* by drawing a distinction between the manufacturer-consumer relationship and the doctor-patient relationship. In the former, the doctor acts as a learned intermediary for disclosure to the patient on behalf of the manufacturer. However, where the manufacturer has failed to adequately inform the doctor of its product's risks such that it influences the non-disclosure by the doctor and the patient's decision to take the product, the learned intermediary will drop out of the causal sequence; the *Riebl* test thus only applies where the inadequate disclosure has undermined the doctor-patient relationship.¹⁷³

Note that where the doctor's actions break the causal sequence between manufacturer and patient, the principle of intervening causation applies such that the manufacturer may be shielded from liability. For example, in *Davidson v. Connaught Laboratories*,¹⁷⁴ the Court held that notwithstanding that the manufacturer had failed to adequately warn the plaintiff's doctors of the risks of its drug, the decision of the doctors to prescribe the drug was found to be an intervening cause of the plaintiff's harm.¹⁷⁵ The Court found that the plaintiff had failed to produce sufficient evidence that full disclosure would have made a difference in his doctors' decision to prescribe. However, where the level of promotional materials from the manufacturer is enough that the doctor can be said to be dependent on or lulled by the company, the doctor may not be held to act as an intervening cause.¹⁷⁶

In addition to the reliance on a subjective test, in product liability cases the Supreme Court of Canada has either reversed or relaxed the ordinary burden that rests on the plaintiff to prove causation. In *Ortho*,¹⁷⁷ the Ontario Court of Appeal held that once the breach of duty to warn has been established, a rebuttable presumption exists that the inadequacy of the warning was a contributing cause of the plaintiff's decision to accept treatment. The presumption is that the doctor would disclose the risk acting non-negligently and thus the plaintiff should not be required to prove this element to reach the subjective test of causation. The defendant must then rebut this presumption by showing that a warning would have made no difference to the doctor's conduct. The Supreme Court of Canada adopted this analysis in *Hollis*,¹⁷⁸ with La Forest J. holding that the plaintiff's burden had

¹⁷² *Ortho*, *supra* note 127.

¹⁷³ Peppin, *supra* note 127 at 509. This approach was subsequently adopted by the Supreme Court of Canada in *Hollis*, *supra* note 135.

¹⁷⁴ *Davidson v. Connaught Laboratories*, (1980) 14 C.C.L.T. 251.

¹⁷⁵ Peppin, *supra* note 127 at 512.

¹⁷⁶ *Ortho*, *supra* note 127.

¹⁷⁷ *Ibid.*

¹⁷⁸ *Supra* note 135.

been discharged once she established that the defendant had breached its duty to warn of the risk of rupture of the breast implant, thereby not requiring her to further establish that the breach in question was the *cause* of the injury.

Note, however, that this presumption was formulated in the context of manufacturer liability and based on the notion that it is foreseeable that a manufacturer's failure to warn of material risks would cause harm to the patient. Thus it may not apply where intervening causation is an issue, for example where both the manufacturer and doctor are sued, since it is possible that a court might conclude that a doctor's failure to disclose was foreseeable.¹⁷⁹ However, in the *Rothwell* case, both the manufacturer and the doctors were sued and the Court held, despite the finding that it was not customary for doctors to warn of the possibility of brain damage, that the presumption that the doctor would have warned of the risk had the manufacturer been given adequate disclosure could not be overcome. Despite the lesser burden applicable in product liability cases, in the context of vaccine-related injury cases, even where the plaintiff has the benefit of the rebuttable presumption, the combination of other hurdles in causation create an impossibility of success. Ultimately, the plaintiff in *Rothwell* was unsuccessful.

d) Indeterminate Defendants

The final hurdle in the causation analysis to be discussed is 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. For example, 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 the plaintiff was injured by. In *Sindell v. Abbott Laboratories*,¹⁸⁰ a California Supreme Court in response to this problem applied the theory of market share liability to apportion liability to those substantial manufacturers (90% of the market) of the drug DES based on the percent market share each had held at the time the plaintiff had been injured. This solution alleviates the burden from the plaintiff of having to prove which of a number of negligent defendants caused her harm (although the problem of proving causation itself still exists), but has yet to be accepted in relation to vaccine-injury claims.¹⁸¹ Furthermore, this is a U.S. doctrine that has not received acceptance by Canadian courts;¹⁸² thus, plaintiffs in Canada are faced with yet another causation hurdle in trying to receive compensation for their vaccine-related injuries through the tort system.

¹⁷⁹ Peppin, *supra* note 127 at 514.

¹⁸⁰ *Sindell v. Abbott Laboratories*, 607 P. 2d 924 (Calif. Sup. Ct. 1980).

¹⁸¹ The court in *Shackil v. Lederle Laboratories*, 116 N.J. 155, 561 A. 2d 511 (N.J. 1989) [*Shackil*] considered this solution in a DTP vaccine case and ultimately rejected the application of market share liability to vaccines. The overriding concern was that this theory would deter immunization production and research: *ibid.* at 528.

¹⁸² This approach was rejected by the Supreme Court of Canada in *Snell v. Farrell*, [1990] 2 S.C.R. 311.

(iii) Results and Other Problems Associated with the Tort System

Aside from the problem of causation in vaccine-injury claims, the tort system is an unlikely candidate for recompense for a variety of other factors. First, it is a costly route. In the *Rothwell* case, it was estimated that the legal costs associated with the litigation were over \$1 million.¹⁸³ Second, the tort process is excessively lengthy and is characterized by court delay, often with years passing between the time the vaccine was administered and the time the statement of claim is filed.¹⁸⁴ Third, the lack of success in Canada and abroad of these types of claims has resulted in a lack of jurisprudence and grave uncertainty, further deterring potential claimants from using the system to obtain compensation for their injury. Lastly, procedural and financial obstacles impede access to the tort system. In sum, the tort system is clearly insufficient to deal with the numerous minor and more rarely, the serious cases of vaccine injuries that result from their use each year. As the trial judge in *Rothwell* stated, "...the normal process of litigation is an utterly inappropriate procedure for dealing with claims of this nature."¹⁸⁵

(iv) The Liability Crisis

To contrast the situation in Canada and the UK, consider the litigation climate in the U.S. Since as early as the 1960s and '70s, plaintiffs in the U.S. have brought successful claims against vaccine manufacturers, many of which held the manufacturer liable for breach of the duty to warn.¹⁸⁶ At that time, comment k of the second Restatement of Torts¹⁸⁷ classified vaccines as "unavoidably unsafe" products and set out that a manufacturer of such a product cannot be held liable so long as the vaccine was shown to have been properly prepared and that adequate warning of possible adverse effects had been disclosed. This exception to strict liability applied in the case of prescription products, such as the DPT vaccine approved by the Food and Drug Administration.¹⁸⁸ However, even where the exception applied, a plaintiff could still bring a successful claim in negligence. For example, in a product liability action involving the DPT vaccine Tri-Immunol, notwithstanding that the jury found the vaccine to be unavoidably unsafe, the court held that the jury verdict was not inconsistent with the verdict that found the manufacturer was negligent in connection with the vaccine and that such negligence was the proximate cause of the child's injuries.¹⁸⁹ Similarly, the exception in comment k of the Restatement only applied if the product's design was as safe as the best available testing and research permitted; thus in *Graham*, where the expert asserted in his affidavit that the

¹⁸³ *Rothwell*, *supra* note 140.

¹⁸⁴ Manitoba Law Reform Commission, *supra* note 36 at 12.

¹⁸⁵ *Supra* note 140.

¹⁸⁶ *Stromsodt v. Parke-Davis and Company*, 257 F. Supp. 991 (N.D. Dist. Ct. 1966); *Tinnerholm v. Parke Davis*, 285 F. Supp. 432 (S.D.N.Y., 1968); *Ezagui v. Dow Chemical Corporation*, 598 F. 2nd 727 (2d Cir. 1979).

¹⁸⁷ *Restatement (Second) of Torts* §402 (1965).

¹⁸⁸ *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332 (Cal. 1987).

¹⁸⁹ *Toner v. Lederle Laboratories, Division of Cyanamid Co.*, 828 F.2d 510 (Idaho 1979).

manufacturer of the DPT vaccine alleged to have caused the severe and irreversible brain damage of the infant plaintiff had the capability to produce a safer vaccine, the court held that this precluded dismissal of the strict liability claim based on the exception in the Restatement.¹⁹⁰

The doctrine of strict liability that existed in the U.S. in the early 1980s resulted in a situation where plaintiffs were filing over 100 new cases each year and requesting \$3.5 billion in damages.¹⁹¹ The rationale underlying the strict liability doctrine was that, since immunization is compulsory, those injured should be appropriately compensated. Of course, it follows that the government should incur liability since it is the entity forcing vaccinations. However, since the swine flu epidemic of 1976 in which the U.S. government was left with thousands of lawsuits after assuming liability for a nation-wide inoculation program,¹⁹² it has yet to adopt strict government liability. Similarly, the Supreme Court of Canada in *Lapierre v. Attorney-General of Quebec*¹⁹³ rejected the plaintiff's arguments for strict liability of government for the adverse consequences of immunization programs funded and supported by it. In contrast, the vaccine manufacturers argued against the doctrine of strict liability by pointing out that the product was so inherently beneficial and the incidence of problems so low that public interest demanded that the manufacturers be free from liability.¹⁹⁴

In the U.S., this rise in litigation combined with the doctrine of strict liability and a pro-plaintiff approach by the Court's guided by "deep-pockets" law,¹⁹⁵ resulted in what has been termed a "liability crisis" whereby the supply of critically needed vaccines is threatened because manufacturers can no longer afford to invest in vaccines in the face of costly lawsuits and settlements.¹⁹⁶ In response, vaccine manufacturer's dramatically raised the price of vaccines or were forced to leave the market entirely, which in turn threatened the supply of vaccines.¹⁹⁷

2. Other Means of Compensation — the Question of Burden

Other options for vaccine-injured children are few and far between, and are not adequately tailored to meet the needs of these unique victims. One possibility for compensation is through private first party life and disability insurance. Although increasingly common, these schemes are mainly devised for adults and provide no coverage for childhood vaccine injuries.¹⁹⁸ In addition, a large propor-

¹⁹⁰ *Graham*, *supra* note 148.

¹⁹¹ *Supra* note 72 at 354.

¹⁹² M. Brody, *Immunization Dice* (New York: Priority Press Publications, 1987) at 4.

¹⁹³ *Lapierre v. Attorney-General of Quebec*, [1985] 1 S.C.R. 241.

¹⁹⁴ *Shackil*, *supra* note 181.

¹⁹⁵ "Deep-pockets" law refers to a Court finding liability against whichever Defendant is perceived to have the "deepest pockets", or unlimited funds.

¹⁹⁶ See generally *supra* note 192 at 1-6. See also *infra* note 199 at 1035.

¹⁹⁷ *Supra* note 192.

¹⁹⁸ Manitoba Law Reform Commission, *supra* note 36 at 14.

tion of the population will not be able to afford this protection. As it is often this segment of society that is most at risk of succumbing to the dangers of vaccines unaware, this clearly is not a viable option. Furthermore, on a philosophical level, one might question the justifiability of a system whereby an individual incurs an unavoidable risk for the benefit of society, but who is expected to further incur the economical burden if injured in the process.

Ultimately, someone is going to have to incur the cost of compensating victims of vaccinations. If it is to be the manufacturer, the result is the so-called "liability crisis" discussed above, whereby the supply of critically needed vaccines is threatened because manufacturers can no longer afford to invest in vaccines in the face of costly lawsuits and settlements. If the individual is to incur the cost, a valuable system will continue to erode as individual rights continue to be balanced against the public interest and the result may threaten public health in the long run. The final and most logical option is to place the burden on the public itself. If society expects to reap the benefits of an immunization program, it must be prepared to compensate those few that are harmed in the process.¹⁹⁹ It is arguably a small price to pay in ensuring a sustainable system of vaccine innovation and production, public health and government responsibility.

Currently in Canada, sources of compensation available through the government include social welfare programs such as Employment Insurance, Canada Pension Plan and some provincial no-fault plans such as the Manitoba Personal Injury Protection Plan, Worker's Compensation plans and Criminal Injuries Compensation plans. As well, there are federal contributions to health services insurance, tax provisions allowing deductions for the expenses of disabled individuals and finally, provincial social allowance programs.²⁰⁰ However, each plan is specific to a particular circumstance and a vaccine-related injury may or may not qualify. As well, most apply only to adults or would function only to alleviate the economic burden of the parent providing for the injured child and would provide no recompense to the victim herself. Finally, the nature of the circumstances in which a vaccine injury arises is unlike any other in that it is not the result of an unfortunate accident or even by the fault of another, rather it comes as a result of an unavoidable risk inherent in the act of immunization, which benefits both the individual and the public. Thus, from a moral standpoint, society has a responsibility to develop a compensation scheme that will specifically meet

¹⁹⁹The Honourable Mr Justice Horace Krever in the Commission of Inquiry on the Blood System in Canada made a similar argument in recommending a no-fault compensation scheme for blood-associated injuries: "Although the risks to the users of blood components and blood products today may be low, serious disease and some deaths will continue to occur as a result of the therapeutic use of blood...A system that knows that these consequences will occur and what brings them about has, at the very least, a moral obligation to give some thought to the question of appropriate relief for those affected by the inevitable events.": Canada, *Final Report of the Commission of Inquiry on the Blood System in Canada*, vol. 3 (Ottawa: Canadian Government Publishing, 1997) at 1029 [Krever].

²⁰⁰Manitoba Law Reform Commission, *supra* note 36 at 13.

the needs of the victims of vaccines. Thus, the underlying rationale should not only be compensation but also recognition of the victim's human dignity and worth in relation to the rest of society.

This concept of societal responsibility for the victims of immunization has been endorsed by Canadian Courts for over two decades. Linden J. in *Davidson v. Connaught Laboratories*,²⁰¹ notwithstanding the plaintiff's unfavourable outcome in the case, advocated for government consideration of a compensation scheme for those individuals injured by vaccinations in the absence of fault. Other proponents of the idea of placing the burden of compensation on society argue that, regardless of cause or fault, every individual injured by a vaccine should be compensated to the exclusion of any civil tort claim.²⁰² Finally, in the Quebec case of *Lapierre*²⁰³ in which a four-year-old girl contracted viral encephalitis after a measles vaccination and was left permanently disabled, the lower Court granted the child damages based on the no-fault liability of the State, Section 1057 of the Civil Code.²⁰⁴ However, the Québec Court of Appeal reversed this decision²⁰⁵ and the Supreme Court of Canada similarly rejected arguments advocating strict liability of the government.²⁰⁶ Notwithstanding this decision, it was still recognized by the Quebec government that a child injured as a consequence of a vaccination was entitled to be compensated by society, and the province of Quebec implemented the first and only no-fault compensation scheme for victims of immunizations in Canada to date.

VI. The Solution: a No-fault Vaccine-related Injury Compensation Scheme

Several jurisdictions around the world²⁰⁷ have introduced national compensatory initiatives to specifically address vaccine-related injury and illness. The justification, however, is based on the fact that most have mandatory vaccination programs. Notwithstanding that in Canada there is no mandatory vaccination program, as argued *supra* the immunization system in place is so institutionalized and the pressures so great as to create in effect a scheme of mandatory vaccination. Furthermore, there are other special circumstances in which mandatory vaccinations may arise and where a compensation scheme would be relevant, for example,

²⁰¹ *Supra* note 174.

²⁰² Medico-Legal Society of Toronto submission to Prichard Commission on Health Care Liability Cost Issues (24 November 1988).

²⁰³ *Supra* note 193.

²⁰⁴ F. Campeau, "Children's Right to Health under Quebec Civil Law" in B.M. Knoppers, ed., *Canadian Child Health Law: Health Rights and Risks of Children* (Toronto: Thompson Educational Publishing, Inc., 1992) 209 at 216.

²⁰⁵ *Supra* note 193.

²⁰⁶ See *supra* note 193 and associated text.

²⁰⁷ Distinct no-fault compensation schemes have been implemented since as early as 1961 and currently exist in Germany, France, Japan, Switzerland, Denmark, New Zealand, Sweden, the United Kingdom, the United States, Taiwan, Italy, and Norway and Quebec (See Table, Manitoba Law Reform Commission, *supra* note 36 at 58).

in response to a perceived threat of bioterrorism, for health care professionals and in the educational system. Again, the government must first recognize how the system actually operates to understand the rationale and imperative behind a publicly funded compensation scheme.

In summary, some of the major features of these compensation schemes are as follows:²⁰⁸

- a) *Administration*: all programs are overseen at the national level with some legislated and administrated at the state level.
- b) *Immunization Scheme and Vaccines Covered*: where vaccines are mandatory or where vaccines are routinely administered, they are covered by the compensation schemes. Where vaccines are not compulsory, those that are recommended are covered. In Sweden, all products marketed by the Pharmaceutical Insurance Association and all vaccines used in clinical trials are covered.
- c) *Claim Filing Deadlines*: deadlines range from none to within one, three or six years of injury (or in some cases from the time of vaccination) with some limitation periods, and other requirements if death ensues.
- d) *Compensable Injuries*: range from all injuries caused by vaccines, to those injuries exceeding normal and usual reactions to only rare and severe injuries or death. Various methods are used to assess severity or compensability including percent disability scales, vaccine injury tables or medical literature.
- e) *Standard of Proof*: where it is specified, the majority of the schemes require proof on a balance of probabilities or reasonable and/or probable cause. Only one jurisdiction (France) requires clear and convincing evidence.
- f) *Scope of Compensation*: very few provide a lump sum and most include medical costs, a disability pension, death benefits and funeral expenses. Very few allow for non-economic damages or lost wages.
- g) *Funding Source*: the majority compensate through the national treasury, some being divided among local and even municipal jurisdictions. Others have created a fund that is paid into by manufacturers and/or society (employers, wage earners, auto licensing etc.) through an excise tax.

²⁰⁸ See generally Appendix D, Manitoba Law Reform Commission, *supra* note 36 at 58.

- h) *Appeal Rights*: all jurisdictions with the exception of Norway allow the right to appeal a decision of a claim.
- i) *Litigation Rights*: the majority allow a victim to further litigate their claim, but half of these place limits on that right. Few deny the right to litigate if a claim is awarded under the scheme.

In developing a comprehensive vaccine-related injury compensation scheme, it is useful to compare existing schemes in an effort to evaluate the aspects that work and those aspects that need improvement. In the Canadian context, an assessment of the Quebec scheme in relation to the comprehensive scheme in the U.S. will provide a template for devising a sustainable national scheme for Canada.

1. Summary and Critique of the Scheme in Quebec

As mentioned above, the vaccine compensation scheme in Quebec arose after the *Lapierre* case in response to the fact that the tort system had been historically rigid in awarding damages to victims of vaccinations. It was enacted in 1985 as an amendment to the *Public Health Protection Act* entitled Division III.1 Indemnities for Victims of Immunizations.²⁰⁹ This plan compensates claimants who have suffered grave and permanent mental or physical damage caused by a vaccine, or by a disease caused by an immunized person or as a result of being a foetus of an immunized person; the claimant must prove that the harm can be causally linked to the vaccine on a balance of probabilities.

The source of compensation is through the consolidated revenue fund of the Province of Quebec.²¹⁰ The quantum of compensation is based on principles in the Quebec no-fault automobile insurance plan²¹¹ and includes income replacement, compensation for physical disability, future care costs, rehabilitation expenses and death benefits to family.²¹² Claims must be brought within three years of the date of the vaccination or for latent effects, within three years of the onset of symptoms. Finally, a claimant maintains the right to sue civilly but must reimburse any benefits that were paid out through the no-fault scheme.

The no-fault scheme in Quebec represents an efficient and relatively uncomplicated compensation model. Its main advantage comes from the fact that it “piggy-backs” on an already existing no-fault scheme so many administrative and procedural barriers that would arise in establishing a completely new system can be immediately avoided. The scheme is also broader than many others, in that it allows for compensation of any child, adult or foetus i.e. through the vaccination of the mother, injured by a vaccine either directly or indirectly. Unfortunately, the

²⁰⁹ *Public Health Protection Act*, R.S.Q. c. P-35.

²¹⁰ Manitoba Law Reform Commission, *supra* note 36 at 21.

²¹¹ *Automobile Insurance Act*, R.S.Q. c. A-25.

²¹² Manitoba Law Reform Commission, *supra* note 36 at 19.

effectiveness of the program in practice, at least from the perspective of rejected and potential claimants, is doubtful. The program's greatest weakness stems from the fact that the causation requirement has resulted in the same phenomenon as in the tort system — very few victims are able to meet the burden of proof when it comes to vaccine injuries. For example, since its inception, only 20 claimants of 117 in a 15-year period have been compensated under this scheme, the average pay out being \$135,000.²¹³ This translates to a success rate of roughly 17% and the payout seems meagre. The bright side is that a claimant is not barred from bringing a claim to court, thus any compensation received may be an immediate temporary relief for those individuals who wish to litigate but cannot afford to rely on the uncertain outcome of a lengthy and costly trial to fund the immediate needs of their vaccine-damaged child.

2. Summary and Critique of the Scheme in the U.S.

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. Interestingly and in complete contrast to the Canadian context, it arose in response to the so-called “liability crisis” that threatened the vaccine supply in the early 1980s (see discussion above). The *National Childhood Vaccine Injury Act*,²¹⁴ enacted in 1986, created the Vaccine Injury Compensation Program (VICP), a federal no-fault scheme whereby a child injured by a routinely administered vaccine may receive compensation. Although the scheme is narrower in that it is 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.

Furthermore, the burden of causation that is placed on the claimant in the Quebec scheme and in the tort system is alleviated somewhat in the VICP through the implementation of a Table of Injuries and the Qualifications and Aids to Interpretation.²¹⁵ The Table and Aids list all of the compensable injuries and respective time frames for their occurrence for each vaccine that is mandated before entry to school. If a claimant's injury is listed in the Table and occurs within the prescribed time, a presumption of causation arises. The onus of proof then shifts to the government to show that there is another likely intervening cause of the injury unrelated to the vaccine. If a claimant's injury falls out of the scope of the Table and Aids, they are not excluded from claiming but must show “a logical sequence of cause and effect supported by a reputable medical or scientific explanation that the vaccine was the reason for the injury.”²¹⁶ As well, a claim for a vaccine aggravating an existing condition can, if proven, be compensated for.

²¹³ *Ibid.* at 21.

²¹⁴ *National Childhood Vaccine Injury Act*, 42 U.S.C. §§ 300aa-1 to 33 (1986).

²¹⁵ Hereinafter referred to as the *Table* and *Aids*.

²¹⁶ *Grant v. Secretary HHS*, 956 F.2d. 1144 (Fed.Cir. 1992).

Funding for the VICP comes directly from vaccine manufacturers paid as a flat-rate excise tax²¹⁷ on every dose of childhood vaccine sold. Currently, the Vaccine Injury Compensation Trust Fund (Trust Fund) is at a surplus balance of \$1.8 billion.²¹⁸ In roughly a 15-year period since its inception, there have been 5,335 claims and 1,390 successful claimants,²¹⁹ thus resulting in a success rate of approximately 25%. In contrast to the payouts in the Quebec scheme, the average award in 1999 was \$1.4 million with awards as high as \$8 million.²²⁰

A final point to mention is that claimant's right to sue a manufacturer is severely limited if, after filing a claim with the VICP, they are rejected or reject the award offered. The claimant in this scenario is only able to sue for fraud, misrepresentation, or other criminal or illegal activity on the part of the manufacturer in relation to the vaccine and is barred from asserting breach of the duty to warn. This is because the statute creates a presumption²²¹ that the vaccine included all proper warnings if the manufacturer can show that it complied with the necessary requirements under the *Federal Food, Drug, and Cosmetic Act*.

Although there are some obvious advantages to the VICP that can be incorporated into a national Canadian scheme, there are several criticisms that must be addressed. First, compensation under the VICP is only available to children, and proposed amendments seek to further exclude vaccine-damaged children where genetic factors played a role in vaccine reactions.²²² Regardless of the underlying cause-in-fact of the injury, if the vaccine is a factor in setting off a predispositive condition, it is nonetheless a causative factor. The Quebec scheme is broader in recognizing instances when a vaccine has aggravated a pre-existing condition. Furthermore, there is no rationale for excluding an adult from a compensation scheme since the purpose of such a scheme is to compensate those individuals that have placed themselves at risk for the benefit of society. As was argued *supra*, the informed consent process, even with respect to adults may not occur in reality. Similarly, where adults are subject to forced immunization, such as U.S. military personnel²²³ or health care workers, or when faced with an

²¹⁷ Initially, the excise tax was assessed on the basis of the degree of risk associated with each vaccine but in 1997, a flat-rate of 75¢ per dose was introduced (Manitoba Law Reform Commission, *supra* note 36 at 25).

²¹⁸ ACCV Minutes, *supra* note 23.

²¹⁹ See Table, Manitoba Law Reform Commission, *supra* note 36 at 58.

²²⁰ Manitoba Law Reform Commission, *supra* note 36 at 26.

²²¹ *Supra* note 214 at §§ 300aa-22(b).

²²² B.L. Fisher, "Compensating Vaccine Injuries: Are Reforms Needed?" (Statement of the National Vaccine Information Centre, Hearing of the House Subcommittee on Criminal Justice: Drug Policy and Human Resources, 28 September 1999) [unpublished], online: National Vaccine Information Centre <<http://www.909shot.com/>>. (last modified: 2 December 2002)

²²³ See generally R.L. Scott, "Is Compulsory Vaccination Compatible with Informed Consent?" (2000) Health Law Perspectives, online: Health Law & Policy Institute Homepage <<http://www.law.uh.edu/healthlawperspectives/Bioethics/homepage.html>> (last modified: 25 February 2000). Note that in Canada, a military personnel who refuses to submit to an immunization procedure on order and without "reasonable excuse" is guilty of an offence and liable to imprisonment for less than

emergency threat of bioterrorism or an epidemic, the rationale of compensating adults is even stronger.

Second, the system has been criticized on the basis of its low success rate. The 75% denial of compensation rate, combined with the \$1.8 billion surplus in the Trust Fund, suggests a grave problem in the operation of the VICP. Of course, this criticism assumes a causal relationship between the injuries and vaccines in those children denied compensation. Assuming denial is based for the most part in these cases on a lack of proof of causation (i.e. the injury falls outside of those listed in the Table), there exists another identified system problem: the broad discretionary power of the Department of Health and Human Services (DHHS) to add or remove vaccines and related injuries from the Table. It has been argued that the intent of the legislature in granting this broad discretion was to enable additions to be made to the Table as more and more scientific evidence is accumulated.²²⁴ Furthermore, the Table was compiled after an extensive review of the medical literature and after years of discussion amongst experts and manufacturers and was designed to alleviate the burden of proof on the claimant.²²⁵ Instead, DHHS has single-handedly restricted the definition of encephalopathy and has removed several compensable injuries despite their acceptance by the medical community.²²⁶ The result has been fewer successful victims because once again, they are faced with a high burden of proof and limited litigation rights.

This discretionary power has further contributed to the increasingly adversarial nature of the system, the third main critique of the VICP. The system has been described as adversarial due to increased tensions between lawyers for the claimants and government lawyers, with both sides fighting so hard that it has elevated the system to the level of a Court.²²⁷ The system, which was originally devised as a form of alternative dispute resolution, has instead become a mere “microcosm of the system it had hoped to replace.”²²⁸ Even though both sides may be equally to blame for this, the claimant and her lawyers are nonetheless on an uneven playing field: government lawyers are full-time employees paid a regular salary — claimants do not receive any reimbursement until the ordeal has ended;²²⁹ government lawyers have unlimited funds and access to resources and thus can

two years pursuant to s. 126 of the *National Defence Act*, R.S. 1985, c. N-5. In *R. v. Kipling*, [2002] C.M.A.J. No. 1, the respondent, a member of the Armed Forces since 1973, had refused anthrax vaccination while en route to Kuwait and was deployed to Canada shortly thereafter. On his return, he was charged pursuant to s. 126. The military judge ultimately stayed the charge by finding that the anthrax vaccine was unsafe and hazardous. On appeal, Strayer C.J.C.M.A.C. overturned the stay and ordered a new trial on the basis that the military judge’s finding that to order, in good faith and with reasonable care, the administration of a vaccine that in future might be found by some court on a balance of probabilities to be unsafe was wrong in law.

²²⁴ *Supra* note 222.

²²⁵ *Ibid.*

²²⁶ *Ibid.*

²²⁷ *Supra* note 72 at 362.

²²⁸ *Ibid.*

²²⁹ *Supra* note 222.

recruit the best experts — claimants pay their experts out of their own pockets and miscellaneous expenses may be as high as \$10,000.²³⁰ In turn, the system has become costly and lengthy for claimants. Waiting periods have been reported from three to up to seven years; since a claimant must incur all related expenses throughout that time and will not be reimbursed until after the claim has been settled, one wonders how any victim could afford to go through the system.

A final policy-based criticism of the VICP is that in limiting manufacturer liability it emphasizes the protection of the manufacturer over the rights of the victim. This is further evident when the DHHS too hastily adds a new vaccine to the compensation program in the absence of adequate scientific knowledge; the program then appears to exist only to protect manufacturers from liability for products whose risks have not been thoroughly quantified prior to licensure.²³¹ An added danger is that the addition of such vaccines creates the illusion in the public's mind that conclusive knowledge does exist with respect to specific vaccine-related injuries where often it does not.²³²

3. Developing a No-Fault Vaccine-Related Injury Compensation Scheme in Canada

A review of the advantages and disadvantages of both the Quebec and U.S. schemes provides a useful starting point in developing a national scheme in Canada. It must be remembered as well that the rationale underlying the U.S. scheme arose from very different circumstances, and thus aspects of the U.S. scheme may not be relevant in the Canadian context. In general, a no-fault vaccine compensation program should include the following elements:²³³ (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. The following is a discussion of some of the considerations involved in developing a compensation scheme in Canada and is not an attempt to set out in full a proposed scheme.

(i) The vaccines to be covered

As in Quebec, the scheme should cover all children under the age of majority for all vaccines administered as a part of a routine immunization program as well as all adults who are injured as a result of a vaccination. As argued *supra*, there is no clear rationale for excluding an adult from compensation for an act that is undertaken that serves to benefit society on the whole notwithstanding the informed consent process, which is a process only in theory and one that is unreliable in

²³⁰ *Supra* note 72 at 362.

²³¹ *Supra* note 214 at §§ 300aa-22(b).

²³² *Ibid.*

²³³ *Supra* note 13 at 3.

practice. If adults who freely consent shall be excluded, then an exception should be made for those adults who are required by law or otherwise to be immunized.

(ii) The compensable injuries

The Table and Aids used in the VICP is an ideal mechanism in theory since it can function 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. To work in practice, the table of injuries should be carefully designed in consultation with medical experts and manufacturers and after a careful review of the scientific evidence. A panel of experts or consultants should review the table on a regular basis and any amendments to such table should be approved first by the panel. The Bureau of Infectious Diseases of the Population and Public Health Branch of Health Canada has already in place a National Advisory Committee on Immunization (NACI) that is comprised of recognized medical experts and federal and public servants. The NACI could serve the purpose of reviewing and approving a table of injuries, however, there should be appointed to this Board members of the general public who can represent special interest groups.

A presumption of causation shall arise if an injury falls within the table, and if not, the standard of causation should remain at a minimum. If the cause and effect is arguably remote, the decision maker should adopt a pro-claimant attitude to find a link in the absence of any clear evidence indicating a more likely intervening cause of the injury. In these instances, there should be discretion as to what damages are awarded so that if causation is truly questionable, the award could reflect this. Since Canada has a publicly insured health care system in place, medical care for minor adverse reactions to vaccines should be sufficiently covered. Thus, the table of injuries could be limited to those more serious and permanent adverse reactions.

Finally, there should be no limitation period preventing a claim, at least for latent injuries that can be causally linked to the vaccine. Obviously, injuries prescribed in the table will have specific on-set periods so any latent injury that exists will fall outside of the table and will require proof of a causal link. This will be difficult for latent injuries so there can be no floodgate argument that will necessitate limiting latent claims. Furthermore, clinical trials of vaccines and other drugs do not include long-term studies, thus, the availability of compensation in the event a long-term injury is suffered as a result of a vaccine, is justified. It would be irresponsible for a compensation scheme that has as its rationale the protection of society's victims, to prevent their compensation if 20 years later, medical science proves a link between a vaccine and a serious medical disorder.

(iii) The kinds of compensation

Compensation should include reimbursement of all medical expenses incurred outside of publicly insured health care services, including rehabilitation and counselling to some reasonably set limit. Comprehensive awards should be calculated on accepted tort principles and should include future care costs and loss of

income paid out in an annuity as in the VICP.²³⁴ As well, some award should be available on non-pecuniary grounds but may be limited. Furthermore, disbursements should be paid out within a set time limit in the event the claim has been delayed. Any awards that a claimant receives through other social service, insurance programs or as awarded in a civil suit, should be disclosed and the program should be entitled to reimbursement.

(iv) The administrative mechanisms

The source of funding is appropriately accumulated through an excise tax paid by the manufacturer on each dose of vaccine sold. As the Trust Fund through the VICP has demonstrated, this mechanism is adequate in raising the necessary funds to compensate the victims of immunizations. Furthermore, in Canada where the "liability crisis" is not an issue, manufacturers are not threatened by litigation for vaccine-related injuries so the concept of an excise tax would be reasonable. The government should also be partly responsible in providing a proportion of the compensation through general revenues to reflect the benefit of mass immunization to society overall. The provision of medical care through the public health care system is one example of this responsibility realized.

(v) The relationship with existing compensation programs

As outlined *supra*, the public health care system in place in Canada is adequate to cover most of the associated health care costs that may accrue in a vaccine-related injury. As well, to the extent that a victim is compensated through other programs, the scheme should be entitled to reimbursement. Finally, with respect to civil litigation rights, 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 litigation climate in Canada has never reached the state of crisis as in the U.S. and it is unlikely to occur in the future. This concern would be further alleviated if a comprehensive compensation system were in place that could adequately meet the needs of those individuals injured through immunization.

VII. Conclusion

The sustainability of a viable immunization system requires a thorough assessment of the associated benefits and risks on both theoretical and practical grounds. To summarize, the benefits of wide-scale immunization programs include prompt eradication of harmful diseases, thereby improving public health, enabling the government to fulfill its directive to ensure the health and well-being of Canadians through reduced death and suffering, creation of "herd immunity" to protect those individuals who are unable to receive vaccines for medical reasons, enormous savings to the public health care system, creation of a market incentive

²³⁴Manitoba Law Reform Commission, *supra* note 36 at 24.

for manufacturers to develop and produce vaccines, and increased productivity of the population.

In comparison, the risks inherent in Canadian immunization programs consist of both unavoidable risks associated with the nature of vaccine products, namely that there are occasions of serious adverse events following immunizations among a significant number of children each year, and the inherent "system risks" that exist in the administration and operation of the immunization system in practice. These "system risks", including government promotion and support by way of accessible programs and funding for vaccines, legislation indirectly creating compulsory immunization for school children, overemphasis of benefits with little or no attention placed on medical risks, a lack of an endorsed informed consent process for immunizations, underlying utilitarian principles, and a lack of adequate compensation for the victims of vaccines all combine to create a coercive and practically compulsory immunization scheme that has resulted in growing fear and mistrust among the public.

The need for an adequate system of compensation for the victims of vaccines is integral to a public system of immunization and is a matter of public and governmental responsibility. Such a system would serve to demonstrate the government's recognition of the individual dignity and worth of societies' youngest soldiers in the war against disease, thereby ensuring government accountability and increasing public trust. But more importantly, adequate compensation must be guaranteed when a child suffers harm through an imposed medical intervention to which she did not consent so that she may obtain the necessary medical and rehabilitative care, adequate living expense support and compensation for pain and suffering. Current modes of compensation in Canada are insufficient to meet these needs.

The tort system has historically rejected claims of vaccine-related injuries for lack of establishment of a causal link between vaccine and injury. There remain several causation problems specific to vaccines that raise the burden of proof to an unattainable level, thereby effectively barring such claims. Furthermore, other possible routes of compensation such as first party private insurance and government social programs are not specific enough to deal with the unique nature of vaccine-related injuries. The proposed alternative argued in this paper is a no-fault compensation scheme similar to those that have been established in several jurisdictions worldwide including the United States and Quebec.

A comparison of the schemes in these jurisdictions reveals that there are several common features that must be considered in developing a vaccine-related injury compensation scheme. These include *inter alia* how the scheme would be administrated and by whom, the vaccines to be covered, the compensable injuries, the scope of the compensation, how to fund it and whether or not to limit litigation rights. In devising a scheme specific to Canada, the U.S. and Quebec versions could serve as a useful template, taking the features that work best in each and improving on or avoiding any problems that exist. However, this scheme must be tailored to emphasize the unique Canadian context in which it will operate and will necessarily

be different from the U.S. scheme that has as its rationale a very different incentive, namely to avoid a liability crisis. A Canadian scheme should have as its underlying rationale first, the compensation of victims of the immunization system and second, the recognition of the human dignity and value of each and every individual who has put their own personal well-being on the line for the benefit of society.