

I. Elements of a Vaccine-Injury Compensation Program

As a result of a previous report on Federal Vaccine and Immunization Policies, which included an option to compensate persons for injuries resulting from public immunization programs, the Office of Technology Assessment (OTA) was requested by the House Committee on Interstate and Foreign Commerce to delineate the specific elements and principles necessary for inclusion in a legislative proposal to implement this option. This technical memorandum is OTA's response to that request.

Vaccines can cause harm even when properly manufactured, distributed, and administered. In legal parlance, they are known as "unavoidably dangerous products," which are socially-useful but which also are associated with a statistically small degree of risk.

Typically, adverse vaccine reactions are mild and self-limiting; e.g., a sore arm or one or two days of fever. Less frequently, transient reactions occur which are more frightening; e.g., DTP (diphtheria tetanus, and pertussis or whooping cough) vaccination may be followed by convulsions (1 in 5,000), but these are reasonably short-lived and leave no permanent brain damage. For an exceedingly small number of vaccinees, long-lasting or permanent disability and even death may be the result. For example, live oral polio vaccine carries a 1 in 4,000,000 vaccinations risk of polio disease itself. And a person receiving a vaccine may develop a very severe allergic reaction (anaphylactic shock) and die immediately (with an estimated risk of 1 in 10,000,000 vaccinations).

As there is no one "at fault" for these reactions, the injured vaccinee would not be able to successfully sue the manufacturer, doctor, or other defendant in a lawsuit based on negligence; e.g., faulty manufacturing of the vaccine such that it was contaminated, or faulty vaccination such that a nerve was damaged by the injection. However, the courts have developed a legal basis for a potentially successful lawsuit in the doctrines of "informed consent" and

the "duty to warn." Summarily stated, these legal concepts say that: (1) a person about to be vaccinated should be given a clear explanation of the benefits of vaccination and of the potential side-effects that might occur; and (2) someone in the chain from manufacturer to purchaser (such as a state or federal health agency) to the person who administers the vaccine bears the responsibility to give that explanation. There has been considerable difficulty in determining what constitutes an adequate warning and whether or not a truly informed decision had been made to be vaccinated (the ultimate test of whether the condition had been satisfied takes place by hindsight in a lawsuit, when the injury has already occurred and the answer is crucial to the success or failure of the lawsuit). Furthermore, "informed consent" and the "duty to warn" imply that the potential vaccinee can refuse the vaccination, but almost all states require that children receive certain vaccinations as a condition of attending school.

Even if the "duty to warn" had been discharged successfully and adequate "informed consent" had been given, the injury would not have been averted. The only result would have been that the economic burden of the injury would be borne by the injured vaccinee and not shifted toward, for example, the vaccine manufacturer or the doctor administering the vaccination.

Vaccines may serve two purposes: (1) protection of the individual vaccinee, and (2) providing "herd immunity," or protection of the population in which a high proportion of its individual members has been vaccinated. Herd immunity occurs because the chances of exposure of unvaccinated individuals to the infectious agent are greatly diminished and is an important public health concept because it is a practical impossibility to immunize every individual.

The public health benefits of participating in certain vaccination programs are not reflected in our country's present system of handling the problem of those few individuals who are inevitably harmed as a consequence of that participation. The injured vaccinee must seek compensation on his or her own initiative through the judicial system and its emphasis on vaccines as a

commercial product. This has led the courts to find ways of compensating the injured vaccinee within the limits of the judicial approach. Thus, the "duty to warn" derives from product liability for unavoidably dangerous but socially useful products, where vaccines are viewed in the same manner as, for example, dynamite. And "informed consent" originates in the theory of battery, where harm results from an unconsented touching, as, for example, between agreeing to participate in a boxing match and being mugged.

Currently, uncertainty over fulfilling the legal duties of an adequate warning of potential risks and of obtaining "informed consent" to proceed with vaccination have led to: (1) concern by vaccine manufacturers over their liability, reflected in difficulty in insuring against such risks and decreased numbers of manufacturers involved in vaccine research and production, and (2) difficulties in trying to achieve a balance between giving vaccinees adequate information on the risks of vaccination and scaring them into not being vaccinated at all.

How to insure against the risks and how to obtain informed consent have drawn most of the attention in efforts to address the problem of vaccine-related injuries and have obscured the primary reason for addressing that problem -- public immunization programs are designed to protect not only the individual vaccinee but also those who are not vaccinated. Thus, when the vaccinee is harmed instead of protected, society has the obligation to minimize the consequences of injury.

California and several countries have, in varying degrees, taken such steps to minimize those consequences. (see Chapter VI). Generally, these compensation programs consist of the following elements: (1) the vaccines to be covered, (2) the injuries to be included, (3) the kinds of compensation, (4) the administrative mechanisms, and (5) the relationships with existing compensation programs (lawsuits, social insurance).

In California a person who suffers a severe adverse reaction not more than 30 days after any immunization required by state law to be administered to children under 18 years of age is eligible for reimbursement of medical expenses up to \$25,000. While reimbursement is without regard to ability to pay, the state does reserve the right to recover payments from other sources such as health insurance. The California law does dictate one element of the proof of causality between a vaccine and an injury by imposing a time limit of 30 days after immunization, but has left it up to the State Department of Health to determine which injuries that occur within the 30 day period are the result of the vaccine. The Department also determines what is a "severe adverse reaction." No compensation for economic loss is provided in California, although some countries do provide such compensation. California has also chosen to protect persons involved in the immunization programs from lawsuits for vaccine-related injuries except in cases of willful misconduct or gross negligence.

The following options are grouped according to the five elements that Congress must address in formulating a vaccine-injury compensation program.

What Vaccines Should Be Covered?

Option 1. Include all vaccines.

Unavoidable injuries occur with all vaccines, although the types of injuries and their severity may differ among specific vaccines. Thus, all vaccines, present and future, could be included in a compensation program.

But all drugs have side effects, both mild and severe, as with vaccines. So a compensation system that includes all vaccines raises the question of why there should be a distinction between vaccines and all other drugs.

Option 2. Include only vaccines that offer public health protection in addition to protection of the individual vaccinee.

A public compensation program would be better suited for vaccination

programs which also protect the public's health. There may be some difficult interpretive questions in this approach, especially for vaccines targeted at high-risk populations where the total population recommended for vaccination is substantial. For example, influenza vaccines are targeted at high-risk populations, but they are presently recommended for approximately 40 million people; 25 million of whom are 65 years or older.

Option 3. Include only vaccines that are recommended in childhood immunization programs.

This is the approach commonly used in existing programs. Children would be the primary beneficiaries (apart from contact cases in adults, e.g., polio), and public policy might want to pay special attention to this portion of the population. Also, vaccination is mandatory for attending school in the great majority of states. As the states vary in the specific immunizations required, national guidelines will have to be formulated, rather than relying on each State's list of mandatory vaccines.

What Injuries Should Be Included?

Including all adverse reactions, from a sore arm to severe, permanent disability or death, is not a viable option. Not only would the costs be prohibitive and not subject to reasonable estimates, but the administrative mechanisms for dealing with claims might quickly be overwhelmed. In addition, the compensation system need not be an exclusive remedy, nullifying (if at all possible, subject to judicial review) the injured parties' right to pursue a claim through a lawsuit. Injuries that fall below the threshold of entry into the compensation system still can be pursued in the courts.

The question of what reactions to include is addressed in two parts: (1) were they caused by vaccination, and (2) how severe must they be to be included?

Causality

Determining whether or not a particular injury was the result of vaccination involves establishing a statistical correlation between administration of the vaccine and the injury in question. What this means in practice is to observe what injuries occur after vaccination and compare the results to the incidence of that injury in the unvaccinated population. This is done to separate injuries that are coincidental with vaccination from those caused by vaccination. The Center for Disease Control's monitoring system for vaccine-related injuries covers the 30 days immediately following vaccination, and the California law states that injuries must manifest themselves within 30 days. Some vaccine-related reactions, however, do appear after 30 days.

Option. Whether or not to specify a time period within which the reaction must occur for inclusion in the program.

Severity

If all vaccine reactions are not to be included, some standard of severity must be introduced, either explicitly in the legislation or through the regulations. California defines a severe adverse reaction as one requiring extensive medical care (as determined through regulations) and manifesting itself not more than 30 days after the immunization. Recall that California's compensation is limited to medical expenses Up to \$25,000. In Great Britain, the compensation system pays a lump-sum of 10,000 for any disability 80% or greater. In Denmark, no compensation is payable where the disability is less than 5%; for disability between 5 and 50% a lump sum is paid; and for 50% or more an annuity is granted.

Thus, the questions on severity of injury that must be resolved depend on the compensation approach taken. A compensation program limited to reimbursement of medical expenses need not address questions concerning functional capacity.

Severity of injury can be determined thorough intensity of medical services and costs of care (including funeral expenses, should death occur). In a compensation program providing additional economic benefits, the degree of disability must be specified for determining eligibility and/or for scheduling the level of payments.

Option 1. Determine severity of injury by the intensity of medical services.

Option 2. Determine severity of injury by the degree of physical disability.

These are not mutually exclusive options. For example, option 1 could be used to determine whether or not medical expenses will be reimbursed. Thus, the acutely ill person with high medical expenses but who recovers completely would be covered. For longer-lasting disabilities, however, some type of physical evaluation system will be needed.

What Kinds of Compensation?

The system would cover, at the minimum, medical costs. The primary question on medical costs is whether or not there will be limits on the amount dispensed from the program. California's approach is to put a limit of \$25,000 on medical expenses covered, and, although it will reimburse regardless of ability to pay, it reserves the right to recover payment from other sources such as health insurance.

For medical expenses:

Option. Whether or not to place a limit on reimbursement for medical expenses for eligible injuries.

Option: Whether medical reimbursement will be "first dollar" coverage or

supplemental insurance.

Economic compensation has typically been in the form of annuities or lump sum payments for specified degrees of disability. As noted earlier, Great Britain pays a lump sum of \$10,000 for disabilities 80% or greater. Denmark pays nothing for disabilities under 5%, a lump sum for disabilities between 5 and 50%, and an annuity for disabilities 50% or more.

For economic compensation:

Option 1. Provide no compensation beyond reimbursement of medical expenses.

Option 2. Provide compensation only for severe disability.

Option 3. Provide compensation for varying degrees of disability.

Through What Administrative Mechanisms?

Addressing this question involves not so much considering a separate set of options as raising specific issues once choices among the previous options have been made. These issues arise in two areas: (1) Federal/State relationships, and (2) the relationships between the compensation program and other federal health care and income support programs such as Medicare and Social Security. As we shall see, the more comprehensive the program's benefits, the more such specific issues have to be addressed.

First, however, is the question of how to finance the system, and though we frame it in the form of two options, it seems clear that the first option is most appropriate.

Option 1. Use general tax revenues, either as part of a federal agency's budget or as part of existing federal health insurance programs.

We estimate that, for the seven major childhood vaccines, there are probably no more than 100 or so injuries occurring annually that result in long-lasting or

permanent disability. If, as some experts allege, the estimates of brain damage due to pertussis (whooping cough) vaccination are inflated, this estimate might be lowered by as much as 40 percent. In addition, there are probably another 100 - 250 cases of vaccine-related illnesses serious enough to require some period of hospitalization, but these estimates may also be inflated. Both the small size of the vaccine-related injury estimates and the uncertainty over them point to a flexible financing approach that is administratively simple until actual experiences can be accumulated.

Option 2. Finance the system through a surcharge on vaccines, including it as part of the costs of a vaccine.

This would be more appropriate to an approach which used financial incentives to decrease the incidence of injuries, which is not applicable to the situation here. In addition, as the Federal and State governments are the principal purchasers of vaccines, this would be a particularly inefficient method of financing the system, considering the administrative costs that would be incurred in putting such a mechanism in place and administering it.

Federal/State Relationships

Two issues are involved here: (1) accommodation with existing California law, and (2) the apportionment of responsibilities between Federal and State agencies. On the first issue, Congress may simply want the Federal program to take precedence. The California law covers vaccines for children under age 18 as required by State law. These vaccines probably comprise the minimum number of vaccines that would be covered under a Federal program. If the Federal program covers less than California's program, the injured vaccinee could use the California program as supplemental insurance.

How the States and the Federal government would share responsibilities for a vaccine-injury compensation program depends a great deal on the benefits

included. A program similar to California's, where only medical expenses are covered up to a limit (\$25,000), could be readily established. For example, Congress may define a "severe adverse reaction" as one requiring "extensive medical care as determined through regulations issued by the Secretary of the Department of Health and Human Services" with or without a specified time period in which the injury must manifest itself. The States could then establish their own mechanisms for determining whether a claimant qualifies, subject to final approval of the Secretary of DHHS.

If the Federal program does not place a limit on reimbursement of medical expenses, as in the case of long-lasting injuries requiring continued medical rehabilitative care, then perhaps such benefits might be covered through Medicare. In this case, the States might be primarily involved in identifying potential program beneficiaries, with the existing Medicare mechanism used to determine eligibility.

If economic benefits are also included, the type and method of payment again would affect the particular Federal and State roles. A lump sum payment might be administered, as for limited medical benefits, by standards set at the federal level, with actual determination at the State level subject to Federal review. Annuity payments for total disability could be merged into Social Security and its eligibility - determining mechanism used. A workmen's compensation type system, however, with different annuities for different degrees of disability, would be a new experience for Social Security. If the program provides economic benefits for different degrees of disability, then a program similar to Denmark's might be used; i.e., lump sum payments for lesser degrees of disability, and annuities for disabilities that presently qualify for Social Security. Of course, eligibility requirements (aside from severity of disability) would have to be changed if the vaccine-injured were to be covered by Social Security.

Should the Remedy be Exclusive?

Recall that the primary purpose for establishing a vaccine-injury compensation program is that, when the vaccinee is harmed instead of protected in public immunization programs, society has the obligation to minimize the consequences of injury. Secondary reasons were the vaccine manufacturers' concerns over their liability and difficulties in trying to give adequate warning to potential vaccinees and obtaining their informed consent without scaring them into not being vaccinated at all. Vaccine manufacturers would prefer to have the compensation system as an exclusive remedy, thereby removing the uncertain legal status over their liability. Under present arrangements, the Federal government has assumed the "duty to warn" through the vaccine purchase contracts, but vaccine manufacturers still can be sued. If they lost the "duty to warn" issue, only then could they sue the Federal government for breach of contract. Moreover, claimants can allege both a defect in manufacture and failure of the duty to warn, and the jury might return a general verdict without specifying which of the two was the basis for its decision. For these reasons, the manufacturers would prefer a program similar to the 1976 swine flu legislation, where all claims had to be filed against the Federal Government, who in turn could sue the manufacturers if negligence was the basis for injury.

Congress might want to consider similar legislation for the vaccines covered in a vaccine-injury compensation program. Such an approach, however, would mean a tradeoff between a claimant's "day in court" and the benefits of the compensation program. This would probably mean that the compensation program would have to include some type of economic benefits in addition to medical expenses reimbursement. And, since such an approach would be a substitute for present avenues of compensation instead of being supplemental, more issues must be addressed and more potential interests accommodated.

As for participation in public immunization programs, we do not know if

either a supplemental or substitution approach will make a difference. The point, however, is that, in either case, informed consent forms may become less of a way to avoid liability and truly become what DHHS has labelled them -- "Important Information Forms."

The remainder of this technical memorandum examines some of the foregoing issues in more detail and provides the information on which this analysis was based.