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Liability and Compensation Aspects of Immunization Injury: A Call for Reform

LIABILITY AND COMPENSATION ASPECTS OF IMMUNIZATION INJURY: A CALL FOR REFORM

By WILLIAM K. McINTOSH*

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I. INTRODUCTION

It is generally accepted that immunization is one of society's most valuable weapons for combatting communicable diseases. Health authorities exhort the public to participate in immunization programmes. Nearly all the American states have legislation making immunization a mandatory condition for school entry.¹ Compulsory vaccination is seen as an extreme emergency measure in Canada,² but there is little doubt that Canadian public health planners, administrators and practitioners are firmly committed to mass immunization.³

It must be recognized that vaccination is far from a panacea for the control of contagious disease. Dr. Frank White, a respected Canadian epidemiologist, cautions:

The potential hazards of immunization are numerous and include a variety of possibilities: simple reactions (such as local pain or swelling at the site of injection), problems associated with faulty production (such as abnormal toxicity or injectivity, and microbial contamination), faulty administration (such as the use of non-sterile apparatus, or contamination by the vaccination), individual susceptibility (such as various allergic manifestations, from local allergy to anaphylactic shock), damage to the foetus (such as may occur with smallpox vaccination), and the provocation of disease.⁴

Mass immunization programmes have contributed enormously to the suppression and virtual eradication of some once dreaded diseases. Poliomyelitis paralyzed 10,000 Canadians in the 1950's. Polio vaccination was implemented in this country in 1955, and has been a staple element of government supported immunization programmes ever since. In the 1970's there were less than fifty known cases of polio in Canada.⁵ These great gains against poliomyelitis over the past three decades have been attributed largely to vaccination.⁶

Until recently, the magnitude of the benefits of the use of vaccines to fight polio and other major communicable diseases made consideration of the

¹ E.g., *Health and Safety Code*, 39 West's Cal. Code Ann., §3381 (1977):

The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, or development center, unless prior to his or her first admission to the institution he or she has been fully immunized against diphtheria, pertussis (whooping cough), tetanus, poliomyelitis, and measles in the manner and with immunizing agents approved by the state department.

Public Health Law, 44 McKinney's Consol. Laws N.Y. Ann., §2164 (1966):

No principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school without the certificate provided for in subdivision 5 . . . or some other acceptable evidence of the child's immunization against poliomyelitis, mumps, measles, diphtheria and rubella.

² See *Public Health Act*, R.S.M. 1970, c. P-210, s. 18(d).

³ White, *Immunization and Other Measures in Control of Communicable Diseases: Some Ethical Considerations* (Ottawa: Second National Conference on Health and the Law, 1979) at 4.

⁴ *Id.*

⁵ *Id.* at 5.

⁶ Oral polio sabin vaccine, in common use since 1961, has been associated with paralysis, at a risk level estimated to be in the order of 1 in 5 million doses. *Id.* at 4.

risks and costs implicit in vaccination almost irrelevant. The dangers and costs associated with large scale use of vaccines, however, gain prominence as the likelihood of outbreak of the diseases being combatted declines.

It is important to understand that all vaccines, including those properly manufactured and administered, are capable of producing adverse reactions. In a recent study of vaccine-related injuries, the U.S. Office of Technology Assessment states that while most adverse reactions are mild and self-limiting,

[A] few vaccinees do experience severe adverse reactions that result in permanent disability or death. While such reactions are rare, many are unavoidable, i.e. they are caused, not by a defective vaccine product or negligence on the part of the vaccinator, but by the inherent properties of a particular vaccine.⁷

The central thesis of this article is that the law governing the compensation of victims of immunization injury in both Canada and the United States fails to recognize the fundamentally public nature of the immunization process. In the context of massive public commitment to immunization as a tool for controlling communicable disease—evidenced *inter alia* by government administered mass immunization programmes and widespread vaccination of children through the school systems—it is fallacious to regard the vaccinee's decision to submit to immunization as a purely private matter.

The premise that immunization is a matter of private decision and responsibility has led to reliance on the judicial process as the mechanism for the compensation of immunization injury victims. This article seeks to demonstrate the serious and undesirable ramifications of that reliance for both injured vaccinees and public health policy.

Much of the discussion that follows is devoted to revealing the perverse complexity and uncertainty of the body of law faced by the injured vaccinee considering pursuit of compensation through the courts. Canadian legislation and jurisprudence is canvassed. The severe limitations and inadequacies of the fault allocation oriented judicial process as a compensation vehicle are discussed. Recent, extremely important developments in the United States are surveyed and analyzed. The contradiction and tension between private law and public health policy is examined and linked with the critical misconception of immunization as a private matter.

Finally, a plea is entered for prompt, serious consideration of alternatives to the current Canadian law, and to the law looming south of the border.

II. THE CANADIAN EXPERIENCE

In sharp contrast to the experience of the United States, Canada has relatively little jurisprudence or academic writing on the issue of immunization injury. Several factors could explain this phenomenon.

⁷ Office of Technology Assessment, "A Review: Legal Liability and Compensation for Vaccine-Related Injuries," in *A Review of Selected Federal Vaccine and Immunization Policies* (Washington: U.S. Congress, 1979) at 83 [hereinafter O.T.A.]. See also: Wilson, *The Hazards of Immunization*, Keith Clark Lectures, (London: U. of London, 1966).

First, since Canada's population is about one-tenth that of the United States, it is most likely that far fewer incidents of serious⁸ adverse reaction to immunization have occurred in this country. Second, examination of immunization related legislation suggests that to date Parliament and the legislatures have left unaddressed the problems of the responsibility for compensation of victims of immunization injury. Third, it is very likely that victims have been deterred from seeking compensation through litigation because of the highly uncertain prospect of recovery under the current law, and by the structural disincentives posed by our fault-oriented civil litigation process.

A. *Incidence of Immunization-Related Injury in Canada*

Solid statistics to quantify the incidence of serious adverse reactions to vaccinations in Canada are unavailable. The federal Bureau of Biologics collects reports of adverse reactions to vaccination,⁹ but the information obtained is of limited value. The sources of reports of suspected adverse reactions vary widely in their reliability. The Bureau is more interested in general patterns and trends than in the veracity of a particular report and, accordingly, encourages all interested parties, regardless of their professional training or interest, to submit reports.

Some interested parties might be tempted to construe the unavailability of conclusive statistics as indicating the absence or unimportance of the immunization injury problem in Canada. Such a construction would be unjustified. Epidemiologists in a number of provinces report cases involving communicable diseases that almost certainly were induced by vaccination.¹⁰ Law suits alleging serious injury and damage as a result of swine flu vaccination are outstanding.¹¹

In any event, to focus too narrowly on the difficulties of quantifying the immunization injury problem is to miss the real issue. Even advocates of major, structural reforms in the compensation of injured vaccinees freely concede that serious adverse reactions to immunization occur rarely.¹² For the injured parties, their families and friends, the cost of adverse reactions such as vaccine induced paralytic polio is extremely high.

It is not suggested that large numbers of people are harshly, inequitably

⁸ Minor inflammation, swelling and fever commonly accompany vaccination. The concern, of course, is with an adverse reaction of a far more serious and uncommon nature that results in serious injury.

⁹ Interview with Dr. D.C. Pope, Assistant Director, Bureau of Biologics, Drugs Directorate, Health Protection Branch, Health and Welfare Canada (February 22, 1980). Interview with Dr. Richard Mathias, former Director of the Division of Communicable Disease Control, Saskatchewan Health (February 22, 1980).

¹⁰ Interview with Dr. Frank White, former Director of Epidemiology and Communicable Disease Control, Alberta Social Services and Community Health (March 10, 1980).

¹¹ Interview with Anne H. Russell, Legislative Planner, Alberta Social Services and Community Health (March 10, 1980).

¹² Dept. of Health, Education and Welfare, *Liability Arising Out of Immunization Programs: Final Report to Congress* (Washington: D.H.E.W., 1978) at 14 [hereinafter D.H.E.W.].

treated by the current approach to compensation. Surely the argument for reform should not rest on such statistics. The Ontario Law Reform Commission makes this point in advocating the reform of the law of products liability:

The case for reform of the law of products liability does not rest on the assertion that there is a large number of cases in which persons injured by defective products wrongly go uncompensated. . . . the case for reform is, rather, that the present law contains serious anomalies. If anomalies and irrationalities in the structure of the law cause injustice in even a comparatively small number of cases, there is an argument for reforming the law and putting it on a more rational basis.¹³

B. *Review of Legislation*

1. Federal

While formal jurisdiction to legislate regarding matters of health is clearly held by the provinces under Section 92(7) of the *British North America Act, 1867*,¹⁴ the manufacture, packaging and sale of vaccines in Canada is governed federally by *The Food and Drugs Act*.¹⁵

The focus of *The Food and Drugs Act* is the protection of the public from the unsafe manufacture and misleading merchandising of food and drugs. Section 25(1) makes this orientation clear. The Governor in Council may make regulations regarding *inter alia*:

- b) . . . preventing the consumer or purchaser (of food, drugs, cosmetics and devices) from being deceived or misled as to its quantity, character, value, composition, merit or safety or to prevent injury to the health of the consumer or purchaser;
...
- e) respecting the method of preparation, manufacture, preserving, packing, storing and testing of any food, drug, cosmetic or service in the interest of, or for the prevention of injury to the health of the consumer or purchaser;
...
- m) adding anything to any of the schedules, in the interest of, or for the prevention of injury to, the health of the consumer or purchaser, or deleting anything therefrom;
...

The Food and Drug Regulations¹⁶ discharge the mandate laid down in section 25(1) by setting out manufacturing specifications, licensing requirements and terms and conditions for testing.

The federal authorities closely monitor vaccine use, and maintain a computerized information system for the collection and analysis of data indicating potential adverse reactions to vaccinations. As was noted above, the information is not amenable to overly close analysis. Officials look for dis-

¹³ Ont. L. Ref. Comm'n., *Report on Products Liability* (Toronto: Min. A.G., 1979) at 33 [hereinafter *Products Liability*].

¹⁴ 30 & 31 Vict., c. 3.

¹⁵ R.S.C. 1970, c. F-27 derives its constitutional validity from the federal criminal law power provided by s. 91(27) of the *British North America Act, 1867*, *id.* See Hogg, *Constitutional Law of Canada* (Toronto: Carswell, 1977) at 280-81.

¹⁶ 8 C.R.C. 1978, c. 870, Part C, Div. 4.

proportionate levels of incidence of immunization injury by comparing such things as geographic regions, vaccine lots,¹⁷ and time periods.¹⁸

The reliance by the federal authorities on this information system and the specifications in the Food and Drug Regulations "for the prevention of injury to the health of the purchaser or consumer"¹⁹ rests on the following premise: that serious adverse reaction to vaccination is caused by vaccine defect. To be fair, it must be stressed that officials are well aware of and are troubled by the fact that this approach fails to address the "inherent risk problem." With good reason, they consider themselves without mandate or resources to go further.

The Food and Drugs Act is directed at controlling the defective manufacture and misleading merchandising of food and drugs. Its focus is regulatory; the issue of compensation of persons injured through the use of vaccines or other drugs is completely ignored.

2. Provincial

While the provinces have communicable disease control provisions in their public health legislation and regulation, the compensation issue is unaddressed. Examination of the public health legislation of a number of provinces indicates that the general preoccupation is with the control of outbreaks of communicable diseases.

Ontario's main communicable disease provisions are in *The Public Health Act*.²⁰ Any number of outbreak-related matters are provided for: precautions against the spread of infection,²¹ isolation of confirmed and suspected carriers,²² entering and disinfecting public conveyances,²³ removal of persons from unsanitary dwellings,²⁴ and reporting requirements.²⁵ There is only one compensation provision and it deals with the outbreak context:

Upon evidence satisfactory to the Minister that a person is such a carrier and that he has been deprived of his means of livelihood by an order or direction of the medical officer of health, the Department may, out of any monies appropriated by the Legislature for the purposes of the Department, pay compensation to such person, the amount of which to be determined in the regulations.²⁶

The Public Health Acts of Manitoba,²⁷ Saskatchewan,²⁸ Alberta²⁹ and

¹⁷ Vaccines are manufactured and labelled in discrete batches termed "lots."

¹⁸ Interview with Dr. Napke, Bureau of Epidemiology, Health Protection Branch, Health and Welfare Canada (February 22, 1980).

¹⁹ *The Food and Drugs Act*, R.S.C. 1970, c. F-27, s. 25(1)(e).

²⁰ R.S.O. 1970, c. 377, ss. 60-84.

²¹ *Id.*, s. 65(1).

²² *Id.*, s. 68.

²³ *Id.*, s. 75.

²⁴ *Id.*

²⁵ *Id.*, s. 64(1).

²⁶ *Id.*, s. 70(4).

²⁷ *The Public Health Act*, R.S.M. 1970, c. P-210.

²⁸ *The Public Health Act*, R.S.S. 1978, c. P-37.

²⁹ *The Public Health Act*, R.S.A. 1970, c. 294.

British Columbia³⁰ contain similar communicable disease provisions. Each Act deals with a good number of outbreak-related matters but leaves the problem of compensating victims of immunization related injury unaddressed.

C. *Review of Canadian Jurisprudence*

This review is not intended to be a formal examination of the various strands of common law doctrine that might be shown to touch on the immunization injury problem. The purpose is to substantiate the claim made earlier that in Canada the judicial process has demonstrated itself to be ill-suited as a vehicle for dispensing immunization injury compensation.

Reported Canadian cases involving immunization questions are completely unhelpful. The facts and points of law raised in these cases fairly reflect the legislative perspective. The focus of the litigation has been on the rights and duties of parties in the context of imminent, suspected or actual outbreak of communicable diseases.³¹ It seems that there are no reported Canadian court decisions dealing directly with the issue of immunization related injury.

It would seem that a victim of immunization injury seeking to impose liability on someone for the damages he has suffered must proceed somewhat obliquely. Two broad legal avenues are open to the potential plaintiff: (a) the absence of informed consent, and (b) products liability. These are not the only approaches to the problem,³² but even this breakdown should more than adequately demonstrate the confusion and uncertainty marking the injured vaccinee's legal position.

1. *Informed Consent*

Two legal truisms are that: (a) generally a patient must consent to medical treatment, and (b) the patient's consent must be informed. These truisms, like so many others, lose a good deal of their simplicity in their application to facts.

According to Professor Picard, the term "informed consent" emerged in the United States in the 1960's.³³ Picard and others³⁴ agree that much confu-

³⁰ *The Health Act*, R.S.B.C. 1960, c. 170.

³¹ See, e.g., *Mills v. City of Vancouver* (1908), 10 B.C.R. 99 (B.C.S.C.). The Court held that the good faith retention by the City of Vancouver of a party believed to be a carrier of smallpox but in fact infected with measles was sustainable by regulations under *The Public Health Act*. See also *R. v. Ritchie* (1902), 35 N.B.R. 581 (C.A.); *Yarwood v. Smith's Falls Bd. of Educ.* (1922), 23 O.W.N. 38.

³² Rozovsky, *Immunization and Its Legal Problems* (Ottawa: Second Conference on Health and the Law, 1979). Rozovsky, *Report of the National Immunization Policy Committee* (unpublished paper prepared pursuant to a contract with the National Immunization Policy Committee) [hereinafter *Report*]. Rozovsky breaks down the legal issues regarding immunization injury into: (a) negligence, (b) products liability and (c) consent.

³³ See Picard, "The Tempest of Informed Consent," in Klar, ed., *Studies in Canadian Tort Law* (Toronto: Butterworths, 1977) 129 at 130.

³⁴ E.g., Plante, *An Analysis of "Informed Consent"* (1968), 36 Fordham L. Rev. 639.

sion has resulted. "Courts have vacillated on the proper basis for a suit where the consent was not informed, on the scope of information the doctor must provide, and on the materiality of the information to the plaintiff."³⁵

While the term "informed consent" may not have been coined until the 1960's, the underlying concept has long been part of Canadian law.³⁶ For many years courts in this country have regarded inadequate consent to medical treatment as grounding liability in two distinct lines of cases: (a) in battery,³⁷ and (b) in negligence.³⁸ The two actions are very different in law. Battery involves the intentional application of force on the body of another without consent.³⁹ Intention plays no part in the law of negligence. The essence of negligence has been described as "certain conduct that falls below the standard required by society."⁴⁰ Rozovsky points out a number of significant distinctions between suits in battery and in negligence; including differences in limitation periods, matters of proof, insurance implications and admissibility of evidence.⁴¹ Taking the admissibility question as an example, "if an action is categorized as assault and battery, medical treatment testimony may not be permitted to illustrate acceptable medical practice since the standard with which the procedure was performed becomes irrelevant."⁴²

A strong judicial warning regarding the implications of a plaintiff's decision to plead in battery rather than negligence is presented by Morden J. in *Kelly v. Hazlett*:

How the case is pleaded in many cases is more than a matter of mere academic interest. It will have important bearing on such matters as the incidence of the onus of proof, causation, and the importance of expert medical evidence, the significance of medical judgment, proof of damage and, most important, of course, the substantive basis upon which liability may be found.⁴³

Kelly v. Hazlett, a much discussed and maligned decision of the Ontario High Court, is an attempt to clear up the confusion as to the proper meaning of informed consent in battery and in negligence. Morden J. attempts to tie together the battery and negligence approaches to informed consent. His view is that while informed consent is relevant in both battery and negligence, in

³⁵ Picard, *supra* note 33.

³⁶ See *Marshall v. Curry*, [1933] 3 D.L.R. 260, 60 C.C.C. 136 (N.S.S.C.); and *Mulloy v. Hop Sang*, [1935] 1 W.W.R. 741 (Alta. C.A.).

³⁷ See, e.g., *Marshall, id.*; *Murray v. McMurchy*, [1949] 2 D.L.R. 442, [1949] 1 W.W.R. 989 (B.C.S.C.); *Turner v. Toronto Gen. Hosp. Trustees*, [1934] O.W.N. 629 (Ont. H.C.); and *Halushka v. Univ. of Sask.* (1965), 53 D.L.R. (2d) 436, 52 W.W.R. 608 (Sask. C.A.).

³⁸ See, e.g., *Kenny v. Lockwood*, [1932] O.R. 141, [1932] 1 D.L.R. 507 (Ont. C.A.); *Male v. Hopmans*, [1966] 1 O.R. 647, 54 D.L.R. (2d) 592 (Ont. H.C.), *varied on other grounds*, [1967] 2 O.R. 457 (Ont. C.A.).

³⁹ Fleming, *The Law of Torts* (5th ed. Sydney: The Law Book Co., 1977) at 23.

⁴⁰ Linden, *Canadian Negligence Law* (Toronto: Butterworths, 1972) at 4.

⁴¹ Rozovsky, *Consent to Treatment* (1973), 11 Osgoode Hall L.J. 103 at 105-106.

⁴² *Id.* at 106.

⁴³ (1976), 15 O.R. (2d) 290 at 311, 75 D.L.R. (3d) 536 at 556, 1 C.C.L.T. 1 at 25 (Ont. H.C.).

the latter instance the breadth of information required is greater. The learned judge writes:

If the basic nature and character of the operation performed is substantially that of which the plaintiff was advised, and then agreed to, then there has not been an unconsented to invasion of the person of the plaintiff, regardless of any failure to disclose any collateral risks flowing from the operation. However, such failure, if it can be shown to have resulted in damage to the patient, and was not justified by reasonable medical considerations, may properly be subject-matter for a claim based on negligence.⁴⁴

Recognizing that it may be difficult to determine whether a given fact in the context of a specific case goes to the "basic nature and character of the operation or the procedure to be performed" or is merely collateral, Morden J. provides this "helpful" guidance:

The more probable the risk the more it could be said to be an integral feature of the nature and character of the operation. Further, even if a risk is truly collateral, but still material, it could be said that its disclosure is so essential to an informed decision to undergo the operation that lack of such disclosure should vitiate the consent.⁴⁵

Professor Picard wryly observes that:

If "A" is a certain and serious part of the procedure it goes to the basic nature and character of the operation. But even if "A" is decided to be collateral it may go to the "nature and character" if it is material. The determination of the place of facts like "A" will give the medical and legal professions pause.⁴⁶

Assessing the "materiality" of information requires a standard for measuring the patient's comprehension. The completeness of communication and comprehension is extremely important in the negligence context, since the plaintiff's proof of causation will turn on his establishing that had he been adequately informed he would not have consented to the operation or treatment which led to the injury.⁴⁷

The two obvious standards of comprehension are: (a) that of the particular patient—a subjective standard, and (b) that of an ordinary, reasonable, "Clapham omnibus" patient—an objective standard. It seems clear that the interests of the medical and health services professions would be best served by the objective standard, and conversely, that a patient would be best served by the subjective standard. After reviewing the Canadian cases, Picard concludes that our courts generally apply the subjective standard.⁴⁸

This discussion of standards would be incomplete without a brief consideration of the duty of disclosure. A good summary of the two standards, professional and full, is provided by Seidelson:

Two basically different views emerge from the existing opinions: (1) the extent of disclosure required will be determined by the application of a professional standard, or (2) all material risks incident to the proposed treatment must be revealed.

⁴⁴ *Id.* at 313 (O.R.), 558 (D.L.R.), 27 (C.C.L.T.).

⁴⁵ *Id.* at 313 (O.R.), 559 (D.L.R.), 27 (C.C.L.T.).

⁴⁶ Picard, *supra* note 33, at 137.

⁴⁷ *Canterbury v. Spence*, 464 F. 2d 772 (D.C. Cir. 1972).

⁴⁸ Picard, *supra* note 33, at 142.

The first view, currently the prevailing one, is predicated upon a judicial conclusion that the degree of revelation in each case is a matter to be determined by a medical judgment, taking into account not only the risks incident to the proposed procedure but, as well, the adverse effects on the patient's physical or emotional well-being which might result from a full disclosure. The second view, presently the minority conclusion, but apparently attracting new adherence, is based on judicial recognition of the patient's right of self-determination in regard to what is to be done with or to his body.⁴⁹

Seidelson's discussion is in reference to American law and practices, but it is applicable to Canada as well.⁵⁰

Thus, two standards must be considered: (a) the completeness of the patient's comprehension, measured on a subjective standard, and (b) the adequacy of disclosure, measured on an objective, professional standard.

Before leaving this discussion of the Canadian law of informed consent, two recently reported decisions of the Supreme Court of Canada must be addressed.

In *Hopp v. Lepp*,⁵¹ the Supreme Court was forced to determine the liability of an orthopaedic surgeon for damages in negligence and battery in connection with a spinal disc operation. The Court regarded the main issue as whether there had been informed consent; that is, whether there had been sufficient disclosure of the attendant risks by the surgeon.

In summarizing the duty of disclosure under Canadian law, Laskin C.J.C. said:

[I]n obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. . . . [t]he scope of the duty of disclosure and whether or not it has been breached are matters that must be decided in relation to the circumstances of each particular case.⁵²

From this it would appear that no general rule spelling out the extent and nature of the risk information to be conveyed to a potential vaccinee can be laid down.⁵³

*Reibl v. Hughes*⁵⁴ is an important case. Its movement through the courts has been widely discussed and criticized. A brief review of the decisions may illustrate the confusion and uncertainty of this area of law.

⁴⁹ Seidelson, *Medical Malpractice: Informed Consent Cases in "Full Disclosure" Jurisdictions* (1976), 14 Duquesne L. Rev. 309 at 309-12.

⁵⁰ See *Male*, *supra* note 38 at 652 (O.R.), 597 (D.L.R.) for the adoption into Canadian law of the classic statement of the professional standard of disclosure, laid down by Woodhouse J. in *Smith v. Auckland Hosp. Bd.*, [1964] N.Z.L.R. 241, *rev'd* [1965] N.Z.L.R. 191 (C.A.).

⁵¹ (1980), 32 N.R. 145 (S.C.C.).

⁵² *Id.* at 161.

⁵³ *Report*, *supra* note 32, at 17.

⁵⁴ (1980), 33 N.R. 361 (S.C.C.), *rev'd* (1977), 16 O.R. (2d) 306 (H.C.), *rev'd* (1978), 21 O.R. (2d) 14 (C.A.).

The initial action was brought in the Ontario High Court of Justice, with Haines J. presiding.⁵⁵ The plaintiff suffered from very severe headaches. Examination by the defendant neurosurgeon revealed a significant narrowing of the left carotid artery, caused by a build-up of plaque. Although the arterial constriction was unrelated to the headaches, the defendant surgeon recommended that the condition be remedied surgically. The defendant warned of the risk of stroke and even death if the condition were left uncorrected, but did not warn the patient of the fourteen per cent risk of paralysis or death as a result of the surgery.⁵⁶ The plaintiff agreed to the operation, and either during or immediately after the operation, the plaintiff suffered a massive stroke which paralyzed the right side of his body.

The resultant action was pleaded in both battery and negligence. *Kelly v. Hazlett*⁵⁷ had been decided only six months before, and could hardly be ignored. Haines J., the trial judge in *Reibl v. Hughes*,⁵⁸ was uncomfortable with Morden J.'s use of probability as his criterion for determining whether a risk is an "integral feature of the nature and character of the operation." Haines J. suggested that it is not only the probability of a particular risk but the severity of its realized consequences which controls its characterization as an "integral feature of the nature and character of the operation."⁵⁹

The learned judge found that the plaintiff's consent to the operation had been inadequate:

a patient who is asked to consent to an operation which carries with it the hazard that one in seven patients suffers neurological damage to the central nervous system causing death or permanent disability, has not been apprised of a central and fundamental feature of the proposed procedure unless these risks are plainly and unambiguously brought home to him. . . . a description of the procedure without clear reference to those risks is misleading as to the nature and quality of the procedure; a consent given in ignorance of that central and salient property of the surgery is no consent at all.⁶⁰

Haines J. went on to find the defendant liable both in battery and negligence, characterizing the operation-related risk of paralysis and death as going to the basic character and nature of the procedure in the battery context, and as collateral in the negligence context.⁶¹

With her fine analysis of Canadian informed consent law virtually completed when *Reibl v. Hughes*⁶² was handed down, Professor Picard took comfort from Haines J.'s refusal to follow *Kelly v. Hazlett*:⁶³

Reibl v. Hughes may forecast the future. The subjective patient test and the profes-

⁵⁵ (1977), 16 O.R. (2d) 306, 78 D.L.R. (3d) 35 (Ont. H.C.).

⁵⁶ Sharpe, *Recent Canadian Court Decisions on Consent* (1977), 117 C.M.A.J. 1421 at 1423.

⁵⁷ *Supra* note 43.

⁵⁸ *Supra* note 55.

⁵⁹ *Supra* note 55 at 312 (O.R.), 42 (D.L.R.).

⁶⁰ *Id.*

⁶¹ See Picard, *supra* note 33, at 144.

⁶² *Supra* note 55.

⁶³ *Supra* note 43.

sional disclosure standard will stand. The courts may grapple with the theoretical difficulties of characterizing risks as basics or collateral but will not be barred from allowing recovery to the patient who has not given an informed consent.⁶⁴

Less than a year after those words were published, the decision of Haines J. in *Reibl v. Hughes* was reversed by the Ontario Court of Appeal.⁶⁵ Speaking for the Court, Brooke J.A. seemed to adopt a professional medical standard for determining the adequacy of the explanation of risk: "The manner in which the nature and degree of risk is explained to a particular patient is better left to the judgment of the doctor in dealing with the man before him."⁶⁶

Brooke J.A. objected that Haines J. had "resorted to a description of the risk that no doctor has used or would use as he did and in so doing has ignored the evidence that he accepted."⁶⁷

More significantly, Brooke J.A. rejected the subjective standard for determining the causation question. Citing several American authorities,⁶⁸ he urged that Canadian courts take heed of the reliance by American courts on an objective standard.⁶⁹ Brooke J.A. stopped just short of adopting a wholly objective standard when he said: "I think a safe practice here is to test the plaintiff's case objectively before proceeding to consider it subjectively."⁷⁰

After ordering a new trial on the negligence issue Brooke J.A. turned to the question of battery. It was noted above that the prevailing Canadian view has been that inadequate consent to treatment may give rise to suits in both battery and negligence. Commentators regarded the judgment of the trial court in *Reibl v. Hughes*⁷¹ as consistent with that view.⁷² Evidently, Brooke J.A. reads the Canadian cases very differently. He cited *Cobbs v. Grant*⁷³ and Prosser⁷⁴ as authority for the proposition that

in some of the State Courts of the United States of America where the doctrine of informed consent is applied, the prevailing view is that cases for failure to disclose risks inherent in recommended surgery which may cause a plaintiff's loss or damages should be pleaded in negligence rather than in battery.⁷⁵

He went on to say:

save for the judgment at trial here, Canadian cases have in fact conformed with

⁶⁴ Picard, *supra* note 33, at 144.

⁶⁵ (1978), 21 O.R. (2d) 14, 89 D.L.R. (3d) 112, 6 C.C.L.T. 227 (Ont. C.A.).

⁶⁶ *Id.* at 23 (O.R.), 122 (D.L.R.), 239 (C.C.L.T.).

⁶⁷ *Id.* at 27 (O.R.), 125 (D.L.R.), 244 (C.C.L.T.).

⁶⁸ *Barnette v. Potenza*, 359 N.Y. Supp. 2d 432, 79 Misc. 2d 51 (Sup. Ct. 1974); *Canterbury*, *supra* note 47; and *Cobbs v. Grant*, 8 C. 3d 229, 502 P. 2d 1 (S.C. 1972).

⁶⁹ *Reibl*, *supra* note 65, at 27 (O.R.), 125 (D.L.R.), 244 (C.C.L.T.).

⁷⁰ *Id.* at 27 (O.R.), 125 (D.L.R.), 243 (C.C.L.T.).

⁷¹ *Reibl*, *supra* note 55.

⁷² Picard, *supra* note 33, at 144.

⁷³ *Supra* note 68.

⁷⁴ Prosser, *Law of Torts* (4th ed. St. Paul: West, 1971).

⁷⁵ *Reibl*, *supra* note 65, at 28 (O.R.), 126 (D.L.R.), 244 (C.C.L.T.).

the view expressed by Professor Prosser, *Law of Torts*, 4th ed. (1971), and in *Cobbs v. Grant*, *supra*. . . I agree with that view. In cases such as this, the notion of battery seems quite inappropriate.⁷⁶

In a unanimous decision handed down on October 7, 1980, the Supreme Court of Canada reversed the Ontario Court of Appeal and restored the judgment of Haines J. at trial.

Laskin C.J.C. considered that the Court of Appeal went too far in adopting what amounted to a professional standard when judging the adequacy of an explanation to a particular patient regarding the degree and nature of the risk attendant upon the particular medical treatment. In the Chief Justice's words:

What a doctor knows or should know that the particular patient deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge. . . . the materiality of non-disclosure of certain risks to an informed decision is a matter for the trier of fact, a matter on which there would, in all likelihood, be medical evidence but also other evidence, including evidence from the patient or from members of his family.⁷⁷

On the question of causation, Laskin C.J.C. refused to be swayed by earlier decisions of lower Canadian courts apparently applying a subjective test, and viewed the matter as *res integra* in the Supreme Court. The Chief Justice went on to reject the combined "objective-subjective" test apparently employed by Brooke J. in the Ontario Court of Appeal:

[It is] the safer course on the issue of causation to consider objectively how far the balance in the risks of surgery or no surgery is in favour of undergoing surgery . . . [T]he objective standard is the preferable one on the issue of causation . . . [A]lthough account must be taken of a patient's particular position, a position which will vary with the patient, it must be objectively assessed in terms of reasonableness.⁷⁸

In dealing with the battery ground, Laskin C.J.C. agreed with Brooke J.A.'s view that battery is an inappropriate ground for a suit alleging inadequate disclosure attendant to medical treatment or surgery otherwise consented to.⁷⁹ In Laskin C.J.C.'s view, suits in battery should be available only in those surgical or other medical treatment cases:

Where surgery or treatment has been performed or given to which there has been no consent at all or where, emergency situations aside, surgery or treatment has been performed or given beyond that to which there was consent. . . . [u]nless there has been misrepresentation or fraud to secure consent to the treatment, a failure to disclose the attendant risks, however serious, should go to negligence rather than to battery. Although such a failure relates to an informed choice of submitting to or refusing recommended and appropriate treatment, it arises as the breach of an anterior duty of due care, comparable in legal obligation to the duty of due care in carrying out the particular treatment to which the patient has consented. It is not a test of the validity of the consent.⁸⁰

⁷⁶ *Id.*

⁷⁷ *Supra* note 54, at 373-74.

⁷⁸ *Id.* at 377-79.

⁷⁹ *Id.* at 368-69.

⁸⁰ *Id.* at 370-71.

In reversing the Court of Appeal and restoring the judgment at trial, the Chief Justice concluded that since the plaintiff was under the mistaken impression (as a result of the defendant's breach of his duty of disclosure) that the surgery would relieve his continuing headaches, a reasonable person in the plaintiff's position would, on the balance of probabilities, have rejected the surgery.⁸¹

The decision of the Supreme Court of Canada in *Reibl v. Hughes* has two principal effects: firstly, to narrow the availability of battery to surgery or treatment cases where treatment is either completely unconsented to, or "given beyond that to which there was consent,"⁸² and secondly, to strike a delicate balance on the standards by which (a) the materiality of non-disclosure of certain risks to an informed decision, and (b) causality are to be judged. A professional, medical standard for assessing the materiality of non-disclosure is insufficient; "what the doctor knows or should know that the particular patient deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge."⁸³ Assessment of the materiality of non-disclosure is a matter for the trial judge.

The issue of causality (the degree to which a patient's decision is determined by non-disclosure) is to be dealt with by considering "objectively how far the balance in the risks of surgery or no surgery is in favour of undergoing surgery."⁸⁴ Laskin C.J.C. takes pains to note that although his objective test does not and should not preclude consideration of a "patient's particular position, a position which will vary with the patient, it must be objectively assessed in terms of reasonableness."⁸⁵

Although Laskin C.J.C.'s judgment imposes a formidable duty of disclosure on the provider of medical service or treatment, and probably produces a fair result in the instant case, the decision provides little predictive value to a potential plaintiff. Application of the *Reibl v. Hughes* standards of materiality and causality must be accompanied by the careful assessment and delicate weighing of the facts of particular cases.

The point of this discussion of informed consent has been simply to demonstrate the uncertainty pervading this area of law. A number of important and difficult questions, such as the capacity of the mentally handicapped and minors, have been deliberately excluded, with the view and hope that the point has already been made.

2. Products liability

Products liability is too broad and complex an area of law to be more than highlighted here. Warranty and negligence, the two general grounds

⁸¹ *Id.* at 408-10.

⁸² *Id.* at 370.

⁸³ *Id.* at 373.

⁸⁴ *Id.* at 377.

⁸⁵ *Id.* at 379.

upon which a manufacturer may be held responsible for harm caused by his product, both require proof of defect.⁸⁶

The Sale of Goods Act of Ontario codifies the implied warranties of (a) reasonable fitness for particular purpose, and (b) merchantable quality.⁸⁷ The provision has been generally taken to impose what is, in effect, strict liability on a business seller for the supply of defective goods.⁸⁸ Section 15 and the implied warranties it represents, however, are severely and strictly circumscribed by the old rule of privity of contract: "[t]he section applies only when there is a contract between the plaintiff and the defendant for the sale of goods."⁸⁹ Such a contract virtually never exists between the manufacturer and ultimate recipient of vaccine. Consequently, the implied warranties provide little assistance to the injured vaccinee.⁹⁰

The law of negligence is far more flexible. Canadian courts have demonstrated their willingness to incorporate aspects of the doctrine of strict liability into negligence, while stopping short of open acceptance and application of strict liability.⁹¹ The malleability of negligence law, and the tremendous pressures created by a series of American cases discussed later in this paper signal the need to outline at least the basic features of this area of law.

a) *Negligence*

Writers disagree widely on the purposes and elements of negligence law. Linden defines negligence as "certain conduct that falls below the standard required by society."⁹²

The foundation of the manufacturer's duty of care to the ultimate consumer of his product is considered to have been laid by Lord Atkin in *Donoghue v. Stevenson*.⁹³ He stated his privity-shattering principle as follows:

a manufacturer of products which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care.⁹⁴

This new strand of negligence doctrine was received with widespread approval by the common law courts, and applied to a very wide range of products and defendants.⁹⁵ The plaintiff's burden of proof of causation has been eased by the courts' readiness to apply the procedural device of *res ipsa*

⁸⁶ *Products Liability*, *supra* note 13, at 13, 23.

⁸⁷ R.S.O. 1970, c. 421, s. 15.

⁸⁸ *Products Liability*, *supra* note 13, at 22.

⁸⁹ *Id.* at 26-27.

⁹⁰ Rozovsky, *supra* note 32, at 6.

⁹¹ *Products Liability*, *supra* note 13, at 18.

⁹² Linden, *supra* note 40, at 4.

⁹³ [1932] A.C. 562, [1932] All E.R. Rep. 1, 48 T.L.R. 494 (H.L.).

⁹⁴ *Id.* at 599 (A.C.), 20 (All E.R. Rep.), 504 (T.L.R.).

⁹⁵ Linden, *supra* note 40, at 398-404.

*loquitur*⁹⁶ where the victims of immunization injury are able to prove that the vaccine used failed to meet reasonable standards—the standards set out in the Food and Drug Regulations—courts are likely to find negligence.⁹⁷

In the mid-nineteenth century a special negligence category for “inherently dangerous” products was developed as a judicial device to escape the harsh privity rule.⁹⁸ Although the need for and use of this device largely disappeared after *Donoghue v. Stevenson*,⁹⁹ a legacy of the “inherently dangerous” products doctrine is that a higher standard of care is demanded of manufacturers of dangerous products than of producers of “inherently innocuous” products. This higher standard is not a special or independent rule; it reflects the general negligence principle that “[t]he burden of taking precautions increases as the probability of harm and the severity of the damage threatened increase.”¹⁰⁰

The “reasonableness” element of the manufacturer’s duty of care is a vital limitation of the law of negligence—particularly in the context of immunization injury. As Fleming notes:

[i]n determining the requisite standard of safety, negligence does not demand more than what reasonable care should have assured. . . . negligence law does not demand protection against risks which proper care *could* not have eliminated. Excluded therefore are defects which are (practically) undiscoverable, like serum hepatitis in blood plasma; even more, risks which remained unknown despite all proper precautions, as possibly with new drugs.¹⁰¹

Negligence law holds manufacturers subject to a duty to warn users of their products about dangers either inherent in those products or attendant on their use.¹⁰² Warnings must explicitly and clearly describe the dangers involved. In *Lambert v. Lastoplex Chemicals Co.*,¹⁰³ the Supreme Court of Canada stressed the importance of explicitness in warnings. As Laskin J. (as he then was) said:

Where manufactured products are put on the market for ultimate purchase and use by the general public and carry danger, . . . although put to the use for which they are intended, the manufacturer, knowing of their hazardous nature, has a duty to specify the attendant dangers, which it must be taken to appreciate in a detail not known to the ordinary consumer or user. . . . The required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product.¹⁰⁴

Rozovsky views the *Lambert* case as laying down “[t]he most important duty on a manufacturer” and concludes, without elaboration, that “[t]here is reason to believe that we will follow the American example and impose

⁹⁶ Fleming, *supra* note 39, at 508-509.

⁹⁷ *E.g.*, *Sterling Trust Corp. v. Postma*, [1965] S.C.R. 324, 48 D.L.R. (2d) 423.

⁹⁸ Fleming, *supra* note 39, at 513.

⁹⁹ *Supra* note 93.

¹⁰⁰ Linden, *supra* note 40, at 420-21; see *Rae v. Eaton* (1961), 45 M.P.R. 261 at 276, 28 D.L.R. (2d) 522 at 535 (N.B.S.C. App. Div.).

¹⁰¹ Fleming, *supra* note 39, at 510.

¹⁰² Linden, *supra* note 40, at 417.

¹⁰³ [1972] S.C.R. 569, 25 D.L.R. (3d) 121.

¹⁰⁴ *Id.* at 574-75 (S.C.R.), at 125 (D.L.R.).

greater obligations on everyone who supplies any type of product to warn them [*sic*] of the inherent risks apart from any actual defects."¹⁰⁵ Rozovsky has also stated that "[t]he courts have also required manufacturers to warn the consumers of their products of any inherent dangers."¹⁰⁶ He cited a 1955 case involving a glue manufacturer,¹⁰⁷ and abruptly concluded "[t]his is of particular importance with respect to immunization."¹⁰⁸ He may well be right, but a deserving injured vaccinee could be forgiven for declining to sue on the strength of such authority.

The special case of immunization injury occurring as a result of the risk inherent in the vaccination process, where the vaccine is manufactured in accordance with prevailing standards, should once again be noted. Since suits grounded in the law of warranty and negligence by definition require proof of defect, neither branch of law can assist the unfortunate vaccinee who was injured by a vaccine meeting the prevailing standards.

b) *Strict Liability*

The general principle that a manufacturer of a defective product that causes injury should be strictly liable in damages has been widely accepted in the United States and elsewhere,¹⁰⁹ but has yet to be approved by the Canadian courts.¹¹⁰ That the doctrine of strict liability will eventually spill over into this country is widely predicted and advocated by highly respected academics and research bodies.¹¹¹ To date, however, strict liability provides no assistance to the victim of immunization injury in Canada.¹¹²

These "highlights" of Canadian law show the complexity and confusion of the legal position of the injured vaccinee under current Canadian law. Two critical ingredients contributing to that position are the paucity of Canadian court decisions dealing directly with the question of compensation of injured vaccinees, and the fundamentally fluid nature of negligence law.¹¹³ The com-

¹⁰⁵ Rozovsky, *supra* note 32, at 6.

¹⁰⁶ *Report*, *supra* note 30, at 42.

¹⁰⁷ *Stewart v. Lepage's Inc.*, [1955] O.R. 937 (H.C.).

¹⁰⁸ *Report*, *supra* note 32, at 42.

¹⁰⁹ Linden, *supra* note 40, at 425.

¹¹⁰ *Products Liability*, *supra* note 13, at 64.

¹¹¹ *Id.*; Linden, *supra* note 40, at 425-26; Waddams, *Products Liability* (Toronto: Carswell, 1974) at 233.

¹¹² The Saskatchewan and New Brunswick legislatures have enacted consumer protection legislation that comes very close to strict liability. Both the Saskatchewan *Consumer Products Warranties Act*, 1977, S.S. 1976-77, c. 15 and New Brunswick's *Consumer Product Warranty and Liability Act*, 1978, S.N.B. 1978, c. C-18.1, apply only to "consumer products" which are defined so narrowly as to exclude vaccines. See *Products Liability*, *supra* note 13, at 39-44.

¹¹³ Linden, *supra* note 40, at 1-2. In introducing his text on negligence, Linden stresses the importance of fluidity in negligence law:

Negligence law is a vibrant and dynamic instrument. It has to be. As soon as some new type of activity emerges, its conduct is accommodated within the general framework of negligence principles. Because of this, it has been said that "the categories of negligence are never closed." This may be merely the instinct of self-preservation at work, for if negligence law abandoned its fluidity, it would probably wither away.

bined effect of these ingredients is to make recent developments in the United States extremely relevant.

III. THE AMERICAN JURISPRUDENCE

In a line of cases beginning with *Gottsdanker v. Cutter Laboratories*¹¹⁴ in 1960, United States courts have been placing increasing liability on vaccine manufacturers. Plaintiffs have relied on three grounds for recovery: negligence, breach of implied warranty and strict liability in tort.¹¹⁵ Strict liability has almost completely superseded implied warranty in recent years, as the courts have moved with the trend toward broader recovery in the products liability field.¹¹⁶

In *Gottsdanker*, fifty-four separate claims were launched, alleging that the method employed to kill the virus in salk polio vaccine used in a mass immunization programme in the western states was defective. The defendant did not challenge the causal link between use of the vaccine and the plaintiff's injuries, but argued that because their manufacturing process satisfied Federal government standards, no negligence could be found. The California Supreme Court found for the plaintiffs, ruling that "no negligence need be proved since the manufacturer was liable for any personal injury caused by his product since it was 'sold' under a guarantee or warranty of its purity and safety for human consumption."¹¹⁷ The Court refused to be deterred by the absence of a contractual relationship between the defendant and the ultimate users of the vaccine, and held that the defendant was bound by a relationship of responsibility, running directly from the manufacturer to the eventual and foreseeable user.¹¹⁸

The next case of note, *Davis v. Wyeth Laboratories*,¹¹⁹ represents a major extension of the vaccine manufacturer's liability to the ultimate recipient. Until *Davis*, it was generally thought that the manufacturer's duty to warn of inherent risks in vaccination applied only to the party administering the vaccine, who was in turn responsible for warning the vaccinee.¹²⁰ The Court found Wyeth Laboratories strictly liable in tort for failure to ensure that the ultimate recipients of their vaccine received adequate warning.

In *Davis*, a thirty-nine year old man contracted polio after receiving the defendant's Type III sabin polio vaccine at a mass immunization clinic. Six months before Davis was vaccinated, the U.S. Surgeon General released a statement indicating the existence of the risk of contracting polio through use

¹¹⁴ 6 Cal. Rptr. 320, 182 Cal. App. 2d 602 (1960).

¹¹⁵ Mann, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn* (1976), 29 Van. L. Rev. 235 at 243.

¹¹⁶ *Id.*

¹¹⁷ Curran, *Influence of the Courts of Law on Biologicals Development: Regulation and Use* (Geneva: Int'l Conference on the Individual and the Community in the Research, Development and Use of Biologicals, 1976) at 1-2.

¹¹⁸ *Id.*

¹¹⁹ 399 F. 2d 121 (9th Cir. 1968).

¹²⁰ D.H.E.W., *supra* note 12, at 27.

of the Type III vaccine, and that adults were especially susceptible. While excerpts from the Surgeon General's report were included in the vaccine package insert, the defendant's representative did not attempt to warn either the administering pharmacist or the public of the vaccine's risk. The insert was not read by the pharmacist, and the plaintiff was not warned. The appellate court found it significant that the manufacturer had taken an active part in organizing the immunization programme, and knew that the warnings contained in the package insert were not reaching the vaccinees.¹²¹ The Court rejected the defendant's argument that the less than one in a million chance of serious injury to the vaccinee was "trifling" when compared to the social benefit of immunization, ruling that: "When in a particular case, the risk qualitatively (e.g., of death or major disability) as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, medical or personal, the warning must be given."¹²²

The holding in *Davis* was significantly extended by the important and controversial case of *Reyes v. Wyeth Laboratories*,¹²³ where an eight month old child received the defendant's trivalent polio vaccine¹²⁴ in a Texas public health clinic and subsequently contracted poliomyelitis. Wyeth Laboratories was found strictly liable for the injury, despite the fact that an epidemic was in progress in the community at the time of the infant's vaccination, and despite strong medical evidence suggesting that the child's polio was not vaccine induced.¹²⁵

In deciding the strict liability question, the U.S. Court of Appeal applied a two-step analysis to determine "first, whether the product is so unsafe that marketing it at all is 'unreasonably dangerous per se', and, if not, whether the product has been introduced into the stream of commerce without sufficient safeguards and is thereby 'unreasonably dangerous as marketed'."¹²⁶

For the first step, the Court relied on the "reasonable man" standard for balancing the utility of the properly used product against the risks inherent in the product's use. The Court regarded the defendant's vaccine as an "unavoidably unsafe product"¹²⁷ and recognized that the use of such products raises at least a small element of danger,¹²⁸ but found Wyeth Laboratories justified in marketing the vaccine despite the danger. Stressing the severity of the disease being combatted, the Court ruled "only if the potential harmful effects of the product—both qualitative and quantitative—outweigh the legitimate public interest in its availability will it be declared unreasonably dangerous per se and the person placing it on the market held liable."¹²⁹

¹²¹ *Davis*, *supra* note 119, at 131; D.H.E.W., *supra* note 12 at 28; Baynes, *Liability to Vaccine Related Injuries: Public Health Considerations*, Report under Contract with Communicable Disease Control (Washington: D.H.E.W., 1975) at 37.

¹²² *Davis*, *supra* note 119, at 129-30.

¹²³ 498 F. 2d 1264 (5th Cir. 1974).

¹²⁴ That vaccine uses a live virus to effect immunity.

¹²⁵ Baynes, *supra* note 121, at 35.

¹²⁶ *Reyes*, *supra* note 123, at 1273.

¹²⁷ This point was uncontested by Wyeth Laboratories.

¹²⁸ *Reyes*, *supra* note 123, at 1274.

¹²⁹ *Id.*

With regard to the second step, the *Reyes* Court turned to section 402A and comment K of the *Restatement (Second) of the Law of Torts*¹³⁰ requiring

a seller who has reason to believe that danger may result from a particular use of his product to provide adequate warning of the danger. . . . failure to give such a warning when it is required will itself present a "defect" in the product and will, without more, cause the product to be "unreasonably dangerous as marketed."¹³¹

The Court concluded, upon examination of the particular facts of the *Reyes* case that the defendant failed to escape step two:

Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug, and therefore was required to warn foreseeable users, or see that the Texas Department of Health warned them. . . . Wyeth's failure to warn was a breach of its duty and made the vaccine "defective"—hence "unreasonably dangerous"—as marketed.¹³²

The Court continued:

[I]n the case of a prescription drug which is unavoidably unsafe, and to which there is a certain, though small, risk throughout the population, there must be either a warning—meaningful and complete so as to be understood by the recipient—or an individualized medical judgment that this treatment or medication is necessary and desirable for this patient.¹³³

Under the rationale of *Davis* as applied and extended by *Reyes*, the determination of a manufacturer's liability for "an unavoidably unsafe drug" (*i.e.* a vaccine the danger of which inheres from its very nature, and not from any deficiency in its manufacture) turns on a two-step analysis. First, it must be determined whether the utility of the vaccine's availability to the public is outweighed by the probable public harm. If so, the vaccine will be found "unreasonably dangerous per se" and the party placing it on the market will be held liable.¹³⁴ Second, where the manufacturer knows or should reasonably be expected to know of dangers raised by use of its vaccine, it will be held liable unless it gives adequate warning of those dangers. Generally a warning to the physician will suffice. In the mass immunization and public health clinic contexts, unless there is a physician present at the time of the vaccination such that an "individualized medical judgment that this treatment or medication is necessary and desirable for this patient"¹³⁵ can be made, to avoid liability the manufacturer must ensure the warning reaches the vaccinee.¹³⁶

The 1977 case of *Givens v. Lederle*¹³⁷ further extended the scope of the vaccine manufacturer's duty to warn. There, the plaintiff contracted polio

¹³⁰ Am. L. Inst., *Restatement (Second) of the Law of Torts* (Chicago: Am. L. Inst., 1965).

¹³¹ *Reyes*, *supra* note 123, at 1275.

¹³² *Id.* at 1277.

¹³³ *Id.* at 1295.

¹³⁴ *Id.* at 1274.

¹³⁵ *Id.* at 1295.

¹³⁶ Baynes, *supra* note 121, at 38.

¹³⁷ 556 F.2d 1341 (5th Cir. 1977).

after her infant daughter was immunized with sabin oral polio vaccine in a private physician's office.

The manufacturer's defence did not seriously question the extension of liability to injury suffered by a person in contact with a vaccinee, but focussed on the nature of the dispensation of the vaccine and the adequacy of the warning.¹³⁸ Lederle argued that because the vaccination took place in a private physician's office, the "individualized medical attention" referred to in *Davis* and *Reyes* had been provided, thereby dissolving the causal link between the manufacturer and the injury.

The Court was unimpressed. Summarizing and relying on the holding in *Davis*, the *Givens* Court ruled that

when a manufacturer knows or should know that the drug will be used without prescription, as in a mass inoculation, he has a duty to warn each individual consumer. . . . Dr. LaRue, the private pediatrician, testified that the administration in his office "really doesn't differ" from that of the Public Health Centre. . . . [i]f so, then Lederle is responsible for taking definite steps to get the warning directly to the consumer.¹³⁹

The Court went considerably further by holding that even if "individualized medical attention" had been provided, the warning provided by the manufacturer in the form of a package insert was so inadequate that the jury's finding of liability would have been upheld.¹⁴⁰ The manufacturer's package insert conceded that some vaccinees immunized with live vaccine, and people who had been in close contact with such vaccinees had contracted polio. The insert also stated, however, that "such occurrences are rare, and it could not be definitely established that any such case was due to the vaccine strain and was not coincidental with infection due to naturally occurring poliomyelitis." The Court considered that the jury was justified in concluding that "the warning did not sufficiently point out the possibility that the live vaccine could cause polio."¹⁴¹

For the vaccine manufacturer, *Givens* is a very important case. *Reyes* left the manufacturer two escape routes for avoiding liability: (a) a warning of risk, and (b) "individualized medical judgment" that the particular vaccination was necessary and desirable for the particular vaccinee.¹⁴² The *Givens* decision effectively seals off the second route.¹⁴³

¹³⁸ D.H.E.W., *supra* note 12, at 34n. 7.

¹³⁹ *Givens*, *supra* note 137, at 1345.

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Reyes*, *supra* note 123, at 1295.

¹⁴³ O.T.A., *supra* note 7, at 92. The fact and outcome of this case essentially forced the manufacturer to assume that the vaccines will be dispensed without "individualized medical judgment" regardless of the forum and the form of dispensation. A report of the U.S. Dept. of Health, *supra* note 12, at 35 provides a succinct statement of the crucial legal implications of *Davis*, *Reyes* and *Givens* for the vaccine manufacturer:

a manufacturer will have to ensure that a warning is given to vaccine recipients in all circumstances. After *Givens*, it cannot even assume that an insert will be sufficient to exempt it from liability when a physician fails to warn a vaccinee in a private office. Moreover, the warning given must warn recipients fully of the

A great number of vaccination injury law suits have reached the American courts in recent years.¹⁴⁴ *Davis, Reyes* and *Givens*, all decisions of the United States Court of Appeals, have been the subject of considerable academic criticism, but clearly represent the current American law. The *Davis, Reyes* and *Givens* cases have yet to be applied by, or even argued before a Canadian court. There are indications, however, that Canada's immunity will not last much longer.¹⁴⁵ The extreme flexibility of the law of negligence, the willingness of Canadian courts to adopt some of the characteristics of strict liability "in order to allocate losses in ways that seem to them appropriate, and in order to compensate the victims of accidents,"¹⁴⁶ and the dearth of Canadian authority directly on point suggest that these American cases are likely to have a tremendous impact on the development of Canadian law in this area.

Accordingly, consideration of some of the policy implications of the *Davis, Reyes* and *Givens* cases is appropriate.

IV. POLICY ASPECTS AND IMPLICATIONS OF *DAVIS, REYES AND GIVENS*

A. *Imposition of Strict Liability on the Manufacturer*

If these cases are viewed in the products liability context, the courts' application of strict liability comes as no surprise. It is generally accepted in the United States that compensation of injured persons is better treated through the law of torts than through the law of contracts.¹⁴⁷ Much of the impetus for shifting the ground for compensation of personal injury victims from contractual to tortious liability was provided by the 1960 New Jersey Supreme Court decision of *Henningesen v. Bloomfield Motors Inc.*¹⁴⁸ The theory of warranty liability laid down in that case was *de facto* strict liability in tort.¹⁴⁹

qualitative and quantitative risks of a vaccine. Finally, if no warning is in fact given, or if it is insufficient, a rebuttable presumption will arise that failure to warn was the proximate cause of a vaccinee's injury.

¹⁴⁴ Four hundred and sixty-four lawsuits were filed alleging injuries suffered as a result of vaccination under the swine flu immunization programme, and as of September 1979, less than 50 claims had been settled. O.T.A., *supra* note 7, at 100.

¹⁴⁵ A recent Statement of Claim filed in the Alberta Court of Appeal alleges that the plaintiff suffered "injury as a result of receiving a Swine Flu Shot," and that both the province and the Canadian manufacturer of the vaccine were negligent in "[n]ot warning the public, including the male Plaintiff, that there was a possibility of adverse reactions to the shot prior to supplying and promoting the serum for use."

One would certainly expect the plaintiff to argue the *Davis, Reyes* and *Givens* line of cases.

See also Rozovsky, *supra* note 32, at 6.

¹⁴⁶ *Products Liability*, *supra* note 13, at 18.

¹⁴⁷ *Id.* at 51.

¹⁴⁸ 32 N.J. 358, 161 A. 2d 69, 75 A.L.R. 2d 1.

¹⁴⁹ *Products Liability*, *supra* note 13, at 51.

Spurred by the efforts of Prosser,¹⁵⁰ in 1965 the American Law Institute enshrined the principle of strict liability in tort in the *Restatement (Second) of the Law of Torts*.¹⁵¹ The strict liability principle has been adopted by the courts of most American jurisdictions. As is noted above, although strict liability is not yet generally accepted in Canada, the Ontario Law Reform Commission strongly recommends the adoption of the principle, and also, two provinces have enacted legislation holding manufacturers and retailers strictly liable in a narrowly defined "consumer products" context.¹⁵²

While this doctrine justifiably enjoys widespread support in the general products liability context, there is less than universal agreement that the rationale for strict liability applies equally well in the narrower context of liability for immunization injury.

Probably the strongest argument generally advanced on behalf of strict liability is that it is an efficient, effective means of spreading the risk and cost of compensating accident victims.¹⁵³ Proponents of strict liability argue that, "[t]he drug manufacturer is in the best position to assess the risks of his products, and better able than any party, save perhaps the government, to spread the cost of accidents broadly among those who benefit from their use."¹⁵⁴

Those who oppose the imposition of strict liability on vaccine manufacturers express strong concern regarding the implications of cases like *Davis*, *Reyes* and *Givens*. They argue that the spectre of high damage awards and the enormous practical difficulties of avoiding future liability are driving manufacturers out of vaccine production.¹⁵⁵ Certainly the number of firms engaged in the manufacture of vaccines in the United States has declined dramatically over the past 15 years. Ohta notes that, "of the three major firms producing live polio virus vaccine during the past 15 years, only one remains; of the six producing live measles virus vaccine, only one remains; of the eight producing inactivated influenza virus vaccine, only four remain; and of the four producing live rubella virus vaccine, only one remains."¹⁵⁶

The Canadian vaccine manufacturing industry is even more concentrated. Three manufacturers share the market in Canada: Connaught Laboratories Limited of Toronto, Institut Armand-Frappier of Montreal and the American firm of Merck, Sharpe and Dome Ltd.¹⁵⁷

¹⁵⁰ Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)* (1965-66), 50 Minn. L. Rev. 791.

¹⁵¹ *Supra* note 130, §402A.

¹⁵² See, *supra* notes 111, 112.

¹⁵³ *Products Liability*, *supra* note 13, at 69.

¹⁵⁴ Merrill, *Compensation for Prescription Drug Injuries* (1973), 59 Va. L. Rev. 1 at 109.

¹⁵⁵ Mann, *supra* note 115, at 235, 251.

¹⁵⁶ Ohta, *Immunization Injuries: Proposed Compensatory Mechanisms—An Analysis* (1978-79), 11 Conn. L. Rev. 147 at 160.

¹⁵⁷ McIntosh, *A Study of Vaccine Use in Alberta* (unpublished report prepared for Alberta Social Services and Community Health, 1980).

It is not suggested that the prospect of the adoption of strict liability is responsible for this concentration of vaccine supply. Indeed, it is not surprising that the lion's share of the Canadian vaccine market is controlled by one manufacturer. The market is not large, and potential suppliers are confronted by prohibitive barriers to entry. The facilities, technology and expertise required are extensive and expensive; there is simply not enough demand to support a large number of manufacturers.

It should also be noted that manufacturers already view vaccine production as a marginally profitable venture. The major American vaccine producers are broadly diversified drug manufacturing houses that produce vaccines as sidelines to their more profitable operations. Connaught Laboratories Limited researches and manufactures a diverse range of scientific, medical and biological products. Connaught is not dependant on vaccine manufacture for survival, and would be able to halt vaccine production should that operation become financially prohibitive.¹⁵⁸ Institut Armand-Frappier, on the other hand, is a small, financially vulnerable manufacturer of a limited number of biological products. Its management is extremely worried about the prospect of the imposition of strict liability.¹⁵⁹

While it may be economically rational that Canada's limited vaccine market be serviced by a small number of manufacturers, such a concentration only exacerbates the threat to security of vaccine supply created by the imposition of strict liability.

The serious vaccine supply difficulties that plagued the Swine Flu Immunization Program illustrate the danger of imposing strict liability on vaccine manufacturers. The Swine Flu Immunization Program, initiated by the U.S. federal government in the spring of 1976, called for the development, manufacture and administration of enough swine flu vaccine so that every American citizen could be inoculated against the influenza.¹⁶⁰ A cooperative effort of major manufacturers and public health officials resulted in the successful development of the new vaccine, but the entire programme very nearly foundered on the liability question. Insurance companies were made wary by the *Davis, Reyes and Givens* line of cases, and by the enormous liability potential of such a large scale immunization programme. They refused to underwrite manufacturers' liability for vaccine-related injuries.¹⁶¹ The manufacturers refused to supply the vaccine without protection against liability. Aided by an unlikely and fortuitous combination of circumstances,¹⁶² Con-

¹⁵⁸ Interview with Terrance D. Macaulay, Director of Finance, Connaught Laboratories Ltd. (Jan. 11, 1980).

¹⁵⁹ Interview with Pierre Diotte, Director, Marketing and Sales, Institut Armand-Frappier (January 16, 1980).

¹⁶⁰ Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on Swine Flu Experience* (1977), 21 St. Louis U. L. J. 44 at 62-63.

¹⁶¹ The insurance companies' reluctance seems to have been justified. By September 1979, 3,694 claims and 464 lawsuits alleging injury caused by the swine flu vaccine had been filed, seeking nearly \$4 billion in damages. To that date, less than 50 claims had been settled. O.T.A., *supra* note 7, at 100.

¹⁶² Baynes, *supra* note 160, at 65-66.

gress was able to circumvent the impasse by passing the National Swine Flu Immunization Program of 1976.¹⁶³ The legislation indemnified manufacturers against all claims alleging personal injury or death as a result of the manufacture, distribution or administration of the vaccine.¹⁶⁴ The insurance industry subsequently restored the vaccine manufacturers' products liability coverage.

This *ad hoc* legislation averted a particular crisis, but fell far short of addressing the underlying issue of the utility of applying the strict liability doctrine in the vaccine context. Economists are attracted to strict liability because costs of compensating accident victims are treated as part of overall product cost. Economists are untroubled by the fact that production of certain products may thereby become unprofitable and unfeasible. They argue that "[a] product that can only be produced at the expense of innocent persons injured by its defects perhaps ought not to remain on the market."¹⁶⁵

In *Products Liability*, the Ontario Law Reform Commission concurred with the English Law Commission's refusal to exempt manufacturers of pharmaceuticals from the principle of strict liability: "We know of no conclusive evidence that establishes that the introduction of a principle of strict liability will impede research and development in the pharmaceutical field. Even if there were such evidence, and we are not convinced that research and development should be at the expense of individual plaintiffs."¹⁶⁶

This reasoning is inapplicable in the immunization context. The security of the supply of vaccine should be viewed as an incident to the public interest in the control of communicable disease. The public interest in the availability of vaccine should not be compromised by the wholesale application of strict liability.¹⁶⁷

Even if it were conceded that the security of supply of vaccine might not be jeopardized by application of strict liability, we are still left with the compensation problem.¹⁶⁸ Strict liability undoubtedly puts the plaintiff in a better position than under negligence law. With strict liability, the causal link between the defect and the plaintiff's injury need not be proven, and the defendant cannot rely on the defence of reasonableness. Nonetheless, responsibility for pursuing compensation through the litigation process remains squarely on the shoulders of the injured vaccinee.

¹⁶³ 42 U.S.C.A., §247b(j)(1).

¹⁶⁴ Ohta, *supra* note 156, at 158.

¹⁶⁵ *Products Liability*, *supra* note 13, at 69.

¹⁶⁶ *Id.* at 90. While advocating the general application of strict liability to the field of products liability, the Commission concedes strict liability may be inappropriate where the public has an interest in a product's availability.

¹⁶⁷ *Id.*

¹⁶⁸ Ohta, *supra* note 156, at 159-160n. 82. Ohta's dramatic statistics on the concentration of vaccine supply in the United States over the past 15 years make this a difficult concession.

B. *Litigation as a Compensation Vehicle*

It is not difficult to find support for the proposition that even with the movement to strict liability in "warning of risk" cases, "the system remains primarily a system for assigning fault, rather than for providing assistance to victims of unavoidable accidents."¹⁶⁹ If vaccination injury victims do not receive adequate warning of risk, then they face the daunting prospect of seeking compensation through the courts. High legal costs, long delays and the uncertainty of recovery act as powerful disincentives. Perhaps of more importance is the situation where the victim has been adequately warned of the inherent dangers of injury from a "no fault" adverse reaction. In that case the victim bears full responsibility for the loss incurred as a consequence of the injury.¹⁷⁰

Strict liability may ease the plaintiff's burden, but it certainly does not remove it. It is inappropriate and unfair to require innocent victims, injured in the course of serving the public interest in controlling communicable disease, to seek compensation through the judicial process. That elaborate, unwieldy mechanism, premised on an adversarial relationship between the parties and directed at allocation of fault between them, is ill-equipped to serve as a compensation vehicle.¹⁷¹

It must be recognized that the vaccinee's decision to submit to immunization is not simply another private decision by a patient to submit to medical treatment. Society has an interest in and derives benefit from that decision.

Vaccination is a prophylactic measure; generally the vaccinee is in good health before receiving the vaccine. Great gains have been made in the suppression of communicable diseases over the past few decades and it is now quite possible that a potential vaccinee faces a greater risk of having a serious vaccine-induced adverse reaction than of contracting the disease through wild virus in the community.¹⁷²

Immunization is fundamentally a public health matter. Even when tempered by the application of the strict liability doctrine, the fault allocation oriented judicial process is a woefully inadequate compensation vehicle. Responsibility, not fault, is at issue. The public's interest in and benefit from the vaccinee's "private" decision to submit to immunization must be accompanied by public responsibility for the compensation of the victim. This is not an argument for absolving vaccine manufacturers or administrators of responsibility for their negligence or fault. In the special context of immunization, it is inequitable and irresponsible to force the injured vaccinee to pursue

¹⁶⁹ D.H.E.W., *supra* note 12, at 39. Ladimer, *Legal and Regulatory Perspectives in Mass Immunization Programs*, [1976] *Ins. L. J.* 459. Merrill, *supra* note 154, at 87.

¹⁷⁰ D.H.E.W., *supra* note 12, at 39.

¹⁷¹ There is no shortage of critics of the litigation process—in particular, private tort law—as a vehicle for the provision of compensation to accident victims. See, e.g., Glasbeek and Hasson, "Fault—the Great Hoax," in Klar, *supra* note 33, at 395-424; Franklin, *Replacing the Negligence Lottery: Compensation and Selective Reimbursements* (1967), 53 *Va. L. Rev.* 774.

¹⁷² Merrill, *supra* note 154, at 100. Davis, *supra* note 119, at 129.

the parties at fault through the courts. Any alternate approach to compensation could simply require vaccinees to subrogate their rights against potential defendants to the body or authority providing the compensation. Whether the victim subrogates to and receives fair compensation from that intervening body, or pursues those legal rights directly and independently is a decision that should be made by the vaccinee.

In the no-fault context, where injury is caused "not by a defective vaccine product or negligence on the part of the vaccinator, but by the inherent properties of a particular vaccine,"¹⁷³ the argument for public responsibility for the compensation of the victim is even stronger. In arguing the case for no-fault insurance, Krugman concedes that the lawsuit may be an adequate compensation mechanism in situations involving malpractice, *i.e.* where fault is present.¹⁷⁴ Krugman asserts, however, that:

in the majority of cases . . . there is no one at fault, and dyspractice, not malpractice has occurred.

If society is to benefit from immunization practice, as it obviously does—witness the dramatic decline in poliomyelitis, measles, diphtheria, and other diseases—then society, through its government, should logically be responsible for immunization dyspractice.¹⁷⁵

C. *Warnings: Informed Consent Versus Public Participation in Immunization Programmes*

The goals and priorities of public health authorities are not always in perfect harmony with the goals and priorities of the private citizen.¹⁷⁶ There is almost always tension between the public's interest in the health of the population at large and the individual's interest in making informed, independent decisions.¹⁷⁷

A number of commentators¹⁷⁸ have warned of a potentially very serious side effect of strenuous efforts to provide adequate warnings by vaccine manufacturers, health professionals and immunization programme administrators. Their concern is that the standard of detail set by the courts may lead to over-emphasis of the dangers of vaccination, resulting in "unnecessary deterrence of public participation."¹⁷⁹

The individual's right to receive information in sufficient detail and clarity such that he is in a position to give an "informed consent" to medical treatment is well recognized by both Canadian and American courts.¹⁸⁰ The

¹⁷³ O.T.A., *supra* note 7, at 83.

¹⁷⁴ Krugman, *Immunization "Dyspractice": The Need for "No Fault" Insurance* (1975), 56 *Pediatrics* 159.

¹⁷⁵ *Id.*

¹⁷⁶ Rozovsky, *supra* note 32, at 1.

¹⁷⁷ Franklin and Mais, *Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes* (1977), 65 *Cal. L. Rev.* 754 at 764-65.

¹⁷⁸ *E.g.*, Sharpe, *supra* note 56; Baynes, *supra* note 121 at 38; and D.H.E.W., *supra* note 12, at 38.

¹⁷⁹ D.H.E.W., *id.*

¹⁸⁰ Kenny, *supra* note 38; Halushka, *supra* note 37; Male, *supra* note 38; Kelly, *supra* note 43; and Reibl, *supra* note 54.

decisions of the United States Court of Appeals in *Davis*, *Reyes* and *Givens*, make it clear that in the United States potential vaccine recipients are entitled to adequate warning of a vaccine's inherent risk, even in the mass immunization and public health clinic contexts. In *Reyes*, the Court ruled that "[a] drug manufacturer is held to the skill of an expert in his field, and is presumed to possess an expert's knowledge of the arts, materials and processes of the pharmaceutical business."¹⁸¹

The general doctrine of informed consent is well established in Canada, but the law is unclear regarding the degree of detail required in the immunization context. Rozovsky suggests:

the patient should be told as much as possible about the risks without the necessity of informing him of the extremely rare risks—unless he asks in which case he must be informed of them. At the commencement of any preventative immunization programme, a list of *all* risks should be compiled and a decision made as to how and if the patients are to be informed of them.¹⁸²

The interaction of the societal interest in large scale public participation in immunization programmes and the private and legal interests in informed consent yields contradiction and tension. This is inevitable, given the misconception implicit in the current approach to compensating victims of immunization injury that the vaccinee's decision to be immunized is essentially a private matter.

The absurdity of treating the decision to submit to immunization and the burden of seeking compensation for resultant injury as the private responsibilities of the vaccinee is particularly evident in the context of mandatory immunization programmes.

Although compulsory immunization legislation is extremely limited in Canada,¹⁸³ such schemes have become commonplace in the United States. By September 1973, forty-one American states had implemented legislation making immunization mandatory for school admission.¹⁸⁴ Such legislation renders the protection afforded by warnings of risks inherent in the use of vaccines illusory. Since school attendance is required by law, parents must subject their children to immunization or risk criminal prosecution for failing to send their children to school.¹⁸⁵

¹⁸¹ *Reyes*, *supra* note 123, at 1277. See Mann, *supra* note 115, at 255.

¹⁸² *Report*, *supra* note 32, at 19. In Rozovsky's view, "[t]here is no clear answer to this dilemma except to say that the patient should be told as much as possible about the risks without the necessity of informing him of the extremely rare cases—unless he asks in which case he must be informed of them."

¹⁸³ *Id.* at 35-37. But note Manitoba's *Public Health Act*, R.S.M. 1970, c. P-210, s. 34(10).

¹⁸⁴ Geeson and Sowell, *A School Immunization Law is Successful in Terms* (1975), 90 Public Health Reports 21 at 21.

¹⁸⁵ Baynes, *supra* note 160, at 62:

In mandatory immunization programmes, a warning becomes a fiction. There is no choice on the part of the patient, or other persons receiving the vaccine. The court in *Reyes* suggests that one would have a choice to be innoculated with killed virus Salk vaccine, whether to provide complete immunity or as a precautionary prelude to ingesting oral vaccine. The problem is there are not always

While the fallacy and invalidity of the "immunization is a private matter" argument is perhaps most visible in the mandatory immunization context, one need not go that far to reject the proposition. In Canada, the United States and most other developed nations, the state takes an active role in the establishment of immunization programmes. Local health authorities and various levels of government vigorously solicit public participation in those programmes. School systems are widely used as vehicles for immunization programmes.¹⁸⁶

In short, immunization is a public matter. Large scale public participation is essential to the success of immunization programmes, and the public at large is the primary beneficiary of those programmes. The public interest in and benefit from the individual's decision to submit to immunization should be matched by a concomitant public commitment to ensure that vaccine related injury is fairly and expeditiously compensated.

V. CONCLUSION: ALTERNATIVES

The purpose of this article has been to demonstrate the inadequacy of current Canadian law as a vehicle for the compensation of victims of immunization injury—particularly where injury occurs as a result of risk inherent in a vaccine that meets applicable standards. It has been argued that private tort law, which is fault-oriented and rooted in the adversarial litigation process, is a fundamentally inappropriate approach to this public health issue.

Recent American cases, imposing strict liability and a formidable duty to warn on vaccine manufacturers were assessed. It was argued that the approach indicated by the *Davis*, *Reyes* and *Givens* cases fails to address the compensation problem, and may pose a serious threat to security of vaccine supply and to public participation in immunization programmes. It seems inevitable that this American trend, like so many others that have preceded it, will spill over into Canada unless deliberate, prompt action is taken to avert it.

It is hoped that the need to consider alternative compensation mechanisms has been established. The list of options is wide-ranging, and must include: major modifications of tort law,¹⁸⁷ a publicly administered and funded compensation system,¹⁸⁸ government indemnification of vaccine man-

alternatives such [*sic*] in the case of measles, or small pox vaccine. Further Salk vaccine is possibly no longer available and if it was, do we warn about the possibilities of another *Gottsdanker* incident, and even if not, any warning would still provide no protective function where the patient must take the vaccine.

¹⁸⁶ In early 1979, the Ontario Ministry of Health proposed that all school children should be immunized unless their parents specifically refuse to grant permission. At that time Dennis Timbrell, the Minister of Health, stressed the proposal was "just at the discussion stage." The suggestion has been regarded by public health officials in other jurisdictions as a first step toward compulsory immunization. *Ontario Proposal Seen as a Step Toward Compulsory Immunization* (1979), 25 Can. Fam. Physician 262, at 262.

¹⁸⁷ D.H.E.W., *supra* note 120, at 73.

¹⁸⁸ Nat'l Immunization Work Groups, *Report and Recommendations on Liability* (Washington: Office of Ass't Sec'y for Health, 1979).

ufacturers' and other participants' losses arising from participation in immunization programmes,¹⁸⁹ government sponsored reinsurance backing to primary insurers for vaccine-related risks¹⁹⁰ and "no-fault" insurance.¹⁹¹

Legislative schemes premised on the recognition that immunization is fundamentally a public matter, and that the compensation of victims of immunization injury should be a public responsibility, have been in place in several European countries for a number of years.¹⁹² In 1979 Britain enacted the *Vaccine Damage Payments Act*,¹⁹³ enabling the Secretary of State to "make a flat payment of £10,000 [not any portion of it] to the benefit of the injured person or to his personal representatives if the Secretary of State is satisfied that the person is, or was immediately before his death, severely disabled as a result of vaccination against any of the diseases to which the Act applies."¹⁹⁴ This new British legislation is not without its difficulties, or its critics,¹⁹⁵ but it is a vast improvement over the common law approach to compensation.

In recent years public health authorities in a number of provinces have responded to serious cases of immunization-related injury with the *ad hoc* provision of assistance and compensation.¹⁹⁶ This responsible conduct is laudable, but not enough. More than the discretionary, informal and unofficial availability of government largesse is required; a coherent, visible approach to compensating victims of immunization injury must be developed.

There are encouraging signs that some Canadian public health administrators and policy makers are growing dissatisfied with the prevailing law and practice of compensation.¹⁹⁷ It is to be hoped that dissatisfaction proves to be highly contagious.

¹⁸⁹ Curran and Pies, *Vaccines and Liability: Final Report* (Washington: D.H.E.W., 1975). See also D.H.E.W., *supra* note 12, at 87.

¹⁹⁰ *Id.*

¹⁹¹ Krugman, *supra* note 174; and D.H.E.W., *supra* note 12, at 87.

¹⁹² Curran, *supra* note 117, at 7-9; Curran and Pies, *supra* note 189, at 9; and *Report*, *supra* note 32, at 25-27.

¹⁹³ 1979, c. 17 (U.K.).

¹⁹⁴ *Report*, *supra* note 32, at 25.

¹⁹⁵ Dworkin, *Compensation and Payments for Vaccine Damage*, [1978-79] J. Soc. Welfare L. 331.

¹⁹⁶ Discussions with Frank White and Richard Mathias, epidemiologists for the province of British Columbia (July 2, 1980). Details of specific cases were withheld out of understandable reluctance to prejudice pending and possible legal actions.

¹⁹⁷ British Columbia and Alberta are currently considering major amendments to their public health legislation; public health legislation planners in both provinces are wrestling with the immunization injury compensation problem.