An Experiment in Tort Reform

The National Childhood Vaccine Injury Compensation Act of 1986

GEMMA FLAMBERG, JD

In 1986, Congress passed Title III of Public Law 99-660, the National Childhood Vaccine Injury Compensation Act, a no-fault compensation system designed to assist persons who are injured by certain childhood vaccines *(1)*. The Act was the result of increased pressure on Congress to address the crisis in vaccine production caused by an increase in litigation against vaccine manufacturers in the 1970s and early 1980s.

Although vaccines are overwhelmingly safe and effective, some children experience adverse events in the days following the administration of routine childhood vaccines. Civil actions brought against the manufacturers and administrators of these vaccines to obtain compensation for these injuries often proved unsuccessful for the plaintiffs, given the difficulty in proving causation and negligence.

At the same time, vaccine manufacturers were becoming increasingly burdened by the transaction costs of litigation, as well as the difficulty in finding affordable product liability insurance. By 1986, several manufacturers had withdrawn from the vaccine market *(2)*. In fact, at the time the Act was passed, there was only one manufacturer of each type of polio vaccine (inactivated and oral), one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the Diphtheria, Tetanus and Pertussis (DTP) vaccine *(2a)*.

Thus, the act was passed as a result of two concerns, *(a)* the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those damaged by a vaccine and *(b)* the instability of the nation's vaccine supply as a result of the manufacturers' reactions to the cost of litigation *(2a)*.

To address the problems experienced by plaintiffs in proving both negligence and causation, Congress designed a system whereby certain people would be eligible to receive compensation without proving either negligence or causation. To address the second goal of the program, Congress included various protections from liability for both vaccine administrators and manufacturers.

The Statute

The Act created the Vaccine Injury Compensation Program, a process whereby anyone who believes he or she has been injured by a childhood vaccine may file a petition seeking compensation for medical and related expenses in the U.S. Court of Federal Claims, naming the Secretary of Health and Human Services (HHS) as the respondent. Special Masters adjudicate all claims based on the burdens of proof described in the statute. The respondent evaluates each claim to determine whether to concede that the case has met the requirements for compensation or to oppose the case. The Department of Justice represents the Secretary in all proceedings before the Claims Court. Claims for cases where the vaccine was administered prior to October 1, 1988 (the effective date of the Act), are paid out of general fund appropriations. Claims for cases involving vaccines given on or after October 1, 1988, are paid out of a trust fund set up by the Act and financed by excise taxes on vaccines *(3)*.

Protection for manufacturers from liability. The Act includes several important provisions that provide protections from liability for manufacturers and administrators of vaccines. First, petitioners who receive vaccines on or after October 1, 1988 *must* proceed under the program and must reject a judgment under the program before they are eligible to file a civil action. Second, the Act includes provisions that limit manufacturers' liability for injuries that are unavoidable if the product was prepared properly and accompanied by proper directions and warnings consistent with Food and Drug Administration standards. Third, the Act limits the instances in which punitive damages may be assessed against vaccine manufacturers.

Compensation without causation or negligence. Under the Act, a petitioner may obtain compensation either by proving causation in fact or by demonstrating that he or she experienced an injury described in the Vaccine Injury Table. The table sets out a list of the vaccines currently covered under the Program, particular adverse events associated with each vaccine, and a specific time frame during which the adverse event must occur in order to establish what is commonly referred to as a "table injury" *(1a)*.

If opting to prove a table injury, the petitioner must demonstrate by a preponderance of the evidence that the first manifestation or onset of a listed injury occurred within a particular time frame after receipt of the covered childhood vaccine. For instance, in order to establish a table injury, the petitioner may demonstrate that he or she experienced the first manifestation of an encephalopathy within three days after receipt of a DTP vaccine. If the claim is proven by a preponderance of the evidence, the petitioner has established a "rebuttable presumption of causation." The burden then shifts to the respondent to rebut the petitioner's claim by proving that the injury or condition was due instead to

"factors unrelated" to vaccine administration. If the special master determines that the petitioner either has proven successfully a table injury occurred and the respondent cannot demonstrate that the injury was due to factors unrelated to vaccine administration or has proven causation-in-fact and a series of jurisdictional requirements are met, the petitioner is eligible for compensation.

If compensation is awarded, the petitioner must file a "life care plan" that projects the amount and specific types of medical and related expenses that the person will incur each year. If compensation is awarded in a case brought on behalf of someone who has died, a lump sum of $250,000 is awarded. Typically, the Court orders the Secretary to purchase an annuity that will provide the person with sufficient funds to cover those expenses found by the Special Master to be reasonable and necessary. In addition, limited compensation is also available for pain and suffering, lost wages, and attorneys' fees based on specified formulas.

Modifying the injury table. At the time the Congress drafted the initial table, it recognized that some children whose injuries were not, in fact, vaccine-related, would receive compensation *(2b)*. For this reason and because the initial table might not include some injuries caused by vaccines, the Act also mandates further studies on the relationship between vaccines and certain adverse events and includes a provision directing the Secretary of HHS to revise the vaccine injury table by regulation consistent with the outcome of further research *(1b)*.

Consistent with this mandate, the Secretary published a regulation revising the initial vaccine injury table in the Federal Register on February 8, 1995 *(4)*. By adding certain injuries, deleting others, and revising the Qualifications and Aids to Interpretation that accompany the table, the Department has attempted to bring the compensation program more in line with current medical and scientific knowledge regarding the relationship between certain vaccines and adverse events.

When Is an Injury Vaccine-related?

Evolving standard for proving causation. Although the program functions as a simpler and less adversarial method than the tort system for resolving claims involving vaccine injuries, several difficult issues arose during the first few years involving the standard used by the court to determine when the petitioner had successfully proven a vaccine-related injury.

One of the earliest problems was the standard used by the court to determine whether the petitioner had met the burden of proof in establishing actual causation. The statute sets out two very different methods of proving causation. Causation is presumed if a person can prove a table injury by a preponderance of the evidence. If the case does not meet the requirements of the table, however, the petitioner still has the option of proving causation in fact.

The legislative history indicates that Congress intended to adopt a very different standard for proving causation than that needed to prove a table injury. The House committee report states that in order to prove causation in fact, "the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petition" *(2c)*.

Despite this language, however, the special masters were fairly lax in the beginning years of the program in determining causation. For instance, in a case typical of the early causation cases, the Special Master found that the petitioner had successfully established causation because "there was no more reasonable explanation for the encephalopathy" *(5)*. On appeal, the Department urged the court to adopt a more rigorous causation-in-fact standard, similar to that used by other Federal courts in adjudicating civil actions. The court ultimately agreed with the Department and held that in order to prove causation under the Act, the petitioner must demonstrate "proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect" *(6)*.

Compensation for pre-existing injuries. The second major problem confronting the program in its first few years has been the respondent's difficulty in rebutting the presumption of causation conferred by the table in those cases where the respondent's analysis of the evidence indicates that the injury was due to factors unrelated to vaccine administration. In cases where the petitioner is able to establish that a table injury occurred, the burden then shifts to the Secretary to determine whether the injury was due instead to factors unrelated to vaccine administration. Section 2113(a)(2) of the statute states that the term "factors unrelated to the administration of the vaccine" does not include any "idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition...."

A review of the cases involving DTP indicated that many of the conditions alleged to have been vaccine-related were due instead to infantile spasms, a condition the medical literature indicates is not caused by vaccine administration, but whose precise cause is generally unknown *(7)*. The Department argued that compensation

should not be awarded, because infantile spasms is a "factor unrelated" to vaccine administration. In many cases, the court disagreed, holding that because the language of the statute precluded "idiopathic" conditions from being considered "factors unrelated," a condition cannot fall into this category unless the Department can identify the precise cause of the infantile spasms. Because this is not medically possible in most cases, the petitioners received compensation.

A case involving Rett syndrome, similar to infantile spasms because a precise cause often cannot be identified, illustrates the court's response to these issues. In *Koston v. Secretary of Health and Human Services,* the Federal Circuit Court affirmed compensation for a person who suffered from Rett syndrome. Although there was no evidence to indicate that vaccines cause Rett syndrome, the court held that because Rett syndrome is idiopathic, that is, precise cause unknown, it cannot be used as a factor unrelated to vaccine administration so as to bar compensation *(8)*. The Department has argued in both types of cases that infantile spasms and Rett syndrome are properly considered factors unrelated because they are discrete with a known clinical picture and identifiable symptoms. In the Department's view, if the Secretary can point to a specific condition that logically eliminates the vaccine as the cause of a child's condition, the fact that the cause of the condition is unknown should not prevent it from being considered a "factor unrelated."

A third major problem facing the program has been the type of case where although signs of neurological dysfunction are indicated prior to the vaccine, the child had a manifestation of the dysfunction during the table time frame. If it is clear that the condition became markedly worse during the table time frame—a child who suffered one seizure a day experiences five seizures a day during the table time frame—the petitioner has the option of proceeding under a "significant aggravation" theory.

In this case, the petitioner may receive the rebuttable presumption of causation conferred by the statute if he or she is able to prove by a preponderance of the evidence that the condition was significantly aggravated. This becomes more problematic in those cases where the evidence is unclear whether the condition was significantly aggravated during the table time-frame, and where there is no clearly identified etiology for the preexisting neurologic dysfunction. In these types of cases, the Department has argued, often unsuccessfully, against compensation.

Award for Congenital Microcephaly

Both the second and third issues articulated previously (and in some respects the more general problem of proving causation) were present in the difficult case of *Whitecotton v. Secretary of Health and Human Services.* Maggie Whitecotton was born with microcephaly, a condition defined as a head size smaller than two standard deviations below the norm for a child of the same age and sex. The day after she received her third DTP vaccine, she suffered a series of seizures. There was no evidence that these seizures caused a general worsening or significant aggravation of her condition.

In opposing her petition for compensation, the Department argued that Maggie's condition was not a table condition, because the first symptom of onset of her injury occurred prior to the vaccine and that even if her injury could be considered a table injury, it was due instead to a factor unrelated to vaccine administration. The parents countered that Maggie's microcephaly could not be considered a "factor unrelated" because its precise cause was unknown. Although the petitioner was unsuccessful at the Special Master's level and before the Claims Court, the Court of Appeals for the Federal Circuit overturned both prior decisions and held that Maggie was entitled to compensation.

In its ruling, the Court of Appeals focused on the introductory language to the Vaccine Injury Table to the effect that the table provides the "time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the program" *(1c)*. The Court held that this language means "the table language is that the first symptom after vaccine administration must occur within the table time, not, as the Secretary argues, that the first of all manifestations must so occur" *(9)*. The Court ultimately held that because Maggie Whitecotton's encephalopathy manifested itself in the form of seizures occurring within the table time after vaccination, she had successfully established a table injury.

Once the court found that the petitioner had successfully established a table injury, it was then required to analyze whether the Secretary of HHS had successfully proved that the injury was due instead to factors unrelated to vaccine administration. Basing its decision in large part on the decision in the Koston case described previously, the court held that because the Secretary could not point to any particular cause of Maggie's microcephaly, she could not successfully argue that the injury was due to factors unrelated to vaccine administration. The court held that petitioners are due a presumption of causation where there is an unknown cause and symptoms of a table injury occurring within the table time frame *(9a)*.

Supreme Court Reverses Appeals Court

The Department was very con-

cerned that this decision would lead to other decisions to compensate petitioners who, in the Department's view, suffered from illnesses and conditions that were not vaccine-related. At the Department's urging, the Department of Justice successfully petitioned the U.S. Supreme Court to accept the case for review. In her petition, the Secretary argued that the Court of Appeals' holding would require compensation to be awarded in those cases where the weight of the evidence indicated that the child's injury or disability was due to a known preexisting condition. In the Department's view, this holding contradicts both the plain language and underlying intent of the statute. In cases where there is a preexisting condition, the statutory language requires the petitioner to demonstrate that the preexisting condition was significantly aggravated before the court can find that the petitioner is entitled to a presumption of causation. In addition, the Secretary argued that the court's interpretation of the "factors unrelated" section was flawed.

Basing its decision on arguments presented by the Department, the Supreme Court overturned the Court of Appeals' decision and remanded the case for further proceedings *(10)*. The Court found the Appeals Court's analysis at odds with the statutory language. Simply put, the Supreme Court held that if there are symptoms before the vaccine, a symptom that occurs after vaccine administration cannot be the first symptom or indication of onset. Common sense dictates that there cannot be two first symptoms or two first onsets. In order to receive the rebuttable presumption of causation conferred by the table, the claimant must demonstrate that there was no evidence of the injury prior to vaccination, unless, of course, he or she is pursuing the case under a significant aggravation theory. Justice O'Connor points out in her concurrence that the Appeals Court's decision would render meaningless the significant aggravation language in the statute. As she notes, however, the Court of Appeals did not even address this issue, and, therefore, whether the Special Master's findings are arbitrary and capricious regarding the significant aggravation of Maggie's condition could be revisited on remand.

Although the Supreme Court's decision in the Whitecotton case addresses some of the problems faced by the program, its limitations need to be recognized. In striking down the Court of Appeals' analysis, the Supreme Court decision should minimize the number of petitioners who are compensated for injuries that are not vaccine-related in those cases presenting fact patterns similar to that of Maggie Whitecotton. The decision does little however, to rectify the problem raised by the Koston case regarding idiopathic conditions that are not vaccine-related, according to the best scientific evidence available. This issue remains unresolved and could reach the Supreme Court again, depending on the circumstances of the remand in the Whitecotton case or the outcome of other similar cases.

Conclusion

In general, the Vaccine Injury Compensation Program has been successful in providing an alternative to the tort system for resolving cases of vaccine-related injuries. As of May 1, 1995, a total of 767 claims have been found compensable. In addition, a survey conducted by Department officials in November 1994 indicated that few petitioners have rejected the judgment of the Claims Court, and even fewer have gone on to file civil actions against vaccine manufacturers. Data obtained from the Centers for Disease Control indicate that in 1986, 255 suits were filed against manufacturers for vaccine-related injuries. In 1992, however, only 11 such lawsuits were filed.

These statistics demonstrate that the program has made significant strides in addressing the goals articulated by Congress when it enacted the statute. The program is still relatively new, however, and the method of analyzing the difficult medical and legal issues involved in determining when a condition is vaccine-related is constantly evolving. In an effort to ensure that only those cases that reasonably can be deemed vaccine-related receive compensation, the Secretary will continue to raise these issues before the Court, and revise the Vaccine Injury Table when appropriate.

Ms. Flamberg is a Senior Attorney in the Office of the General Counsel, Public Health Division, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857; tel. 301-443-8376.

Tearsheet requests to Ms. Flamberg.

References

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3. 26 U.S.C. 4131
4. 60 Fed. Reg. 7678 (February 8, 1995) (to be codified at 42 C.F.R. Part 100).
5. *Strother v. Secretary of HHS,* No. 88-32V, 1989 U.S. Cl.Ct. Lexis 298 (Sept. 18, 1989).
6. *Strother v. Secretary of HHS,* 21 C.Ct. 365, 369 (1990) citing *Hasler v. United States,* 718 F.2d 202, 205-06 (6th Cir. 1983).
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9. *Whitecotton v. Secretary of HHS,* 17 F. 3d 374, 376 (Fed. Cir. 1994); *(a)* 378.
10. *Shalala v. Whitecotton,* 115 S. Ct. 1477 (Decided April 18, 1995).