

Policy Statement on Vaccination

By Catherine Diodati

INFORMED CONSENT

The Vaccination Risk Awareness Network recognizes that vaccines are not without risk and supports the right of each individual to adequate disclosure prior to providing consent.

It is recognized that informed patients, and their parents or guardians, will make the best healthcare decisions. In order to provide truly informed consent, individuals must be apprised of potential risks, benefits and alternatives to vaccination.

Pertinent information should include the actual risk of contracting a particular disease, based upon epidemiological evidence, probable outcome and available treatments. Disclosure should also include vaccine ingredients and their known hazards, possible adverse effects and vaccine efficacy.

Information should be made available in a format that is appropriate to the patient, parent or guardian, including a variety of languages, in print, on tape and in braille. (1) No vaccine should be administered if any hesitation is detected and until all questions have been answered.

Information should be at least as complete as that found on vaccine package inserts. Information sheets should include documentation and information on the source(s). Original vaccine package inserts should be available upon request. Information should be provided well in advance of the vaccination appointment to allow time to understand the information presented and to address any questions. Vaccination consent should be based upon accurate and adequate disclosure and not upon fear. The probable outcome of natural infection should be explained including, available treatment for complications, the effect of proper nutrition and vitamins on outcome, and this information should be relevant to the patient's health and environment. For example, any disease-related morbidity and mortality statistics used, must be relevant to Canadians.

VOLUNTARY CONSENT

The Vaccination Risk Awareness Network is opposed to mandatory vaccination, and upholds the right of individuals to exercise "Informed Consent" when considering an invasive medical procedure such as vaccination

While most Canadian provinces have adopted a voluntary policy regarding vaccination, and others provide exemptions to vaccination, most Canadians are not informed of their rights. The consent process should include information on the legal status of vaccination recommendations as well as the types of, and how to obtain, exemptions.

Where mandatory vaccination legislation does not exist, individuals clearly should be informed that vaccination is voluntary. In regions where vaccination legislation does exist, *thorough* information regarding exemptions should be made available prior to obtaining consent.

While medical exemptions do carry certain limitations, patients, and their parents or guardians, should be informed that religious and philosophical exemptions carry no such limitations. Exemption forms, where required, should be readily available.

No pressure should be exerted to gain vaccination compliance. No individual should be refused medical treatment or threatened in any way should the individual choose not to vaccinate.

Parents and educators should be informed that the only time an unvaccinated child can be removed from school is during an outbreak, and only for the duration of the outbreak, if the child is not already immune. No inference should ever be made that would tie educational rights to vaccination status. Consent forms used for school-based vaccination campaigns are frequently misleading in that they tend to emphasize statements such as "**Childhood Immunizations: It's the law,**" "**This student will be suspended from school if you do not complete and return this form,**" while minimizing exemption information, if it is present at all.

At no time should any coercion be exerted to influence a vaccination decision. Neither social service payments, medical treatment, employment, professional standing, nor the patient-care provider relationship, should be threatened based upon vaccination status.

The decision to refuse vaccination must be respected and under no circumstances should any health care provider endeavour to gain consent from a child whose parent or guardian has refused consent to vaccination. The inherent ambiguity of the "mature minor" rule, coupled with certain provincial policies such as the BC Infant's Act, has repeatedly been abused by pressuring school children to provide consent to vaccination against their parent's explicit wishes. There is an underlying presumption that the child is capable of making specific health care decisions if he or she is able to comprehend the nature and consequences, including the benefits and risks, of the proposed treatment. (2) While there may be certain benefits to such policies, they are abused when parental consent to vaccination is overridden because these children are provided with minimal and biased information that rarely represents actual risks associated with vaccination. Furthermore, the child may provide consent merely due to the overwhelming coercion of the school, a health care provider who is unfamiliar with the child's history or solicited peer-pressure, effectively invalidating informed and voluntary consent requirements.

VACCINATION RECOMMENDATIONS

Vaccine recommendations continue to be expanded despite a lack of supporting evidence demonstrating need, safety, or efficacy.

"The recent development of hepatitis B and varicella vaccination recommendations broke new ground in the history of immunizations. For the first time, universal immunizations

were recommended for a problem that the community and its physicians did not agree presented a danger sufficient to justify such an intervention." (3) Recently, Ontario expanded recommendations for influenza vaccination, even employing mandates amongst some groups, without adequate supporting evidence demonstrating need, safety or efficacy.

Chickenpox is an innocuous disease for healthy children. Universal childhood varicella vaccination carries the risk of altering the disease's epidemiology by deferring the disease to adolescence or adulthood, when the disease is more severe. (4) The varicella vaccine is said to "protect modestly, if at all, against infection, moderately well against clinical disease (rash), and very well against severe disease." (5) In children, who are most frequently infected, the disease is generally innocuous, causing few fatalities and generally minor morbidity. (6) Vaccinated individuals have developed vaccine-induced varicella and have transmitted the disease to contacts. (7) The varicella vaccine has been associated with the development of varicella zoster (shingles) in both healthy and immunocompromised children. (8) This expensive vaccine has been promoted as a means to reduce parental absence from work to care for their infected child, thus creating an economic benefit. However, the cost benefit, at best, has been estimated at approximately US "\$2.00 per American." (9) Since the vaccine became available, marketing strategies have inflated and misrepresented the risks associated with contracting varicella. These strategies have effectively instilled an unwarranted fear of the disease in order to secure vaccine sales. "The promotion of the varicella vaccine has been based upon habit and profit rather than science, and has exposed the premise of immunization to doubtful legitimacy." (10)

Throughout Canada, recommendations have been made to vaccinate children against hepatitis B. Universal childhood hepatitis B vaccination is unnecessary; impractical, and dangerous. Less than 3%, of the approximately 1000 - 3,000 cases of natural hepatitis B infections, occur in children <15 years of age. (11) According to the LCDC's Notifiable Diseases On-Line, there were only 25 reports of hepatitis B in children under 15 years of age, throughout Canada, in 1998. Many of these occur by perinatal transmission and could be addressed sufficiently through maternal screening and perinatal treatment. There is no justification for promoting universal childhood hepatitis B vaccination. Antibody response rates for children 2-19 years (99%) are comparable to response rates for adults aged 20-29 years of age (95%), and 30-39 years (90%), providing no benefit to vaccinating children over adults when risk factors can be accurately assessed. (12)

There is no evidence demonstrating that vaccine-induced immunity to hepatitis B will persist to adulthood when children may be at actual risk of infection due to occupation or lifestyle choices. (13) According to US figures, the incidence of serious hepatitis B vaccine-related adverse events grossly exceeds the number of childhood infections each year. (14)

Ontario has recently expanded influenza vaccination recommendations to include all individuals >6 months of age. Studies have not demonstrated a reduction in influenza transmission by this strategy (15) and have not demonstrated the safety, efficacy, or cost-

effectiveness of mass vaccinating low-risk groups. (16) Further, of the thousands of suspected influenza samples submitted to Health Canada, 85-90% are found to be respiratory illnesses caused by pathogens other than influenza, such as coronavirus, respiratory syncytial virus, adenovirus, rhinovirus and et cetera, which cannot be positively affected by influenza vaccination. (17)

The Ontario Government has spent a minimum of \$38 million (in 2001) to provide the influenza vaccine to its citizens while removing funds from hospital emergency rooms, cancer programs and other vital services. A recent US study indicated that vaccination of healthy individuals actually creates a cost-deficit of \$11.17 US, when vaccine virus strains corresponded well with circulating influenza strains, and \$65.59 US, when strains did not correspond well. (18) >From a financial perspective, the mass influenza vaccination campaign in Ontario cannot be justified. This strategy should be abandoned and not adopted by other provinces.

Health care workers are being coerced into accepting annual influenza vaccination or face suspension, without pay, from their jobs. Financial coercion should never provide the basis of any medical decision. Since there is no scientific justification for this strategy, and no justification in law for abrogating the right to freedom of choice and security of the person, this action should be halted immediately. (19)

As a condition of continued employment, Ontario paramedics and long term care facility care workers have been required to receive the influenza vaccine. As a condition of vaccination, they have been required to sign consent forms which include waivers releasing their employer, the vaccine manufacturers, etc., of liability in the event of an adverse event.

In the event of a serious adverse reaction, these workers have no compensatory recourse. Ontario does not have a vaccine-injury compensation program and injured individuals will be made dependent upon inadequate, and diminishing, social service and health care programs. Mandating vaccination programs violates the bioethical principle of respect for autonomy and the general refusal of compensatory responsibility for vaccine injuries violates the principle of justice.

RISKS ASSOCIATED WITH VACCINATION

Universal vaccination has been adopted as an utilitarian good, by governments internationally, as a means to prevent personal and social burdens associated with natural infection. Neither the benefits nor the risks can be predicted for all individuals.

Vaccines are inherently hazardous products which contain attenuated live, or inactivated, antigens, germicides, detergents, preservatives, adjuvants, and residues from culture media and host tissues.

Vaccine manufacturers are allowed a certain amount of competitive secrecy regarding the formulation of vaccines. While this protects the manufacturer's competitive edge, it neither protects vaccine recipients nor facilitates the informed consent process.

Thimerosal is a neurotoxin which is included in hepatitis B and influenza vaccines. In October 1998, the US FDA ordered the removal of thimerosal from over-the-counter drugs due to inherent risks. (20) In July of 1999, they further called for the removal of thimerosal from all vaccines although follow-up has been discouraging. Canada continues to defend the safety of this neurotoxin in vaccines. (21)

Many vaccines contain formaldehyde as a disinfectant. Formaldehyde is not only carcinogenic but it is known to be unpredictable as a disinfectant, sometimes causing antigenic proteins to clump, hardening the outer gelatinous debris, which is digested by the body allowing fully virulent particles to be released in the vaccinee. (22) The Cutter Incident, which caused 260 cases of vaccine-associated polio in vaccinees and their contacts from the inactivated vaccine, provides a valuable lesson regarding formaldehyde's inadequacy. (23)

Other vaccine chemicals are equally toxic and can cause cumulative and long-term adverse effects on the body. For example, phenol is a highly caustic coal tar derivative used in vaccines. Phenol is a protoplasmic poison (i.e. toxic to all cells), inhibits phagocytic activity, and has been associated with systemic poisoning among other adverse effects. (24) Canadian DPT-Polio based childhood vaccines no longer contain thimerosal as a preservative. (25) Instead, a compound called *2-phenoxyethanol* has become the preservative of choice. 2-Phenoxyethanol is "obtained by treating phenol with ethylene oxide in an alkaline medium." (26) The ethylene oxide portion of this combination is an irritant which may cause severe dermatitis, blisters, eczematous dermatitis, and burns. Prolonged exposure has caused cancer in female mice and, in 1978, the EPA issued "a rebuttal presumption against registration of ethylene oxide for pesticidal applications ... on the basis of mutagenicity and testicular effects." (27)

Aluminum salts and gels, used as vaccine adjuvants, have been associated with motor paralysis, fatty degeneration of the kidneys and liver, learning disabilities, dementia, bone dissolution, et cetera. (28)

Host tissues and culture media may contain undetected pathogens that are passed on to the vaccinee. During the 1960s, for example, there were over 40 simian viruses found to contaminate polio vaccine host tissues. One of these viruses, identified as *SV40*, has re-emerged in tumours of individuals who received the contaminated vaccines. Further, SV40-related cancers have appeared in the children of individuals who received the contaminated vaccines. (29) Recent Swiss research discovered the presence of an enzyme, *reverse transcriptase*, in avian tissues used for vaccines. (30) Reverse transcriptase is associated with retroviruses and, in this case, a leukemia-type illness. Currently, there have been concerns expressed over the potential presence of BSE prions in vaccines due to the bovine fetal serum used as a base for culture media. (31)

Vaccines clearly have the potential to introduce novel pathogens, and genetic material, into humans. The result of which may well be the permanent alteration of the human genome and the perpetuation of vaccine-induced degenerative diseases ad infinitum.

Prelicensure studies generally focus upon vaccine efficacy and safety studies are too limited to predict outcomes over an extended period and do not adequately account for genetic diversity. (32) It is only when vaccines are used *en masse* that most adverse events are discovered. Once a vaccine has reached licensure, it is very unusual to have the product, or even dangerous components, removed in a timely fashion.

As with the whole cell pertussis vaccine, health officials resisted acknowledging serious adverse events caused by the product. Once an acellular vaccine was available, officials readily admitted hazards associated with the original product. Similarly, although officials knew that polio vaccines were contaminated, they did not disclose this information to the public but, instead, continued to use the contaminated vaccines until they quietly changed the simian host tissues. (33)

Vaccine manufacturers incur significant expenditures in developing new vaccines which creates a need to recoup losses, sometimes at the expense of safety. Questions ultimately arise concerning conflicts of interest between those manufacturing, licencing and recommending vaccines. The rotavirus vaccine was demonstrated to increase the risk of intussusception 30-fold in infants during pre-licensure studies but this data was not revealed to physicians nor to the public. (34)

The AAPS "has concluded that the FDA and CDC may have ignored or concealed data that showed the problems from the outset." (35) As a result, numerous infants suffered intussusception following vaccination which may result in nutrient absorption difficulties throughout their lives. In this case, the vaccine was removed from the market within one year of licensure but it is more often the case that the public is kept uninformed, and the vaccine is still used, because health officials fear that such disclosure will destroy public trust in vaccination programs.

Vaccinated individuals often succumb to the very diseases against which they are vaccinated. Unvaccinated individuals are frequently told they are a threat to public health. An uninfected individual poses no threat whatsoever. "Immunization of a child who is already infected (or who becomes infected in spite of the vaccine) is of no protective value to anyone." (36)

Vaccines have been known to provoke disease, particularly when an individual harbours a subclinical infection, while individuals are frequently advised not to defer vaccination during, what is presumed to be, mild illness. In 1901, Almroth Wright, inventor of the typhoid vaccine, described a *negative phase* following vaccination whereby bactericidal properties of the blood significantly decreased. During this phase, Wright observed the activation of latent typhoid infections, as well as jaundice, liver damage, cardiac arrest, severe disturbances of the nervous and circulatory systems and death. (37)

During the 1950s, many studies demonstrated a link between the administration of diphtheria and pertussis vaccines and the onset of poliomyelitis. (38) Despite this knowledge, the DPT vaccine continues to be used in polio-endemic areas during

outbreaks, with disastrous results. (39) The unconjugated PRP Hib vaccine demonstrated a *minus* 86% efficacy rate, according to Minnesota epidemiologist Michael Osterholm, and vaccinees faced a five-fold increase in Hib disease. (40)

Oral polio vaccine use was continued for decades in Canada and the US despite the known risk of vaccine-associated paralytic poliomyelitis to vaccinees and their contacts and despite the disease's elimination in these regions. Similarly, the smallpox vaccine was used for decades after the disease threat diminished. In both cases, it was the vaccines, and not the wild pathogens, that provided the primary source of complications and deaths.

Vaccines can be made unstable by minor temperature variations. While it is recognized that manufacturers and health ministries have worked diligently to resolve cold chain problems, there can be no guarantee that vaccines will not be corrupted by transient breaks in the cold chain.

Many new vaccines are under development but science has failed to identify and remedy risks associated with current vaccines.

There has been compelling evidence linking vaccines to SIDS, autism, diabetes, transverse myelitis, arthritis and many other long-term disabilities. (41) Currently there is no screening method used to determine which individuals will be placed at risk. The development of appropriate screening methods should be given priority and they should be used prior to the administration of any vaccine.

Vaccines are generally not tested for carcinogenic or teratogenic effects and are not tested for effects on fertility or safety during pregnancy and breast feeding.

As with the hepatitis B and influenza vaccines, once the product is licensed for use, the target market is expanded without due consideration to necessity, safety or efficacy. Frequently, children are targeted for expanding vaccination recommendations because they are the most accessible group. Accessibility is not an appropriate determinant.

Initial hepatitis B vaccination strategies targeted groups that were at greatest risk. The strategy failed to produce favourable results, partly due to the practical application of the vaccination program which, in practice, reversed the order of priority due to accessibility. (42) The failure of this strategy led health officials to adopt a new strategy which involves targeting all children for hepatitis B vaccination. Previously, vaccinating children was not recommended because incidence is "confined to small, well-defined groups, e.g., infants born to HBV-infected mothers [or who reside in endemic communities] for whom prevention programs already exist." (43) Some provinces persist in initiating the vaccine series at 0-2 months without evidence of need or evidence of safety in this age group. (44) The need for vaccinating children against hepatitis B was not established before recommendations were made and accurate adverse event data has not been made available to the public from Canadian sources. The financial extravagance of universal childhood hepatitis B vaccination cannot be supported.

The Association of American Physicians and Surgeons estimate that "*for most children, the risk of a serious vaccine reaction may be 100 times greater than the risk of hepatitis*

B." (45) The AAPS also also notes that only approximately 10% of reactions are ever reported, indicating that the actual adverse event rate may be much higher. (46) In a study conducted by the National Vaccine Information Center, it was reported that, in 8 US States during 1997, there was a total of 25 cases of hepatitis B amongst children <5 but there were 106 serious hepatitis B vaccine-related adverse events and 10 deaths reported for children < 5 in the same 8 States. (47) Neither necessity, nor safety, of vaccinating children against hepatitis B have been established. Yet health officials continue to mislead parents by stating that the hepatitis B vaccine is both necessary and safe for their children.

Recently the influenza vaccine recommendations have been expanded to include children. Healthy children are not considered to be at high risk for influenza-related complications. The recommendation has been made for proposed utilitarian purposes: primarily to prevent transmission to family contacts. Neither necessity, safety, efficacy, nor cost-effectiveness have been established for this group. Recent evidence suggests that vaccinating children against influenza *increases* the incidence of respiratory illnesses amongst this group and, logically, could not reduce transmission amongst contacts. In fact, the vaccine was found to have a *negative* 23% efficacy rate against respiratory illnesses in daycare children without pre-existing antibodies to influenza and only 11% in those with high titres of pre-existing antibodies. (48) While this study claimed that the strategy was successful in reducing respiratory illness amongst household contacts, the only significant reduction was amongst *unvaccinated* 5-17 year old contacts who undeniably would have acquired immunity due to prior natural exposures. Despite claims to the contrary, the data derived from this study does not support vaccinating children against influenza as an effective method of preventing infection or transmission.

ADVERSE EVENT REPORTING

Adequate adverse event reporting and investigation is recognized as a corner-stone to maintaining public safety and trust.

Every year approximately 4,000-5,000 adverse events are reported to Health Canada. Based upon the passive nature of adverse event reporting, this figure most certainly represents only a fraction of actual adverse events incurred. (49) Of these reported adverse events, only a small number are investigated. The actual frequency of adverse events cannot be predicted under the current paradigm. (50)

Legislation regarding mandatory vaccine-related adverse event reporting exists only in Ontario but does not seem to be enforced. (51) In all provinces, the under-reporting of adverse events unnecessarily endangers the health of vaccinees.

Under-reporting of adverse events seriously limits the medical practitioner's ability to present appropriate precautions and warnings to patients prior to vaccination.

The reporting and thorough investigation of suspected adverse events would provide an accurate means to determine who may be at greatest risk for adverse events, thereby preventing serious injury, and would alert health care officials to particularly reactogenic vaccine lots more quickly.

Under-reporting of adverse events serves to instill mistrust in the vaccination program and in medicine in general.

Vaccine-associated fatalities appear to have been summarily dismissed as a valid reportable event. The Canadian National Immunization Report, 1998, excludes death in its list of *Vaccine Associated Adverse Events* (Table 10). (52) In their Appendix 1, they note that "All sudden infant death syndromes were excluded because they were deemed to be unrelated to vaccine administration according to previously published papers." The implications associated with the absence of fatalities in proximity to vaccination are grave: the frequency of fatalities will be obscured thereby preventing further investigation, adequate information for physicians and their patients and redress for dangerous vaccines.

A further, and no less important, implication of not recognizing the true incidence of vaccine-associated fatalities is that parents may, and have, been wrongly accused of abuse.

Physicians and nurses administering vaccines should be made aware of their responsibility to report adverse events, without relying on personal opinion, and should be taught how to file an adverse event report. Further, they should be equipped to inform their patients of the reporting and follow-up procedures.

Raw data on adverse event reports should be made available to health care professionals and to the general public which exclude any personal identifiers but include information on potentially contributory preconditions, as well as, the vaccine used, the manufacturer, lot numbers and the size of the lot distributed.

COMPENSATION FOR VACCINE INJURIES

Through no fault of their own, individuals sometimes become injured through the normal use of vaccines.

Excluding Québec, which established a vaccine injury compensation program in 1987 (53), no other Canadian province currently has established a compensation program to address vaccine-related injuries and deaths. (54) Provincial health plans cover only a portion of the costs associated with vaccine injuries and do not address the inherent inequity burdening affected families.

Justice Osler, while presiding over a Canadian vaccine injury case, noted that the Canadian Court System is not the proper venue for addressing such cases and recommended legislative reform. Justice Osler recognized that the type of evidence required by the court is not available from science and that, not only will plaintiffs go uncompensated by the court, they will incur exorbitant legal debts, further diminishing their chance to live a decent equitable life. (55)

Provincial compensation programs would have the additional benefit of providing more accurate adverse event data which would reveal trends, lead to further investigation and improvements, and ultimately reduce adverse events.

Canadian health ministries promote universal vaccination as an utilitarian benefit. In other circumstances, when individuals are acting for the public good, and are injured through no fault of their own, compensation is available. When an individual submits to vaccination, and is subsequently injured, there is no means available to provide compensation.

Due to the universal vaccination recommendations, each province should establish adequate compensation programs.

NEW VACCINES

The quest for new vaccines continues to target both serious and innocuous diseases.

Vaccines are frequently combined for the convenience of administration and to improve recall rates. Monovalent vaccines should be made available upon request so that patients, or their parents or guardians, will not feel coerced into accepting unwanted or unnecessary vaccines but will have the option of selecting which vaccines are appropriate to their given circumstances.

MANUFACTURERS, OFFICIALS AND PUBLIC TRUST

Public-trust in pharmaceutical companies has diminished severely. Public confidence in government and health officials has eroded.

While vaccine manufacturers were once perceived to be altruistic in intent, they continue to lose public confidence through the release of unnecessarily dangerous and expensive products, unsupported claims regarding safety, efficacy and need, persecution of researchers whose results do not support the use of their products, inadequate and contaminated production lines, and market manipulation.

In October 2000, CNN reported that due to the influenza vaccine shortage in the United States, some manufacturers raised their price from approximately \$30.00/vial to as much as \$100.00/vial for the influenza vaccine. The vaccine shortage was caused by safety violations at some of the manufacturing plants and other manufacturers, who were unaffected, responded by price-gouging. (56)

Michigan Biologic Products Institute, now called BioPort Corporation, knowingly supplied contaminated anthrax vaccines to US and Canadian troops. (57) The company has repeatedly been cited by the FDA for numerous and serious violations, their vaccine continues to be used on members of the military. (58)

Individuals who have refused the anthrax vaccine have faced various punishments, court martial and discharge. The anthrax vaccine contains only 2 anthrax strains, there are at least 50 - 100 strains of the bacteria. Further, there have been no tests verifying that this vaccine is safe in humans or effective against inhaled exposure. (59) Animal tests have shown a variable efficacy ranging from 4% - 100% when vaccinated animals have been challenged with anthrax. (60) The vaccine was licensed in 1970, 2 years before efficacy data was required. The only human vaccine trial conducted in the West was conducted in

the 1950s, evaluated cutaneous exposure, and was conducted using a completely different vaccine than the one currently in use. (61) The US DOD, in an attempt to allay concerns, stated that this "vaccine had been administered in the US to veterinarians, laboratory workers and livestock handlers since 1970." (62) The DOD later had to retract this statement when members of the military actually surveyed veterinarians and found the statement to be untrue.

In the US, universal infant rotavirus vaccination recommendations were made "by the CDC's Advisory Committee on Immunization Practices (ACIP) six months before the vaccine was licensed by the FDA on August 31, 1998." (63) Rotavirus is highly treatable through re-hydration therapy. The vaccine's efficacy rate is variable, offering approximately 57% protection against rotavirus diarrhea and approximately 87% protection against the more severe form of the disease. (64) Rotavirus causes approximately 20 - 40 deaths per year in the US, according to CDC estimates, but they have "not indicated how many of these could have been prevented with proper medical treatment." (65)

Rotavirus is not considered to present a significant threat in developed countries but there is little question that children in developing nations suffer greatly from this disease. In an effort to secure affordable vaccines from manufacturers, for developing nations, UNICEF, in conjunction with WHO and other organizations, have established a price-tiered system for vaccine purchases. (66) The manufacturers will supply vaccines at reduced prices to poorer nations and can be guaranteed compensation through the sale of bulk vaccines, at higher prices, to richer nations. (67) "When the vaccine was licensed in 1998, there were reports that in order to be able to finance delivery of Rotashield to Third World populations, where the infection is a serious threat, the richer countries like the US would have to use it." (68) The question that remains is whether the US universal infant rotavirus vaccine recommendations were established solely as an incentive to vaccine manufacturers to provide the vaccine to nations where the disease actually does present a significant threat.

The Association of American Physicians and Surgeons recently stated: Public policy regarding vaccines is fundamentally flawed. It is permeated by conflicts of interest. It is based on poor scientific methodology (including studies that are too small, too short, and too limited in populations represented), which is, moreover, insulated from independent criticism. The evidence is far too poor to warrant overriding the independent judgments of patients, parents, and attending physicians, even if this were ethically or legally acceptable. Indeed, evidence is accumulating that serious adverse reactions are being ignored. (69)

References:

1. Dr. Michael Corr, head of the Immunisation Project, Health Education Authority (HEA) in England, has revised public vaccine literature so that it is available in 22 languages, on tape and in braille. This literature is made available to parents on the child's 10-day birth visit. Alison Whyte, "Immunisation Adverse Reactions," Health Visitor 68 no.7 (July 1995): 270.
- 2 Cf. Lorne E. Rozovsky, The Canadian Law and Consent to Treatment (Toronto: Butterworths, 1990), 4-7; Infants Act [RSBC 1996] Chapter 223, Part 2: 17 (1-3).
3. Arthur Lavin, "Questions About Varicella Vaccine," Pediatrics 98 no.6 (6 December 1996): 1225.

4. Stanley A. Plotkin, "Varicella Vaccine," Pediatrics 97 no.2 (February 1996): 252.
5. Ibid.
6. Arthur A. Lavin, "Varicella-Zoster Vaccination for Health Care Workers," The Lancet 343 no.8909 (28 May 1994): 1363.
7. Cf., for example, LaRussa et al., "Transmission of Vaccine Strain Varicella-Zoster Virus from a Healthy Adult with Vaccine-Associated Rash to Susceptible Household Contacts," Journal of Infectious Diseases 176 no.4 (October 1997): 1072-1075; Stanley A. Plotkin, "Varicella Vaccine," 252.
8. Stanley A. Plotkin et al, eds., "Zoster in Normal Children After Varicella Vaccine," The Journal of Infectious Diseases 159 no.5 (May 1989): 1000; Arthur Lavin, "Varicella-Zoster Vaccination for Health Care Workers," The Lancet 343 no.8909 (28 May 1994):1363.
9. Arthur Lavin, "Varicella Vaccination for Health Care Workers," 1363.
10. Arthur Lavin, "Questions About Varicella Vaccine," Pediatrics 98 no.6 (6 December 1996): 1225.
11. National Advisory Committee on Immunization, Canadian Immunization Guide 4th Edition (Ottawa: Canada Communication Group Publishing, 1993), 47; According to statistics issued by the Laboratory Centre for Disease Control, Health Canada, since 1986, there have been between 2.11% to a high of 3.13% of cases in children <15 years of age. For most years, percentages fall at around 2.5%.
12. National Advisory Committee on Immunization, Canadian Immunization Guide 4th Edition (Ottawa: Canada Communication Group Publishing, 1993), 50.
13. It has been shown that "25% to 60% of adults will lose all detectable antibody to hepatitis B vaccine within 6 to 10 years." World Health Organization, "Hepatitis B Vaccines: Immunogenicity Reappraised," WHO Drug Information 8 no.2 (1994): 52f.
14. Dr. Jane Orient, "Statement of the Association of American Physicians and Surgeons: Regarding the Hepatitis B Vaccine," submitted to the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the Committee on Government Reform, U.S. House of Representatives, 14 June 1999.
15. Italian epidemiologist, Dr. Vittorio Demicheli, recently stated that while the vaccine may induce an antibody response in approximately 68% of healthy adults, only 24% will be protected against clinical illness. Vittorio Demicheli, "Mass Influenza Vaccination in Ontario: Is It Worthwhile?" Canadian Medical Association Journal 164 no.1 (9 January 2001):38-39.
16. Cf., for example, J. Potter et al., "Influenza of Health Care Workers in Long-Term-Care Hospitals Reduces the Mortality of Elderly Patients," Journal of Infectious Diseases 175 (January 1997): 1-6; Eugene S. Hurwitz et al., "Effectiveness of Influenza Vaccination of Day Care Children in Reducing Influenza-Related Morbidity Among Household Contacts," Journal of the American Medical Association 284 no.13 (4 October 2000): 1677-1683; Carolyn Buxton Bridges et al., "Effectiveness and Cost-Benefit of Influenza Vaccination of Healthy Adults," Journal of the American Medical Association 284 no.13 (4 October 2000): 1655-1663.
17. Health Canada, "Statement on Influenza Vaccination for the 1999-2000 Season," Canada Communicable Disease Report 25 (ACS-2) (1 June 1999). This report indicates that of 40,489 reports submitted to the LCDC, only 4,449 (11%) were positive for the influenza virus during the 1998-1999 season. Similar results have been reported by Health Canada for other years as well. For example, for the 1999-2000 season, only 7, 027 of 51,439 (13.66%) of the samples were confirmed to be influenza and from August 27, 2000- January 6, 2001, only 977 of 19,007 (5.14%) of the submitted samples were positive for the influenza virus. Health Canada, "Flu Watch: December 31, 200 - January 6, 2001 (Week 01)," http://www.hc-sc.gc.ca/hpb/lcdc/bid/respdis/fluwatch/w01_01/index.html#tab (Data accessed 17 January 2001). Cf., also, J. Potter et al., 4. It should also be noted that, in most cases, an influenza outbreak is declared in long term care facilities after only a few cases have been confirmed thus pathogens which produce similar symptoms may be incorrectly diagnosed as influenza.
18. Carolyn Buxton Bridges et al., "Effectiveness and Cost-Benefit of Influenza Vaccination of Healthy Adults," Journal of the American Medical Association 284 no.13 (4 October 2000): 1655-1663. There is little guarantee that the influenza strains chosen for the coming year's vaccine will match circulating strains. During the 1997-98 flu season, for example, there was only a 16.2% correspondence between the vaccine strains and isolates studied by the LCDC. Health Canada, "1997-1998 Influenza Season: Canadian Laboratory Diagnoses and Strain Characterization," Canada Communicable Disease Report 25 no.2 (15 January 1999).
19. The Ontario Health Care Consent Act, 11.(1) requires consent to be informed and to be given voluntarily for any medical intervention. Further, The Constitution Act 1982, Sections 2, 7, 12 and 15, guarantee: freedom of conscience and religion, freedom of thought, belief, opinion and expression, the right to life, liberty and security of the person, the right not to be subjected to cruel and unusual punishment, and equal protection and benefit under to law, without discrimination. Forcing individuals to submit to vaccination, or face economic ruin, is in direct violation of fundamental protections built into the law.
20. Federal Register 63 (77): 19799-19802, 22 April 1998.
21. National Advisory Committee on Immunization, "Thimerosal in Vaccines," Canada Communicable Disease Report 25 (ASC-7) (1 December 1999).
22. Sir Graham S. Wilson, Hazards of Immunization (London: The Athelone Press, 1967), 46.
23. Ibid., 45f.
24. Marshall Sittig, Handbook of Toxic and Hazardous Chemicals and Carcinogens (Park Ridge, NJ: Noyes Publications, 1985): 705; Robert H. Dreisbach, Handbook of Poisoning: Prevention, Diagnosis, and Treatment (Los Altos, CA: Lange Medical Publications, 1983), 704; Gosselin et al., III-344; Kenneth N. Anderson et al., eds., Mosby's Medical, Nursing, & Allied Health Dictionary 4th Ed. (St. Louis: Mosby-Year Book, Inc., 1994): 1208.
25. This includes DPT-Polio, with or without the addition of Haemophilus vaccine.
26. Susan Budavari et al, eds., The Merck Index (Whitehouse Station, NJ: Merck & Co., Inc., 1996), 7415.

27. Marshall Sittig, Handbook of Toxic and Hazardous Chemicals and Carcinogens 2nd ed. (Park Ridge, NJ: Noyes Publications, 1985), 433f.
28. Cf., Diodati, 71.
29. S. C. Stenton, "Simian Virus 40 and Human Malignancy," British Medical Journal 316 (21 March 1998): 877-880; J. R. Farwell, G. J. Dohrmann and J. T. Flannery, "Medulloblastoma in Childhood: An Epidemiological Study," Journal of Neurosurgery 61 no.4 (October 1984): 657-664; G. Barbanti-Brodano, C. TrabANELLI, L. Lazzarin, F. Martini, M. Merlin, N. Claza, A. Corallini and M. Tognon, "[SV40 as a Possible Cofactor in the Etiopathogenesis of Mesothelioma and Other Human Tumours]," Giornale Italiano Di Medicina Del Lavoro Ergonomia 20 no.4 (October-December 1998): 218-224; Janet S. Butel, Amy S. Arrington, Connie Wong, John A. Lednicky and Milton Finegold, "Molecular Evidence of Simian Virus 40 Infections in Children," Journal of Infectious Diseases 180 (1999): 884-887; Drs. John Bergsagel, Benjamin Sweet and Michael Carbone, "Virus Sv40," interview by Trish Wood, The Fifth Estate (25 February 1997); Debbie Bookshin and Jim Schumacker, "The Virus and the Vaccine," The Atlantic Monthly 285 no.2 (February 2000) 68-80.
30. World Health Organization, "Reverse Transcriptase Activity in Chicken-Cell Derived Vaccine," Weekly Epidemiological Record 28 (10 July 1998): 209-212; National Vaccine Information Center, "Animal Virus Enzyme Found in MMR Vaccine," The Vaccine Reaction 1 no.5 (November-December 1995) 1.
31. Charles Marwick, "FDA Calls Bovine-Based Vaccines Currently Safe," Journal of the American Medical Association 284 no.10 (13 September 2000): 1231-1232; Antony Barnett, "Children Exposed to CJD Infection Risk from Vaccines: Potentially Contaminated Stockpile of Drugs May Have Been Used Until 1993, Government Adviser Reveals," Guardian Unlimited (30 May 1999): <http://www.guardianunlimited.co.uk/Archive/Article/0,4273,3870082,00.html>; "Polio Vaccine Recalled in BSE Alert," Guardian Unlimited (20 October 2000): <http://www.guardianunlimited.co.uk/Archive/Article/0,4273,4079237,00.html>; "New Concerns About Mad Cow Disease in Canada," CBC News (23 January 2001): http://cbc.ca/cgi-bin/templates/view.cgi?/news/2001/01/22/madcow_010122
32. Hepatitis B vaccine clinical trials, for example, were far too limited to predict adverse events. Merck, Sharp & Dohme Canada monitored 1,252 healthy adults for only 5 after each dose was administered while SmithKline Beecham monitored their test subjects for *only 4 days*. According to the Association of American Physicians and Surgeons, the most cited long-term study on the hepatitis B vaccine primarily involved Alaskan natives and Asians yet most serious reactions have occurred in Caucasians. Further, "77% of the reactions involve women, who are generally more susceptible to autoimmune diseases." Prelicensure trials did not predict serious adverse events associated with this vaccine and, despite the large number of adverse event reports, the vaccine is still officially supported as being universally safe. Cf., Recombivax HB Vaccine Package Insert, Merck, Sharpe & Dohme Canada, 1992; Dr. Bonnie S. Dunbar, "Hepatitis B Vaccine," 3 January 1997, Dr. Jane Orient, "Statement of the Association of American Physicians and Surgeons: Regarding the Hepatitis B Vaccine," submitted to the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the Committee on Government Reform, U.S. House of Representatives, 14 June 1999.
33. Viera Scheibner, Vaccination: 100 Years of Orthodox Research Shows that Vaccines Represent a Medical Assault on the Immune System (Blackheath, Australia: by the author, 178 Govetts Leap Road, 1993), 152ff.
34. Association of American Physicians and Surgeons, "Rotavirus Vaccine Withdrawal Prompts Doctors to Ask for Congressional Investigation of Vaccine Approval Process: CDC and FDA May Have Ignored or Concealed Data About Life Threatening Side Effects for Infants," Press Release (04/06/2000):
35. Association of American Physicians and Surgeons, "Rotavirus Vaccine Withdrawal Prompts Doctors to Ask for Congressional Investigation of Vaccine Approval Process: CDC and FDA May Have Ignored or Concealed Data About Life Threatening Side Effects for Infants," Press Release (04/06/2000): <http://aapsonline.org/press/nrburton.htm>
36. Dr. Jane M. Orient, "Mandating Vaccines: Government Practicing Medicine Without a License?" The Medical Sentinel 4 no.5 (1999): 166-168.
37. Wilson, The Hazards of Immunization, 250ff.
38. Ibid., 270ff.
39. Thousands of children were paralysed following a DPT immunization campaign in India. Ganapati Mudur, "Flawed Immunisation Policies in India Led to Polio Paralysis," British Medical Journal 316 (25 April 1998): 1261.
40. Robert Mendelsohn, "Beware of Hib Vaccine," Immunizations: The Terrible Risks Your Children Face that Your Doctor Won't Reveal (Atlanta: Second Opinion Publications, inc., 1993): 87.
41. Cf, for example, John Barthelow Classes, "Childhood Diabetes Mellitus," New Zealand Medical Journal 109 no.1022 (24 May 1996): 195; Idem, "The Diabetes Epidemic and the Hepatitis B Vaccines," New Zealand Medical Journal 109 no.1030 (27 September 1996): 366; Harris L. Coulter and Barbara Loe Fisher, A Shot in the Dark (Garden City Park, NY: Avery Publishing Group Inc., 1991). Regarding ongoing research into the MMR-autism connection, see, for example, A. J. Wakefield et al., "Ileal-Lymphoid-Nodular Hypoplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children," The Lancet 351 no.9103 (28 February 1998): 637-641; Andrew J. Wakefield, "MMR Vaccination and Autism," The Lancet 354 no.9182 (11 September 1999): 949-956. Bonnie S. Dunbar, "Hepatitis B Vaccine," (3 January 1997): <http://www.ias.org.nz/dunbar.htm>
42. Intravenous drug users and those engaging in promiscuous sexual activity are among the highest risk groups while health care workers fall near the end of the priority list. Yet, due to accessibility, health care workers were prioritized for hepatitis B vaccination. Health and Welfare Canada, "National Advisory Committee on Immunization: Statement on Hepatitis B Virus Vaccine," Canada Diseases Weekly Report 8 no.45 (6 November 1982): 221-228.
43. Health and Welfare Canada, "Report of the Hepatitis B Working Group," Canada Communicable Disease Report 20 no.13 (15 July 1994): 107.

44. According to LCDC statistics, hepatitis B incidence in children aged 0-1 year has ranged between 2-26 cases per year between 1986-1998. During most years, there are between 6-9 cases of hepatitis B in infants <1 year of age throughout Canada.
45. Dr. Jane Orient, "Statement of the Association of American Physicians and Surgeons: Regarding the Hepatitis B Vaccine," submitted to the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the Committee on Government Reform, U.S. House of Representatives, 14 June 1999.
46. Ibid. In this report it was acknowledged that testimony had been presented indicating that individuals had been "actively discouraged from reporting" adverse events.
47. National Vaccine Information Center, "Hepatitis B Vaccine Reaction Reports Outnumber Reported Disease Cases in Children According to Vaccine Safety Group," Press Release issued 27 January 1999.
48. Eugene S. Hurwitz et al., "Effectiveness of Influenza Vaccination of Day Care Children in Reducing Influenza-Related Morbidity Among Household Contacts," Journal of the American Medical Association 284 no.13 (4 October 2000) 1677-1682.
49. In one study, for example, it was found that the actual risk, as ascertained through active surveillance of adverse events, was five times higher than discovered through passive reporting. P. Farrington et al., "A New Method for Active Surveillance of Adverse Events from Diphtheria/Tetanus/Pertussis and Measles/Mumps/Rubella Vaccines," The Lancet 345 no.8949 (4 March 1995): 567-569.
50. Health Canada, "Canadian National Report on Immunization, 1996," Canada Communicable Disease Report Supplement Vo. 23S4 (May 1997).
51. "The reporting of VAAEs by health-care providers is voluntary, except in Ontario which has specific mandatory reporting requirements. However, there is no evidence of a higher reporting rate with this approach. This is partly explained by the fact that immunization in this province is usually provided by physicians who have lower reporting rates than public-health nurses." [Although legislation exists in Ontario, clearly there is a recognized lack of compliance.] Health Canada, "Canadian National Report on Immunization, 1996," Canada Communicable Disease Report Supplement Vo. 23S4 (May 1997).
52. Canadian Pediatric Society, Canadian National Report on Immunization, 1998," Paediatrics and Child Health 4 Supplement C (July/August 1999): 25C, 34C.
53. For information on the Québec vaccine injury compensation program, see, Ministère de la Santé et des Services Sociaux du Québec, "Programme D'Indemnisation au Québec," (Québec: Ministère de la Santé et des Services Sociaux du Québec, n.d.). See also, Idem, "Règlement D'Application de la Loi Sur la Protection de la Santé Publique," (Québec: Ministère de la Santé et des Services Sociaux du Québec, 25 mai 1988).
54. Manitoba is currently considering a potential vaccine injury compensation program.
55. *Rothwell v. Raes*, (1988) 54 D. L. R. (4th) 193 (Ont. H. C.); *Rothwell v. Raes* (1990) 76 D. L. R. (4th) 280 (Ont. C. A.).
56. Elizabeth Cohen, "Flu Vaccine Costs Climb to Nearly \$100 a Vial," CNN.com/health (30 October 2000).
[Http://www.cnn.com/2000/HEALTH/10/30/vaccine.price/](http://www.cnn.com/2000/HEALTH/10/30/vaccine.price/)
57. Catherine J. M. Diodati, Immunization: History, Ethics, Law and Health (Windsor, ON: Integral Aspects Incorporated, 1999), 248-253.
58. Warning letters sent to Robert Myers, D.V.M., Responsible Head of Michigan Biologic Products Institute, from James C. Simmons (31 August 1995) and Kathryn Zoon (11 March 1997), of the Center for Biologics Evaluation and Research, Department of Health and Human Services.
59. Senate Report 103-97.
60. Kelly Morris, "US Anthrax-Vaccine Producer Saved for Now," Lancet 351 (28 February 1998): 657.
61. Meryl Nass, "Anthrax Vaccine. Model of a Response to the Biological Warfare Threat," Infectious Disease Clinics of North America 13 no.1 (March 1999): 187-208.
62. This statement was printed on the UD DOD's webpage in a document entitled "Frequently Asked Questions & Answers."
63. National Vaccine Information Center, "Vaccine Safety Organization Questions Licensing and Policymaking Standards Applied to Rotavirus Vaccine," Press Release (16 July 1999).
64. Sheila Davey, State of the World's Vaccines and Immunization (Geneva: World Health Organization, 1996), 113.
65. National Vaccine Information Center, "Vaccine Safety Organization Questions Licensing and Policymaking Standards Applied to Rotavirus Vaccine," Press Release (16 July 1999).
66. Sheila Davey, State of the World's Vaccines and Immunization (Geneva: World Health Organization, 1996), 7ff.
67. Ibid.
68. National Vaccine Information Center, "Vaccine Safety Organization Questions Licensing and Policymaking Standards Applied to Rotavirus Vaccine," Press Release (16 July 1999).
69. Dr. Jane M. Orient, "Mandating Vaccines: Government Practicing Medicine Without a License?" The Medical Sentinel 4 no.5 (1999): 166-168.