

Ethical, Legal, and Economic Aspects of Vaccination

Zachary Helms, a one year-old baby from St. Moreno Valley, CA, died on January 27, 1995, within 33 hours after receiving the following eight vaccines at one time: MMR, DTP, Hib, and Oral Polio). Zachary died that night, just 33 hours after his visit to the place where Michelle Helms, his mother, like countless other mothers, take their precious children to immunize them, and supposedly safeguard them against deadly diseases. She, like countless other mothers, didn't recognize the symptoms of the deadly reactions to those vaccinations. Unaware of what to look for, and unaware of the true dangers, she kissed Zachary good night and laid him in his crib where he quietly slipped into a coma and died (1).

Zachary's tragic episode is only one of a series of cases of SIDS (Sudden Infant Death Syndrome) caused by vaccination, a long list of which is accurately kept by the National Vaccine Information Center (NVIC). The numbers are in the order of hundreds of victims every year. The NVIC also keeps an unpublicized detailed record of several cases of devastating side effects which resulted from the use of vaccination, especially DTP (short diphtheria, tetanus, and pertussis). These include: severe fevers of 105 degrees or higher, screaming episodes, shocks, collapses with prolonged shock-like prostration, convulsions, thrombocytopenic purpura or destruction of blood platelets (akin to AIDS), encephalopathy or brain disease, nodules and abscesses, mental retardation with learning disabilities, and epilepsy (2).

Only a few months after the scandal that resulted from the practice of unnecessary surgery

on the heads of infants (3), another practice may be soon discovered dangerous for the life of children, a practice which is so common in our culture, that it may be hard for most people to question its fundamental goodness.

Modern vaccination has been practiced for almost two centuries (4), and the medical establishment claims that the use of antibiotics and vaccines bears a direct relationship with the dramatic drops in diseases such as typhoid, tuberculosis, and cholera (for all of which mass vaccination programs have never been conducted) (5). However, a growing body of evidence is suggesting that vaccination may not be an appropriate means for preventing disease, and that the risks may outweigh the benefits (6), raising controversial issues that are not too dissimilar from the ones raised recently about the new cholesterol-test and treatment guidelines published last March by the American College of Physicians (7). Are vaccines necessary? Are they effective? Are they safe? Does everybody need them, without taking into consideration individual differences?

I believe that an in-depth examination of the issue not only involves medical and scientific aspects, but should also address the ethical considerations that are obviously implied, as well as the economic and legal viewpoint (vaccination is compulsory in most states) (8).

Are vaccines effective and safe? While manufacturers and immunization services keep advertising their necessity and effectiveness, here follows a list of facts that seem to challenge their assertions:

- A 1992 study published in *The American Journal of Epidemiology* shows that children die at a rate eight times greater than normal within three days of getting a DPT vaccination;
- According to International Mortality Statistics from 1990 to 1935, the death rate in the U.S.

- from pertussis had declined by 79% before the introduction of a pertussis vaccine;
- A preliminary study by the Center For Disease Control (CDC) found children who received HIB vaccine in Minnesota were found to be five times more likely to contract the disease than children who had not received the HIB vaccine;
 - In the *New England Journal of Medicine*'s July 1994 issue, a study found that over 80% of children under five years of age who had contracted whooping cough had been fully vaccinated;
 - In 1977 Dr. Jonas Salk (inventor of the polio vaccine) testified with other scientists that 87% of the polio cases which occurred in the U.S. since 1970 were the by-product of the polio vaccine;
 - The Sabin polio vaccine (OPV) is the only known cause of polio in the U.S. today;
 - The February 1981 issue of the *Journal of The American Medical Association* found that 90% of the obstetricians and 75% of the pediatricians refused to take rubella vaccine.
 - Dr. Benchetrit, one of the greatest bacteriologists alive, said in an interview, two years ago: "Vaccines and sera are principally responsible for the increase of those two really dangerous diseases called cancer and heart disease. I have been for a long time a serologist, and I know what I am talking about."

Who should consumers trust? Before making any decision, I think it is important to understand the economics of the issue, and to consider the figures at stake. A drug manufacturer such as Merck & Co. (the developer of the chicken pox vaccine), can have revenues as high as \$439 million per year on the vaccination business alone (9), selling vaccines that range in price between \$39 and \$68 per dose (cost to the physicians). Virtually all of the medical research data

concerning these products belongs to the manufacturers, with consumers having very limited access to it, on the grounds of trade secrecy.

The situation is similar, in some respects, to the trade in securities. The company issuing securities is the party that best knows what their value is, and buyers have to trust the fairness and accuracy of the information provided by the company itself. Similarly, drug manufacturers are in the best position to determine the real value of their vaccines, which is directly related to their effectiveness and safety. Conversely, it is extremely hard for consumers to verify the effectiveness, and therefore the value, of vaccines. As long as vaccination is compulsory, or as long as everybody receives it, consumers will never know if it is the use of vaccines that prevents them from developing diseases, or if they would not develop diseases even without immunization. Unfortunately, to conclude the comparison, there is no SEC to regulate the information that drug manufacturers provide about their vaccines, and there is no GAAP to follow when reporting the results of medical research regarding vaccination.

In addition to this, after last month's multi billion-dollar merger between Ciba-Geigy and Sandoz and the formation of Novartis Inc., there is a rising concern about the lack of healthy competition in the drug industry, and the possible formation of a cartel. (10) If this is the case, and if consumers had to face a monopoly, or even an oligopoly of vaccination providers, the accuracy and fairness in the flow of information would definitely be hurt, let alone price-fixing considerations. Currently, most of the communication about immunization, that flows (one-way) from manufacturers to consumers, consists of thousands of billboards all across America that remind parents that "Your Baby's Counting on You, Call 1-800-909-SHOT."

The only non-profit, educational organization that deals with vaccines currently in existence is the above mentioned NVIC, located in Vienna, VA. On 9/28-10/1/89 the NVIC

sponsored an international workshop on the neurological complications of pertussis and the pertussis vaccine. The scientists concluded that both whooping cough and the current whole cell pertussis vaccine can cause a spectrum of permanent brain damage ranging from learning disabilities to severe retardation and seizure disorders. As a result, the States of Texas and Idaho have dropped requirements for pertussis vaccination as a prerequisite for entry into school. Other states that do not require vaccination against pertussis include Arizona, Kentucky, Missouri, Montana, New York, Oregon, Pennsylvania, Rhode Island, and Washington.

The organization has also been calling for more than one year for voluntary use of the chicken pox vaccine, licensed by the FDA on March 17, 1995, and in doctors' offices by the end of April. The group warns that the government recommendation to inject all *healthy* children with the new live virus vaccine may cause more serious diseases when they become adults.

A mild disease for most children, chicken pox is caused by the varicella zoster virus, a relative of the herpes virus. A vaccine was originally developed to protect high-risk individuals --particularly children with leukemia, kidney disease or immune suppression, etc.-- from serious complications such as brain damage. However, the Centers for Disease Control (CDC) and the American Academy of Pediatrics (AAP) are now recommending that *all* children 12-15-months of age and individuals over 13 years old who have not had chicken pox, be injected with a vaccine developed by Merck & Co.

“The question is: ‘Is what is good for all *high-risk* children also good for all healthy children?’” says Barbara Loe Fisher, NVIC president. “When you recover from the natural disease, which is very mild in most children, you are usually immune for life. We know this vaccine only gives temporary immunity -perhaps only five-to-ten years’ worth. There is a real danger that if everyone gets vaccinated, chicken pox will become an adult disease where it can be

much more deadly.”

“At the same time,” she continues, “no one knows if the live vaccine virus will lay dormant in many vaccinated individuals and reactivate later in life in the form of herpes zoster (shingles) or other immune system disorders.”

The death rate for chicken pox is 1.4 per 100,000 cases in healthy children but rises to nearly 31 per 100,000 cases in adults. According to the government, chicken pox results in more than 9,000 hospitalizations annually and causes between 50 and 100 deaths --mostly in adults.

“Chicken pox is not smallpox,” Fisher points out. “The benefit-risk ratio for healthy children is much different than for high-risk children. The chicken pox vaccine should not be mandated. Parents should be able to choose whether or not they want their children to be vaccinated and get a temporary immunity, which will probably require booster vaccinations throughout life, or have the natural disease and get permanent immunity for life.” (11)

Continuing questions about efficacy and long-term side effects stalled the licensure of a chicken pox vaccine in America for several years. The FDA estimates the chicken pox vaccine is about 70-90% effective in preventing the disease. Common short-term effects include redness, hardness and swelling at the injection site, as well as fatigue and nausea. Long-term side effects are unknown because children in the studies used to license the vaccine were only followed up for ten years. (12)

After having discussed some of the medical and economic implications, let us focus on the legal aspects. I am now going to examine the issue of vaccination in light of three well-known legal theories: product liability, illegal discrimination (against those who are not vaccinated), and the unconstitutionality of compulsory vaccination under the Fifth Amendment.

Let us start with product liability. The law says that there is a duty of a manufacturer not to

injure with its products. If injury results from a lack of due care, the manufacturer can be held liable for negligence. But how can a consumer prove the manufacturer's lack of due care? Given the almost complete ignorance of the general public on the manufacturing process for vaccines, as well as on the specific ways that vaccines operate within our bodies, probably the only applicable negligence theory would be *res ipsa loquitur* (the thing speaks for itself). Even in that case, however, proving that you have been injured by a negligently prepared vaccine remains an extremely difficult task (i.e. it is much easier to prove that you have been killed by a defective lawnmower than to prove that you have been killed by a defective vaccine).

A second theory that may help consumers in a product liability claim is warranty liability, especially the implied warranty of merchantability. After all vaccines are supposed to make you healthier and not sick! Even though warranties cannot be made to the general public, they generally extend from both the manufacturer and the seller (as well as other middlemen) to the consumer and also any member of the consumer household (i.e. the children, in this case), and any other person that can be reasonably expected to use the product. Unfortunately, no warranty theory can apply in the case of vaccines because all manufactured vaccines come with a disclaimer that prevents anybody from suing the manufacturer for damages.

I think that a legal theory that would be more helpful in a product liability case is the one of strict liability. Section 402A of the *Restatements of Tort* says that a manufacturer may be strictly liable when it

[S]ells any product in a defective condition unreasonably dangerous to the user or consumer or to his property and is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

One of the three generally accepted definitions of a defect is :

The product sold was dangerous to an extent beyond what would be contemplated by the ordinary consumer who purchases it (the consumer expectation test).

Let us examine some of the ingredients of DTP, as outlined in a package insert from Wyeth Laboratories:

Mercury, a substance that is officially known to cause depression, brain cell destruction, insanity, inflamed and bleeding gums, neurosyphilis, toxic dementia, and death;

Aluminum, which is indicated as a primary cause of Alzheimer's Disease, and which also destroys brain cells and becomes part of the replacement of them through a process called ossification;

Formaldehyde, a toxic substance that is used as a preservative. It renders everything lifeless, human cells as well as bacterial and yeast cells;

Exotoxin, or neurotoxin, which heavily destroys brain and nerve cells;

Caustic soda, or sodium hydroxide, which destroys both plant and animal cells upon contact;

Muriatic acid, the synthetic version of hydrochloric acid, a medium which quickly destroys enzyme systems and living proteins preparatory to digestion in the stomach. (13)

I believe that, while manufacturers obviously know what is involved in the making of their vaccines, the average consumer is totally unaware of the presence of poisons such as the ones named above. This fact alone would probably be sufficient to make the product "defective" for the purposes of a strict liability claim. However, since assumption of the risk can be a defense

to strict liability, the disclaimer that accompanies all vaccines can be used quite effectively not to hold manufacturers liable. Just like in the case of cigarette manufacturers, I think that the best (and maybe the only) option for consumers is to challenge drug manufacturers on the basis of fraud, alleging that the latter are not fully disclosing the information they have about the dangers of vaccination.

Let us now focus on the theory of illegal discrimination: from a constitutional standpoint, Equal Protection applies each time the government treats a group of people differently from another. Does the fact that all states require children to be vaccinated as a prerequisite for entry into school violate Equal Protection? The so-called rational basis test would apply:

1) Is there a legitimate end being pursued? The answer is yes, it is the prevention of epidemics.

2) Is there a rational basis for the distinction being made? Yes, vaccinated children should have a decreased risk of contracting infectious diseases.

This shows that courts are very likely to find the vaccination requirement perfectly constitutional, given the widespread assumption that vaccines are effective means of preventing disease.

The last legal consideration that I am going to make is about the constitutionality of compulsory vaccination, which most states require of all children. The Fifth Amendment says that no person should be deprived of life, liberty or property, without due process of law. Since everybody would agree that your own body, or your child's can be considered private property, it seems fair to me to allow at least the most basic level of procedural due process, with an opportunity to be heard. On the other hand, I am rather sure that vaccination would pass a substantive due process analysis, in a way that is similar to the rational basis test for

discrimination. Public health and welfare are certainly within the scope of the legitimate police power of the law.

T.C. Fry, president of the Life Science Institute and researcher for American Health Services in Canton, Michigan, claims that people can lawfully avoid having their children vaccinated, even if the state statute is mandatory and allows no exceptions whatsoever. Mr. Fry asserts that there is a United States Supreme Court decision stating that vaccination must be totally voluntary after informed consent has been obtained and that compulsory vaccinations are unlawful. The specifics of the case, however, could not be found. (14)

After having examined the legal aspects, I will now discuss some ethical implications, as well as some possible future developments. I personally believe that anytime human life is in danger, the issue must be taken very seriously, and that thorough investigation is required. Given the documented fact that there are people who die as a result of vaccination, and that the effectiveness and the necessity of vaccines can be questioned, a need for further investigation becomes more than evident. If we also factor in the huge economic interests at stake, and the great inequalities between the level of information and political clout of consumers, compared to that of manufacturers of vaccines, the need for a serious and informed debate becomes almost a compelling necessity.

With the current search for an AIDS vaccine, and the recent introduction of Merck's and Abbot's new treatment drugs, drug manufacturers are getting quicker and quicker approval for their products from the FDA. (15)

Immune Response Corp. is currently launching a large patient study of the controversial AIDS therapy, called Remune, inspired by the late polio-vaccine pioneer Jonas Salk. The drug, which is remarkably similar to the polio vaccine, is not designed to prevent AIDS, but rather to

slow progression of HIV, said company spokesman Steven L. Basta. Remune's developers are hoping the product prolongs life by boosting the immune system's attack on cells infected by the AIDS virus. (16) Also, cancer vaccines have recently begun to be tested on humans by companies such as Therion Biologics, Cytel, Ribicell Immunochem Research, and Biomira. (17) Despite the promises, many cancer drugs that work in the lab have failed to help humans. Other apparent breakthroughs, such as the immune-boosting chemical Interleukin-2 in the mid-1980s, have had only limited success because of the devastating side-effects. Some cancer researchers are also still skeptical about the vaccine approach. "A lot of oncologist colleagues have a 'Where's the beef?' attitude," notes Drew Pardoll, a Johns Hopkins Medical School cancer-vaccine researcher. (18)

What can consumers do to be actively involved in the process, instead of passively waiting for manufacturers to come up with the latest "cures-all" vaccine? While the NVIC is pressing for a new National Childhood Vaccine Injury Act to be passed next year, which will address the issue of manufacturers' and health care providers' liability, there are also things that individual consumers can do. The first and most important one is to become aware, and to realize that having their children immunized should not be an automatic action. It should be a conscious and informed choice, and people should be aware of the potential dangers.

Another important action is to call and write legislators that most people are uninformed of the dangers of vaccines, and that to add a toxic load of chemicals into a child's already inherited toxins can cause problems. Further, administrators should research the number of deaths that have occurred due to vaccines, as well as the havoc of brain damaged children who receive the vaccines, and the fact that this data is not published openly.

In addition to contacting the Health & Environment Sub Committee and the U.S. Senate, in

Washington, D.C., consumers, in the future, may also find it very useful to avail themselves of on line medical databases. Companies such as HealthGate Data Corp., of Malden, Mass., are aggressively targeting health-care consumers with new sites on the World Wide Web portion of the Internet. Says William Reece, HealthGate's chief executive: "We felt there was a real growing demand for patient education." (19)

I certainly hope that Mr. Reece is right, especially in the field of vaccination.

Sources:

- (1) "The Case of Zachary. Another Tragic Incident of Childhood Vaccination," *The Wellness Messenger*, September 1995.
- (2) Neil Z. Miller, *Vaccines: Are They Really Safe and Effective?* 1996, ANHS Press.
- (3) Bob Ortega, "Unkind Cut. Some Physicians Do Unnecessary Surgery On Heads of Infants," *The Wall Street Journal*, 2/23/96, A1.
- (4) Trevor Gunn, *Mass Immunization: A Point in Question*, 1995 ANHS Press.
- (5) McKeown T. *The Role of Medicine: Dream, Mirage, or Nemesis?* Princeton, N.J.: Princeton University Press; 1979.
- (6) "Consumer group warns against new chicken pox vaccine," *The Chiropractic Journal*,

July 1995.

(7) Ron Winslow, "Critics Assail New Cholesterol-Test Guidelines," *The Wall Street Journal*, 3/1/96, B1.

(8) T.C. Fry, *The Fiendish Fraud Called Immunization*, 1994 The Wellness Network Press.

(9) Welene James, *Immunization: The Reality Behind the Myth*, 1993 ANHS Press.

(10) Stephen D. Moore and Margaret Studer, "Multi billion-Dollar Creation of a Drug Colossus," *The Wall Street Journal*, 3/8/96, B1.

(11) H.L. Coulter and B. L. Fisher, "A Shot in the Dark," *Health Science*, September 1995.

(12) Chet Day, *Health & Beyond*, February 1996.

(13) Michael Waldholz, "Controversy Builds Over Threat of Common Chemicals," *The Wall Street Journal*, 3/7/96, B1.

(14) Neil Z. Miller, *Immunization: Theory vs. Reality*, 1993 ANHS Press.

(15) Laurie McGinley, "FDA to Quickly Clear Merck AIDS Drug, After Approving Abbott's Treatment," *The Wall Street Journal*, 3/4/96, B3.

(16) Rhonda L. Rundle, "AIDS Therapy Study to Begin Among Patients," *The Wall Street Journal*, 3/18/96, B5.

(17) Hilary Stout and Laurie McGinley, "Cancer Drugs To Get Speedier FDA Review," *The Wall Street Journal*, 3/29/96, B1.

(18) Robert Langreth, "Cancer Vaccines Move Into Human Tests," *The Wall Street Journal*, 2/15/96, B1.

(19) Laura Johannes, "Patients Delve Into Databases to Second-Guess Doctors," *The Wall Street Journal*, 2/21/96, B1.