Compensation for Vaccine-Related Injuries

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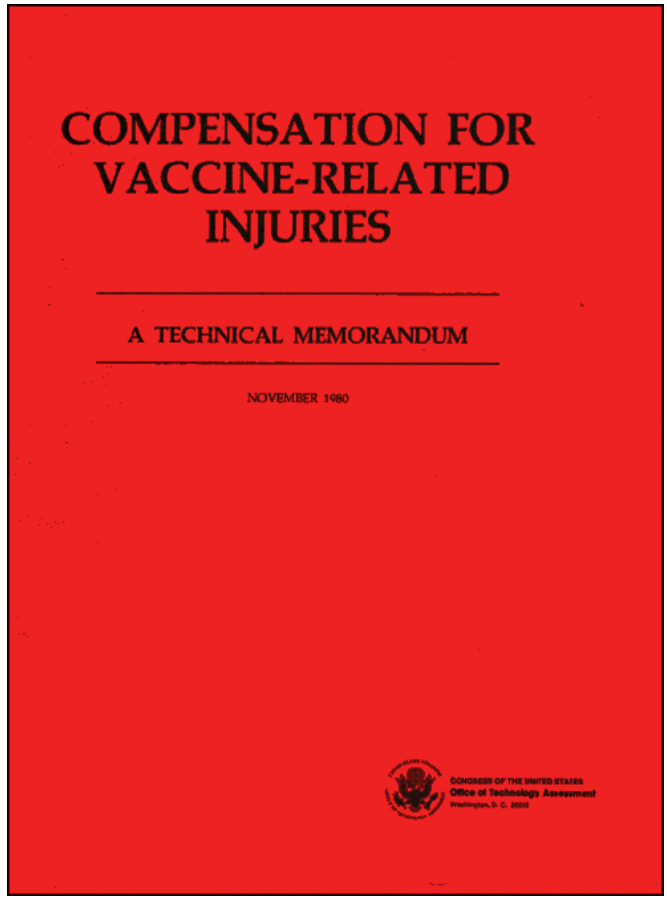

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In September 1979, the Office of Technology Assessment published a report *A Review of Selected Federal Vaccine and Immunization Policies.* That report included a chapter that reviewed issues related to legal liability and compensation for vaccine-related injuries. The report noted that all vaccines, even when properly manufactured and administered, may pose risks to users. Under the existing legal liability system, persons injured as a result of vaccination must go to court and establish fault for their injury in order to receive compensation. To establish fault, the plaintiff (injured person) generally sues one or more of the participants in the vaccination process (e.g., administers the vaccine). The report noted that in three major cases in the past 11 years, plaintiffs have won large judgments against vaccine manufacturers for injuries caused by nondefective and properly administered vaccines. The resulting uncertainty for manufacturers has affected their willingness to produce and supply vaccines.

Because of these problems, OTA suggested that it might be desirable to establish a federally operated program to compensate vaccinees injured as a result of being vaccinated in public immunization programs.

Early in 1980, the House Interstate and Foreign Commerce Committee asked OTA to delineate the specific elements and principles necessary for inclusion in a legislative proposal to implement this option. This memorandum does not analyze the positives and negatives of establishing such a program. It begins with the assumption that establishing a compensation program is desirable, and then discusses the questions that Congress must answer in developing such a program.



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List of Acronyms

CDC :	Center for Disease Control
DHHS :	Department of Health and Human Services (United States)
DHSS :	Department of Health and Social Security (Great Britain)
DT:	Diphtheria toxoid with tetanus toxoid (Pediatric)
DTP :	Diphtheria and tetanus toxoids with pertussis vaccine
GAO :	General Accounting Office
GBS :	Guillain Barre Syndrome
MMR:	mumps, measles, and rubella vaccines
MR:	measles and rubella vaccines
OPV :	oral polio virus vaccine (see TOPV)
SIDS :	sudden infant death syndrome
Td :	tetanus toxoid with diphtheria toxoid (adult)
TOPV:	trivalent oral polio virus vaccine (see OPV)

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: (l)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 $2s,000. In Great Britain, the compensation system pays a lump-sum of bl0,000 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 bl0,000 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 quality 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.

II. The Federal Government's Current Approach to Compensation

The issue of compensation for vaccine related injuries has been brought to congressional and wider public attention most dramatically in the context of the Federal Government's sponsorship of a program of mass immunization against swine flu in 1976. As is well known, the expected epidemic of A - New Jersey influenza or "swine flu" never materialized. However, an unexpected association between swine flu vaccination and a form of paralysis known as Guillain - Barre Syndrome (GBS) did appear. Although only 420 to 460 cases of GBS developed among 46 million vaccinees, as of May 1980, 3,905 claims for all types of alleged injuries -- for a total of $3.5 billion in damages -- had been filed. Of these claims, 1,167 progressed to lawsuits; 2,365 claims -- totalling $2.2 billion had been denied or withdrawn. Only 267 claims or lawsuits had been administratively allowed or settled out of court; 774 were still pending.

The swine flu program is widely regarded as exemplifying the problems inherent in compensating for vaccine related injuries via the tort law system. First, it is clear that most of the claims were trivial at best, mischievous at worst, and that a great deal of time and money has been wasted on distinguishing potentially valid claims from frivolous ones. More significantly, P.L. 94-380 (the legislation under which the Federal Government assumed the liability that would otherwise have remained with the manufacturers of the swine flu vaccine) did not commit the Government to the principle of compensating victims of legitimate vaccine related injuries. Rather, under this law the Federal Government simply assumed the manufacturers' "duty to warn" potential vaccine recipients of any known adverse reactions to the vaccine. This did not mean that the Government thereby assumed an obligation to pay all claims for proven vaccine injuries. Provided that they are warned of the potential dangers, individuals who proceed with vaccination do so at their own risk. Conversely, only if the "duty to warn" were not adequately discharged would the Government be obliged to

compensate for vaccine injuries under the legal theory of strict liability in tort. This fact does not seem to be well understood by the public at large. If there were no element of negligence present and the "duty to warn" were adequately discharged, there would be no obligation to provide compensation even in substantiated cases of vaccine induced injury. Under the Swine Flu Act, the Government agreed only to accept what otherwise would have been the manufacturers' legal liability, and, in prior vaccine injury cases, the courts have never imposed an "absolute liability" on vaccine manufacturers; i.e., liability based simply on a cause-and-effect relationship between vaccination and injury. "Absolute liability" applied to vaccines could by analogy also apply to all pharmaceuticals. The reason is that almost all drugs are, in legal phraseology, "unavoidably dangerous products," as they have the potential for causing adverse reactions in some people.

This confusion over the legal theory of strict liability in tort is compounded by the Department of Health and Human Services' (DHHS) decision to go beyond the bounds of what it is legally required to do and compensate those swine flu vaccinees who developed the Guillain - Barre paralysis. Actually, DHHS did not make the decision to honor the GBS claims until June 20, 1978, when then Secretary Califano issued a statement to that effect.

Many people find it difficult to understand why it has taken so long for the Government to settle the swine flu injury cases -- particularly the GBS cases. However, the Government was under no clear legal obligation to pay these claims, and until June 1978 was unwilling to assume any obligation to compensate beyond the minimum legal requirements to do so. On purely legalistic grounds, the Government might well have been able to prevail in court on the GBS question. The key legal issue was whether or not the Government adequately discharged its duty to warn vaccine recipients prior to vaccination of potential harmful side effects, and the Government could have argued that it should not be held

accountable for a failure to warn of risks that were unknown at the time. Moreover, as of early 1977, an informed consent form that did warn of the possibility of GBS was put into use in the swine flu immunization program. Thus, the Government could have argued that persons who received swine flu shots after the new consent form was adopted had been properly warned and therefore had elected to "assume the risk" of contracting GBS.

Current Federal policy on vaccine related injuries in public immunization programs is patterned largely on the model provided by the Swine Flu Act. DHHS is assuming the obligation to warn of side effects from vaccine manufacturers through the vaccine purchase contracts. In addition, DHHS is requiring, through its grant guidelines, that the State and local health agencies use informed consent forms, or "Important Information Forms," developed by DHHS.

The assumption by DHHS of the "duty to warn" was done at the insistence of the vaccine manufacturers, who would not otherwise have continued to supply vaccines for public immunization programs. Here again, the only way an injured vaccinee can legitimately claim a right to compensation is if s/he can prove that the government's warning was inadequate. To date, DHHS has pursued a strategy of developing informed consent statements and procedures for their distribution that it hopes will meet court tests of their adequacy. Thus, at the present time, DHHS'S posture is a classical "adversary" stance; i.e., the apparent intent is to be in a position to go to court and argue that, by signing an informed consent form, a vaccinee has assumed the risk of injury and is therefore not entitled to compensation.

Of course, the fact that an adequately warned injured vaccinee cannot legally claim an entitlement to compensation does not necessarily prevent DHHS from choosing to provide compensation -- as in the case of GBS from swine flu vaccination. Exercise of this discretion, however, may put the DHHS in the position of appearing to act in an arbitrary manner if it chooses to compensate

some individuals or categories of injured individuals, and not others. DHHS has not issued a clear statement that explains its criteria for deciding when to allow some claims for compensation and not others.

In trying to resolve the issue of responsibility for the consequences of non-negligently caused, unavoidable vaccine injuries, the key question arising out of the swine flu experience would thus appear to be: Should the Government compensate injured vaccinees, and, if so, on what grounds? A clear delineation of the valuative criteria underlying any recognition by the Government of an obligation to provide vaccine injury compensation is an essential element of a compensation program. It is necessary in order to be able to assure those who are accorded compensation, those who are denied it, and the public at large, that compensation decisions have been made fairly rather than capriciously. A clear statement of principles is also the Government's best defense against a plethora of frivolous or invalid claims for compensation. One of the strongest critics of the swine flu compensation program compared it to a lottery. If this was the public perception of the program, then it is understandable that the program might have tended to attract "gamblers" who viewed themselves as having at least an outside chance to gain and nothing to lose by filing claims for compensation.

In the absence of a compensation system, DHHS is more or less locked into developing a legal defense around fulfillment of the "duty to warn." There is cause for concern, however, that this defense may not survive court challenges. First, as a practical matter, the "duty to warn" may not be satisfactorily discharged in mass immunization programs. A recent GAO Report tends to support this contention. GAO found that many vaccinees or parents of vaccinees have problems reading and understanding the forms:

> Even though vaccinees are required to sign the information statements or an accompanying card, we observed, local officials told us, and a CDC study showed that potential vaccinees may not read or understand the significance of the statements. Possible explanations for this are (1) apparent public disinterest in the content of the forms, (2) inadequate attempts by service providers to

explain the importance of the forms, and (3) language barriers.

For example, in one State, the Director of the Bureau of Communicable Disease Control said that, although signature cards are signed as required, he doubted that many of the parents whose children are vaccinated in public clinics read the important information statements. We observed in another State that, in a 30-minute period, 15 children were vaccinated in a public clinic, but only one of the accompanying adults read an important information statement. The statements were available in the vaccination area, but none of the clinic personnel were attempting to have them read. Nevertheless, the adults were signing signature cards indicating they had read and understood the statement.

CDC'S field test of the childhood immunization information statements showed that, for about 20 to 30 percent of the vaccinees, their parents or guardians did not read the entire statement. Another 12 to 25 percent answered "don't know" when asked questions about the disease, the vaccine, and the number of doses and precautions. Sixty-five percent answered "yes" or "don't know" when asked if injectable polio vaccine caused paralysis. Properly constituted injectable polio vaccine is not thought to cause paralytic reactions; however) paralytic polio has been associated with oral polio vaccine.

Problems also exist in securing signatures from appropriate parties on the important information forms (or signature cards). In one State, the signature cards can be signed by any adult accompanying a child. Some State officials said that sometimes getting signatures for children coming to public clinics is difficult because the children are not always accompanied by their parents or guardian.

Several State officials complained about having to get signatures for each childhood disease vaccine given rather than by series. They claim that such a procedure is excessive. An HEW Indian Health Service official told us that getting necessary adult signatures for each vaccine given to Indian children on reservations posed a logistical problem. When children arrive at Indian Health Service clinics for their immunizations, they are not always accompanied by a parent or guardian. In some cases clinic staff travel many miles on a reservation to obtain the appropriate signatures (GAO, 1980).

What is a more serious weakness in the Government's defense strategy is the contention that a properly warned vaccine recipient has assumed all risks of injury. Such an argument does not make sense, however, unless the vaccinee can refuse the vaccine. But vaccination is mandatory in many states for school entry (which itself is mandatory) and refusing vaccination in these cases is very difficult.

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 liabllity 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 aproach 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.

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IV. The Types and Estimated Numbers of Vaccine-Related Injuries

Typically, adverse vaccine reactions are mild and self-limiting, for example, a sore arm or possibly a fever for a day or two. Less frequently, transient reactions occur that are more unpleasant and frightening; for example, some babies (1 in 12,000) display a pattern of abnormal screaming for several days following DTP vaccination. DTP vaccination may also be followed by convulsions (1 in 5,000); however, in the absence of other neurological symptoms, these are short-lived and leave no permanent brain damage. Similarly, children (but more commonly, adult women) occasionally suffer from temporary arthritis (less than two weeks) following vaccination against rubella (German measles).

For an exceedingly small number of vaccinees, adverse reactions take the form of serious illness that result in long-lasting or permanent disability or even in death. Among the least serious of such reactions are cases of encephalitis (inflammation of the brain) which require hospitalization but from which the patient does eventually recover fully. In some cases encephalitis or some other still rarer neurological disorder results in permanent brain damage. Brain damage may manifest itself via physical disability (e.g., loss of motor coordination) but more often takes the.form of mental retardation. Occasionally, encephalitis or other neurological disorders prove fatal.

Live oral polio vaccine carries a very slight risk of resultant polio disease (1 in 4,000,000). It is actually more common for polio to occur in adults who have close contact with young children who have been vaccinated with live oral polio vaccine. Typically, these adults were never vaccinated against polio or received less than the full series of live oral polio vaccine in the days when the three types were administered separately. Apparently, some individuals are more likely to express paralytic polio reactions to the continued very low level of virulence in a given virus.

Guillain Barre paralysis does not appear to be associated to any significant degree with vaccines other than A - New Jersey influenza vaccine (i.e., the swine flu vaccine). A special study carried out by CDC found that the relative risk of developing GBS within 8 weeks of influenza vaccination during the 1978 - 1979 flu season was 1.4 per million vaccinees as compared to a non-vaccine-related natural incidence of 1 per million. In contrast, the incidence rate associated with swine flu vaccination for the equivalent 8 week period was 6.2 per million. Similarly, while CDC'S adverse reaction monitoring system has received reports of GBS occurring within 4 weeks following almost all of the childhood vaccines, the evidence thus far suggests that these are probably naturally-occurring cases coincidental with vaccination. One of the difficult decisions that will have to be made if a compensation program is established is whether or not to extend the benefit of doubt to such cases and provide compensation. In 1978 - 1979, CDC received 22 reports of GBS occurring within 4 weeks of vaccination.

Finally, there is a slight risk (estimated at 1 in 10,000,000) that a person receiving a vaccine may go into anaphylactic shock (a very severe form of allergic reaction) and die. Almost all such deaths due to anaphylactic shock would be expected to occur within minutes of vaccination. Less severe anaphylactic reactions would not normally be expected to have lasting consequences.

No one really understands why these various adverse vaccine reactions occur. In many cases the biology of the individual vaccinee appears to play a role. Some injured vaccinees may have subtle immunological deficiencies; others may be particularly prone to allergic reactions. On the other hand, certain methods of culturing viruses for vaccine production seem to be associated with higher rates of adverse reactions; e.g., dog-kidney versus duck-embryo cultured rubella vaccines.

Also, it can take years of experience for scientists to determine the proper

degree of attenuation (weakening of the virus so that infection is inhibited but the immunological response is retained) for live viruses that will secure maximum immunity with a minimum risk of adverse reactions. However, over the years, continued research on improving vaccines as well as various immunization policies (such as focusing immunization campaigns on children, who tend to be less susceptible than adults to adverse vaccine reactions) have resulted in a lowering of the adverse vaccine reaction rates for most vaccines currently in wide use.

The major adverse vaccine reactions are described in the following pages (A.D. Little, 1979). Some of the adverse vaccine reactions described below in connection with a specific vaccine may occur in connection with other vaccines as well. Anaphylaxis is an example; it is believed to occur or to have a potential for occurrence with all vaccines, although it is expected to be more common in connection with DTP, due to the comparatively less-refined character of pertussis vaccine.

DTP (Diphtheria/Tetanus/Pertussis) Vaccine

Potential adverse reactions that have been linked to DTP vaccination include: anaphylaxis, convulsions, peripheral mononeuropathy, and encephalitis.

Most of the adverse vaccine reactions associated with DTP vaccine are attributed to the pertussis (whooping cough) component, as researchers have not yet succeeded in developing a pertussis vaccine that is as refined as most other vaccines currently in use.

Anaphylaxis: Anaphylaxis is a form of allergic reaction whose outcome can range from rapid death to benign local reactions that subside spontaneously. Most serious reactions occur within 12 hours of exposure; fatal reactions usually begin within minutes of exposure. Accordingly, a presumptive causal linkage between the vaccine and severe cases of anaphylaxis should not be too difficult

to establish. There is a possibility that in some cases death due to SIDS (Sudden Infant Death Syndrome) could be mistakenly attributed to DTP induced anaphylaxis or vice versa.

Anaphylactic reactions to DTP vaccines, and fatal ones in particular, are quite rare. The most frequently reported outcome is complete recovery.

From the perspective of a compensation system, the most costly potential outcome is a recovery with brain damage. Although theoretically possible, no such cases have actually been reported. It is hypothetically possible, however, that modern resuscitative techniques could result in an improved survival rate at the expense of brain damage among some percentage of those saved from death.

Medical costs in the event of mild to moderate anaphylaxis would be expected to be low because no or only brief (l-2 day) hospitalization would characteristically be required, and long-run effects requiring medical attention would not be expected. Medical costs associated with death would also be expected to be low because death, when it occurs, is usually an immediate reaction.

Convulsions: Convulsions occurring within 48 hours of immunization are considered most likely to be causally related to vaccination. The frequency of convulsions following DTP vaccination is uncertain. One set of estimates based on recent prospective studies gives a range of 1 per 1,000 to 1 per 2,200 vaccinations. Other estimates range from 1 per 3,200 to 1 per 50,000. The estimate by the Center for Disease Control is 1 in 5,000.

Patterns of convulsive episodes are apparently quite variable. There may be a single short convulsion, multiple short convulsions over a period of hours to several days, a prolonged 5-10 minute convulsion, or continued convulsive activity. Convulsions alone are rarely fatal.

In most cases the outcome is complete recovery with medical costs being primarily a matter of diagnostic tests and follow-up visits for monitoring purposes. In rare. instances patients may develop chronic epilepsy with or without mental retardation or become hyperactive and retarded. Should hyperactivity and/or retardation develop, the need for special education or long-term care would generate high medical costs.

Encephalitis, Encephalomyelitis and Aseptic Meningitis: These terms refer to various conditions involving abnormal necrologic function due to inflammation of the central nervous system. It is thought that such conditions, occurring within 48 hours of DTP vaccination, have a high probability of being vaccine related. Some encephalitic reactions are relatively short-lived (36 hours at most) and always end in complete recovery. These short-lived reactions include unusual and persistent crying and a syndrome known as “collapse” that is marked by decreased spontaneous activity, extremely poor fluid intake, lethargy and pallor. One prospective study of 2,298 children found the incidence of persistent crying to be 5.9% and of “collapse” to be 0.2%. Medical costs associated with these types of reactions would be low because patients appear always to recover without lasting effects and only in the case of the comparatively infrequent “collapse” syndrome is hospitalization (of about three days on average) considered warranted. .

There is a great deal of uncertainty surrounding the incidence of encephalopathic reactions following DTP immunization. At a 1977 PHS Immunization Conference, CDC officials cited an estimate of 0.009 cases of encephalopathy per 1,000 associated with pertussis vaccination and an incidence of 0.006 per 1,000 of retardation. In 1977, a British commission tentatively concluded that the risk of brain damage following DTP vaccination was probably about 1 in 300,000. Good data on the incidence of encephalopathy related to DTP does not appear to be available. In Britain, where adverse reactions related to pertussis vaccine

became a political issue due to the efforts of the Association of Parents of Vaccine Damaged Children, there has been more attention paid to the question of the incidence of encephalopathy or other neurological disorders following DTP vaccination than in the United States. The following quote from an article on the British controversy both summarizes the available data and the problems with the data:

> Encephalopathy or other serious neurological complications following whooping cough vaccination have been recorded by several individuals, but to establish an association between the event and the vaccine is again not easy. The problem is usually made more difficult because the evaluation of the illness and the evidence has usually been made in retrospect.... The available reported information on the frequency of serious neurological complications of all types following whooping cough vaccine are variable, and estimates of their frequency have varied from no cases of encephalopathy in about 19,000 children who were following up in the MRC trials of 1948 and 1957 in the United Kingdom to four or five serious neurological illnesses in 215,000 children inoculated in Sweden in 1955-58 (Malmgren et al., reviewing the data of Strom) which gives a rate of 1:50,000 and three cases of 'destructive encephalopathy' between 1959 and 1965 in 516,276 children in Strom's second series in Sweden. A guess of 1:10,000 to 1:50,000 which was based on unconfirmed data from various sources using vaccines which were available in the UK prior to 1968 was made by Dick. This guess is very similar to the estimates arrived at by Malmgren et al. and Strom for the vaccines used in Sweden in the 1960s. Hannik has recorded cases of encephalopathy associated with quadruple vaccine in the Netherlands, but it is not possible to calculate the frequency.
>
> No serious neurological complications have been reported in a study which began in January 1975 and is as yet incomplete and unpublished, in 80,000 children in the North West Thames Region who had recently received a primary dose of triple vaccine. The number so far studied is too small to make it possible to draw any sensible conclusion. All of the above studies except that of Pollock were essentially retrospective.
>
> From personal experience of trying to evaluate retrospectively neurological complications allegedly associated with the administration of whooping cough vaccine, perhaps less than 20% of them merit serious consideration because of inaccurate diagnosis (see also Stephenson and Ounsted) and of the onset of an event in time which could in no way be rationally associated with immunization (Dick, 1978).

Occasionally serious encephalitic reactions end in death, typically after a hospital stay of about 10 days. The medical costs associated with such deaths would tend to be high because of the lengthy hospitalization and intensive nursing and physician care during hospitalization. Survival with serious permanent neurological disability is, of course, costly, both in terms of the

lengthy and intensive hospital care involved but even more so because of the need for intensive rehabilitation therapy, special schooling, and sometimes long-term institutional care for retardation.

Peripheral mononeuropathy: Peripheral mononeuropathy is a reaction that affects the peripheral nerves causing disorders of sensation, mobility or visceral function. Typically the symptoms begin 7-10 days after vaccination, but the onset of the reaction may range from a few hours to six weeks following injection.

Patients exhibit weakness in the tendons and often a decreased sense of touch in the area. The reaction reaches maximum severity within a few days. Maximum severity may range from a complete paralysis of the affected muscles to a mild paresis. Most patients make a complete recovery but in a few instances there may be residual weakness or impairment of movement. The most serious type of residual impairment that can be anticipated is a “winged scapula” that diminishes shoulder mobility for life.

Development of mononeuropathy following DTP vaccination seems to be mainly characteristic of adult males. Of the 21 cases ever reported, only four were children, the rest were adult males. The main population at risk appears to be men in military service who undergo strenuous exercise involving possible trauma to nerves, as well as mutiple immunizations.

Peripheral neuropathy can also be caused by physical trauma to the affected areas or by a toxic reaction to heavy metals. It may sometimes be mistaken for Guillain-Barre syndrome.

Medical costs can be anticipated to be fairly high because recovery is slow -- 2 to 3 weeks at best and may take up to a year -- and physical therapy is indicated. In the few instances of permanent disability, vocational counseling and/or retraining might be necessary.

Measles Vaccine

Adverse reactions associated with measles vaccine include: acute aseptic meningitis and acute encephalitis syndrome.

Acute Aseptic Meningitis and Acute Encephalitis Syndrome: There has been great difficulty in clearly associating live measles virus vaccine with acute central nervous system syndromes occurring soon after vaccination. The Center for Disease Control has, however, adopted the rule of reporting all such syndromes occurring within 30 days of vaccination as vaccine related. Over the years since live measles vaccine was introduced, reported rates of meningoencephalitis have varied between 0.92 and 1.16 cases per million doses of vaccine dispensed. The reported incidence of measles-vaccine meningoencephalitis is thus approximately 1,000 times less frequent than the rate associated with natural measles virus infection. Acording to one published research report (Landrigan & Witte, 1973), from 1963 through 1971, 84 cases of necrologic disorders with onset less than 30 days after vaccination were reported in the United States. 13 cases could be accounted for by causes other than vaccine, and another 11 were uncomplicated febrile convulsions probably related to vaccination. One case met the diagnostic criteria for subacute sclerosing panencephalitis. The remaining 59 showed clinical features of encephalitis or encephalopathy. The causes of these cases could not be established, but 45 had onset between 6 and,15 days after vaccination, which suggests a causal relationship with the vaccine. All 59 cases involved serious neurological disorders. Five cases were fatal. 26 recovered fully. 19 were left with residual disability: ataxia in two cases, retardation in 11, learning disability or hyperkinesis in another 3, seizure disorders in 9, and hemiparesis in 4.

Symptoms of encephalopathic disorders are quite variable and may include fever, vomiting and seizures, irritability and lethargy, possibly followed by coma or stupor. For this reason these disorders may readily be confused with a

host of other neurological problems or other diseases having similar symptoms.

The illness may last only a few days, followed by complete recovery, or may be prolonged and severe with residual neurological impairment including paralysis, epilepsy, and mental retardation. Death occasionally occurs.

In most cases of prolonged severe illness medical costs can be expected to be high both because of the lengthy hospitalization and the fact that those most severely afflicted often require intensive life maintenance measures during the period when cerebral inflammation is at the maximum. Similarly, in cases where the eventual outcome is death, lengthy hospitalization and heroic life support measures would lead to high medical costs. Recovery with residual impairment would also be expected to entail high costs because of special equipment, intensive physical therapy and, in the case of mental retardation, the long-term care that might be needed.

Mumps Vaccine

The adverse reaction associated with mumps vaccination is encephalitis.

Encephalitis: Encephalitis following natural mumps infection has been well documented; accordingly, it was expected that there would be some incidence of vaccine-induced encephalitis. The incidence of mumps vaccine related encephalitis has been calculated at 9 cases per million vaccinees, an incidence rate that might be too low because of underreporting and poor documentation. The reason for considering this estimate as too low is that the reported incidence of mumps vaccine related encephalitis contrasts strongly with the reported incidence of 2,600 cases of encephalitis per million cases of mumps.

Meningoencephalitis, with symptoms including headaches, photophobia, and stiff neck, appears to be more common than true encephalitis, with symptoms including confusion, loss of memory, weakness or paralysis and coma in severe

cases. Other reported conditions specifically known to have occurred with vaccine associated encephalitis include seizures, dizziness, deafness, cranial nerve palsies, diplopia, hemiparesis, and optic atrophy. The latency period between vaccination and onset of the disease appears to range from 1 to 55 days. Length of illness is expected to last from 4 days in mild cases to six weeks in severe cases.

In all reported cases of vaccine induced encephalitis in which the outcome is known, there was recovery. It is generally believed that recovery was complete, with no residual impairment, although lack of documentation makes this uncertain; however, wild virus induced encephalitis has not been known to leave residual effects and, typically, vaccine related side-effects are less severe than naturally occurring ones. The only lasting impairment that is hypothetically anticipated as potentially occurring is partial blindness.

Polio Vaccine

Vaccine associated adverse reactions include encephalitis, meningal encephalitis and encephalopathy without paralysis, and paralytic polio.

Encephalitis, Meningal Encephalitis, and Encephalopathy: The medical literature on these conditions -- often referred to collectively as “nonparalytic polio” -- appears to be rather confusing. Cases have been reported of adverse reactions to both live and killed polio virus vaccines, but descriptions of such reactions tend to be sparse and lack precision of definition.

Thus, as well-defined clinical syndromes, descriptions of these reactions must be taken from the pre-vaccine poliomyelitis literature. On such a basis, these syndromes are described as typically beginning with an acute onset of fever, headaches, nausea and vomiting, which may be accompanied by pain in the legs and neck, cough, sore throat, backaches, nasal discharge, drowsiness, photophobia, convulsions, seizures, frothing at the mouth and constipation. The

course of the disease is quite variable and despite the label “nonparalytic polio” may include muscle weakness or even temporary paralysis as a component. Typically, the course of the disease is benign though prolonged; symptoms such as headache and stiff neck may last more than two weeks. Though total recovery is anticipated in most cases, death can occasionally occur (following about three weeks hospitalization and use of a respirator to sustain breathing artificially). In addition, permanent impairment in the form of serious behavioral disturbances, convulsions or mental retardation can occasionally result. Medical costs in these instances would be quite high due to the need for special education and vocational training. Lifetime placement in a residual facility for the emotionally/behaviorally disturbed or mentally retarded might be necessary.

Paralytic Polio: The occurrence of typical paralytic poliomyelitis following immunization with live virus vaccine has been documented in four clinical circumstances: (1) in vaccine recipients, (2) in contacts of vaccine recipients in the household, (3) in communities where live polio vaccine is being utilized but where clearcut contact by the afflicted person has not been demonstrated, and (4) in immunodeficient individuals in all the above categories.

Recent CDC estimates of risk for live polio vaccine induced paralytic polio in the U.S. are 10/193,000,000 doses of vaccine for recipients and 32/193,000,000 doses of vaccine for contacts. Taken together, these translate, rounded off, to the 1 in 4,000,000 estimate often cited. The risk for immunodeficient individuals is estimated at 10,000 times the above risk factors.

Recipient cases occur in children, since the risk of live polio vaccine for adults was recognized some time ago and its use in adults has been discontinued. Contact cases, however, are mainly adults in the household, exposed to vaccinated infants. Cases in adult contacts as well as among the immunodeficient are more likely to be lethal.

Typically, the disease is non-progressive with paralysis limited to the sites of original involvement. Residual weakness or paralysis of varying degree, rather than complete recovery, is the rule.

Generally speaking, vaccine association is readily accepted if polio occurs in a vaccine recipient within 3-60 days of vaccination. There is disagreement as to the earliest onset, with periods of 4-15 days having been cited. Most cases occurring before 4-12 days are thought to be due to natural polio, with vaccination being coincidental.

"Mild polio" is defined as illness requiring less than two weeks hospital stay, with the outcome being complete recovery or some residual paralysis in one limb only or a unilateral weakness. "Moderate" polio involves 2 to 3 weeks or more of hospitalization and permanent limb paralysis in one or multiple limbs. These cases typically require physical and occupational therapy for 3-6 months to a year, some home health care for several months, special equipment (wheelchairs, braces, home modification, etc.) and possibly a short stay (e.g., two months) in a rehabilitation facility. "Severe" paralytic polio requires a lengthy (2-3 months) acute care hospital stay and leaves a significant handicap, often affecting respiration. In some cases mechanical assistance to sustain breathing and other life support measures might be needed. Some of these cases would be expected to result in death after 2 to 3 months of intensive hospital care or as long as 2 years in a skilled nursing home. In cases of severe polio not resulting in death, extensive physical and occupational therapy, home health services over a period of months to a year or more, special equipment, and 2 to 6 months stay in a rehabilitation facility, would be required. Long-term institutionalization is, however, not expected to be necessary.

Rubella Vaccine

Adverse vaccine reactions associated with rubella vaccine include

arthritis/arthralgia, neuritis, and thrombocytopenic purpura.

Arthritis and Arthralgia: Arthritis/arthralgia following rubella vaccination may take either an acute or chronic form with the former much more common than the latter. Onset is expected to occur within 60 days of vaccination. Since the replacement of dog-kidney by duck-embryo vaccine, the probability of this reaction in children appears to have been all but eliminated. The population at risk is thus adult women of childbearing age who take the vaccine primarily in order to guard against birth defects that might be caused by having rubella during pregnancy. The incidence of rubella associated arthritis/arthralgia among adult women is rather high; 10% of women 15 to 17 years of age and 43% of women 22 to 41 years of age developed arthritis with the duck-embryo vaccine. The risk is greater for those individuals with a personal or family history of arthritis.

The prognosis is almost always excellent in rubella vaccine associated arthritis. In general there is no need for hospitalization and the period of disability lasts less than two weeks. Occasionally an acute case might need surgical intervention and an attendant short hospital stay. In the less frequent cases of chronic, recurrent disease there may be complete recovery or there may be a need for surgical intervention with residual impairment. Occasionally, severe permanent disability may result, necessitating extensive physical or occupational therapy and lifetime placement in an intermediate care facility. A more likely occurrence in the case of chronic arthritis would be mild to moderate recurrent disease in which there would be occasional loss of time from work or decreased productivity. These outcomes are rare, however, and would be far more likely to occur in adult women than in children, who are the main population affected in mass immunization programs.

Neuritis: The incidence of rubella induced neuritis appears to have been markedly reduced following the replacement of dog-kidney by duck-embryo vaccine.

Onset of symptoms has occurred between 7 and 99 days, with the mean interval in connection with the duck-embryo vaccine being 2 weeks. No cases involving adults have ever been reported.

There are two distinct syndromes: (1) brachial radiculoneuritis or the so-called "arm syndrome" in which the patient awakens at night with pain in the forearm, wrist and hand that lasts 30 to 60 minutes, abating, then recurring a short time later during the night; and (2) lumbosacral radiculoneuritis or so-called "catcher's crouch syndrome" in which the patient has pain in the knees and walks on the toes with a characteristic crouching gait. Typically the gait disturbance is worse in the morning and may disappear by noon. In a prospective study of 32 patients with rubella associated neuropathy, there were 8 children with the "arm syndrome," 19 with "catcher's crouch syndrome," and 5 mixed cases. Only 2 cases of "catcher's crouch syndrome" qualified as severe and recurrent.

Complete recovery is the anticipated outcome in all instances, typically within 1 to 6 weeks, though in chronic recurrent cases complete recovery may require as long as 6 months. Hospitalization is not anticipated with the exception of rare instances of chronic recurrent "arm syndrome" with immobility of thumb and index finger, in which a brief hospital stay for neurological testing might be required.

Thrombocytopenic Purpura: Thrombocytopenic purpura refers to a low platelet count in the blood, which, as a naturally occurring complication of rubella, has been known to lead to gastrointestinal hemorrhages or cerebral hemorrhages, the latter leading in turn to brain damage. Although these are theorized to be possible outcomes of a rubella vaccine induced low platelet count, no such case has ever been documented. Although low platelet count per is thought to be a fairly common occurrence following rubella vaccination, the actual incidence is not known, because the condition has no clinical manifestion that would cause the patient to be given the blood test necessary for detection. The only clinical

manifestations associated with rubella vaccination are red spots, indicating slight bleeding under the skin. No medical care other than two office visits to a pediatrician has been required in actual known cases.

Influenza Vaccine

The association between influenza vaccine and Guillain-Barre syndrome came to light during the 1976 mass immunization campaign against swine flu. It is not currently known whether Guillain-Barre syndrome is associated with other influenza vaccines as well.

The latency period is typically 1 to 3 weeks. The first symptom of Guillain-Barre is muscle weakness followed by progressive paralysis (often ascending up the torso). Typically the progression of paralysis takes two weeks but can occur gradually over a period of up to 2 months. Facial weakness and involvement of cranial nerves takes place in 50 to 80% of cases, especially vaccine associated cases. Urinary incontinence or retention occurs in 20% of cases but is transient. From 10% to 25% of patients may have paralysis of breathing and require artificial respiratory support. Pulmonary complications, seizures, and residual necrologic defects may occur but, typically> complete recovery is gradually achieved in one year. Mortality, usually from respiratory involvement, is approximately 5%. Residual paralysis occurs in 10 to 30% of cases.

Generally speaking, it is expected that 50 to 60% of Guillain-Barre victims can return to their normal routine within one year. Approximately 15% will be completely disabled permanently. Relapses can occur weeks or even years following the original attack.

The relative risk in swine flu vaccinated persons was found to be 12 times greater than in unvaccinated persons. All ages were at risk, though the risk was higher among adults, especially young adults (25-44) and those over 65. The most

recent calculation of comparative risk is 6.29 per million among those vaccinated against swine flu versus 0.58 per million for the unvaccinated poulation (DHEW, 1980).

Even a mild case is estimated to require a minimum of 3 weeks hospitalization and 3 months of frequent physical therapy following hospital discharge. Severe cases could require a two month hospital stay on average, up to six months in a rehabilitation facility, physical and occupational therapy, nursing care at home, and considerable need for special equipment and home modifications.

It is important to note, however, that DHHS has agreed to provide compensation in substantiated cases of GBS following swine flu vaccination and is in the process of settling these claims. Swine flu vaccine is not now in use and it appers highly unlikely that it will be in use again in the future.

The significant quesiton is thus whether there is a similar risk of Guillain-Barre syndrome associated with influenza vaccines currently in use. A study carried out by CDC in concert with state epidemiologists and the American Academy of Neurologists has calculated the risk of Guillain-Barre to be 1.4 per million population with the vaccine used during the 1978-79 influenza season (DHEW, 1980).

The natural incidence rate of GBS -- that is, non-vaccinated related -- is about 1 case per 1,000,000. The rate of association between Guillain-Barre syndrome and influenza vaccines currently in use is quite close to the normal background incidence, and it is much lower (1.4 per million vs. 6.2 per million) than the rate of incidence associated with the swine flu mass immunization campaign.

summary

Estimating the number of serious adverse vaccine reactions that occur

annually in the United States cannot be accomplished with absolute certainty. There are conflicting incidence estimates for the various adverse reactions, and no one really knows how many doses of vaccine are actually administered (versus distributed) annually, particularly by private physicians. An often-used conservative rule of thumb is to estimte one-fourth wastage,

However, OTA has compiled what we believe are reasonable “ballpark” estimates. Our best estimate of the number of instances of long-lasting disability due to vaccination of children (diphtheria, pertussis, tetanus, polio, mumps, measles, and rubella) is that there are unlikely to be more than 200 or so such cases occurring annually. Also, we suspect that this estimate is likely to be in error on the high rather than on the low side. The main source of uncertainty is the incidence rate of brain damage caused by adverse neurological reactions to the pertussis vaccine or the pertussis component of the DTP vaccine (See Table 4). In addition, we estimate that there might possibly be as many as 100 - 250 cases of vaccine related illnesses requiring hospitalization but where the outcome would be full recovery.

Since almost all known adverse reactions to the major childhood vaccines are extremely rare as naturally occurring, non-vaccine-related illnesses, it would be feasible to draw up a schedule of adverse reactions (and time periods following vaccinations) for which the causal role of the vaccine would be assumed and compensation provided. Proof could be limited to documentation of vaccination within the alloted time period and diagnosis of the particular illness in question.

Tables 1-4 summarize the information on vaccine-related injuries.

TABLE 1

REPORTED REACTIONS TO COMMONLY USED LIVE VACCINES
(IN IMMUNOLOGICALLY NORMAL RECIPIENTS)

	Known	Probable	Possible
Measles	Fever Rash Convulsions (Primarily Febrile)	Encephalitis Encephalopathy Subacute Sclerosing Panencephalitis (SSPE) Reye's Syndrome	Other Necrologic Disorders -Guillain-Barre Syndrome -Transverse Myelitis -Atixia -Cranial Nerve Paralysis -Teratogenesis
Mumps		Parotitis	Encephalitis, Aseptic Meningitis Unilateral Nerve Deafness Allergic Reactions Rash, Pruritis, Purpura Reye's Syndrome Deafness and Other Necrologic Disorder: -Teratogenesis
Rubella	Lymphadenopathy Fever Rash Arthralgia Arthritis Peripheral Nueitis	Teratogenesis	Thrombocytopenia Encephalitis, Aseptic Meningitis Other Necrologic Disorder -Transverse Myelitis -Guillain-Barre Syndrome -Hemiparesis -Ataxia -Convulsions
Polio	Paralytic Polio	Teratogenesis	Reye's Syndrome
Smallpox	Local Infection (Pustule) Regional Lymphadenopathy Fever "Toxic" Eruption Dissemination and Eczema Vaccinatum	Encephalitis, Encephalopathy	Transverse Myelitis Hemiplegia Reye's Sydnrome Guillain-Barre Syndrome Teratogeneiss
Diphtheria and Tetanus Toxoids and Pertussis Vaccine (DTP)	Local Swelling Sterile abscesses Fever Convulsions	Encephalopathy encephalitis Persistent Screaming	Reye's Syndrome Guillain-Barre Syndrome Peripheral Neuritis

TABLE 1 continued

	Known	Probable	Possible
Tetanus Toxoid and Tetanus-Diphtheria Toxoids (T,DT, & Td) Adult	Hypersensitivity Local Reactions Fever Convulsions (Febrile)		Encephalitis, Aseptic Meningitis Other Necrologic Disorders -Peripheral Neuropathy -Cranial Nerve Palsy (Neuritis)
Polio Vaccine Inactivated (IPV)			Allergic reactions Guillain-Barre Syndrome Teratogenesis (Neurogenic Tumors)
Influenza	Local Reactions Fever, Malaise Guillain-Barre Syndrome Allergic Reactions		Peripheral Neuropathy -Neuritis

Source: Center for Disease Control.

TABLE 2

RATES OF COMPLICATION (Per 1000)* FOLLOWING VACCINES AND NATURAL DISEASES

Disease or Vaccine Complications	Natural Disease	Vaccine	Background Rate (Unknown Cause)	Ratio:Disease/Vaccine
Measles				
Fever >103°F	900-1000	60-350	50	2.6-16.7
Rash	900-1000	30-100	0-20	9-33.3
Otitis Media	25.2-90		(?)	
Pneumonia (and other resp)	38-73		(?)	
Febrile Convulsions	6.9	1.9	0.3	3.6
Encephalitis (and other necrologic disorders)	1-4	.001	.001-.003	1000-4000
SSPE*(l)	.006-.022	.0004-.001	+	6-55
Death	0.1-1.0	.0002		300-5000
Mumps				
Fever ≥103°f	100-200(?)	0-0.2	.001	500-1000(?)
Parotitis	500-660	?	?	
Orchitis	100-250(Males)	?	?	
Oophoritis	+		?	
Pancreatitis	+		?	
Meningoencephalitis (& other necrologic complications)	10-150	.001	.001-.003	10000-150000
Deafness	.005-.07	(1 case)	?	
Death	0.18			

*I_n the 30 day period following vaccination or onset of natural disease

(1) Occurs 1 month-20 years after measles or vaccine.

TABLE 2 Continued

Disease or Vaccine Complications

Rubella	Natural Disease	Vaccine	(Background Rate (Unknown Cause)	Ratio:Disease/Vaccine
Lymphadenopathy	500-1000	110-440	?	1-9
Rash	360-1000	10-120		3-1oo
Fever ≥100oF	600(est)	10-40	10-40	15-60
Arthralgia	250-500	30-300	40	1-17
Arthritis	10-300	1-1oo	2	0.1-300
Peripheral neuritis	+	.1	?	
Thrombocytopenic purpura	0.3(?)	+		
Encephalitis (& other necrologic disorders)	0.2	0.0005	1.0-3.0	400
Death	0.8	+(2 cases)		
Polio (live vaccine)				
Paralytic polio	1-1o	0.0002		5000-50000
Death	0.6-0.8	.00001		60000-80000
Smallpox				
Fever ≥101oF	1000	20-40(?)		25-50(?)
Toxic eruption	?	+		
Dissemination	1000	.03		33,333
Vaccinia necrosum	?	.001		
Encephalitis, encephalopathy	1.0	.002-.006		167-500
Death	10-300	.001		10000-300000

TABLE 2 Continued

Disease or Vaccine Complication	Natural Disease	Vaccine	Background Rate (Unknown Cause)	Ratio:Disease/Vaccine
Diphtheria				
(Pharyngeal) Fever ≥101o	500-800(?)			
Airway obstruction	100(?)			
Myocarditis	i-t			
Motor paralysis	20-750			
Anaphylaxis		+(very rare)		
Other allergic reactions		+(rare)		
Convulsions	+	0.014(DT)		
Death	18-100			
Tetanus				
Pneumonia	+++			
Peripheral or cranial neuropathy	++	+(5 cases)		
Myopathy	+			
Fever		70)		
Hives or rash		20)		
Swollen arm (severe)		10) jTd		
Abscess or infection		7)		
Death	500	+(rare)		

TABLE 2 Continued

Disease or Vaccine Complication	Natural Disease	Vaccine	Background Rate (Unknown Cause)	Ratio:Disease/Vaccine
Pertussis				
Pneumonia	+++			
Convulsions	-1+	0.03-0.45	0.9-2.0	-tl-
Encephalopathy	8-140	.009		890-15500
Retardation	+	.006		
Persistent screaming				
Hypersensitivity		+(very rare)		
Death	1-1o	+(very rare)		
Influenza A				
Fever ≥1O1o	>800	1-100		
Rash	+	.005		
Pneumonia	30-200			
Myocarditis	+			
Myopathy	+	+		
Guillain-Barre Syndrome	+	.01	.OO1	
Death	1.0	?		
Influenza B				
Fever ≥1O1o	>700	1-100		
Pneumonia	30-200			
Reye's Syndrome	.3-.6	–		
Death	+	?		

Source: Center for Disease Control

Center for Disease Control Notes to Table 1 and 2

Introduction

Reactions following the administration of vaccines have received increased attention in both the scientific and lay press in recent years. It is important that vaccine recipients be informed of the possible side effects from vaccines. Decisions regarding the use of vaccines must take into account several factors in order to balance the risks associated with the vaccines against the risks of remaining unvaccinated. If reasonably accurate information regarding the rates of complications following the vaccine and natural disease, and the risk of acquiring the natural disease are known, then it is relatively easy to "balance the risks." Therefore, we have attempted to compile a tabulation of the rates of complications occurring after vaccinations and the natural diseases that the vaccines protect against. We have not attempted to include the important factors of vaccine efficacy and the risks of acquiring the natural diseases.

Although toxoids (tetanus and diphtheria) are not technically vaccines, we have included them in this report.

Data Sources

The data in the attached tables have been derived primarily from reports published in the medical literature. These reports are of 3 general types:

1. Individual case reports of specific disorders noted following the receipt of a vaccine.

2. Field trials and other studies where vaccinees were actively followed to determine the rates of disorders.

3. Retrospective studies of specific disorders where a higher rate of vaccination was noted in persons with the disorder as compared to a control group.

In addition, we have utilized reports from vaccine manufacturers, practicing physicians, state and local health departments and other interested parties.

The background rates of disease have been obtained from several different sources and therefore the numbers vary considerably. Where possible, we have used the data collected from a control (or placebo) population. Therefore the age of the population and the case ascertainment were the same for the vaccinated and unvaccinated populations (for an example see Measles: rash and fever). In some cases, Particularly with rare disorders, we have had to use other sources such as community surveys or cases of the disorder reported to CDC that were not associated with known cases (e.g., encephalitis). Many of the background rates have been left blank. This does not mean that the disorders do not occur. We elected to leave blank those disorders where we did not have reliable data and the rates varied considerably depending upon the factors discussed in the next section.

Important Qualifications

The rates are not meant to be interpreted (or quoted) as absolute and firmly established numbers. We are merely trying to provide you with data to help in balancing the relative risks associated with vaccines and natural diseases. There are many variables that have been shown to affect the rates of vaccine reactions:

Vaccinees: age, sex, previous doses of vaccine, allergies, immune competence

Vaccine: culture media, type or strain of organisms, number of organisms, inactivation process, purification processes, adjuvants, stabilizers and preservatives

Administration: jet gun vs. needle and syringe, site of injection, tissue injected (ID, SC, IM or oral)

With regard to most reported reactions, a causal relationship between the vaccine and the disorder cannot be established with certainty. Most "reactions" also occur at some low but finite rate in an unvaccinated population and are usually of unknown cause. Limitations of the individual case investigation or of our scientific knowledge usually prohibit firm conclusions, often leaving us with a temporal relationship only. We must decide whether or not the temporal relationship suggests something other than a coincidental association. With live vaccines, most reactions occur when the vaccine virus or bacteria has had time to multiply within the body. This is usually 7-21 days after vaccination. With killed (inactivated) vaccines, the most common reactions usually occur early, within the first 24-72 hours.

Some disorders, such as encephalitis following measles vaccine, occur at a rate that is less than the known background rate in unvaccinated persons. However, a definite temporal clustering of cases occurs in the 7-15 days after vaccination. This timing of the reaction, plus the findings noted on post mortem examination in fatal cases and the occasional isolation of vaccine-like virus from the cerebrospinal fluid imply that a causal relationship exists with the vaccine.

Other rare disorders, such as peripheral neuritis following rubella vaccine and Guillain-Barre' Syndrome following influenza vaccine, were not detected until mass vaccination programs led to a clustering of cases in localized areas. Therefore, it is possible that other, as yet unknown, disorders, following vaccination might be detected under similar circumstances.

Some vaccines were developed and licensed many years ago. For some, we do not have field trial data which include control groups. Therefore, the rate of common reactions such as fever following DTP and smallpox vaccines are based on estimates, and not actual studies.

The early studies on diphtheria toxoid and pertussis vaccines were carried out using different preparation techniques and potency than are currently in use. Therefore, those studies are not applicable to what one would expect with today's vaccines.

For all of the reasons outlined on the previous pages, we urge you to be very cautious in the interpretation and use of the data in the accompanying tables. These data are the best currently available but are rough estimates and are therefore not intended for publication in the mass media. They are for your use in anticipating reactions to vaccines and answering questions in a general manner.

TABLE 3

TOTAL NET DOSES DISTRIBUTED

UNITED STATES, 1974-1978

BIOLOGICS	1974	1975	1976	1977	1978
Influenza Virus Vaccine, Bivalent[2]***	21,142,461	[illegible]	36,426,235	21,749,[illegible]	19,892,960
Influenza Virus Vaccine, Monovalent	**	**	48,992,625	5,199,[illegible]	[illegible]18,020
Diphtheria Toxoid with Tetanus Toxoid (pediatric)	1,107,220	1,060,365	1,111,653	904,966	823,326
Diphtheria and Tetanus Toxoids [illegible] Pertussis Vaccine	[illegible]7,491,646	17,333,487	19,021,934	16,862,740	17,992,360
Tetanus Toxoid with Diphtheria Toxoid [illegible]Adult)	6,875,790	8,763,624	9,843,770	9,650,244	9,191,122
Diphtheria Toxoid	**	**	3,716	3,590	960
Tetanus Toxoid	15,253,744	13,343,429	17,721,235	12,942,190	10,971,238
Pertussis Vaccine	106,626	47,766	91,133	21,110	100,610
Poliomyelitis Vaccine. Live. Oral. Trivalent	25.[illegible] Immoolln	24,804,475	19,474,835	23,211,560	**
Measles Virus Vaccine, Live, Attenuated[1]	7	7,378,229	7,478,646	10,675,623	8,931,344
Mumps Virus Vaccine [illegible]Live[1]	3	4,811,000	4,417,000	4,092,773	4,648,810
[illegible]bella Virus Vaccine, Live[1]	7	7,809,057	6,398,353	7,698,639	7,552,861
Smallpox Vaccine	6	6,232,300	3,802,743	4,493,239	4,648,810
Rabies Vaccine		**	181,516	**	**
Immune Serum Globulin, Human (reported in cc's)	6,676,509	6,684,871	8,144,494	4,905,267	4,005,759
Tetanus Immune Globulin, Human (reported in cc's)	1,121,428	1,075,563	1,548,325	1,320,590	1,339,681

**Not shown since fewer than three distributors reported
***Includes [illegible] lent [illegible] biva[illegible] vacci[illegible]

[1]All products containing this vaccine
[2]June-December 1975 includes polyvalent and bivalent vaccines

Source: Center for Disease Control Biologics Surveillance Report No. 76 (USDHEW/PHS/CDC:1978 .

TABLE 4

Estimates of Serious Illness Associated With Immunization
Against the Seven Major Childhood Infectious Diseases

Cases Per Year

Illness or Injury	Incidence Estimate	Estimated Annual Doses Administered on Average 1974-1978 (very rough estimate)*	Estimate of Annual Cases
Encephalitis following DTP	9-20 per million	13.5 million	122-270
Brain damage	Low: 1 in 300,000 doses (British Royal Commission Estimate) High: 6 per million (CDC estimate of retardation)		(45-81)
Peripheral Mononeuropathy following DTP Vaccine	very rare ?	13.5 million	? probably too rare for even 1 case annually
Polio contracted from Polio Vaccine	1 in 4,000 doses	18 million	5 (most would be adult contacts)
Encephalitis following Measles Vaccination	0.92-1.16 cases per million doses (based on doses distributed)	9 million doses distributed in 1978	8-11 (some of these would probably result in permanent brain damage)
Encephalitis following Mumps Vaccine	Lowest Estimate: 1 per million		3-4
	Highest Estimte: 9 per million (possibly too low)	3-4 million	27-36 (Note: none are expected to leave permanent brain damage)
Death Due to Anaphylactic Shock (All Vaccines Commonly Given To Children)	1 in 10 million doses	50-60 million	5-6

Abased on net doses distributed (Table 3) minus one-quarter wastage.

v. Costs of Vaccine Injury Condensation Programs

A compensation program could be designed that would provide compensation to more vaccine injured persons, at lower average per person cost, and with more of the money going toward compensation rather than to transaction costs (lawyers' fees, court costs, administrative overhead, etc.) as compared to the present system of reliance on tort law. In terms of absolute costs, however, our review cannot furnish solid assurances that the total costs of a compensation program would be less than the total costs under a system of continued reliance on tort law. The reason is that the costs of the tort law approach depend very greatly on the willingness of the vaccine injured to bring suit and to hold out for a successful court judgment or a generous out-of-court settlement. To illusrate: GAO has reported that in *1975* a plaintiff won a suit against the Public Health Service for vaccine related polio. The original claim was for $7,000,000; the plaintiff was awarded $1,029,973 plus $3,201 in allowable costs. Clearly, if each of the 5 cases of vaccine related polio estimated to occur annually were to result in similar court awards, the costs to the Federal Government would be substantial. Because manufacturers have been disinclined to release much information on their legal liabiity, data is not available that would enable us to calculate what percentage of vaccine related polio cases (or other vaccine related injuries) results in lawsuits. It is also difficult to predict to what extent assumption of the manufacturer's "duty to warn" responsibility will expose the government to increased lawsuits. However, as of 1979, GAO reported that, according to Public Health Service records, this one court case represents the Federal Government's only payout for vaccine injury compensation for all vaccines other than swine flu.

Available evidence thus suggests that many injured vaccinees either do not file suit or settle early for amounts far less than what they might be awarded by a court. One State health official interview for this study related two

anecdotes involving adult contact vaccine related polio. In one case, the polio-stricken elderly relative of a vaccinated child did not seek any compensation. In the other case, a young mother who contracted polio from her vaccinated child reportedly settled for $20,000. In both cases, the injured person had suffered some degree of permanent paralysis.

Without a special and expensive research project, it would be difficult to find out in any systematic fashion what actually happens to most vaccine injured persons, how they cope financially and otherwise, etc. State and Federal health officials do not follow-up on these cases beyond the requirements of CDC'S monitoring system, which does not monitor outcomes beyond the four weeks immediately following vaccination.

We conclude therefore that, unless or until vaccine injured persons begin to pursue legal remedies more vigorously than they have in the past, catastrophic-sounding estimates of the Government's legal liability should be viewed with skepticism.

Our study has not attempted to estimate total costs of a vaccine injury compensation program, in large part because such an exercise would be best carried out after some basic policy decisions have been made. In the following discussion we will outline some of the major cost-relevant decisions that need to be made and some of the factors that might lend support to a given choice viewed in cost/benefit terms.

Medical costs are easier to gain a handle on than other costs. DHHS commissioned a study by the Arthur D. Litle (ADL) management consulting firm of the costs associated with vaccine related injuries (A.D. Little, 1979). Table 5 lists our best estimates of the number of cases of the most common serious or potentially serious adverse vaccine reactions likely to occur annually, alonside ADL's estimates of the range of medical costs most likely to be associated with

such reactions (for children under age one and assuming a discount rate of 2.5%).

Table 5 includes only conditions that are known to result from vaccination and excludes conditions which have been reported following vaccination but for which no causal relationships have been established. The ADL study included several conditions for which causal relationships have not been established (see exhibit B).

The figures at the high end of the range in Table 5 include estimates of costs for long-term institutional care in the event of very severe brain damage or paralysis so extensive as to require mechanical respiratory assistance.

In considering the medical costs associated with vaccine injuries, it is important to recognize that many injured persons will be covered, in varying degrees, by existing private medical insurance or government health care financing programs. In court settlements, such insurance coverage is not taken into account in determining the size of awards. The reason is that the legal system is fault-oriented. The logic applied is that the party held to be at fault in causing the injury should not benefit from the injured party's foresight in purchasing insurance. A no-fault compensation system need not adopt such an approach, however, and could therefore save an unknown (but probably large) amount by paying only for medical expenditures not covered by the individual's existing private insurance or by government program benefits for which the individual is eligible.

In assessing the medical costs associated with vaccine injuries, it is also important to bear in mind that, for certain types of injuries, government (State, Federal, or both) will likely end up paying most of the bill. Among serious vaccine injuries, the most common are neurological diseases that can result in permanent brain damage. Where such brain damage results in mental retardation or physical disability severe enough to justify long term care in an institution,

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the costs may be covered by existing government programs. One decision Congress will need to make is how to relate vaccine injury medical benefits with other government programs offering medical benefits. One approach would be to pay for short-term acute medical care and rehabilitation expenses out of funds specifically set aside to cover the costs of vaccine injuries, but to treat long term care separately. Under this approach, if, after a certain specified period, vaccine injured persons required long term care, they could be declared automatically eligible to have such services paid for under Medicare, without the individual having to meet the normal eligibility requirements of the program. Exemption from normal eligibility requirements would protect parents or other legal guardians of the vaccine injured from a possible obligation to first meet welfare eligibility criteria before obtaining long term care for a vaccine injured child.

Estimating nonmedical costs is even more difficult, because more policy choices are available. One principle which should probably be followed is that as fault is not at issue, punitive damages are inappropriate and nonmedical payments should be limited to compensation for economic loss. This would militate against the large "pain and suffering" awards that are frequently given out in negligence suits.

In the case of the major childhood disease immunization programs, the vaccine injured are almost always children (the exceptions are adult polio contact cases), which makes economic loss more difficult to calculate. Since there is a tendency to view vaccine injury compensation in terms of the swine flu experience, it is important to understand that the situation of the vaccine injured in current immunization programs is quite different from that of persons who developed GBS after having had swine flu shots. Many of the swine flu vaccine GBS cases were adults who were employed and who were often supporting dependents as well as themselves. Others fulfilled essential though non-paid economic roles

in their families that would be expensive to replace. Moreover, the nature of GBS is such that, even though a majority of those afflicted eventually do recover, recovery usually takes several months to a year or more, during which time the individual is not likely to be able to work or fulfill other responsibilities. In the case of vaccine injuries associated with such childhood immunizations as DTP, polio, mumps, measles, and rubella, most of the injured are children who will have recovered long before reaching the age of self-support. In some cases, however, these are permanent, highly-disabling injuries. That these injured persons are most likely to be children poses some difficult questions. Is it appropriate under such circumstances to try to relate compensation to the concept of lost earnings? If a child dies as a result of a non-negligently caused vaccine injury, is there a useful purpose to be served by paying economic compensation (over and above funeral expenses) to the parents? The same question can be asked about an individual who has suffered severe brain damage and requires long term institutional care. As long as this individual requires long term institutional care and such care is covered by medical payments, are additional compensation payments of any benefit to that individual?

One of the ironies here is that those children whose injuries are the most severe may be the least able to benefit from or the least in need of economic, as distinct from medical, compensation payments. The individual for whom economic compensation is likely to be most meaningful would seem to be those who are not so seriously disabled as to require long term institutional care.

In Great Britain (see next chapter) vaccine injured persons who suffer 80% disability or more are given a flat compensation payment of %10,000 (this is over and above medical expenses, which are covered by the National Health Service). In practice, these payments appear to go primarily to the parents to compensate them for added financial and other strains that a severe vaccine injury imposes on the family.

Thus, rather than award economic compensation solely on the basis of severity of injury, Congress might wish to approach economic compensation in terms of such goals as: keep disabled persons at home insofar as possible; minimize the economic burden of vaccine injuries on families and compensate parents for the fact that a vaccine injured child may never be able to be wholly self-sufficient economically and may never be able to live independently of his/her parents outside an institutional setting.

If these principles were to be followed, this would suggest that no or comparatively low economic compensation payments be made to institutionalized persons or to parents in the event of a child's death. More generous compensation payments would be made to disabled persons able to function outside institutions in an effort to keep them outside institutions and to provide the individual with an alternative or supplement to the conventional social insurance payments available to disabled persons.

Here again there is a need to consider how disability payments specific to vaccine injured persons should relate to other benefits available more generally to disabled persons. One approach would be to establish a compensation schedule keyed to the extent of disability -- 20%, 30%, 40%, etc. Assessment of percent disability would be based on the same criteria used to make such determinations under workmen's compensation or veterans' benefits programs. Payments could be made in the form of periodic payments or in the form of a tax free lump sum payment. Periodic payments would obviously add more administrative overhead and create a need for more staff. There is also the problem to consider that there are not enough vaccine injured persons to justify a full-blown administrative unit to process such periodic payments. If the periodic payment method is chosen, vaccine injury disability payment might be grafted onto the existing Social Security disability benefits payment program. However, Social Security disability payments are based on total disability. Thus, for ease of

integration, economic compensation through Social Security might be limited only to those totally disabled, with no payment or lump sum payments to those disabled to a lesser degree (e.g. , see Denmark in the next chapter).

An alternative approach would be to have the size of compensation awards determined in an individualized manner by a compensation board. Such boards could be appointed for a term or on an *ad hoc* basis at the direction of the Secretary of DHHS, or, at the State level, by the State Department of Health, in the manner of a special commission or panel of consultants. The major advantage of this method is that it replicates the kind of individualized treatment and consideration for special circumstances and needs that an individual might obtain via the courts. Here again, this would add to the administrative costs of the program, but the small number of severe vaccine injuries that would be anticipated does make such an approach feasible.

TABLE 5

Estimated Annual Number of Severe Vaccine Reactions & Associated Medical Costs

Adverse Reaction	Estimated Range of Annual Cases	ADL Medical Cost Estimate Per Case**
Encephalitis* following DTP vaccination	122 - 270 (of these, 45 - 81 would be expected to involve retardation or other brain damage)	$2,487 - $170,270
Peripheral Neuropathy following DTP	<1	$1,443 - $16,018
Encephalitis following measles vaccination	6 - 8 (permanent brain damage is expected to be quite rare)	$1,313 - $247,889
Encephalitis* following mumps vaccine	3 - 36	$2,167 - $15,123
Polio following live oral polio vaccine	5 (most are adult contact cases)	$1,766 - $141,055
Anaphylactic shock leading to immediate death (for all vaccines given to children)	5 - 6	Not calculated (medical costs minimal if death is immediate)

*There is controversy concerning the incidence estimates for these reactions (see previous chapter)

**For children under age one and assuming a discount rate of 2.5% (A.D. Little, 1979).

VI. Current Approaches to Vaccine Injury Compensation

In the U.S., California created an Immunization Adverse Reaction Fund in 1977, and a bill patterned after the California law was introduced in the Rhode Island legislature in 1979. Six nations provide compensation for vaccine injuries; Great Britain, Japan, France, West Germany, Switzerland, and Denmark.

California

Medical, institutional, supportive, and rehabilitative care are to be provided for severe vaccine reactions to any immunization required by state law to be administered to children under 18 years of age (see Exhibit C). A severe reaction is defined as one which manifests itself not more than 30 days after the immunization and requires extensive medical care, as defined by regulation of the Department of Health.

Expenses will be reimbursed by the State in an amount not to exceed $25,000. Reimbursement will be made without regard to ability to pay, but the State can claim any reimbursement for medical expenses from third parties.

An Immunization Adverse Reaction Fund has been created in the State Treasury, to be administered by the State Department of Health.

The statute also absolves any person of liability for vaccine injuries, provided the vaccine is required by state law and no willful misconduct or gross negligence is involved.

To date, only one claim has been filed, alleging polio in an adult male (Kavet, 1980).

Rhode Island

The bill introduced in the legislature in 1979 is identical to the California law, except that it also specifies that $50,000 be appropriated for

the Immunization Adverse Reaction Fund. This bill has not become law.

Great Britain

The British compensation program is of recent origin, dating from the Vaccine Damage Payments Scheme of April 6, 1979 (Barnes, 1980). The main impetus appears to have been the public controversy that had been going on for some years concerning pertussis (whooping cough) vaccination. No vaccines are compulsory in Britain, but pertussis and other standard childhood immunizations are recommended by the National Health Service. In August 1973, the Association of Parents of Vaccine Damaged Children was formed and began to draw public attention to the issue of vaccine injury, most especially in relation to pertussis vaccination. The Association gave testimony to the Royal Commission on Civil Liability and Compensation for Personal Injury (The Pearson Commission), which was established to consider the problem. Most of the testimony concerned brain damage alleged to have resulted from childhood vaccinations. The Association told the Commission that -- as there was no hope of recovery from injury due to vaccine damage -- normal family life was impossible, holidays were limited, great expense was incurred (e.g., special education, shoes, clothing and food), and families sometimes broke up under the strain. The Association had registered 356 alleged cases of serious vaccine damage, 240 of which they claimed were the result of whooping cough vaccination.

The Pearson Commission Report noted that the Association's figures on the numbers of vaccine damaged children had not been officially confirmed. The Department of Health and Social Security (DHSS) accepted that severe damage could occur rarely but underlined the difficulties in establishing clear causal links. The Joint Committee on Vaccination and Immunization said in its Review of the Evidence on Whooping Cough Vaccinations that "infants frequently develop convulsions for the first time in the first two years of life. By chance some of these will occur shortly after a child has been vaccinated and will be wrongly

attributed to the vaccine. ” In 1976 the British government undertook a National Childhood Encephalopathy study to address prospectively the causal relationships among immunization, convulsions and brain damage. Results from this study are not yet available.

The Pearson Commission also heard testimony from the following groups in support of vaccine injury compensation: the British Medical Association; the Royal College of Physicians and Surgeons of Glasgow; the Royal College of Surgeons, Edinburgh; the Association of the British Pharmaceutical Industry; and the British Insurance Association. The Standing Medical Advisory Committee of the Department of Health and Social Security also told the Commission that, in its view, there was a reasonable case for paying compensation where vaccination was proven as the cause of the damage.

The British compensation plan provides for the payment of %10,000 (tax free) to persons who have been severely disabled as a result of vaccination against a specified disease or to that person’s personal representatives. The diseases currently specified are diphtheria, tetanus, pertussis, polio, measles, rubella, tuberculosis, and smallpox. Injuries arising from contact with a vaccine recipient (e.g., polio, fetal damage) are also eligible for compensation. Eligibility for compensation is retroactive to 1948. An individual is defined as “severely disabled” for purposes of vaccine damage compensation if the disability is 80% or more, a judgment reached by applying the same criteria used by the industrial injuries compensation scheme.

The initial determination to grant or deny compensation is made by physicians within the Department of Health and Social Security on behalf of the Secretary of State. The DHSS Vaccine Damage Payments Unit reviews various medical records concerning the case, may request a specialist report with respect to the causal role of the vaccine, or call upon a medical board to give advice with respect to the extent of the individual’s disability. If a vaccine damage

payment is refused because the Secretary of State is not satisfied that the medical criteria have been met, the claimant may apply for a review of his/her case by an independent vaccine damage tribunal. Tribunals consist of two specialists and a lawyer as chairman. The DHSS does not adopt an adversarial stance on review and does not seek to defend the initial disallowance. The Department presents the evidence and assists the claimant in presenting his or her case by assembling and making evidence available, but the burden of proof rests with the claimant.

The Secretary of State is empowered to reconsider all unfavorable determinations within 6 years if: (1) there has been a change in circumstance, or (2) factual ignorance or error was involved in the original determination. Favorable determinations may be reconsidered at any time if it appears that factual misrepresentation or failure to disclose was involved. Otherwise, the decision of the vaccine damage tribunal is conclusive. There is no further right of appeal except for judical review on a point of law.

Table 6 summarizes the status of claims filed as of June 20, 1980. Recall that the British system provides for claims retroactive to 1948. About 13% of the claims reviewed by DHSS (which is all but a handful of the claims filed to date) received a compensation award on initial determination. Of the claimants initially denied compensation, 58% requested review by an independent tribunal. Of the cases thus far reviewed by independent vaccine damage tribunals, approximately three quarters (73.5%) have been denied compensation upon review as well.

If these percentages hold constant in the future, we might project that the British system would end up making compensation payments on 753 out of the 2619 claims filed as of June 1980. This would entail a payout of %7,530,000 for vaccine injuries covering a 32 year period.

Japan

Compensation for vaccine injuries covers government subsidized vaccines and includes a medical allowance, an annuity for persons taking care of individuals disabled by a vaccine injury, a disability pension, and a funeral grant (Dowdle et al., 1980).

Reports of vaccine reactions are evaluated by a National Judgment Committee consisting of twelve physicians and two lawyers appointed by the Minister of Health and Welfare. Some local governments have their own judgment committees, so that it would be possible for a person with a vaccine reaction to receive compensation from either a local government, the national government, or both. There are no written guidelines. Judgment Committees base their decisions regarding the validity of claims on available clinical information, the interval between vaccination and onset of illness, and whether similar adverse reactions have been reported in the literature.

The Japanese compensation system is of special interest, because influenza vaccine given to children is covered under Japan's vaccine injury compensation program. Statistics are available on the numbers and types of influenza vaccine related injuries for which compensation has been granted. It is noteworthy that since 1963, when the earliest claim for an influenza vaccine related injury was filed, no claims have been made for Guillain-Barre syndrome. Since 1976, in view of the U.S. experience with swine flu vaccine, a major effort has been made to identify Guillain-Barre cases related to influenza vaccine. None has been found. Japan did not mount an immunization campaign against swine flu. The Japanese experience thus lends support to the thesis that the level of association that was found between Guillain-Barre syndrome and the swine flu vaccine is not characteristic of other influenza vaccines.

In Japan annual vaccination against influenza is compulsory for all school

children aged 3-18. Children are regarded as the major transmitters of the virus, and vaccination of school children is designed both to reduce the extent of influenza epidemics among the population as a whole and to prevent school closures due to influenza epidemics. In contrast, influenza immunization is not mandatory for adults nor even reimbursed under either of Japan's two government-run or supervised health insurance plans. As a result, adults suffering influenza vaccine related injuries are not eligible for compensation.

The number of vaccine related injuries per million doses administered reported to the Tokyo Metropolitan Health Department between 1970-77 was significantly lower for influenza vaccines (0.8) than for smallpox vaccine (98.4) or DTP vaccine (13.5). This 0.8 incidence for influenza vaccine adverse reactions was comparable to that observed for Japanese encephalitis vaccine (1.3), oral poliovirus vaccine (0.3) and BCG (tuberculosis) vaccine (0.7). This suggests that a compensation plan including influenza vaccines (other than swine flu vaccine) would not have a disproportionate effect on the number of claims.

France

Vaccination is compulsory for smallpox, diphtheria, tetanus, polio, and tuberculosis. Most injuries affect children. The vaccines most frequently involved in compensation claims are those for smallpox and, to a lesser degree, tuberculosis. Government compensation is available both to the injured and to the injured's parents. Compensation is assessed by a tribunal and covers established economic and non-economic losses and provides for future support, taking into account payments under social security schemes. The tribunal has the discretion to award a lump sum or periodic payments, although a preliminary award for periodic payments is typically made until the person's condition has stabilized.

West Germany

smallpox vaccination is compulsory; other vaccines are officially recommence d. Compensation is provided for damage caused by any officially recommended vaccination, covers medical and other costs, and includes a pension when earning capacity has been impaired, based on federal invalidity pension regulations. The probability of a causal relationship is sufficient to establish a claim.

Switzerland

A federal law on epidemics obliges all cantons to provide free vaccination against smallpox and other dangerous epidemic diseases. The cantons have the discretion to make vaccinations compulsory or voluntary. The law also requires the cantons to compensate for damage caused by compulsory or officially recommended vaccinations, insofar as the damage is not covered otherwise; e.g., by social security payments or private personal insurance.

Denmark

A vaccine injury compensation program covers smallpox, diphtheria, pertussis, polio, and tuberculosis vaccines. Tetanus is included when it is used in combination with one of the others. A vaccine injured child receives compensation for loss of earning capacity when he or she reaches age 15. No compensation is payable where the disability is less than 5%. For disabilities between 5 and 50%, a lump sum is paid; and for 50% disability or more, an annuity is granted.

TABLE 6

VACCINE DAMAGE PAYMENTS ACT

STATUS ON 6/20/80*

1.	Total number of claims received	2619
2.	Disallowed - a. basic conditions (Section 2) not satisfied	76
	b. medical grounds	2192
3.	Awards made on initial consideration	330
4.	Not yet determined	21
5.	Applications for review	1272
60	Determined by tribunals-	
	awards made	129
	disallowance upheld	359
		488
7.	Awaiting consideration by tribunals	784

*covers period from 1948 to 1980

Source: British Department of Health and Social Security

VII. Vaccine Injury Compensation and Future Developments in Vaccines

> It seems safe to say that, in a decade or less, it will be possible to offer vaccines against all infectious diseases caused by viruses or bacteria. Anti-parasite vaccine, pehaps even anti-tumour vaccines, will also be available. Some may regard such a plain statement as sensational, some as natural progress (Hennessen, 1978).

If, in fact, there is likely to be an explosive increase in the number of vaccines available in the next decade, how might these new developments in vaccines affect a vaccine injury compensation program?

Table 7 lists the vaccines expected to be developed after 1976.

Most of the vaccines currently being researched are targeted at diseases that are moderately contagious at most.[1] The major exceptions are syphilis and gonorrhea. This reflects the fact that major epidemic diseases affecting the U.S. population have been controlled via existing vaccines, other public health measures, and the generally high standard of living enjoyed by most Americans. Most of the vaccines currently being researched are thus being targeted for use among specialized “high risk” populations.

Annual influenza vaccination is presently recommended for approximately 40 million people, 25 million of whom are 65 years of age or older (Foege, 1980). Thus, although influenza immunization is recommended primarily for high risk populations, it nevertheless qualifies as being widely recommended and used.

The target population for a hepatitis B vaccine encompasses health care and laboratory personnel; staff and residents of institutions for the mentally retarded and other large semi-closed institutions; patients on maintenance hemodialysis; patients requiring repeated blood transfusions or ministration of blood products; patients undergoing treatment with immune suppressive or cytotoxic drugs; and patients with malignant diseases and disorders associated with depression of immune response (Plotkin, 1978). Pseudomonas vaccine is even more of a vaccine targeted at a specific population, as these bacteria cause

problems only in persons who are susceptible to them because of other health problems.

What this means is that for many of the vaccines that might be expected to be developed in the next 10 years, the decision to be vaccinated or not will be much more of a private decision taken in consultation with one's physician, which will involve balancing the risks versus benefits for that particular individual.

There are, however, some potential candidates for mass immunization programs among vaccines currently being researched. Vaccines to protect against the bacterial agents that cause meningitis and otitis (a type of ear infection) in children are cases in point. The bacterial agents in question are streptococci, meningococci B&C, pneumococci (approximately 8 strains) and H. influenza. Of these, meningococci C and H. influenza are the most readily spread from person to person, though relative to other contagious diseases they are only moderately contagious. At present vaccines against meningococci C and H. influenza that are effective in adults and older children have been developed. Meningococcal vaccine has been used successfully against small scale outbreaks of meningitis among specific at risk populations such as soldiers. Most of the serious, lasting damage done by these bacterial organisms occurs, however, in children under age 5. For example, with H. influenza meningitis, approximatley 10% of those affected die; 30% suffer neurological damage. Thus, the benefits of a mass immunization program against these bacteria would only occur if a safe and effective vaccine could be developed for use in infants. Existing vaccines do not produce sufficient levels of immunity in children under age two, however. Apparently the immune system is still maturing in infancy with respect to these antigens. Whether or not vaccines against the bacteria that cause meningitis and otitis will become serious candidates for use in mass immunization programs thus depends on solving the problem of how to provide effective immunizations against these bacteria in infants.

A vaccine against chickenpox (varicella) has not yet been developed but is anticipated. This is a common childhood disease which, in the present state of knowledge, does not appear to have the same potential for the serious complications associated with measles, mumps and rubella. Should a disease that is highly unpleasant but seems to run its course in a short time without fatalities or residual disability be made the target of a mass immunization campaign? As the vaccine has not yet been developed, no one can know what the adverse side-effects of such a vaccine might be. Serious adverse reactions to a vaccine tend to be the same as the serious complications of the disease itself, so we might anticipate that a chicken pox vaccine would be quite safe. This does not, however, fully answer the question whether an unpleasant but largely benign disease should be made the target of a mass immunization effort.

Another potential candidate for a mass immunization program is a vaccine against cytomegalovirus. Mass immunization against cytomegalovirus in young girls, in later childhood just before puberty, might will prevent considerable mental retardation, since cytomegalovirus is the most common congenital infection (Table 8). The infant born with intra-uterine infection suffers brain damage in 10-30% of cases (Zuckerman, 1978).

Finally, gonorrhea and syphilis are obvious candidates for mass immunization programs, should effective vaccines become available.

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Table 7

New Vaccines - Expected Development After 1976

Vaccinees	Bacteria Toxoids	Virus	Other
Children	Meningococci B. Meningococci A - B Polyv. pneumococci H. influenza Caries Trachoma	Herpes simplex 1 - 2 Cytomegalo Varicella/Zoster Rota	
Adults	Bact. enterotoxoids Pseudomonas Cholera-toxoids Gonococci Syphilis Rocky Mountain Spotted Fever	Influenza, inactivated Influenza, live, att. Resp. synctytial Parainfluenza 1 - 3 Hepatitis A - B	Parasites Tumour

Sources: Hennessen, 1978 and Foege, 1980.

Table 8

Incidence of Certain Causes of Neonatal Sepsis Syndrome
(per 1000 cases)

Bacterial	1.0-3.5
Cytomegalovirus	5-20
Rubella	0.25-5
Toxoplasma	0.75-1.3
Herpes virus	0.03-0.3
Syphilis	0.1-0.2

Source: Plotkin, 1978.

1. This discussion is based on Hennessen, 1978, and discussions with NIH scientists involved in vaccine research; Drs. John LaMontague, James Hill, and Milton Puziss,

EXHIBIT A

Surveillance of Illnesses Following Immunization
1978-1979

Majorie P. Pollack, M.D.
Center for Disease Control

April 14, 1980

Surveillance of Illnesses Following Immunization

1978-1979

Vaccines are recommended and administered to millions of individuals every year on the presumption that the benefits far outweigh the risks. In the risk-benefit equation, the benefits may be easily defined--vaccinations can and do prevent serious diseases. On the risk side of the equation are the adverse reactions to vaccination. Since some adverse effects may occur very rarely, it is often difficult to recognize their relationship to vaccination and to estimate the rate at which they occur. Additionally, many events reported to occur following receipt of vaccine may not be related directly to the vaccine. Continuing evaluation of the balance of risks and benefits requires the surveillance of reactions following vaccination.

A formal monitoring system has been developed by the Immunization Division, Bureau of State Services, Center for Disease Control. This system collects information from vaccinees who report any illness requiring medical attention during the 30-day period following receipt of vaccine. Reports are made to local and State health departments and are then forwarded to CDC for collation. The system was instituted on a pilot basis in several States early in 1978 and formalized nationwide in October 1978. While reporting of illness following vaccination is now mandatory from all Federally funded Immunization Projects, it is still voluntary from the private sector. Figure 1 is a copy of the form presently used, entitled “Report of Illness Following Vaccination.” This form is triplicate, but the top sheet (shown in Figure 1) is the only copy which contains patient identifying information. This copy is retained locally. This form requests specific information on the individual who experienced an illness following receipt of vaccine. Additional information that will be requested on future forms is the patient’s immunization history prior to the dose in question. The diagnoses and symptomatology described in the section “Brief description of

illness" are coded in accordance with the International Classification of Disease, ninth revision, Clinical Modification (lCD 9-CM).

As of December 31, 1979, a total of 1,440 adverse events following vaccination have been reported. Table 1 shows the number of reports received by CDC, comparing the calendar year 1978 with 1979. Both the absolute number of reports received, and the number of areas reporting increased in 1979, reflecting the gradual implementation of the surveillance system. In 1979, 11.1 percent of reports came from vaccine administered in the private sector, as compared with 9.5 percent in 1978. Fourteen reports concern vaccine administered-by military providers. Table 2 shows the number of reports of adverse events following vaccination by antigen administered, comparing 1978 with 1979. The vaccine most frequently reported to be associated temporally with adverse events was DTP, followed by OPV and MMR. This parallels vaccine practices, with DTP being administered most frequently, followed by OPV.

Table 3 shows the breakdown of reports received by vaccine combinations administered in 1978 and 1979. Of the 514 reports of illnesses following receipt of OPV, only 26 followed the administration of OPV alone. Three hundred thirty-two individuals received DTP simultaneously with OPV, 31 received Td with OPV, 50 received DTP and MMR with OPV, and 14 received Td and MMR with OPV. This simultaneous administration of multiple antigens makes it difficult to assess the role of individual antigens in the etiology of adverse events following immunization.

Table 4 shows the breakdown of reports received, by clinical illness and vaccine type, for the combined period 1978 and 1979. It should be noted that an event following the simultaneous administration of two vaccines is shown in both vaccine columns. Thus, all 193 local reactions reported following receipt of OPV represent individuals receiving OPV simultaneously with a parenterally administered vaccine--i.e, DTP, Td, and/or MMR. Additionally, an individual

having a local reaction at the site of injection could also have had a convulsive episode and thus would be shown in both rows in the table. The clinical illness titles represent composites of symptoms based on the ICD9-CM coding system. The bottom line of the table, labeled “Total Number of Individuals Involved” represents the number of individuals reported to have had adverse events following the receipt of each type of vaccine.

For all vaccine types except MMR, the most frequently reported adverse events are local reactions. These represent approximately 40 percent of the reports received overall, decreasing from 45 percent of reports in 1978 to 38 percent in 1979. This decrease may reflect improved functioning of the system, since the guidelines for implementation of the surveillance system discourage the reporting of local reactions except when there is an increased frequency noted.

The next most frequently reported adverse events were, fever--unaccompanied by other systemic or localizing signs--and rash. In the cumulative file, these two symptoms account for 32 percent of all reports received. If local reactions, fever-only, and rash are considered minor symptoms, then 72 percent of all adverse events reported were minor.

Arthritis and/or arthralgia accounted for 52 percent of all reports of illnesses following receipt of rubella vaccine. All 24 reports involved individuals over age 20 years--a finding consistent with the increased frequency in adults reported in the literature.

Tables 5-9 are estimates of age specific rates of illnesses reported following receipt of vaccine in the public sector in 1979. They are expressed as the number of reports per million doses of vaccine administered. Tables 7-9 include reports relating to all vaccines containing the specific antigen mentioned. The bottom line of each table gives the overall rate of reporting individuals experiencing any adverse event following the receipt of the specific

vaccine.

In Table 5 we see the age-specific rates of illnesses following receipt of DTP. Local reactions were most frequently reported, with an increasing rate with increasing age. Febrile convulsions were most frequent in the 1- to 4-year-old age group.

Table 6 shows the age-specific rates of illnesses following receipt of adult Td vaccine. There is a trend of increasing rates with increasing age. Local reactions in the greater than 20-year-old age group were reported at a rate 10-fold greater than that reported in the 5- to 9-year-old age group. This trend is consistent with reports in the literature of an increased incidence of local reactions following Td correlated with previous immune status.

Table 7 shows age-specific illness rates following receipt of mumps antigen containing vaccines. All reports of encephalopathy were following receipt of MMR.

Table 8 shows age-specific rates of illness following receipt of measles antigen containing vaccines. There is a decreasing rate of febrile illnesses with increasing age.

Table 9 shows the age-specific illness rates following receipt of rubella antigen containing vaccines. The rates of illnesses seen in the greater than 20-year-old age group are much higher than those seen in the younger age groups.

In March of 1979, the Tennessee Department of Health reported that four infants died suddenly in the 24-hour period following receipt of DTP vaccine. An extensive investigation neither established nor refuted a causal relationship A review of the surveillance file for 1978 and 1979 revealed that 43 reports of sudden deaths in infancy in the 30 days following receipt of DTP vaccine had been received. Figure 2 shows the number of cases of sudden death following receipt

of DTP by month of occurrence for the period May 1978 through December 1979. Twenty-five of the 43 deaths (58 percent) had autopsy findings consistent with sudden infant death syndrome (SIDS). Ten (or 23 percent) of the deaths occurred in March. This coincides both with the investigation of the cluster in Tennessee and with the usual seasonal incidence of SIDS.

The age range of the cases was 6 weeks to 13 months, with a mean of 304 months and a median of 2 months. The male to female ratio was 1.6 to 1.

Following receipt of DTP; the range was from several hours to 28 days, with a mean of 5.4 days and a median of 1.5 days.

Of the 43 deaths reported, 28 different lots of vaccine from four different manufacturers were involved. Only one lot was reported to have more than two deaths; this was the lot involved in the Tennessee cluster. Thirty-six (84 percent) had received OPV simultaneously with DTP. Of the 30 infants where the immunization history was known, 73 percent had received their first dose, 20 percent their second dose, and 7 percent their third dose.

The 43 sudden deaths following receipt of DTP have similar age, sex, and seasonal characteristics as reported for SIDS. The usual age at vaccination with DTP coincides with the peak incidence of SIDS. The high proportion of reported deaths that occurred within 24 hours of receipt of vaccine may reflect recall bias, as people are more likely to attribute causality to events occurring shortly before an unexpected and unexplained death.

The maintenance of a surveillance system to monitor adverse events following receipt of vaccines has three main roles. The first and most important role of the system is to learn about previously unrecognized vaccine reactions of low incidence that might surface after wide-scale vaccine use, e.g., Guillaip-Barre syndrome following swine influenza vaccine program.

A second role of the system is to maintain a vigilance for clustering of vaccine reactions following the administration of a specific lot of vaccine. For example, the clustering of sterile abscesses following two lots of Sclavo DTP which resulted in the recall of the lot.

A third role is to refine estimates of the occurrence of known vaccine reactions. In the past, there had been problems in the ascertainment of both the frequency of reactions following vaccination and the number of doses of vaccine actually administered. Until recently, determination of the frequency of reactions was dependent upon vaccine field trials and sporadic reports to the Bureau of Biologics (BOB) at FDA, the vaccine manufacturers, and public health centers. The present surveillance system permits continuing estimation of this frequency--albeit an underestimate due to the relative passive nature of the system. The data reported do not establish causality or lack of causality between an adverse event and the immunization received. The system does highlight areas in which there is a need for special studies to determine causality.

FIGURE 1

Form AvProveC
OMB No. 68-R 1661

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

REPORT OF ILLNESS FOLLOWING VACCINATION

PAT Z

Patient Name:

IPhona:

Patient Addr-

a.c. exe. num.

m cm m ‘ex: ❑M❑’ “ate: m ‘::::” UIn

Mo. Oay Yr.

County of Restdence:

Dateof Report: ~] IT] ~[

Mo Day Vr.

REPORTING SOURCES

Patient's Physician:

Phone:

a.c. exe. num.

Physician's Address:

Parwn Making Report:

Phone:

exe. num.

VACCINES

--at e: m m m

Mo, Day Yr.

Provider: O Public ❑ ;ivate ~M!litary ~ Other

Name of Provider:

lelow, enter all vaccines given on the above date.

Vaccine:	●1	●2	#3	*4
Type				
Manufacturer				
Lot Number				
Roum				
Method				
Site				

ILLNESS

m m m D m q w m s i s :

Mo, Oay Yr.

Brief Description of Illness:

“=’itdiz’’’’n yes EI NO ❑ ’nk ‘fy6Name0fHmpita ”

Laboratory Results:

PREVIOUS HISTORY

Previous Illness or ReactIon to Vaccination: ❑ yes cl NO ❑ lunk ❑ lyes ❑ NO clunk

History of Convulsions in Patient: c l’” cl NO ❑ un’ History of Convulsions in Family: ❑ l’es cl NO ❑ u”k

Descrtba:

7-DAY FOLLOW-UP

m m m ❑ Recovered ❑ partalRecoverYn IIIDDeath

Mo. Day Vr.

Comments

Record additional comments on a separate page and attach to this form,

This report is authorized by law (42 (JSC 247b; 42 c FR 51 b). Its submission is needed to monitor possible rea CtIOn S to VaCCInat iOn and iS voluntary except w hen required as a :ondtt 10 n of immu nIzat Ion grant awards.

CDC 10.365-79

REPORTING AGENCY COPY

Figure 2
Number of SIDS Temporally Associated with Receipt of DTP by Month of Occurrence
May 1978 – December 1979

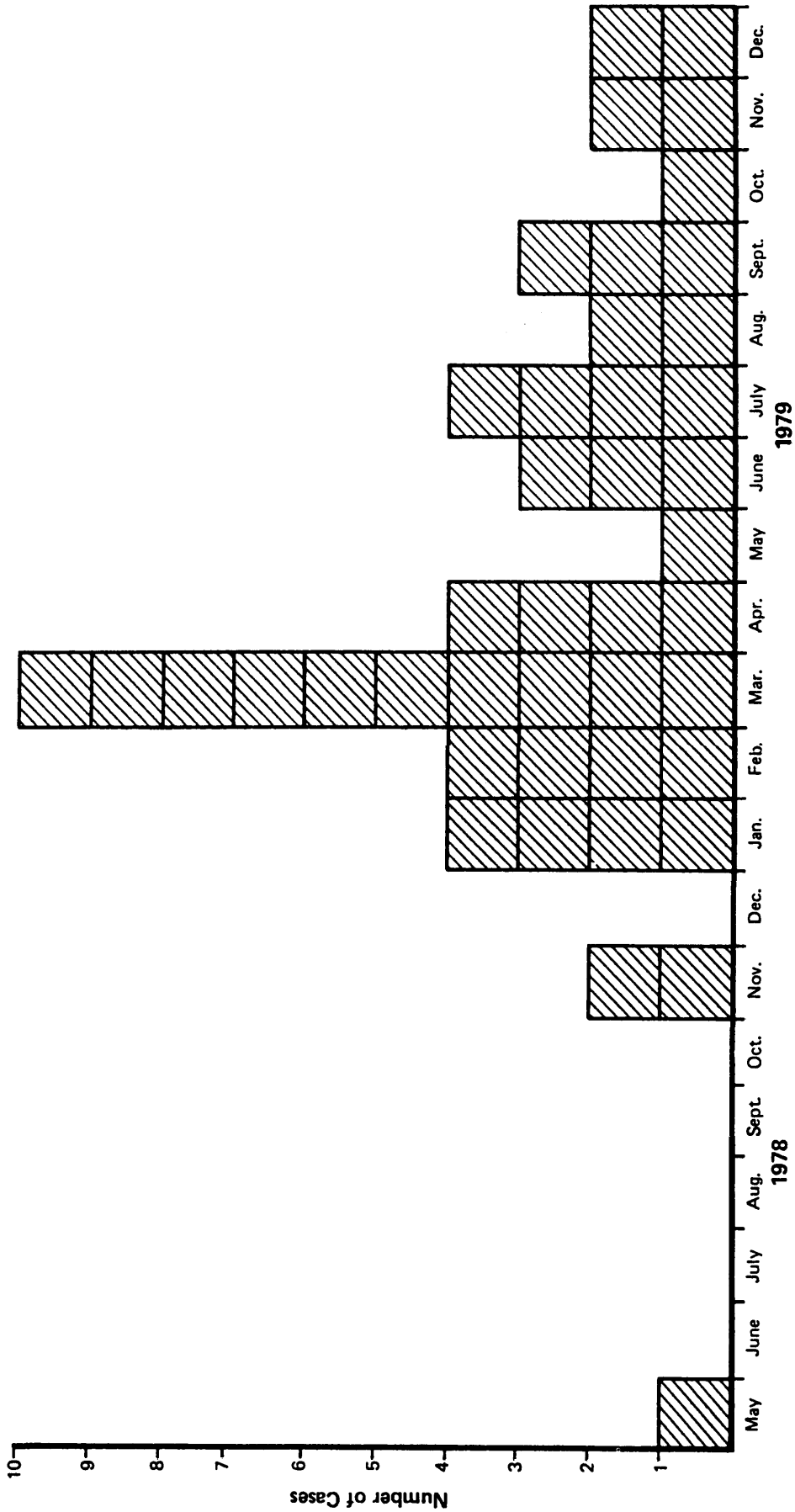

Table 1

Number of Reports Received
1978 and 1979*

	1978	1979	Total
Number of Reports	486	954	1,400
Number of Areas Reporting	33	48	48
Number received vaccine from:			
Public Provider	320	747	1,067
Private Provider	46	106	152
Military Provider	3	11	14

*As of February 15, 1980

Table 2

Number of Reports Received by Antigen
Administered in Decreasing Order
1978 and 1979*

	1978	1979	Total
DTP	230	462	692
TOPV	141	373	514
MMR	80	144	224
Td - Adult	42	123	165
Influenza	69	97	166
Mumps	9	43	52
Rubella	14	32	46
Tetanus toxoid	4	31	35
M-R	18	28	46
Measles	40	25	65
Smallpox	3	16	19
Typhoid	2	9	11
DT - Pediatric	8	8	16
Cholera	0	6	6
Yellow Fever	0	5	5
Pneumovax	2	3	5
Rabies - DEV	0	1	1
Rabies - HRIG	0	1	1
Tuberculosis	0	1	1
IPV	0	0	0

*Reports received as of February 15, 1980

Table 3

Immunizations Received by Individuals
Reported to Have Illnesses in the 30 days
Following Receipt of Vaccine - 1978 and 1979*

Single Antigen Only	1978	1979	Total
DTP	130	143	293
MMR	59	92	151
Influenza	66	96	162
Td	11	79	90
Rubella	8	30	38
Mumps	5	17	22
Measles	30	19	49
TOPV	10	16	26
MR	6	9	15
Two Antigens			
DTP & OPV	76	256	332
Td & TOPV	9	22	31
DTP & MMR	4	5	9
OPV & MMR	2	6	8
MR & Mumps		5	5
Td & Mumps	3		3
OPV & Mumps	1	2	3
Td & MR	1	2	3
Measles & Rubella		2	2
Td & Measles	2		2
Td & MMlt		1	1
DTP & Mumps		1	1
DTP & MR	1		1
OPV & Measles	1		1
OPV & MR	1		1
OPV & Rubella	1		1

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Table 3 Continued

Three Antigens	1978	1979	Total
OPV & DTP & MMR	13	37	50
Td&OPV&MR	7	7	14
OPV & DTP & Mumps	1	10	11
Td & OPV & Measles	4	2	6
Td&OPV&MMR	2	3	5
OPV & DTP & MR	2	3	5
Td & OPV & Mumps	1	1	2
DTP & OPV & Measles	2		2
Td & OPV & Rubella	2		2
DTP & Mumps & MR		1	1
OPV & Measles & Mumps		1	1

*For those reports where full immunization histories are knon.

Table 4

Clinical Illnesses Reported to Have Occurred in the 30-day Period Following Immunization by Vaccine Received
1978 & 1979

Clinical Illness	Vaccine Type								
	DTP	OPV	MMR	Td	Flu	Mumps	Rubella	MR	Measles
Local Reactions	346	193	35	106	55	15	13	7	22
Fever-- only	88	73	29	12	33	12	3	5	7
Rash	90	82	105	20	8	11	14	13	22
Allergic Reactions	29	30	9	5	5	3	4	3	3
Anaphylaxis					1				2
Arthritis and/or Arthralgia	13	19	7	8	9	2	24	2	2
Convulsions-Febrile	52	41	33	1		1		1	4
Convulsions--Non-febrile	18	15	8	6		1	1	4	2
Encephalopathy	11	9	8	1		3		1	3
Guillain Barre Syndrome (GBS)	3	6	4	3	4		1		1
Reye's Syndrome									
Paralysis--non GBS	5	6	2	1	7	1			1
Other necrologic Symptoms	44	41	33	6	17	5	3	6	7
Sudden Infant Death Syndrome (SIDS)	28	25				1		1	
Deaths from All Causes	44	34	2		7	1		1	2
Total number of Individuals Involved	692	513	224	162	159	52	46	45	65

Table 5

Age Specific Reports of Illness in the 30 Days
Following Receipt of DTP Administered in the Public Sector
Expressed as Cases Per Million Doses Administered-1979

	Age (in years)			
Clinical Illness	<1	1-4	5-9	All Ages
Local Reactions	20.4	24.4	3003	25.0
Fever--Only	9.1	9.2	12.7	10.8
Rash	11.5	9.6	8.4	10.5
Allergic Reactions	1.6	3.2	4.2	2.8
Convulsions--Febrile	400	12.3		6.7
Convulsions--non-Febrile	2.4	2.3		2.1
Encephalopathy	0.8	0.9		0.7
Other Necrologic symptoms	2.4	4.6	3.2	3.7
SIDS	6.3	0.5		300
Deaths	9.1	0.5		4.2
Any reaction	58.8	62.5	58.8	62.5

Table 6

Age Specific Reports of Illness in the 30 Days
Following Receipt of Td Administered in the Public Sector
Expressed as Cases Per Million Doses Administered-1979

	Age (in years)				
Clinical Illness	5-9	10-14	15-19	>20	All Ages
Local Reactions	12.7	1106	18.9	166.7	27.8
Fever--Only	2.1	1.9	2.5	409	2.7
Rash		3.9	1.3	14.7	4.3
Convulsions-Febrile			103		003
Convulsions --non-febrile		1.9	2.5	409	1.7
Encephalopathy		1.0			0.3
Other Necrologic symptoms			1.3	4.9	0.7
Any reaction	17.8	20.4	27.8	200.0	38.5

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Table 7

Age Specific Rates of Reported Illnesses in the 30 Days
Following Receipt of Mumps* Administered in the Public Sector
1979 Expressed as Cases Per Million Doses Administered

	Age (in years)					
Reactions	1-4	5-9	10-14	15-19	>20	All Ages
Local Reactions	c 1	6.0	16.9	8.0		1003
Fever--Only	13.1	9.6	1001			11.4
Rash	28.4	6.0	3.4		121.6	20.5
Allergic Reactions	3.5		3.4			2.2
Convulsions-Febrile	1.4					0.7
Convulsions-Non-feb.	3.5					1.8
Encephalopathy	007			8.0		0.7
Other Necrologic Symptoms	7.6	2.4	10.1			6.2
Any reaction	21.4	14.4	23.6	8.0	121.6	19.8

*For all mumps containing vaccines (mUmPS + MMR)

Table 8

Age Specific Rates of Reported Illnesses in the 30 Days Following Receipt of Measles* Administered in the Public Sector 1979 Expressed as Cases Per Million Doses Administered

	Age (in years)					
Reaction	1-4	5-9	10-14	15-19	>20	All Ages
Local Reactions	10.0	8.9	10.0	8.9		10.4
Fever-- only	10.7	7.4	2.9			7.3
Rash	30.7	3.0	10.0		41.7	18.9
Allergic Reactions	2.9	1.5	2.9			2.1
Anaphylaxis			1.4			0.3
Convulsions--Febrile	10.7		1.4	2.2		5.2
Convulsions--Non-Feb.	3.6		2.9	4.5		2.8
Encephalopathy	0.7		1.4	2.2		0.9
Other Necrologic Symptoms	7.9	1.5	7.5			5.5
Any reaction	65.7	22.2	31.4	29.0	125.0	48.6

*For all measles containing vaccines (measles + MR + MMR)

Table 9

Age Specific Rates of Reported Illnesses in the 30 Days Following Receipt of Rubella* Administered in the Public Sector 1979 Expressed as Cases Per Million Doses Administered

Reaction	Age (in years) 1-4	5-9	10-14	15-19	>20	All Ages
Local Reactions	9.3	8.4	11.9	10.9	158.6	12.2
Fever--only	12.2	8.4	2.4			9.1
Rash	29.5	3.4	7.1		238.0	23.2
Allergic Reactions	2.9	1.7	2.4		39.7	3.0
Arthritis and/or Arthralgia	0.7	1.7			515.6	**6.5**
Convulsions--Febrile	10.8		2.4			**6.1**
Convulsions--Non-feb.	3.6		2.4	10.9		3.0
Encephalopathy	0.7			5.5		0.8
Other necrologic symptoms	7.2	1.7	9.5			6.1
Any reaction	65.4	23.6	30.9	43.8	793.2	51.7

*For all rubella containing vaccines (rubella + MR + MMR)

EXHIBIT B

Ranges of Direct, Indirect, and Total Cost by Medical Event

Exhibit B

RANGES OF DIRECT, INDIRECT [illegible] TOTAL COST BY MEDICAL EVENT*
for Persons Less Than [illegible] Year of [illegible], At a Discount Rate of 2.5%

Medical Event	RANGE OF COSTS					
	TOTAL		DIRECT		INDIRECT	
	MALE	[illegible]	[illegible]	FEMALE	MALE	FEMALE
(1) Anaphylaxis/DTP	95-825,769	95-638,380	95-138,880	95-145,999	[illegible]	0-492,381
(2) Arthritis/Rubella	49-869,229	49-692,358	49-182,341	49-199,977	[illegible]	0-492,381
(3) Aseptic Meni[illegible]itis/ Acute Encephalitis/ Measles	1,313-927,533	1,313-740,270	1,313-240,644	1,313-247,889	[illegible]	0-492,381
(4) Convulsions/DTP	259-869,574	259-682,266	259-182,689	259-189,885	0-686,888	0-492,381
(5) Encephalitis/[illegible]	2,487-849,474	2,487-662,651	2,487-162,586	2,487-170,270	0-686,888	0-492,381
(6) Encephalitis/Mumps	2,167-186,649	2,167-138,218	2,167- 14,927	2,167- 15,123	0-171,722	0-123,095
(7) Non-Paralytic Polio	422-903,160	422-715,960	422-220,065	422-227,376	0-686,888	0-492,381
(8) Encephalitis/Rubell[illegible]	2,083- 5,216	2,082- 5,270	2,083- 5,216	2,082- 5,270	0- 0	0- 0
(9) Nerve Deafness/Mump[illegible]	575-462,315	575-345,886	575- 26,905	575- 27,146	0-412,133	0-295,429
(10) Paralytic Polio	1,766-825,550	1,766-633,436	1,766-138,662	1,766-141,055	0-686,888	0-492,381
(11) Peripheral Mono-Neuropa[illegible] DTP	1,443-208,225	1,443-153,885	1,443- 15,896	1,443- 16,018	0-192,329	0-137,867
(12) Neuritis/Rubella	35- 1,293	35- 1,293	35- 1,293	35- 1,293	0- 0	0- 0
(13) Reye's Syndrome/DTP	2,644-878,098	2,644-693,044	2,644-191,201	2,644-200,633	0-686,888	0-492,381
(14) Transverse Myelitis [illegible]P	447,974-891,963	332,036-705,384	35,841-205,075	36,607-213,003	412,133-686,888	259,429-492,381
(15) Cerebellar Ataxia/Measles	2,364-894,790	2,364-707,470	2,364-207,901	2,364-215,089	0-686,888	0-492,381
(16) Guillain-Barre/Influenza[1]	11,694-120,062	11,419-137,151	9,087- 88,933	9,087- 99,513	2,607- 31,129	2,332- 37,634
(17) S.S.P.E.	846,210	651,991	159,332	159,610	686,888	492,381
(18) Thrombocytopenic Purpura/ Rubella	34	34	34	34	0	0

[1]For persons 65-69 years of [illegible] discount rate of 2.5%.

[illegible]: The table prepared by Arthur D. Little (A.D. Little, 1979). For explanation and OTA analysis see Chapter V.

Exhibit C

California Law on Vaccine In-jury Compensation

and

Rhode Island Legislative Proposal on Vaccine Injury Compensation

California Health and Safety Code

ARTICLE 14.5

Immunization Reactions

(Added by Stats 1977 ch 1097 1.)

429.35 Medical etc., care for reactions by minors: Claims reimbursement, and subrogation: Creation of Immunization Adverse Reaction Fund
429.36 Liability for injuries caused by acts or omissions in administration of vaccine or other immunizing agent

($429.35. Medical, etc., care for reactions by minors: Claims, reimbursement, and subrogation: Creation of Immunization Adverse Reaction Fund

It is the intent of the Legislature to provide for care, including medical, institutional, supportive, and rehabilitative care, necessitated because of severe adverse reaction to any immunization required by state law to be administered to children under 18 years of age.

As used in this article, a severe adverse reaction is one which manifests itself not more than 30 days after the immunization and requires extensive medical care, as defined by regulation of the department.

Medical expenses shall be reimbursed by the state department in an amount not to exceed twenty-five thousand dollars *($25,000).*

Eligibility for reimbursement under this section shall be limited to persons requiring extensive medical care, as defined by the state department pursuant to this section. Such reimbursement shall be made without regard to ability to pay and neither the parents nor the estates of such persons shall be liable for repayment to the state of any portion of the amounts reimbursed pursuant to this article.

The state department shall, by regulation, establish procedures for processing claims pursuant to this section.

Whenever reimbursement is provided for medical expenses under this article, the state shall be subrogated to the rights of the person receiving reimbursement of medical expenses for any amounts due to or recoverable by such person from third parties. The subrogation shall be for an amount equal to any claim reimbursed under this article.

There is hereby created in the State Treasury the Immunization Adverse Reaction Fund, which shall be administered by the State Department of Health and is appropriated without regard to fiscal years.

Reimbursements made pursuant to this article shall be made from the Immunization Adverse Reaction Fund.

ff 429.36 Liability for in-juries caused by acts or omissions in administration of vaccine or other immunizing agent.

No person shall be liable for any injury caused by an act or omission in the administration of a vaccine or other immunizing agent to a minor, including the residual effects of the vaccine *or* immunizing agent, if such immunization is required by state law and the act or omission does not constitute willful misconduct or gross negligence.

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Introduced by-
Senators Federico, Flynn and O'Neill

Ordered Printed by-
Senate

Referred to-
Senate Committee on Special Legislation

Date Printed-
January 10, 1979

State of Rhode Island and Providence Placations

JANUARY SESSION, A. D. 1979

An Act Pertaining to "Immunization Reactions't.

It is enacted by the General Assembly as follows:

Section 1₀ Title 16 of the general laws entitled "Education" is hereby amended by adding thereto the following chapter:

"CHAPTER 16-21.2
"Immunization Reactions

"16-21.2-1. LEGISLATIVE INTENT. -- It is the intent of the legislature to provide for care, including medical,, institutional, supportive, and rehabilitative care, necessitated because of severe adverse reaction to any immunization required by state law to be administered to children under eighteen (18) years of age.

'16-21.2-2. REACTION DEFINED. -- As used in this chapter, a severe adverse reaction is one which manifests itself not more than thirty (30) days after the immunization and requires extensive medical care, as defined by regulation of the department of health.

"16-21.2-3. REIMBURSEMENT -- MEDICAL EXPENSES. -- Medical expenses shall be reimbursed by the state in an amount not to exceed twenty-five thousand dollars ($25,000).

Eligibility for reimbursement under this section shall be limited to persons requiring extensive medical care, as defined by the health department pursuant to this section. Such reimbursement shall be made without regard to ability to pay and neither the parents nor the estates of such persons shall be liable for repayment to the state of any portion of the amounts reimbursed pursuant to this chapter.

The health department shall, by regulation, establish procedures for processing claims pursuant to this section

Whenever reimbursement is provided for medical expenses under this article, the state shall be subrogated to the rights of the person receiving reimbursement of medical expenses for any amounts due to or recoverable by such person from third parties. The subrogation shall be for an amount equal to any claim reimbursed under this chapter.

There is hereby created in the state treasury the immunization adverse reaction fund, which shall be administered by the department of health and is appropriated without regard to fiscal years. Reimbursments made pursuant to this article shall be made from the immunization adverse reaction fund.

"16-21.2-4. PERSONS LIABLE. -- No persons shall be liable for any injury caused by an act or omission in the administration of a vaccine or other immunizing agent to a minor, including the residual effects of the vaccine or immunizing agent, if such immunization is required by state law and the act or omission does not constitute willful misconduct or gross negligence."

Sec. 2. The sum of fifty thousand dollars ($50,000) is hereby appropriated from the general fund to the immunization adverse reaction fund for the purposes of this chapter.

Sec. 3. This act shall take effect upon passage.

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EXPLANATION

By the Legislative Council

Under existing law, there is no state program which provides for medical or institutional care or indemnification expressly for children who suffer an adverse reaction to a required immunization. Also, nothing in present law exempts physicians and surgeons from liability for damages caused by negligent acts or omissions in the administration of immunizing agents, except with respect to prescribed participation in the National Influenza Program of 1976.

This act would require the Department of Health to reimburse the medical expenses incurred for a child under the age of 18 as a result of a severe reaction to a state-required immunization, as specified. Such reimbursement would not exceed $25,000, would be made without regard to ability to pay, and would be made without requirement of repayment.

This act would subrogate the state to the rights of the person receiving reimbursement for medical expenses to the extent of any reimbursement provided.

This act would exempt a person from liability for injury caused by acts or omissions, not constituting gross negligence or willful misconduct, in connection with the administration of an immunization required by state law.

This act would appropriate $50,000 to the Immunization Adverse Reaction Fund, a continuously appropriated fund created by the act to carry out the provisions of the bill requiring indemnification for medical expenses.

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