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Advisory Commission on Childhood Vaccines (ACCV)
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HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Clarify the Scope of "Factors Unrelated"

Clarify the Scope of the term "Factors Unrelated" as it applies to determining eligibility and compensation.

Current Law: Section 2113(a) of the Public Health Service Act (the Act) sets out the eligibility and compensation requirements of the National Vaccine Injury Compensation Program (VICP). Subsection(a)(1) specifies that compensation shall be awarded if the Special Master or the Court finds on the record as a whole that the illness, disability, injury, condition, or death described in the petition is not due to factors unrelated to the administration of the vaccine described in the petition. Subsection (a)(2) defines the term "factors unrelated to the administration of the vaccine". This term does not include any idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness, or condition, and may include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

Proposal: Add genetic disorders and structural lesions to the list of factors identified in Subsection (2)(B) as potential "factors unrelated," and state that these as well as the currently listed elements may be factors unrelated without regard to whether their cause is known.

Rationale: In order to award compensation, the Act provides that the Court must find by a preponderance of the evidence that the injury in question was not due to "factors unrelated" to the vaccine. Under existing statutory language, infection, toxins, trauma or metabolic disturbances which have no known relation to the vaccine but which are considered the principal cause of the claimed injury may be considered a "factor unrelated" to the immunization and serve as a basis to deny compensation. However, a factor unrelated cannot be an "idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor , injury, illness, or condition." In several cases, the court has broadly interpreted this provision in holding that if the cause of the claimed injury is "idiopathic," or unknown, it cannot be a "factor unrelated" even if it is a well-defined condition and known to be unrelated to immunization.

A statutory amendment is necessary to effectuate Congressional intent that compensation should not be afforded if the claimed injury is due to an alternative cause and not the vaccine. Such an amendment would reflect accurate medical science concerning what constitutes "factors unrelated" or alternative cause. Certain well-defined medical conditions, such as genetic disorders, that are unrelated to immunization and are the known cause of a claimant's condition should qualify as "factors unrelated" even if the cause of the alternative cause is unknown. Such a defined alternative cause is not "idiopathic" and should not be disregarded simply because the "cause of the cause" is unknown. In other words, when the vaccine has no known relation to the

alternative cause, the alternative cause constitutes a factor unrelated, even if the precise cause of the alternative cause is unknown. With the current state of the decisional law, conditions which are clearly not vaccine related have been compensated, placing the medical integrity of the Program in question.

Additionally, the injury "encephalopathy" was redefined in the February 1995 regulations to clarify that an encephalopathy caused by infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder, shall not be considered a Table condition without regard to whether the cause of such condition is known. 42 C.F.R.§100.3(b)(2)(iii). For consistency, a similar clarification of what constitutes a compensable injury should be made applicable to all listed Table injuries. By redefining the term "factor unrelated" consistent with the clarification in the new regulations for encephalopathy, no longer will compensation be paid for injuries that are clearly not vaccine related. When an alternative cause is the known reason for an individual's condition, vaccine compensation should not be paid, even though the cause of the alternative cause is unknown.

Section 2113(a)(2)(B) would appear as follows:

> "(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), *structural lesions, genetic disorders,* or metabolic disturbances, *without regard to whether the cause of the infection, toxin, trauma, structural lesion, genetic disorder or metabolic disturbance is known, but* which have no known relation to the vaccine involved, ~~but~~ *and* which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death."

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Remove the Limitation on Administrative Expenses

Remove the limitation on the amount which can be expended on the payment of administrative expenses for the operation of the National Vaccine Injury Compensation Program (VICP) from the Vaccine Injury Compensation Trust Fund.

Current Law: Section 9510(c)(1) of the Internal Revenue Code as amended by Section 13421(b) of the Omnibus Budget Reconciliation Act of 1993, authorizes the expenditure of funds from the Vaccine Injury Compensation Trust Fund (the Trust Fund) for expenses necessary to administer the VICP, but not in excess of $6,000,000 in any fiscal year.

Proposal: Delete the phrase which limits administrative expenditures to $6,000,000 or less for any fiscal year, from Section 9510(c)(1) of the Internal Revenue Code.

Rationale: The current limitation of $6,000,000 to cover all Federal activities necessary for administrative operations of the VICP, was developed ten years ago based on early estimates of what it would cost to run the VICP. Expenditures chargeable to the Trust Fund for these purposes are generated by three major entities: The Division of Vaccine Injury Compensation of the Bureau of Health Professions within the Health Resources and Services Administration in the Department of Health and Human Services (DHHS), the Civil Division in the Department of Justice (DOJ), and the United States Court of Federal Claims (the Court). The actual requirements of the Program have grown with the increase of the number of petitions filed and the complexity of the cases brought before the Court. The Appropriations Committees responsible for the three operating components, DHHS, DOJ, and the Court, have recognized this expanded need and enacted levels which, when combined, total in excess of $9.4 million in each of the last three fiscal years.

Effect on Beneficiaries: This change will have no effect on beneficiaries.

Cost: There is no change in costs associated with this amendment.

Change Section 9510© of the Internal Revenue Code by deleting the reference to a limitation on expenditures for administrative expenses as follows:

> "...or for the payment of all expenses of administration ~~(but not in excess of $6,000,000 for any fiscal year)~~ incurred by the Federal Government in administering such subtitle".

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Allow the Payment of Family Counseling Expenses

Allow for the inclusion of family counseling expenses in awards under the National Vaccine Injury Compensation Program (VICP

Current Law: Section 2115(a) of the Public Health Service Act sets out the compensation which may be awarded under the Program to a petitioner for a vaccine-related injury or death. Awards may include payments for unreimbursable expenses for rehabilitation, developmental evaluation, special counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities. Compensation may not be for anything not included in this list unless it is specifically for the health, education, or welfare of the person who suffered the vaccine-related injury.

Proposal: Add payment of costs associated with family counseling to subsection (a) under (1)(A)(iii)(II) making compensation for such costs allowable.

Rationale: In its current form, the statute does not specifically allow for amounts to be awarded for purposes other than the immediate needs of the injured party. The Act does allow for counseling for the injured party as part of that person's overall rehabilitation and development. The proposed change recognizes the importance of the family to the overall well-being of the injured party and allows for the award of expenses needed to help all family members cope with the aftermath of such a devastating event. Emotional conflicts among parents and siblings can irreparably damage relationships which are necessary to support and nurture the injured party. In such cases, expenses for counseling, which will ensure the best possible family environment for the injured party, are absolutely appropriate as they are expenses specifically related to the vaccine injury and are for the specific benefit of the injured party. Existing language in Section 2115 providing that expenses must be related to the vaccine injury and incurred on behalf of the injured person will still require that petitioners demonstrate that family counseling is reasonably necessary for the care of the vaccine-injured person, keeping with the intent of the statute. This amendment will make it easier to demonstrate the reasonableness of, and necessity for an award of compensation for family counseling expenses.

Effect on Beneficiaries: This change will improve the family relationships of vaccine-injured persons (mostly children) in family situations where counseling is needed.

Cost: There will be no significant increase in costs associated with this amendment.

Add the phrase "(including family counseling)" to Section 2115(a)(1)(A)(iii)(II) so that it will then read;

"(iii)

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling *(including family counseling)*, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary."

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Allow the Payment of Guardianship Expenses

Allow for the payment of fees and costs associated with the establishment of guardianships.

Current Law: Section 2115(e) of the Public Health Service Act (the Act) sets out the compensation which may be awarded to pay for "reasonable attorneys' fees" and "other costs". Subsection 2115(e)(1)(B) allows for payment of other costs, but does not provide specific guidance on what may be included in these costs.

Proposal: Add a phrase which would specifically allow for the inclusion of reasonable fees and costs associated with the establishment of a guardianship or conservatorship in the definition of "other costs."

Rationale: In its current form, the Act does not specifically allow for costs to be reimbursed for the establishment of a guardianship to oversee the use of funds awarded for the treatment and care of injured individuals. In fact, prevailing case law has reinforced that the statute does not allow compensation for such expenses. See Siegfried v. Secretary, HHS, 19 Cl.Ct. 323, 325 (1990); and Hulsey v. Secretary, HHS, 19 Cl. Ct. 331, 334 (1990). However, there have been cases which supported the opinion that such expenses should be compensable and have in fact awarded guardianship costs as in Thomas v. Secretary, HHS, No. 92-46V, 1997 WL 74664, at 3 (Fed. Cl. Spec. Mstr. Feb. 3, 1997).

Provisions for guardianships/conservatorships are routinely included in settlement stipulations because they are usually required by life insurance companies, and because it protects the integrity of the Program by protecting the award granted to the vaccine-injured individual (who is often legally incompetent). As with other attorneys' fees and costs payable under the Program, permissible guardianship expenses will be limited to those that have already been incurred and documented as part of petitioners' application of attorneys' fees and costs. Fees associated with the future maintenance of a guardianship account would not be included.

Effect on Beneficiaries: This change will enhance the protection of awards granted to injured individuals.

Cost: There is no significant cost associated with this change.

Change Section 2115(e)(1)(B) to read as follows:

" (B) other costs,
incurred in any proceeding on such petition, *including reasonable fees and costs associated with the establishment of a guardianship or conservatorship*. If the judgement of a Special Master..."

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Allow Interim Payment of Costs

Authorize interim payment of costs incurred in adjudicating a post-1988 claim under the Program after a finding of entitlement is established.

Current Law: Section 2115 of the Public Health Service Act sets out the compensation which may be awarded at the conclusion of a vaccine-related injury or death case. Subsection (e) allows for compensation of "reasonable attorneys' fees" and "other costs". Because the payment of attorneys' fees and other costs is included in the compensation awarded at the conclusion of the proceeding, petitioners and their attorneys must pay all costs of filing and presenting their cases out of pocket. As it is currently constructed, the Act does not allow for compensation to attorneys or petitioners for those expenditures required to gather, present, and support their case, prior to the final decision by the Special Master even though attorneys fees and costs ultimately may be paid regardless of the final decision as to whether entitlement is established.

Proposal: Add language to Section 2115 of the Public Health Service Act which would make available to petitioner, even though attorneys fees and costs may be paid regardless of the final decision as to whether entitlement is established, subsequent to a finding of entitlement in any case involving a vaccine administered on or after October 1, 1988, payment of actual costs involved in filing and adjudicating the claim up to the time that such a finding is made. The language would also include a requirement that the payment be based on submission of documentation verifying the expenditure of the amount requested, and that the payment may only be used for those costs allowed under 2115(e)(1)(B) "Other Costs".

Rationale: In the process of filing a petition for compensation based on a suspected vaccine-related injury, the petitioner is often required to personally pay costs related to filing, such as expert witness costs and duplication of medical record costs. In those cases where a petitioner lacks the resources to pay such costs, the case might not be brought unless the petitioner is able to find an attorney who is willing to front those costs for the petitioner, and then carry that debt until the case is concluded. There is evidence that, on occasion, this may inhibit petitioner's ability to obtain legal representation and medical expert witness testimony under the Program. Often, petitioners must provide payment for the up-front costs incurred in filing a claim under the Program, straining already tenuous financial situations. To reduce the hardship on petitioners under the Program and to expand the opportunity for all eligible parties to participate in the Program, this amendment would allow for the payment of actual costs (excluding attorneys' fees) incurred in developing and documenting a vaccine-injury compensation case, much earlier in the process, i.e., at the time the initial determination of entitlement is made.

Effect on Beneficiaries: This change will ease financial burdens currently borne by all petitioners while ensuring that financially disadvantaged petitioners are able to participate in a program to which they are entitled by law.

Cost: There are no significant costs associated with this proposal.

Add a new subsection to Section 2115(e) as follows:

"(4) Subsequent to a finding of entitlement in any case involving a vaccine administered on or after October 1, 1988, [an award of compensation may be made to petitioner limited to actual costs incurred in proceeding on the petition (as defined under paragraph (1)(B), "other costs"), so long as petitioner provides documentation verifying the expenditure of the amount requested.]

[payment of actual costs as allowed under 2115(e)(1)(B) 'Other costs' incurred up to the time that such a finding is made, may be made available to petitioner based on submission of documentation verifying the expenditure of the amount requested."]

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Clarify the Calculation of Lost Earnings

Identifies a specific basis for calculating projected lost earnings resulting from a vaccine-related injury.

Current Law: Section 2115(a) of the Public Health Service Act sets out the compensation which may be awarded under the Program to a petitioner for a vaccine-related injury or death. Subsection (3)(B) specifies that if a person has sustained a vaccine-related injury before reaching the age of 18 and has an impaired earning capacity because of that injury which is likely to continue beyond age 18, compensation after attaining the age of 18 for loss of earnings will be determined on the basis of the average gross weekly earnings of workers in the private non-farm sector less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary of Health and Human Services (HHS).

Proposal: Specify in Section 2115(a)(3)(B) of the statute the use of the figure tabulated by the Bureau of Labor Statistics (BLS) from the Current Population Survey (CPS) based on specifications designed by the Department of Justice (DOJ) in consultation with a team of economic experts to best reflect the statutory criteria. This figure would be calculated annually at the request of the Secretary of HHS for use in the calculation of lost earnings under the VICP.

Rationale: The proposed amendment would codify the method of calculation that is currently in use by the government in vaccine cases. The current statutory language does not specify how average gross weekly earnings of workers in the private, non-farm sector are to be calculated in cases where an individual sustains a vaccine injury prior to age 18 which impairs his or her earning capacity. Until recently, projected lost earnings in such cases were determined based on a Bureau of Labor Statistics (BLS) figure published in the Current Employment Statistics (CES), which computes "the average weekly earnings of production or nonsupervisory workers on private non-farm payrolls". This figure does not include statistics for supervisory workers, a fact which became the subject of legal challenges recently in several cases. As a result, DOJ requested that BLS prepare a special tabulation from data contained in another wage series known as the Current Population Survey (CPS). After consulting with a group of labor economists, the Department requested that this tabulation reflect the average gross weekly earnings of all workers in the private, non-farm sector, including supervisory and nonsupervisory workers, as well as part-year and part-time workers and full-year, full-time workers, and exclude the self-employed. This new calculation more accurately reflects the average weekly earnings of the group identified in the statute (the private, non-farm sector) than the CES figure, and is now being used by the government in pending vaccine cases to determine average gross weekly wages. Annual earnings data is calculated from the CPS in the first quarter of every year and BLS has agreed to provide an update of the special tabulation to the Secretary annually.

In keeping with the purpose of the Program, as stated in House Report No. 99-908, to provide

compensation with certainty and generosity, it is appropriate to apply the special tabulation when calculating potential lost earnings. Codifying the use of this specific calculation would add certainty to the process of compensating injured persons while providing a more generous payment for lost earnings. In the past, the calculation did not include the salaries of supervisory personnel, and was therefore skewed to a lower level. This lower level of compensation has been challenged on the grounds that it unfairly assumes that none of these injured persons would attain a level of supervisory responsibility and the commensurate higher salary.

Effect on Beneficiaries: Codifying the use of this calculation will not affect beneficiaries.

Cost: Enactment of this amendment will not increase Program costs because the method to be codified is the method currently in use. By standardizing the calculation, costs associated with litigation based on the lost earnings calculation method will be reduced.
Amend Section 2115(a)(3)(B) to include a specific description of the calculation used in arriving at an average weekly gross earnings figure so that it will then read:

> "...for loss of earnings determined on the basis of the *annual estimate* of the average *(mean)* gross weekly earnings of *wage and salary* workers *age 18 and over (excluding the incorporated self employed)* in the private non-farm sector *(which includes all industries other than agricultural production of crops and livestock), as calculated annually by the Bureau of Labor Statistics from the quarter sample data of the Current Population Survey,* less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary."

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Change Advisory Commission Meeting Schedule Requirement

Eliminate the requirement that the Advisory Commission on Childhood Vaccines (ACCV) meet at least four times each year.

Current Law: Section 2119(c) of the Public Health Service Act specifies that the ACCV must meet "not less often than four times per year."

Proposal: Delete from Section 2119(c) of the Public Health Service Act, the requirement that the ACCV meet at least four times per year.

Rationale: In its current form, the law limits the flexibility of the Commission to coordinate its meeting schedule with the schedules of related advisory committees which meet three times per year. This would bring the provisions governing the operation of the ACCV more in line with laws and regulations governing other advisory committees reporting to the Secretary of Health and Human Services, which do not have stated requirements for the number of annual meetings. For those years in which the Commission feels it can accomplish its business in less than four meetings, significant savings will be realized in reduced salary, travel, and meeting-related costs.

Effect on Beneficiaries: This change will have no effect on beneficiaries.

Cost: There will be no increase in costs as a result of this change.

Section 2119(c) would be changed to eliminate the phrase "not less often than four times per year" and would read as follows:

"(c) MEETINGS.--The Commission shall meet within 60 days after all members of the Commission are appointed, and thereafter shall meet ~~not less often than four times per year and~~ at the call of the chair. A quorum..."

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Changes to the Rulemaking Process for the Vaccine Injury Table

Change the rulemaking process for amending the Vaccine Injury Table (the Table) by reducing the period for public comment from 180 days to 60 days, and eliminating the requirement for a public hearing.

Current Law: Section 2114(c)(1) of the Public Health Service Act stipulates that in promulgating regulations to modify the Vaccine Injury Table, the Secretary (DHHS) shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

Proposal: Delete from Section 2114(c)(1) of the Public Health Service Act the phrase which stipulates that 180 days be allowed for comments on proposed changes to the Vaccine Injury Table (the Table) as well as that a public hearing be held. The period allowed for public comment will be changed to 60 days.

Rationale: In its current form, the law causes unnecessary delays and an unnecessarily onerous process for making changes to the Table. The shortened timeframe for comment will make it possible to reflect new scientific information relating to adverse events associated with the administration of childhood vaccines on the Table much sooner, and thus provide for a simplified claims adjudication process. Eliminating the requirement for a separate public hearing on proposed changes to the Table will not limit the opportunity of the public to comment and eliminates a requirement that in practice has had limited, if any added value . For example, at the last public hearing, held on September 11, 1997, no one appeared to provide testimony. Changes must still be discussed and acted on by the Advisory Commission on Childhood Vaccines (ACCV) at its meetings, which are open to the public. The public is provided with ample notice of the discussion of such items through publication of ACCV agendas in the Federal Register.

Effect on Beneficiaries: This change will enhance the Program's ability to provide appropriate compensation to beneficiaries by providing a simplified and streamlined process consistent with the general rulemaking process for the DHHS.

Cost: There will be no increase in costs associated with this proposal.

Section 2114(c)(1) would be modified to change the requirement for a 180 day comment period to a 60 day comment period, and would delete the requirement to hold a public hearing when changes are proposed to the Vaccine Injury Table. The section would read:

"(c) ADMINISTRATIVE REVISION OF THE TABLE.--

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice ~~and opportunity for a public hearing~~ and at least ~~180~~ *60* days of public

comment.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Extension of Current Statute of Limitations

Extend the current statute of limitations from 3 years for injury claims and 2 years for death claims, to 6 years for those claiming injury or death resulting from a covered vaccine.

Current Law: Section 2116(a) of the Public Health Service Act establishes timeframes governing the filing of petitions for compensation under the program. Subsection (a)(2) requires that a petition for compensation based on a claim of vaccine-related injury be filed no later than 36 months following the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury. Subsection (a)(3) requires that a petition for compensation based on a claim of vaccine-related death be filed no later than 24 months from the date of the death.

Proposal: Revise the references to filing limits in Section 2116(a)(2) and (a)(3) of the Public Health Service Act by replacing them with one standard limit of six years.

Rationale: For vaccines included in the original Vaccine Injury Table (the Table), petitions must be filed within 24 months for deaths and 36 months for injuries. For vaccines and injuries subsequently added to the Table, petitions may be filed for injuries or deaths resulting from vaccines administered up to eight years prior to the effective date of the change which adds the vaccine or injury to the Table. The proposal to increase the timeframe during which petitions for both injuries and deaths related to vaccines currently on the Table to 6 years takes into consideration the significant difference between the time allowed for filing related to vaccines covered in the current Table and filing related to vaccines and conditions added to the table. Setting the revised standard at six years brings it into conformance with the basic standard established by 28 U.S.C.A. § 2501 for claims unrelated to vaccines filed with the U.S. Court of Federal Claims (the Court). In addition to making the standard consistent with the Court's existing standard, lengthening the period in which petitions may be filed will allow for the more accurate determination of life care needs of the injured party prior to filing. The current situation provides an incentive for petitioners' attorneys to delay litigation proceedings in order to allow for more time to adequately assess the future medical needs of an injured child.

Effect on Beneficiaries: The proposed change will allow petitioners sufficient time to evaluate the long-term effects of the alleged injury from covered childhood vaccines and develop a better estimate of the life-long needs of the petitioner prior to filing a claim. This will allow cases to move more rapidly through the entire process rather than having to remain on hold while such cost estimates are developed subsequent to the filing of the petition.

Cost: There is no significant cost associated with this change.

Change Section 2116(a)(2) and (3) to remove references to 36, 24, and 48 month periods and replace them with a standard 6 year period.

"(2) ...no petition may be filed for compensation under the Program for such injury after the expiration of ~~36 months~~ *6 years* after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program ~~for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months~~ *more than 6 years after the date of the death, or more than 6 years* after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted."

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Elimination of Unreimbursable Expenses Requirement

Eliminate the requirement that claimants must have incurred unreimbursable expenses in excess of $1,000 to file a petition for compensation.

Current Law: Section 2111(c)(1) of the Public Health Service Act specifies the documentation that must be included in petitions for compensation under the Vaccine Injury Compensation Program (VICP). Sub-section (D)(I) requires that documentation be included which demonstrates that the person who suffered a vaccine-related injury, incurred unreimbursable expenses due in whole or in part to such illness, injury, or condition, in excess of $1,000.

Proposal: Delete from Section 2111(c)(1)(D)(I) of the Public Health Service Act, the phrase which requires that more than $1,000 in unreimbursable expenses related to an illness, disability, injury, or condition be spent in order to qualify. Section 2111(a)(2)(A) will also be amended to delete the reference to the $1,000 amount.

Rationale: In its current form, the law limits acceptance of petitions for injury compensation to those cases in which it can be demonstrated that an injury has required the expenditure of more than $1,000 for which the person suffering the injury has not, and will not, receive reimbursement from another source. This creates a situation in which certain otherwise eligible parties are precluded from consideration of compensation for pain and suffering and/or lost wages because they are not otherwise eligible to file due to reimbursement of medical expenses. This requirement effectively excludes certain groups, such as Medicaid recipients, dependents of military personnel, and Native Americans. The fact that these groups are covered already by other Federal programs as far as medical expenses are concerned should not cause them to be left out when it comes to consideration of other compensation to which they may be entitled under the VICP. This also precludes these parties from receiving compensation at a later date should the source of funding for medical treatment which has excluded them from eligibility under the VICP come to an end, e.g., the parent or guardian through whom treatment at a military hospital or facility has been authorized, leaves the military service.

Effect on Beneficiaries: The proposed change ensures that all eligible parties can file for compensation under the VICP.

Cost: There is no significant cost associated with this change.

Section 2111(c)(1)(D)(I) will be changed as follows:

"(D)(I)...for more than 6 months after the administration of the vaccine ~~and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in~~

~~an amount greater than $1,000~~, or (ii) died from the administration of the vaccine, and"

A conforming amendment will also be made to Section 2111(a)(2)(A).

"(2)(A) No person may bring a civil action for damages ~~in an amount greater than $1,000 or in an unspecified amount~~ against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part, and no such court may award damages ~~in an amount greater than $1,000~~ in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 2116, for compensation under the Program for such injury or death and --".

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Change Advisory Commission Membership Criteria

Specify that the two seats on the Advisory Commission on Childhood Vaccines (ACCV) which are set aside for representatives of children injured by vaccines may also be filled by adults who have suffered vaccine-related injuries.

Current Law: Section 2119(a)(1)(B) of the Public Health Service Act specifies that three members of the ACCV must be members of the general public and that of those three at least two must be legal representatives of children who have suffered a vaccine-related injury or death.

Proposal: Expand the scope of potential general public members appointed to the ACCV under Section 2119(a)(1)(B) of the Public Health Service Act to include adults who have suffered a vaccine-related injury either as children or as adults.

Rationale: Current law specifies criteria for membership on the ACCV. The ACCV is made up of experts who either possess specific training, medical or legal, or who have personal experience gained as the legal representatives of vaccine-injured children. While this brings together a diverse group of very knowledgeable individuals, it ignores a pool of potential members who would provide the ACCV with a unique, and desired, viewpoint, i.e., that of an individual who has actually suffered an injury related to a vaccine. While the number of adults injured by vaccines is currently small, this pool of potential members will continue to expand as injured children mature to adulthood. In its current form, the law does not provide an opportunity for adult individuals who have suffered vaccine-related injuries to participate as members of the ACCV. The opportunity to participate on the ACCV should be made available to these individuals in order to obtain their unique viewpoint on ACCV issues.

Effect on Beneficiaries: This change will broaden the scope of potential membership on the ACCV to include adults injured by vaccines, either while children or as adults.

Cost: There will be no increase in costs as a result of this change.

Section 2119(a)(1)(B) would be changed to include vaccine injured adults in the pool of potential ACCV members to be chosen from the general public as follows:

"(B) Three members from the general public of whom at least two shall be *either* legal representatives of children who have suffered a vaccine-related injury or death, *or adults who have themselves suffered a vaccine-related injury.*

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FISCAL YEAR 2000 LEGISLATIVE PROPOSAL

National Vaccine Injury Compensation Program:
Joint Payment of Attorneys' Fees and Costs

Specify that attorneys' fees and costs awarded under section 2115 (e) shall be paid jointly to petitioner and the attorney for petitioner.

Current Law: Section 2115 of the Public Health Service Act sets out the compensation which may be awarded to a petitioner under Section 2111. Existing statutory language requires that all compensation be paid to petitioner, however, it is ambiguous in that it does not prohibit including counsel as a co-payee, nor does it directly address whether joint payment is appropriate.

Proposal: Add language to Section 2115(e) of the Public Health Service Act which would require that reasonable attorneys' fees and costs awarded under this section be paid jointly to the petitioner and to the petitioner's attorney.

Rationale: In its current form the statute is ambiguous regarding the issuance of checks for amounts awarded for attorney fees and other costs. The general requirement is that awards are made to petitioner, but there is nothing that precludes making payment directly to petitioner's attorney or making payment to both the petitioner and the attorney. Clarification is needed to provide consistency in the handling of payments. Joint payment is the appropriate method of issuing awards for attorney fees and other costs because:

- Petitioner may have advanced fees and costs to counsel and may be entitled to reimbursement of such monies. Including petitioner and counsel as joint payees ensures that both have access to these funds.

- The attorney/client relationship is protected and ethical concerns regarding the disbursement of fees and costs between petitioner and counsel are avoided by encouraging petitioner and counsel to resolve any potential conflicts between them.

- Integrity of the Program is promoted by removing HHS as a party to any such disputes between petitioner and counsel.

- Petitioner is made aware of the award for fees and costs that is being made under the Program.

This change would codify the method currently in use and would also clarify that counsel may not be made the sole payee on attorneys' fees and costs checks as certain Special Masters have ordered.

Effect on Beneficiaries: This change will not have a direct effect on beneficiaries.

Cost: There are no significant costs associated with this proposal.

Add a new subsection to Section 2115(e) as follows:

"(4) Any attorneys' fees and other costs awarded under this section shall be paid jointly to petitioner and the attorney for petitioner.