

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 Of these claims, 1,167 progressed to lawsuits; 2,365 claims -- totalling \$2.2 billion -- had been denied or withdrawn.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 evaluative 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.