Compensation for Vaccine-Related Injuries

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Since 1902, when the Serum Act was passed, the federal and state governments have enacted laws and regulations to ensure the widespread availability and use of safe and effective vaccines. The federal government has used public moneys to support vaccine development and to purchase vaccines for public immunization programs. State governments have established laws requiring that children be immunized against diphtheria, pertussis, tetanus, measles, mumps, rubella, and poliomyelitis before they can go to school. (Required dosages and exemption policies vary slightly among states. Most states allow exemption for religious or philosophical beliefs, but the proportion of exempted children is minimal and does not represent a significant problem.) In addition, the American Academy of Pediatrics has stated its goal “to immunize all United States children against the preventable infectious diseases” (Task Force on Compensation for Vaccine-Related Injuries. American Academy of Pediatrics Policy Statement. March 1979.).

Immunization against common infectious diseases benefits society by ridding it of disease. Smallpox, for example, has been eradicated worldwide, and the rare cases of diphtheria, polio, and tetanus are regarded as aberrant phenomena in the United States (1).

The major problem with mass immunization programs is the occurrence of an infrequent but statistically inevitable number of vaccine-related injuries that afflict a small number of recipients, due to no fault or negligence of any party (1, 2). Most injuries are minor, but a few result in severe debilitation and even death (3, 4). These serious injuries may involve a great deal of expense, not all of which is covered by medical insurance, and the victims (or their families) may have difficulty in recovering these expenses by a law suit when the injuries are not caused by negligence or fault of the manufacturer or physician. The problem of compensation to the victims of no-fault vaccine-related injuries has been addressed by legislators, medical societies, and public interest groups, all of whom agree that such compensation is just and that a solution to the problem must be found (5, 6). The notion that a solution should be in the form of a federal compensation program has been promoted since 1977 by the American Academy of Pediatrics and has culminated in the submission of Senate Bill S. 2117 in November 1983 by Senators Paula Hawkins and Orrin Hatch (6). This proposed legislation, the first of what may be a series of bills on the issue, represents in part a joint effort by the American Academy of Pediatrics and Dissatisfied Parents Together, a Washington-based advocacy organization.

Summary of Positions

1. Childhood immunization programs to protect against various infectious diseases are in the public health interests of the nation. The American College of Physicians supports the continuation of these programs.

2. Persons who participate in childhood immunization programs and who, through no fault, suffer vaccine-related injuries should be compensated for expenses resulting from the injury.

3. The federal government, in recognition of benefits to society from childhood immunization programs, should establish an adequately funded and appropriately structured compensation program for victims of vaccine-related injuries.

4. The issue of compensation for adolescents and adults who are non-negligently injured by vaccines is complex and requires further study.

Position 1

Childhood immunization programs to protect against various infectious diseases are in the public health interests of the nation. The American College of Physicians supports continuation of these programs.

Rationale

Immunization is one of society’s most valuable weapons for combating communicable disease. The well-documented reductions in rates of infectious diseases since the inception of mass immunization programs support the contention that such programs constitute a public good. For example, the rate of measles fell from 315.2 cases per 100,000 population in 1950, before mass immunization, to 0.6 cases per 100,000 in 1983 (7). On the other hand, when diphtheria-pertussis-tetanus immunization rates in England dropped from 79% in 1973 to 31% in 1978, an epidemic of pertussis occurred (8). Diseases which have been virtually eliminated in children in the United States by mass immunization programs include tetanus, diph-

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theria, and polio. In 1983, frequencies of occurrence of these diseases were 1, 5, and 8, respectively (8). Frequencies of cases of infectious disease constitute only one indicator of the benefit of mass immunization programs. Savings in health care costs and resources are substantial, and although exact measurement is difficult, it has been estimated that between $135 million and $1 billion are spent treating adult cases of pneumococcal pneumonia, a disease which can be prevented in many people by immunization (9).

This country's childhood immunization programs have contributed enormously to the suppression and virtual eradication of many once-dreaded diseases by creating "herd immunity." This concept refers to group immunity which results when a high proportion of individual group members are resistant to infection (5). The public health benefit of herd immunity has justified mass immunization programs as an essential part of preventive medicine.

However, problems concerning the continuation of these programs exist. One problem concerns a reduction in the number of firms manufacturing vaccines and a consequent reduction in the production of vaccine products (10). Manufacturers have claimed that rising costs and inadequate prices have been a significant factor in the decision to withdraw from vaccine markets. The unresolved public policy problem of liability for unavoidable vaccine injuries is also a concern of manufacturers. The inference that manufacturers' reluctance to produce vaccines has been linked to the possibility of liability for injuries (2, 11) has not been proved, and indeed, recent advances in biotechnology may show a marked increase in vaccine production and safety, with decreased liability risks and costs.

It is incumbent upon both the public and private sectors to ensure that society continues to benefit from the freedom from disease that results when sufficient numbers of persons are immunized.

Position 2

Persons who participate in childhood immunization programs and who, through no fault, suffer vaccine-related injuries should be compensated for expenses resulting from the injury.

RATIONALE

All proposals for compensation programs to date relate to children for whom certain vaccinations are required. It has been noted that "because school attendance is required by law and parents must have their children immunized or risk criminal prosecution for failure to send their children to school, even a properly warned vaccine recipient cannot always be considered to have accepted all the risks of injury" (12). The reward—improved public health—is enjoyed not only by each vaccinee but by society as a whole (4). The number of children receiving vaccinations is large enough to reduce substantially the possibility of infection, even among those who are not immunized. Children who may be exempt from immunization requirements because of parental objection reap the benefit of a lessened chance of contracting infectious diseases, and many nonvaccinated adults also benefit (for example, nonimmunized women who are or may become pregnant benefit from rubella immunization in the general population).

Those members of society who receive vaccinations contribute to the good of society as a whole, while undergoing the risk, albeit slight, of severe injury. (Incidence of encephalitis after receipt of diphtheria-pertussis-tetanus vaccine is 3 to 9 cases per 1 million doses [13]; polio contracted from polio vaccine (vaccinees and their contacts), 1 in 3.2 million doses [14]; and encephalitis after measles vaccine, 1 per 1 million doses [15].) If injury does result from vaccination, it is appropriate for society to assume “responsibility for the consequences of health protection” (TASK FORCE ON COMPENSATION FOR VACCINE-RELATED INJURIES. American Academy of Pediatrics Policy Statement. March 1979.) by compensating the victim for expenses incurred in the course of socially beneficial behaviors.

Compensation programs have been proposed in part due to the nature of the country's legal liability system, whereby a person injured as a result of vaccination must go to court and establish fault for that injury in order to receive compensation. When no party is “at fault” for the injury, the innocent vaccinee would not be able to sue the manufacturer, doctor, or other defendant for negligence with any reasonable hope of winning. The courts have established a legal basis for potentially successful lawsuits in the requirements of “informed consent” and “duty to warn” which require the vaccine recipient or parents to be advised of the probability of injury. However, even when these requirements are not met, recovery of damages for vaccine-related injury is still extremely difficult.

Position 3

The federal government, in recognition of benefits to society from childhood immunization programs, should establish an adequately funded and appropriately structured compensation program for victims of vaccine-related injuries.

RATIONALE

The three major beneficiaries of immunization programs are individuals, society, and vaccine manufacturers. When considering the question of establishing an adequately funded compensation program for victims of vaccine-related injuries, it would seem appropriate that these three beneficiaries should share the costs. One way such costs can be shared is through a surcharge levied on the manufacturers and passed on partially to consumers. Society as a whole, through the federal government, could share in the cost by funding the initial phase of the compensation program. Other possible means of funding such a program include general revenues and increasing the charge for vaccinations.

A compensation program could be state or federally administered. A federally administered compensation program is preferable because it will avoid the inequities in a state-based system due to differential state incomes and to the unpredictable geographic distribution of ad-
verse events. The mobility of the population and the possibility that some states may elect not to establish a compensation program present other arguments in favor of a national system (14).

Designing an easily-administered compensation program will be difficult. Three issues which must be clarified before the design and implementation of such a program are the types of injuries to be compensated; a reasonably accurate estimation of the amount of funds required; and the source of funds. Requiring vaccine manufacturers to fully fund a compensation program would not spread the costs equitably. The surcharge on manufacturers is the most equitable method of funding the program because all beneficiaries of mass immunizations will be contributing.

Position 4

The issue of compensation for adolescents and adults who are non-negligently injured by vaccines is complex and requires further study.

Rationale

Compensation programs proposed to date have been designed for children and cover vaccines received primarily by children (that is, diphtheria, tetanus, polio, measles, mumps, pertussis, and rubella). However, some groups of adolescents and adults are also urged to receive vaccinations. For example, most physicians agree that women should have immunity against rubella before pregnancy, older people should be protected against influenza and pneumococcal disease, and all adults should maintain immunity against tetanus and diphtheria. Immunization of high-risk adult groups raises the question of compensation for vaccine-related injuries, because of the general social good which results from individual acts of vaccination.

The compensation of adults is complicated by the factor of consent. Whereas children do not have the capability to comprehend the risks involved in vaccination and to consent to them, the same is not necessarily true of adults, who have the capability to make a rational choice between the risks of infection and the risks of vaccine-related injuries. There are, however, groups of adults whose choice is highly restricted. These include young adults who must be immunized against certain diseases as a condition of acceptance to state colleges and new military recruits who are still required to receive smallpox vaccinations, among others. In these instances, refusing vaccination can result in serious life and career consequences. The issue of compensation for these groups requires in-depth analyses of the social benefits from their actions as well as the question of freedom of choice. This paper does not address these complex issues which require further study.

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References