Recommendation 91-4

The National Vaccine Injury Compensation Program

(Adopted June 14, 1991)

The National Vaccine Injury Compensation Program (the Program), sections 2110 *et seq.* of the Public Health Service Act, codified at 42 U.S.C. 300aa-10 *et seq.*, is a federal compensation system for permanent injuries and deaths resulting from vaccines to prevent seven infectious diseases of childhood (diphtheria, tetanus, whooping cough, measles, mumps, rubella, and polio). State laws generally require immunizing children against such diseases for school entry.

The Program, which became effective October 1, 1988, is unique among federal benefit programs in its organizational structure and decision-making processes. It was intended to provide an alternative to the tort system for dealing with claims of vaccine-related injury, awarding compensation quickly, fairly, and efficiently. It was also intended to contribute to improving immunization rates, stabilizing the supply and price of vaccines, encouraging new and improved vaccines, and reducing the burden and uncertainty of litigation.

Decisionmaking authority is vested in the United States Claims Court. Claimants submit petitions for compensation to the Claims Court, and bear the burden of proving both entitlement and the losses and expenses to be compensated. The Secretary of Health and Human Services (HHS) is designated as respondent. The National Vaccine Injury Compensation Program Office in HHS (the Program Office) acts on behalf of the Secretary and may oppose compensation in individual cases. The vaccine manufacturer and whoever administered the vaccine are not involved as a party to the proceedings.

Two procedural innovations in the Program are especially noteworthy. First, determinations of eligibility and the amounts of compensation are made by special masters employed by the Claims Court. Under current procedures, the special master issues a judgment that is final unless review by a Claims Court judge is requested by either claimant or respondent. Further review is available in the United States Court of Appeals for the Federal Circuit.

Second, the Act contains a Vaccine Injury Table, which defines the injuries compensable under the Program. This was a policy decision by Congress, intended to avoid controversy over what disabilities were in fact caused by vaccines and to expedite decisions on claims by

eliminating difficult, time-consuming disputes over causation in individual cases.[1] Nevertheless, disputes over whether particular injuries qualify for compensation have sometimes proved time-consuming, even though the Table is accompanied by "Qualifications and Aids to Interpretation." Moreover, in cases of injury, determining the amount of compensation can be difficult and time-consuming because of the need to take into account the net present value of actual non-reimbursable expenses for medical, rehabilitative, and custodial care, actual and anticipated lost earnings, and actual and projected pain and suffering. Paragraphs 2, 3, and 4 address these issues by suggesting that Congress consider whether further clarification would be appropriate, and by recommending development of guidelines that may be used by the Claims Court and the parties. Paragraph 5 suggests study of ways to minimize transaction costs in administering awards under the Program.

The Department of Justice has recently taken steps to speed the processing of vaccine cases by increasing the Assistant Attorney General's settlement authority and modifying its settlement review and approval procedures.[2] Paragraph 6 encourages continued review of the appropriate level of such authority.

No one administrative agency is charged with the duty of interpreting the enabling legislation or issuing general regulations. The Advisory Commission on Childhood Vaccines is empowered to advise the Secretary of HHS on Program implementation. The Secretary may revise the Vaccine Injury Table, but has no authority to impose decisionmaking rules on the United States Claims Court. The Secretary was also required to develop and disseminate vaccine information materials, including a summary of the availability of the Program, not later than December 22, 1988.[3]

Claimants may seek compensation under the Program regardless of when the injury occurred. However, the starting date of the Program, October 1, 1988, serves as a line of demarcation between two somewhat different sets of rules and remedies. Claims based on immunizations prior to that date—"retrospective cases"—may not have received an award based on a judgment or settlement in a civil action. Awards in retrospective cases are paid out of a limited fund specially authorized by Congress.

[1] The Act also allows for compensation if a petitioner can prove that an injury was actually caused by a covered vaccine, even if the specific injury is not listed in the Table.
[2] See 56 FR 8923 (March 4, 1991).
[3] A proposal was published at 54 FR 9180 (March 3, 1989), but the final version has not been published as of the date of this recommendation.

For injuries arising from immunizations on or after October 1, 1988—"prospective cases"—no civil action may be filed unless the claimant has filed a claim under the Program and received and rejected a determination under it. For such cases, the Program is a "first resort." but not an exclusive source of compensation. Awards for prospective cases are paid from the Vaccine Injury Compensation Trust Fund supported by a tax on covered vaccine sales. The Act tolls the statute of limitations governing the civil action until a final judgment is issued on the petition. This tolling provision was intended to preserve a petitioner's right to commence a civil action after the petitioner has exhausted the remedies under the Act. However, because the petitioner has 90 days to accept or reject a final judgment by the Claims Court or the Court of Appeals, the immediate end to the tolling upon final judgment might operate to extinguish an unwary petitioner's right to commence a civil action. Paragraph 7 would remedy this anomaly.

Under the Act, as amended, a final deadline of January 31, 1991, was set for filing claims in retrospective cases. More than 3000 cases were filed in the 5 months preceding this deadline, the vast majority of them retrospective. The large number of filings during this period has created an unusual burden on the Program that can be expected to dissipate in the next few years, as a more regular pattern of filing claims develops. However, a special response, as suggested in paragraph 8, is warranted to ease the temporary burden of deciding these petitions. Measures suggested include a temporary increase in staffing, with funding to support the additional positions.[4] Paragraph 9 is intended to address the possibility there will be sufficient funding due to the substantial number of retrospective cases that have been filed; under the statute the Program would cease to be in effect if there are insufficient funds to pay all of the claims payable for 180 days.

The Claims Court has used teleconferencing successfully in connection with the Program. Congress may find it useful to study this experience and to consider the possible use of the technique in other proceedings.

Finally, we note that section 2117 of the Act grants the Trust Fund the right of subrogation for compensation paid under the Program. The Departments of Health and Human Services and Justice should continue to be alert to appropriate opportunities to pursue this course.

[4] Congress should consider the effects on the Program if money in the Vaccine Injury Compensation Trust Fund is used for this purpose. Currently, section 6601(r) of the Omnibus Budget Reconciliation Act of 1989, Pub. Law No. 101-239, 103 Stat. 2293, authorizes separate appropriations of funds to HHS, Justice and the Claims Court (for FY 1990 and 1991) from the Trust Fund.

Recommendation

1. The National Vaccine Injury Compensation Program Office in the Department of Health and Human Services, in consultation with the Advisory Commission on Childhood Vaccines, should continue to explore additional effective ways and take appropriate steps to disseminate information nationally about the Program, including eligibility and documentation requirements and filing deadlines for petitions, to ensure that affected persons are aware of the available legal remedies and to help them identify necessary supporting information.

2. To simplify the process of determining eligibility, Congress should examine whether further clarification is needed of the "Qualifications and Aids to Interpretation" applicable to the Vaccine Injury Table, which are set forth in section 2114(b) of the Act to explain the symptoms and conditions to be considered evidence of an injury described in the Table.[5]

3. The Advisory Commission on Childhood Vaccines should develop uniform guidelines, such as discount rates for the value of medical and other services to be purchased in future years, for calculating the net present value of specific elements of compensation to be awarded to petitioners. Such guidelines may be used to compute the amount of awards promptly and consistently in similar cases. The guidelines should be reviewed at least annually to ensure that they remain consistent with reasonable estimates of future economic performance.

4. The Advisory Commission on Childhood Vaccines should also consider developing guidelines for the total amount of compensation payable and, where appropriate, for individual elements of compensation, in light of evolving case law and experience with the alternative dispute resolution process used by the Claims Court. The guidelines should provide for appropriate variations on the basis of age, severity of injury, intensity of services, and other relevant factors. The guidelines should present a range of values in each category, with flexible ceilings and floors, to accommodate special circumstances.

5. The Department of Health and Human Services and the Advisory Commission on Childhood Vaccines should study the current use of brokers to provide structured settlements, and should explore alternatives that will decrease transaction costs that result in reducing the funds available for awards to plaintiffs.

[5] Congress may also wish to consider any relevant information from the studies performed by the Institute of Medicine of the National Academy of Sciences pursuant to Pub. L. 99-660, 100 Stat. 3779, 312,313.

6. The Department of Justice should continue to examine the appropriate level of approval authority and dollar limit for settling vaccine injury cases, taking into account the magnitude of awards actually made under the Program, to reduce delay in obtaining final approvals.

7. Congress should amend section 2116(c) of the Act to stay the statute of limitations governing civil actions for personal injuries arising out of a vaccination covered by the Act until the date that the petitioner files an election, or is deemed to file an election, pursuant to section 2121 of the Act, accepting or refusing to accept the judgment.

8. Congress should take the following steps to reduce the burdens placed upon the Program by large fluctuations in the numbers of petitions filed:

(a) Congress should delete section 2121(b)(2) of the Act, as added by the Vaccine and Immunization Amendments of 1990, which withdraws jurisdiction over any petition that is not decided within the time required by the Act.

(b) Congress should amend section 2112(d)(3) of the Act, as amended by the Vaccine and Immunization Amendments of 1990, to permit the chief special master to extend the time for deciding petitions filed in retrospective cases for up to 2 years, in addition to the 240-day time limit plus all other extensions and suspensions currently permitted, when the chief special master determines that the number of filings and resulting work load require such action in the interest of justice.

(c) Congress should amend section 2112(c)(1) of the Act to increase substantially the authorized maximum number of special masters to handle the temporary burden of decision making in retrospective cases. Congress should also authorize additional funds for a limited time period to support these positions, as well as increased staffing needed within the Program Office and the Department of Justice.

9. Congress should address the potential consequences if there were to be insufficient funding for the Program, in view of section 323(b) of Public Law 99-660, 100 Stat. 3784, which provides that the Program shall cease to be in effect if there are insufficient funds to pay all of the claims payable for 180 days.

10. Congress should extend the January 1, 1992 deadline for the Secretary of Health and Human Services to report the results of the evaluation of the Program required by section 6601(t) of the Omnibus Budget Reconciliation Act of 1989, Public Law No. 101-239, 103 Stat. 2293, until the temporary burden of retrospective cases in substantially reduced, because

inclusion of information with respect to these cases is essential to a useful evaluation of the Program.

Citations:

56 FR 33850 (July 24, 1991)

__ FR _____ (2011)

1991 ACUS 27