

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 illustrate: 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 liability, 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. Little (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, alongside 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,

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

<u>Adverse Reaction</u>	<u>Estimated Range of Annual Cases</u>	<u>ADL Medical Cost Estimate Per Case**</u>
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).