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