

111. Major Arguments For And Against Establishing A Compensation Program

One of the major arguments against a Government-funded vaccine injury compensation program is also the argument against the current policy in which the Government has assumed strict liability in tort for non-negligently caused vaccine injuries. The argument is that, because the injuries are foreseeable in terms of being statistically predictable, the costs of vaccine injuries should be regarded as among the costs of doing business and therefore should be borne by the vaccine manufacturers. Those who make this argument can cite the opinion of the court in the Reyes decision (a vaccine induced polio case). The court noted a "policy factor" at work and stated:

Statistically predictable as are these rare cases of vaccine-induced polio, a strong argument can be advanced that the loss ought not to lie where it falls (on the victim), but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on in the form of price increases to his customers (Reyes v. Wyeth Laboratories, 1974).

Here, the court was trying to address compensation for faultless injury through the existing tort law system, but the judicial approach to compensation has severe limitations.

The rationale for compensating victims of vaccine injuries is that such persons have suffered personal tragedy in the pursuit of a public good. Where vaccination is mandatory, vaccine injured persons have sustained their injuries in an effort to comply with the law as well. The purpose of mass immunization programs is not only to protect each single vaccinated individual from a disease but also to provide "herd immunity," a concept which refers to the resistance of a group or population, based on the immunity of a high proportion of individual members of the group to invasion and spread of an infectious agent. Because of "herd immunity," the immunization of the many serves also to protect the few who are not immunized.

The fact that vaccines also confer benefits on those who do not take them

make them into a classic example of what economists term a "collective good." Thus, if an ethicist were to argue the case in favor of mandatory vaccination laws (as is the case in most states), one argument that would probably be made to justify the coercion is that it prevents "free riding." Nowhere is this more starkly evident than in the case of polio vaccination, where, as long as the rate of immunization among the total population remains sufficiently high to maintain herd immunity, the chances of contracting polio from the vaccine are likely to be greater than the chances of contracting polio via natural exposure. Under these circumstances, those few persons who contract polio from the vaccine can be said to have made a sacrifice on behalf of society at large.

Judicial doctrines like duty to warn, informed consent, and assumption of risk, based on paradigms of commercial relations between private individuals, cannot fully capture the responsibilities that hold between the individual and society as a whole. They operate capriciously in some cases to impose unfair costs on manufacturers or the government, in other cases to leave the entire burden of injury on the individual. In addition, the high cost of administering compensation rules through the judicial system imposes unnecessary burdens on plaintiff and defendant alike (Gaskins, 1980).

In other words, a judicial approach to compensation would be inequitable and inefficient. Those successfully seeking compensation through the courts may receive high monetary awards, while those not seeking judicial recourse would receive nothing. Yet, even for the successful litigants, actual compensation would be made several years after the injury, a typical time-table for judicial resolution.

In addition, the uncertainty of exposure to lawsuits makes it difficult to predict the expenses of such a compensation approach. Accordingly, manufacturers and their insurance companies would be likely to determine prices based on a worse-case estimate. And whatever monies the government would pay out to cover the potential costs of vaccine injuries would, if paid via the pricing mechanism, be lost to the government regardless of whether or not these monies were ever used to pay injury claims.

Two arguments are frequently made that suggest that an administrative compensation program is necessary to maintain the integrity of Federal immunization programs and to enable these programs to attain their goals.

These arguments are: (1) In the absence of a compensation program for vaccine injuries, people will refuse in increasing numbers to be immunized. (2) Vaccine manufacturers are likely to stop producing vaccines unless they can be assured of protection against financially devastating lawsuits for non-negligently caused vaccine injuries. A compensation program is therefore necessary if high rates of immunization are a public policy goal and to provide vaccine manufacturers with protection.

On the question of whether fear of vaccine injuries has adversely affected public participation in mass immunization programs, the Opinion Research Corporation of Princeton, New Jersey, conducted two nationwide telephone surveys for the Center for Disease Control (CDC) in September 1977 and February 1978, in each of which more than 2,000 parents and other adults were asked about their attitudes toward immunization for themselves and their children. 90% of those interviewed believed generally that vaccinations are moderately to very safe. Poor, uneducated, low income blacks were, however, significantly more skeptical about vaccine safety than others. The majority of people (82%) felt that trying to immunize people by a mass program is an effective way to fight a very contagious disease. 79% said that they personally would want to be immunized against a contagious disease such as polio. More specifically, fears concerning safety were not cited as significant reasons for not having one's children immunized, except in the case of the flu vaccines. For Influenza B, 4% of parents said they would not have their children immunized because they considered the vaccine unsafe. Another 4% said they would not have their children immunized against Influenza B because the vaccine would not do any good. The percentages were the same for the Asian flu vaccine.

Not surprisingly, concerns about vaccine safety and efficacy were greatest in regard to the swine flu vaccine. 17% of parents interviewed in 1977 said they would not have their children immunized against swine flu; in 1978, this percentage dropped to 8%. Only 53% of respondents said they would want a flu shot if there were to be a national immunization program against flu.

Data on public attitudes toward immunization are of added interest because public health officials have been concerned in recent years about falling immunization rates in the population as a whole.

...vigilance in maintaining immunization levels has waned and large numbers of children are not adequately immunized. In 1976, more than a third of all children under age 15 were not properly protected and the following year rubella cases increased by 63% measles cases by 39% and whooping cough cases by 115 percent (USDHEW, 1979).

Fears about vaccine safety and efficacy are not the major reasons for the falling rates. Among interviewees who said they did not intend to have their children immunized, the single major reason given was that they did not believe vaccination was necessary. For some diseases (measles, rubella, and, especially, mumps and influenza) the belief that immunization is not necessary seems to be related to a belief that the disease itself is not serious. In other cases, (e.g., polio, diphtheria, tetanus) the disease is regarded as very serious, but highly unlikely to occur. Another opinion survey indicates that people believe immunizations are now unnecessary because most children's diseases have been conquered (Yankelovich et al., 1979). This belief is held by a significant portion of minority parents, 22% of the minority parents in the survey sample.

The majority (80%) of parents surveyed in the Opinion Research Corporation study were aware of state laws or regulations requiring children to be immunized. Most of these (92%) would have their children immunized even if no such requirements existed. The findings suggest that at least 6% of parents might not have their children immunized were it not for state laws. 20% of parents were unaware of state immunization laws although all but 1% lived in states having

such laws.

These findings indicate that DHHS will need to engage in more public education campaigns in order to meet its announced goal of attaining and maintaining 90% immunization against the major childhood diseases.

Currently, vaccine manufacturers have agreed to continue to supply vaccines for government programs, contingent on DHHS'S contractual assumption of the "duty to warn." Under the 1976 swine flu legislation, claims of injury have to be filed exclusively against the Federal Government. Under current contractual arrangements, however, a manufacturer or other vaccination program participant can be sued, and the contract only allows the manufacturer to sue the government if damages were awarded because the government failed in its duty to warn. Additionally, a plaintiff can allege that an injury resulted either from a defect in manufacture or from a failure to warn, and a jury might return a general verdict of liability without specifying the reasons for its decision. For these and other reasons, vaccine manufacturers still feel vulnerable to lawsuits for non-negligently caused vaccine injuries and favor a compensation system that would be the exclusive remedy for persons who allege injuries caused by participation in public immunization programs (Kingham, 1980). This would be similar to the 1976 swine flu legislation, where suit had to be brought against the Federal government, which retained the right to recover damages from program participants who negligently caused the injury.