# Advisory Commission on Childhood Vaccines (ACCV)
# Summary of Recommendations to the Secretary
# through May 2009

**06/09/1989 to Secretary Louis W. Sullivan, MD, from Stephan Lawton, ACCV Chair**

The ACCV makes the following recommendations to the Secretary on an urgent basis:

1. As a general rule, HHS should work to insure that the procedure before the Claims Court becomes simpler and less time consuming. We believe that existing rules and procedures unnecessarily create an adversarial process through imposition of requirements that may be appropriate for the usual type of civil case, but inappropriate for what Congress intended to be "a Federal 'no fault' compensation program under which awards can be made to vaccine injured persons quickly, easily, and with certainty and generosity.' House Report No. 908, Part I, 99th Cong., 2d Sess. At 3, reprinted in 1986 U.S. Code Cong. & Admin. News 6344. We believe that rules and procedures should encourage discussions, and settlement negotiations, through informal procedures. We would appreciate very much receiving any documents prepared by HHS that represent efforts to change or modify Claims Court rules or practices in this regard. We would be pleased to review such documents and provide you with the ACCV's advice concerning their appropriateness. We would also be pleased to meet with representatives of HHS, DOJ, and the Court to facilitate resolution of this issue.
2. While the ACCV recognizes that the Torts Branch of the DOJ Civil Division is severely understaffed, it does not believe that staffing problems require a suspension of proceedings by the Claims Court. In addition, the ACCV is opposed to earmarking money from the Trust Fund for the purpose of paying staff of the DOJ for representation proceedings. The ACCV concluded that monies in the Trust Fund should be reserved for the compensation of injured children, which is the primary purpose of the Trust Fund. We note that if the nature of the Claims Court proceedings were made less adversarial, clearly costs to all parties would be minimized.

**09/20/1989 to Secretary Louis W. Sullivan, MD, from Stephan Lawton, ACCV Chair**

The ACCV has developed a package of recommendations and urges the Secretary to support their adoption as a unit. **Vote: Unanimous except 1 abstention on recommendation #4**

1. The ACCV supports limited earmarking funds from the Trust Fund for necessary legal and administrative support within the Claims Court, DOJ, and HHS. Because Trust Funds were intended to benefit children injured by childhood vaccines, their use to pay the costs of government administration system should be carefully limited in amount and time. Thus, the ACCV would support authorizations of appropriations from the Trust Fund of $1.5M for the Claims Court and HHS for FY 1990. The ACCV also would support an authorization for the DOJ to enable it to hire up to 1 attorney per Special Master and essential support staff, as Judge Smith recommended, for FY 1990. With the approximately 160 petitions for compensation filed to date, this would probably mean that each DOJ attorney would have a caseload of approximately 20 cases at any one time. We point out that this position constitutes the modification of our previous recommendations on the use of Trust Fund monies.

2. The ACCV recommends that once the DOJ begins providing HHS with legal representation in the Claims Court, HHS should make its physician experts available to testify in support of their medical reports. When HHS physicians present information for the Court's consideration, they should be subject to cross examination to the same extent as the petitioner or any witness called on the petitioner's behalf. Cross examination of any witness in compensation proceeding should be limited, however, and permitted only to the extent necessary to clarify key issues in the proceeding. In many instances, cross examination by telephone conference may be appropriate. These principles of fairness and reliable fact finding should be reflected in the Claims Court's rules and in the underlying legislation.
3. The ACCV supports the use of panels of experts to help evaluate compensation claims. These panels can help ensure that valid claims are paid quickly and without dispute. They can also help HHS physicians develop medical reports when a claim is to be contested. These expert panels should not be used, however, in a manner that would circumvent the principles of fairness and reliable fact finding identified in recommendation 2 above. That is, the expert panels' sole function should be to advise HHS. Neither the panels' existence, nor their advice should be disclosed to, or considered by, the Court; unless HHS is prepared to have panel members testify and are subject to limited cross examination as necessary. HHS physicians should be able to state under oath that the testimony, opinions, and reports they are presenting to the Court are their own. If HHS physicians are to be required to present testimony in support of medical reports, then opinions contained in the reports must be those of the HHS physician who wrote it. In order to assure admissibility of the reports, HHS physicians must be able to state under oath that the opinions are theirs, and demonstrate that they are supported by fact and a well reasoned analysis. Simple concurrence with the recommendations of panels would risk the medical reports being ruled inadmissible. Thus, great care must be taken to insure that panels are advisory in nature only, and that the medical reports constitute the views of the HHS physicians themselves.
4. In view of the significant resources that will be available to HHS and DOJ for preparation of medical reports and their presentation in Court, if Trust Fund monies become available for such purposes, the ACCV believes that Congress should eliminate the statutory "cap" on amounts that may be awarded for petitioners' attorneys' fees in connection with cases resulting from vaccines administered before the effective date of the compensation law. See section 2115(B) of the PHS Act. The effect of current law and Trust Fund appropriations to the DOJ and HHS as Respondent to petitions may create an unfair and inappropriate imbalance of resources that could hinder petitioners' ability to get a fair hearing of their claims. We point that this change would not and should not eliminate the limitation under section 2115(e) of the Act that attorneys' fees be "reasonable." The ACCV recognizes that some of its recommendations involve action by the Congress, DOJ, and the Claims Court, as well as HHS. We request that you transmit our recommendations to appropriate officials of these other entities.

**06/21/1990 to Secretary Louis W. Sullivan, MD, from Stephan Lawton, ACCV Chair**

The ACCV has agreed to recommend that, in lieu of the 10/26/1989 draft, the Secretary promulgate a final rule which includes the material and language which is included in the attachment to this letter.

**12/31/1990 to Secretary Louis W. Sullivan, MD, from Stephan Lawton, ACCV Chair**

The ACCV recommends amendments to the National Childhood Vaccine Injury Act of 1986 as follows:

1. Funding for HHS. We recommend legislation authorizing appropriations from the Trust Fund established under the Act so that the total sums received by HHS equal $3.5M for FY 1991, FY 1992 and FY 1993. At present, $1.5M has been appropriated for FY 1991.
2. Funding and Personnel for the Claims Court. The childhood vaccine law should likewise be amended to authorize the hiring by the Claims Court of 15 special masters (there are currently 6 and the law authorizes a total of 8.) Additionally, in Section 2113(c)(1) of the PHS Act, legislation should authorize appropriations from the Trust Fund for the support of the VICP by the Claims Court as follows: $3.5M for FY 1992 and $3.5M for FY 1993.
3. Authority of the Chief Special Master. Amendments to the childhood vaccine law should give specific direction to the Chief Special Master to establish an orderly schedule for the handling of pre-enactment cases. The special master should be given additional authority to suspend any case for an additional year (beyond the 20-month period authorized under existing law) in order to comply with such schedule. The schedule must be such that a complete judgment by special masters on all pre-enactment cases is completed by 9/30/1993.

**03/18/1991 to Secretary Louis W. Sullivan, MD, from Martin Smith, MD, ACCV Chair**

The ACCV recommends that an amendment to the Act be accomplished creating a moratorium to be placed on judgments and awards for a period of 180 days from the date of enactment from this amendment. **Vote: 5 for, 2 against, 1 abstention, 1 absent**

**04/24/1991 to Secretary Louis W. Sullivan, MD, from Martin Smith, MD, ACCV Chair**

It was recommended that the government should commission a study of any adverse events that can be associated with the conjugate *Haemophilus influenzae* type b vaccine and the hepatitis B.

**08/16/1991 to Secretary Louis W. Sullivan, MD, from Martin Smith, MD, ACCV Chair**

Considering the pending crisis, the proximity of the adjournment of Congress, and having concluded there is an urgent need to act due to fiscal constraints or by law, the VICP will "cease to be in effect", the ACCV is concerned that the Department has not taken any action to address the situation….The ACCV now would like to make the following set of observations and conclusions with respect to our study of these options and to the current situation:

The ACCV reviewed the issues concerning the processing of claims and concluded that there is little that can be done, at this point in time, beyond the recommendations included in the ACCV Policy Paper, to enhance the ability of all the parties to process the pending claims.

The best estimate of the dollar total of the pending retrospective claims is approximately $2B. Barring a major restructuring of the VICP, the ACCV has been unable to identify a more practical way of arriving at a different estimate due to the available data, current trends, and program experience.

Based on program experience and the IOM, the ACCV encourages the continued re-assessment of the Aids and Table for possible changes.

The ACCV examined the 4 annual installment provisions for the purchasing of annuities and endorses any effort to repeal the statutory provision – it is estimated that purchasing an annuity all in one year could save approximately 14-18% of the purchase price of the annuity.

The ACCV encourages the ongoing efforts underway within the Department of the PHS Task Force on the VICP, established by Dr. Mason, to examine the VICP and to develop a comprehensive set of recommendations to address the problems facing the VICP. In light of this effort, the ACCV encourages the Secretary to work with Congress to achieve a timely solution to the crisis.

**06/22/1992 to Secretary Louis W. Sullivan, MD, from Martin Smith, MD, ACCV Chair**

The ACCV recommends:

- The VICP should be expanded to include other vaccines; the first priority is vaccines intended primarily for children that are recommended by either the ACIP or AAP Committee on Infectious Diseases for routine child immunization schedules.
  **Vote: 7 for, 1 against**
- Once a vaccine meets this criterion, the ACCV will request that the Secretary appoint a committee to advise the ACCV on the Table with respect to the scientific information available on the adverse events of the vaccine being considered. The ACCV will review and revise its recommendations based on new reports by scientific advisory bodies as deemed appropriate. **Vote: 7 for, 1 against**
- Every new vaccine should have a surtax. The Secretary should determine the amount of the surtax. The Secretary should consider a flat surtax on new vaccine until more information is gathered on specific vaccine adverse events. **Vote: 7 for, 1 against**
- Recognizing the need to go well beyond current funding for the VICP and recognizing that funds should not be taken from other health and social programs, the ACCV recommends that the Secretary urge Congress to declare a budget emergency (as defined in the Budget Enforcement Act of 1990) and be urged to authorize and appropriate for FY 1993, 1994, and 1995 sufficient funds to finance all awards for pre-10/01/1988. **Vote: Unanimous**

- As a short term solution, the ACCV recommends that the Secretary urge Congress to adopt legislation prohibiting any transfer from the Trust Fund to any other account of the Treasury. Further, use 25% of annual Trust Fund gross receipts and all interest earned on investment for the payment of pre-10/01/1988 cases. **Vote: Unanimous**

**02/04/1993 to Secretary Donna Shalala from Gerald Fenichel, MD, ACCV Chair**

The authority to use the Trust Fund to make awards for injuries and deaths caused by vaccines administered after September 30, 1992 no longer exists. Further the Treasury Department notified the IRS that the vaccine excise tax has been terminated as of 1/1/1993. The ACCV feels that a remedy must be found as quickly as possible and looks to your leadership in this matter.

**03/22/1993 to Secretary Donna Shalala from Gerald Fenichel, MD, ACCV Chair**

The ACCV recommends that the Secretary urge the Congress to quickly restore authority to process claims retroactive to 9/30/1992, restore the excise tax on vaccine sales, and prohibit the refund of excise tax on expired vaccines. **Vote: Unanimous**

The VICP should be expanded to include other vaccines; the first priority is vaccines intended primarily for children that are recommended by either the ACIP or the AAP Committee on Infectious Diseases for routine child immunization schedules. Once a vaccine meets this criterion, the ACCV will request that the Secretary appoint a committee to advise the ACCV on the Table with respect to the scientific information available on the adverse events of the vaccine being considered. The ACCV will review and revise its recommendations based on new reports by scientific advisory bodies as deemed appropriate. Every new vaccine should have an excise tax that contributes to the Trust Fund (if such taxes are still in existence). The Secretary, HHS, should consider a flat tax on new vaccines until more information is gathered on specified vaccine adverse events.

The ACCV is committed to compensating awards for pre-1988 vaccine injuries and unanimously urges the Secretary to propose legislation that in addition to reinstating the excise tax, will also request the full $110M appropriation for pre-1988 cases this year and in future years until such time as compensable pre-1988 cases are paid, and further recommends that the two financial systems for pre-1988 and post-1988 claims be merged into a single program from which all claims are paid. If that merger is not feasible, the ACCV recommends that the law be amended to enable borrowing from the Trust Fund balance to pay pre-1988 cases and the funds restored to the Trust Fund from future appropriations.

**06/24/1993 to Secretary Donna Shalala from Gerald Fenichel, MD, ACCV Chair**

The ACCV recommends to the Secretary that hepatitis B vaccine (HBV) and *Haemphilus influenzae* type b vaccine (Hib) be covered by the VICP and be taxed at a rate of $1/per dose until such time as program experience would dictate an adjustment of the rate. **Vote: Unanimous**

The ACCV believes that it is fiscally responsible to lower the excise tax on acellular pertussis vaccine and thereby reduce the cost to consumers. We recommend to the Secretary by a vote of 6 to 1 that acellular pertussis vaccine be taxed at a rate of $1/per dose until such time as program experience would dictate an adjustment of the rate.

**12/14/1993 to Secretary Donna Shalala from Gerald Fenichel, MD, ACCV Chair**

1. The ACCV recommends that the Trust Fund balance be maintained at a sufficient level to support a reserve to fund 3 years of awards and to permit borrowing from the Trust Fund to pay pre-1988 awards in accordance with existing ACCV policy and to finance administrative costs of the HHS, DOJ, and Court to expedite adjudications and awards. **Vote: Unanimous**
2. The ACCV recommends the adoption of a uniform, flat tax rate on the sale of all vaccines covered by the VICP at a rate of $.50; and that the $.50 tax rate be applied to each vaccine intended to prevent a general category of disease caused by an organism (e.g. TOPV is one vaccine taxed at $.50, DTP is 3 vaccines taxed at $1.50) and that the tax apply automatically at the time the covered vaccine is added to the Table. **Vote: 7 for, 2 against**
3. The ACCV recommends that HHS, in conjunction with the DOJ, the Court, the plaintiff's bar, and other interested parties, explore the proposals currently under review by the Subcommittee on Process as well as other proposals to alleviate the concerns of petitioners and petitioners' attorneys regarding the above-stated timing, amount, and conflict issues under the VICP. **Vote: Unanimous**

**03/22/1994 to Secretary Donna Shalala from Georges Peter, MD, ACCV Chair**

The ACCV recommends that the Secretary defer action on the proposed revision of the Table until appropriate consideration is given to the IOM's 3/02/1994 report concerning DTP vaccine and chronic nervous system dysfunction.

**03/06/1995 to Secretary Donna Shalala from Curtis Webb, ACCV Chair**

The ACCV recommends that the Secretary indefinitely postpone the effective date of that portion of the Final Rule which removes seizure disorders associated with the administration of vaccines containing pertussis bacteria or pertussis antigens from the Table, and that portion of the Rule that changes the definition of encephalopathy in the Aids. **Vote: 5 for, 4 against**

**06/07/1996 to Secretary Donna Shalala from Calvin Sia, MD, ACCV Chair**

The ACCV urges that the sequential schedule [for OPV/IPV] be implemented as soon as possible, but no later than 1/1997 with the goal of phasing in an all IPV schedule over the next 3-5 years. Because of the importance of this issue and the direct impact on the potential number vaccine injury cases filed, the ACCV wishes to express support for the ACIP draft recommendations with the hope that any proposed changes be implemented as soon as reasonably possible in order to minimize the future cases of vaccine associated polio injuries.

**10/11/1996 to Secretary Donna Shalala from Calvin Sia, MD, ACCV Chair**

The ACCV voted that the Secretary make the following recommendations:
1) Section 2111 (c) (1)(1)(1) be amended by striking "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury or condition in an amount greater than $1,000. This legislative modification would eliminate circumstances where deserving claimants (e.g. certain Medicaid recipients, dependents of military personnel, and Native Americans) may become ineligible to file a claim under the VICP because they cannot meet the test for "unreimbursable expenses. **Vote: Unanimous**

2) payment for expert witness and life care planners based on reasonable charges should apply to the petitioner, as well as the Secretary and DOJ. This recommendation addresses concerns regarding the accessibility of expert witnesses and life care planners for petitioners filing under the VICP. **Vote: 6 for, 2 against, 1 abstention**

**01/31/1997 to Secretary Donna Shalala from Calvin Sia, MD, ACCV Chair**

The ACCV recommends to the Secretary that: the current Aids to the Table at 42 C.F.R. §100.3 (b) (2) (I) be revised to strike the words "An acute encephalopathy is one that is sufficiently severe so as to require hospitalization" and to insert thereof "Acute encephalopathy." **Vote: Unanimous**
**Action: Language suggested by ACCV included in the Final Rule**

**04/18/1997 to Secretary Donna Shalala from Marian Sokol, PhD, ACCV Chair**

The ACCV recommends to the Secretary to: seek legislation to amend the current statute of limitations for filing a claim under the VICP to provide up to 8 years from the date of the injury or death to file a claim under the VICP; seek legislation to allow for an interim payment of costs incurred in the adjudicating of post-1988 claims under the VICP after a finding as to an entitlement is established. Such an interim payment would be made prior to entry of a final judgment and upon the finding that there was good faith and a reasonable basis for the claim; and take all actions necessary to expedite the passage of the excise tax legislation proposed to Congress by the Administration on 7/18/1995. **Vote: Unanimous**

**07/07/1997 to Secretary Donna Shalala from Marian Sokol, PhD, ACCV Chair**

The Secretary of HHS should urge Congress to give favorable consideration to the passage of the excise tax legislation as proposed to Congress by the Administration on 7/18/1995. This proposal reflects a consensus among vaccine manufacturers, the medical community, and parents regarding the appropriate tax structure for the VICP. The ACCV emphasizes the imperative need within such legislation of the provision of the automatic application of the excise tax to any vaccine added to the Table to facilitate coverage for new vaccines. **Vote: Unanimous**

Furthermore, the ACCV opposes any provision which would exempt Federal vaccine purchases from the excise. The purchase of any covered vaccine should be subject to the excise tax as has been the case since the inception of the VICP. It would be unfair to exempt Federal purchases of vaccines from the excise tax while keeping the tax burden solely within the private sector. **Vote: Unanimous**

**09/10/1997 to Secretary Donna Shalala from Marian Sokol, PhD, ACCV Chair**

The ACCV voted unanimously to recommend the following to the Secretary of HHS: Recognizing the need for additional, stable, ongoing financial support for national vaccine safety activities, including surveillance (such as the vaccine safety datalink), assessment, and prevention of vaccine associate adverse events, the ACCV recommends that the Secretary of HHS propose legislation to provide an increase in appropriations for a sufficient level of funding solely for the purposes of enhancing national vaccine safety activities, which are key to both fair compensation and prevention of vaccine associated adverse events. **Vote: Unanimous**

**01/29/1998 to Secretary Donna Shalala from Marian Sokol, PhD, ACCV Chair**

Recognizing the need for additional, stable, ongoing financial support for national vaccine safety activities, including surveillance (such as the Vaccine Safety Datalink), assessment, and prevention of vaccine associated adverse events, the ACCV recommends that the Secretary of HHS propose legislation to amend Section 9510 of the Internal Revenue Code to provide:

1) that the gross revenues derived from the excise tax be deposited in the Trust Fund; and
2) that funds that otherwise would have been transferred to the General Fund of the Treasury from the excise tax collections be appropriated each year instead to be used solely for the purposes of enhancing national vaccine safety activities, which are key to both fair compensation and prevention of vaccine associated adverse events.

Further, the ACCV recommends that the Secretary propose legislation to make further reductions to the excise tax for childhood vaccines to a level of $.25 per dose to bring excise tax receipts more in line with program needs. Finally, the ACCV recommends that the Secretary propose legislation to provide for the expedited coverage of new vaccines under the VICP.

The Secretary of HHS seeks legislation to allow awards under the VICP to include the payment of fees and costs associated with the establishment of a guardianship or conservatorship;

The Secretary seeks legislation which will allow injury compensation awards to include coverage of family counseling expenses; and

The Secretary seeks legislation which will specifically identify the new method of calculating potential lost earnings in the statute.

**08/05/1998 to Secretary Donna Shalala from James Strain, MD, ACCV Chair**

The ACCV recommends that the Secretary of HHS seek legislation to expand the definition of a "factor unrelated" to vaccine to include: structural lesions or genetic disorders, without regard to whether the cause of the infection, toxin, trauma, structural lesion, genetic disorder or metabolic disturbance is known. **Vote: 5 for, 2 against, 1 abstention**

**10/02/1998 to Secretary Donna Shalala from James Strain, MD, ACCV Chair**

The ACCV recommends that the Secretary of HHS propose legislation to broaden the membership criteria for the ACCV to allow for the inclusion of an adult person who has been injured by a vaccination. Specifically, the ACCV recommends that Section 300aa-19(a)(1)(B) of the Act be amended to read "three members from the general public, of whom at least one shall be a legal representative of a child who has suffered a vaccine related injury or death, and one who has either suffered a vaccine related injury or is a legal representative of a child who has suffered a vaccine related injury or death.
The ACCV recommends that the Secretary of HHS propose legislation to allow the Court, in exceptional circumstances and with good cause shown, to have the discretion to provide for an attorneys' fees and costs check for expenses incurred under the VICP to be made payable solely to the attorney for the petitioner. **Vote: Unanimous**

**06/14/1999 to Secretary Donna Shalala from Duane Edwards, ACCV Chair**

The ACCV recommends that the Secretary propose legislation to add the hepatitis A vaccine to the list of taxable vaccines as defined in Section 4132(a)(1) of the Internal Revenue Code. **Vote: Unanimous**

**10/02/2001 to Secretary Tommy Thompson from Robert Block, MD, ACCV Chair**

The ACCV recommends that the Secretary propose legislation to amend the (Act), as amended, to permit increases of the $250,000 benefit cap for pain and suffering, and the $250,000 benefit cap for death to account for inflation. This legislation would restore the original intent of Congress, set forth in the authorizing legislation of 1986, to provide for automatic annual inflationary adjustments to these benefit caps. Repeal of this provision in 1987 has precluded any adjustments to the benefit caps, which have remained at the original levels sine the Act's inception. **Vote: Unanimous**

The ACCV recommends that the Secretary propose legislation containing 2 separate, but related provisions. The first provision would adjust the $250,000 benefit caps to account for inflationary increases since 1988. The second provision would provide for future automatic annual adjustments to the benefit caps, as envisioned by Congress in the repealed section 2118 of the PHS Act. The ACCV recommends that these inflationary adjustments be made based upon the Consumer Price Index – All Urban Workers (CPI-U). **Vote: Unanimous**

**01/11/2002 to Secretary Tommy Thompson from Robert Block, MD, ACCV Chair**

The ACCV recommends that the Secretary propose legislation to amend the (Act), as amended, to preclude covered individuals who have not filed a petition with the VICP from filing a civil action for damages in an amount of $1,000 or less against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine related injury of death. This amendment would be a conforming change and corrective in nature to section 2111(a)(2) of the PHS Act. **Vote: 8 for, 1 against**

**04/02/2002 to Secretary Tommy Thompson from Elizabeth Noyes, ACCV Chair**

The ACCV concurs with the following sections of HR 3741 which were included in the 1999 Amendments:

Section 4(a), "Family Counseling Expenses in Post-1988 Cases";
Section 4(c), "Conforming Amendment for Cases from 1988 and Earlier";
Section 6, "Procedure for Paying Attorneys' Fees";
Section 7(a), "General Extensions";
Section 7(c), "Claims Based on Revisions to the Table";
Section 7(d), "Reports";
Section 8, "Advisory Commission on Childhood Vaccines";
Section 9, "Conforming Amendment to Trust Fund Provision";
Section 10(b), "Administrative Expenses of Bureau of Public Debt"; and
Section 12, "Application" which was not included in the 1999 Amendments.

The ACCV concurs with modification to the following sections:

For Section 2, "Basis for Calculating Projected Lost Earnings," the modifications adds "(excluding the incorporated self-employed)" after "age 18 and over" because the Bureau of Labor Statistics (BLS) cannot tabulate the average earnings of the incorporated self-employed. Because this exclusionary language is omitted in HR 3741, this Section could invite future litigation as the implication could be that this exclusion was removed because this group is to be included in the calculation.

For Section 4(b), "Expenses of Establishing Guardianships in Post-1988 Cases," the modifications delete the words "trust," adds "or" between "guardianship, conservatorship," and adds "(7)" as a new provision which addresses paying expenses for establishing and maintaining trusts. Under this new provision, to prevent problems that may arise with trusts that may allow the payment of expenses which are not authorized by the VICP, only compensation for expenses of establishing and maintaining a trust approved by the Court will be allowed.

For Section 11, "Public Service Announcement Campaign," the modification replaces "by conducting a public service announcement (PSA) campaign." with, "but not limited to research and other outreach activities to increase the public's, attorneys', and healthcare providers' awareness of the VICP." The ACCV believes that research should be conducted to determine the most effective communication strategies for the target audiences. Therefore, several communications strategies may be needed, and the

Secretary should not be limited to just a single strategy, a PSA campaign. If this ACCV recommendation is accepted, the title of this Section should be changed to "Publicity."

The ACCV recommendations on other sections are as follows:

For Section 3, "Increase of Award in the Case of a Vaccine Related Death," the ACCV voted to not concur with this Section. We urge Congress to accept our 2001 recommendation to increase $250,000 benefit caps for both death and pain and suffering. These $250,000 benefit caps should be retroactively increased since 1988, and increased annually, thereafter, to account for inflation using the Consumer Price Index for All Urban Worker (CPI-U). We believe this to be a fairer determination and consistent with the original intent of Congress.
**Vote: Unanimous**

For Section 5, "Allowing Payment of Interim Attorneys' Fees and Costs," the ACCV agreed with the interim payment of costs, but was divided over the issues of interim fees. Members opposing this Section believe that the time involved in fee determination would likely result in significant delays in the resolution of the pending cases. In addition, this Section raises concerns over the need for a payback provision if interim fees were paid and the special master determined that the claim was not brought on a reasonable basis and in good faith. Members supporting this Section believe that the payment of interim fees would be an improvement over the current practice of attorneys awaiting payment until the resolution of the entire claim, a process which can sometimes take years.
**Vote: Divided**

For Section 7(b), "Additional Extensions," the ACCV members were divided. Members opposing this Section believe such a provision would create a considerable influx of claims resulting in increased administrative burdens and significant delays in the resolution of cases. The implementation of this Section would require additional staff resources at the Court, DOJ, and HRSA. If this and other sections of this bill which increase the amount of the awards to petitioners are enacted, members are concerned about the equity of awarding a potentially larger award to petitioners who did not file claims in a timely manner as compared to the smaller awards to petitioners who filed their claims in a timely manner. Members supporting this Section believe that it would give individuals who did not know about the VICP or learned of the VICP after the filing deadline an opportunity to file a claim. These members are being sensitive to criticisms that the public is not adequately informed about the availability of the VICP. **Vote: Divided**

For Section 10, "Increase in Limit on Administrative Expenses," the ACCV deferred voting on this Section because additional increases in administrative expenses will be necessary if various sections, such as Sections 7(b) and 11 of HR 3741, are enacted.

If Congress does not enact HR 3741 in its entirety, the ACCV encourages you to send the 1999 recommendations to Congress as a draft bill.

**06/19/2002 to Secretary Tommy Thompson from Elizabeth Noyes, ACCV Chair**

The ACCV recommends that the Secretary propose legislation to amend the ("Act"), as amended, to require special masters to issue a certificate of completeness once a determination is made that a petition is complete in accordance with section 2111. The time period described in sections 2112(g) and 2121(b) of the PHS Act would begin from the date the special master issues a certification of completeness. This would allow for a period of 240 days (excluding any period of suspension or any time the petition is on remand) for the parties to consider all of the evidence and for a decision to be reached. If the special master fails to issue a decision within this time period, calculated from the date the certificate of completeness is issued, the petitioner could withdraw from the VICP and pursue outside litigation.

In addition to the previous request, we also ask that you consider our recommendations regarding legislation introduced by Sen. William Frist, (R-TN), "Improved Vaccine Affordability and Availability Act," (S 2053). The ACCV concentrated on Title II of the bill that has provisions to ensure that all claims for a vaccine-related injury or death are first filed with the VICP. The ACCV makes the following recommendations:

The ACCV concurs with the following sections of S 2053 which are the same as or very similar to proposals made in the "Vaccine Injury Compensation Program Amendments of 1999, which were developed from the recommendation made by the ACCV and sent to Congress as legislative proposals by the former Secretary: **Vote: Unanimous**

Section 206, "Clarification of When Injury is Caused by Factor Unrelated to Administration of Vaccine";
Section 208, "Basis for Calculating Projected Lost Earning";
Section 209, "Allowing Compensation for Family Counseling Expenses and Expenses of Establishing Guardianship";
Section 211, "Procedure for Paying Attorneys' Fees";
Section 212, "Extension of Statute of Limitations";
Section 213, "Advisory Commission on Childhood Vaccines"; and
Section 218, "Conforming Amendment to Trust Fund Provision."

The ACCV concurs with the following sections of S 2053: **Vote: Unanimous**

Section 204, "Jurisdiction to Dismiss Actions Improperly Bought";
Section 215, "Clarification of Definition of Manufacturer";
Section 216, "Clarification of Definition of Vaccine Related Injury or Death";
Section 217, "Clarification of Definition of Vaccine"; and
Section 220, "Pending Actions".

The ACCV does not concur with the following sections of S 2053 and recommends: **Vote: Unanimous**

Replacing Section 201, "Administrative Revision of Vaccine Injury Table", which changes the public comment period from 180 to 90 days with Section 2, "Administrative Revision of Vaccine Injury Table" of the 1999 Amendments which changes the public

comment period from 180 to 60 days and shortens from 90 to 60 days the period that the ACCV has to review a proposed rule;

Modifying Section 202, "Equitable Relief", and Section 214, "Clarification of Standards of Responsibility" to add "past or" in front of "present physical injury". Some individuals may have sustained a vaccine related injury in the past, but do not have a present physical injury. These individuals should not be prohibited from obtaining relief in a civil action filed against a vaccine manufacturer or administrator;

Replacing Section 207, "Increase in Award in the Case of a Vaccine Related Death and for Pain and Suffering" with the 2001 ACCV recommendation to increase the $250,000 benefit caps for both death, and pain and suffering. These $250,000 benefit caps should be retroactively increased since 1988 and increased annually, thereafter, to account for inflation using the Consumer Price Index for All Urban Workers (CPI-U) as envisioned b the Congress in the original Act of 1986.

Replacing Section 210, "Allowing Payment of Interim Costs" which does not stipulate a timeframe for when the interim payment is to be made with Section 6, "Allowing Payment of Interim Costs" of the 1999 Amendments which states that the interim payment can only be made after a determination has been made concerning whether or not the petitioner is entitled to compensation.

Modifying Section 219, "Ongoing Review of Childhood Vaccine Data" by deleting the phrase, "together with recommendation for changes in the Table"; and

Replacing Section 221, "Report" with this language, "The ACCV shall provide the Secretary with annual status reports on the Trust Fund, including recommendations on the allocation of funds from the Trust Fund."

With regard to Section 203, "Parent Petitions for Compensation," the ACCV believes that the language in this section must be modified. The issue of compensating parents and third parties was raised when the original Act was drafted, but the focus remained on the need for an adequate compensation package that would cover the life of the injured child. Over the years, a few parent or third party petitions for compensation have been filed in State and Federal courts. However, many of the class action suits contain parent petitions which prompted ACCV to revisit the issue. The ACCV strongly believes that parent or third party petitions for compensation are more appropriately managed and adjudicated through the VICP rather than through outside litigation. Because of our concern for the well being of the child, the ACCV recommends that the award to the vaccine injured child be separate from any award offered to the parent. At your request, the ACCV will develop options for such an award. In addition, this section, as is currently drafted, raises serious constitutional concerns. The ACCV recognizes that the proposed provision as drafted many need to be supplemented to: (1) address potential constitutional concerns; and (2) assure that such parents or third party claims may be properly administered by the VICP. Moreover, the ACCV believes that further consideration should be given to review whether a third party's claim should be tied to the injured party's claim in civil action.

Section 205, "Application", is a conforming change to Section 203; and therefore, the ACCV does not concur with this section until the language in Section 203 is sufficiently modified.

The ACCV recommends that the Secretary take all steps necessary to protect the privacy of patient data in order to ensure the continued support and viability of this important project.

**07/31/2002 to Secretary Tommy Thompson from Elizabeth Noyes, ACCV Chair**

The ACCV supports the following sections in S 2053: **Vote: Unanimous**

Section 24. Jurisdiction to Dismiss Actions Improperly Brought.
Section 26. Clarification of When Injury is Caused by Factor Unrelated to Administration of Vaccine.
Section 28. Basis for Calculating Projected Lost Earnings.
Section 31. Procedure for Paying Attorneys' Fees.
Section 33. ACCV
Section 35. Clarification of Definition of Manufacturer.
Section 36. Clarification of Definition of Vaccine Related Injury or Death.
Section 40. Pending Actions.

The ACCV Supports and extends its appreciation to Sen. Frist for incorporating the changes suggested in our letter of June 19 to the following sections:

Section 22. Equitable Relief. **Vote: Unanimous with revisions**
Section 30. Allowing Payment of Interim Costs. **Vote: Unanimous**
Section 34. Clarification of Standards of Responsibility. **Vote: 7 for, 1 against**
Section 39. Ongoing Review of Childhood Vaccine Data. **Vote: Unanimous**
Section 41. Report. **Vote: Unanimous**

The ACCV requests the following revisions be made to various sections of the bill:

Section 21. Administrative Revision of Table. In addition to this provision, the ACCV recommended that the time the ACCV has to review a proposed rule be shortened from 90 to 60 days, as proposed in the Department's draft bill, the 1999 Amendment. **Vote: Unanimous with revisions**

Section 27. Increase in Award in Case of a Vaccine Related Death and for Pain and Suffering. The ACCV once again reiterates increasing the caps for pain and suffering and death to annually account for inflation using the Consumer Price Index. **Vote: Unanimous**

Section 29. Allowing Compensation for Family Counseling Expenses and Expenses of Establishing Guardianship. Subsection 2115(a)(6)(p.22) could be changed to refer both to the expenses of establishing guardianships and to the expenses of maintaining guardianships, rather than the current language "expenses of establishing guardianships." If this change is made, corresponding modifications would need to be made to subsection (c)(4)(p.23).
**Vote: Unanimous**

Section 32. Extension of Statute of Limitation. Subsection (d) differs from the ACCV's recommendation that the special master issue a certificate of completeness, indicating that the 240-day period can commence. The ACCV's proposal would be simpler to administer and would lead to less litigation. Given that supplemental records are often submitted long after the petition is filed and that petitioners are permitted to submit an affidavit, in lieu of certain records, explaining the unavailability of required documents, the determination of whether all required documents have been submitted may be a matter of subjective opinion. We suggest that the ACCV's proposal, requiring the special master to issue a certificate of completeness, be included in the bill so that this issue will be resolved quickly and fairly. **Vote: Unanimous**

Section 37. Clarification of Definition of Vaccine. In subsection (7)(p.31), add back "but not limited to" after "including". **Vote: Unanimous**

Section 38. Amendments to Trust Fund. In subsection (b)(p.32), the "base amount" needs to be determined.

The ACCV suggests that a provision be included in the bill as amended to preclude covered individuals who have not filed a petition with the VICP from filing a civil action for damages in an amount of $1,000 or less against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine related injury or death.

**09/05/2002 to Secretary Tommy Thompson from Elizabeth Noyes, ACCV Chair**

The ACCV suggests that a provision be included in S 2053 and HR 5282 to preclude covered individuals who have not filed a petition with the VICP from filing a civil action for damages in an amount of $1,000 or less against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine related injury or death.

The ACCV opposes subsection (b) of Section 210, "Effect of Amendment on Previously Untimely Claims, of HR 5282. This subsection would be inherently unfair to petitioners because it would effectively establish two different statute of limitations periods depending on the alleged theory of causation. In addition, it would be extraordinarily difficult to administer. In essence, petitions for injuries on the Table would enjoy the expanded 6-year statue of limitations, whereas cases involving injuries not listed on the Table would be limited to the existing 3-year period. In addition, this language does not seem to accommodate significant aggravation claims. The ACCV reiterates its strong support for its prior recommendation to extend the statute of limitations to 6 years for all claims. **Vote: Unanimous**

The ACCV offers the following recommendations and comments on S 2053 and HR 5282:

For Section 23, "Parent or Other Third Party Petitions for Compensation" of S 2053 and Section 203, "Parent Petitions for Compensation" of HR 5282, the ACCV supports the concept of requiring derivative suits to first be filed with the VICP before such actions may be pursued in civil court. However, these Sections, as they are currently drafted, appear to prohibit civil actions by parents (as well as derivative

petitions under the VICP) if the child on whose behalf a VICP petition was filed is not compensated under the VICP. These Sections could potentially take away a State right from a parent or third party that currently exists without replacing it with another right. If one part of the Act is held invalid by reason of a violation of the Constitution, it is possible the entire Act could be considered invalid. Thus, we strongly advise that a "separability of provisions" section be included in each bill to specify that if any part of the amended Act is found to be invalid under the Constitution, then the Act without the unconstitutional provision would continue in effect.

Furthermore, some of the subsections in Section 23 of S 2053 and Section 203 of HR 5282 which establish the process for filing derivative petitions need further clarification.

- Definitions of "parent," "other third party," "legal guardian," and "spouse" should be provided. Does "parent" include only a biological mother or only biological father? Does "parent" include a stepmother, stepfather or an adoptive parent? The Act currently included the term "legal representative," which is defined as "a parent or an individual who qualifies as a legal guardian under State law." These definitions could be included in section 2133 of the PHS Act.
- Subsections (c)(2)(B) of S 2053 and HR 5282 appear to permit the filing of only one derivative petition for each underlying petition; however, it is unclear whether the intent is: 1) to allow only one derivative petition by only one derivative petitioner for each administration of a vaccine to an injured party; 2) to allow multiple persons to be a party to and file only one derivative petition for each administration of a vaccine to an injured party and apportion the derivative award amongst the eligible derivative petitioners; or 3) to allow one derivative petition to be filed by each party who may have suffered a loss as a result of each administration of a vaccine to an injured party. In the latter case, for example, could the biological mother of the injured party, the biological father of the injured party, adoptive parents of the injured party, and spouse of the injured party each file a separate derivative petition? If so, each could receive a separate derivative award based on one injured party's award.
- In subsections (f)(2)(b), "Derivative Petitions," of S 2053 and HR 5282, compensation awarded under the VICP to a parent or third party who files a derivative petition is to be in an amount not to exceed the lesser of $250,000 or the total amount of compensation awarded to the injured party. Section 27, "Increase in Award in the Case of a Vaccine Related Death and for Pain and Suffering," proposes increasing the current statutory $250,000 benefit cap for pain and suffering to $350,000. If the cap on the derivative petition award is derived from the current $250,000 cap on pain and suffering, then consideration should be given to increasing the maximum derivative petition award to $350,000 to correspond to the newly increased pain and suffering award if it is the intent of Congress to keep these benefits equal.

Section 32, subsection (d)(1) of S 2053 and Section 210, subsection (e)(1) of HR 5282, "Special Masters Decision," should be replaced with the ACCV recommendation that was forwarded to you in my letter dated 6/19/2002. Given that important medical records are often submitted long after the petition is filed, the determination of whether all required documents have been

submitted may be a matter of subjective opinion. Requiring the special master to issue a certificate of completeness will resolve this issue more quickly and fairly.

**12/06/2002 to Secretary Tommy Thompson from Elizabeth Noyes, ACCV Chair**

At the 12/4/2002 meeting, the ACCV reviewed sections 1714-1717 of the Homeland Security Act (P.L. 107-296), which affect the VICP, and renewed its support. These sections are the same as sections 215-217 and 220 in the 3/21 version of the "Improved Vaccine Affordability and Availability Act," S 2053, introduced by Sen. William Frist (R-TN). However, a comprehensive package is urgently needed for balance and fairness in addressing the needs and concerns of all parties involved. Therefore, the ACCV strongly recommends that you take immediate action to work with Congress to enact the broader legislative package, similar to S 2053.

**06/24/2004 to Secretary Tommy Thompson from Thomas Gallagher, JD, ACCV Acting Chair**

The ACCV recommends that the Secretary take appropriate steps to add the influenza vaccine to the Table. **Vote: Unanimous**

**11/23/2004 to Secretary Tommy Thompson from John Schreiber, MD, ACCV Chair**

The ACCV recommends that the effective date of the excise tax for trivalent influenza vaccines should be July 1, 2005. **Vote: Unanimous**

**04/19/2005 to Secretary Mike Leavitt from Don Wilber, MD, ACCV Chair**

The ACCV recommends that the Secretary take the appropriate steps to add to the Table the following injuries or conditions and the timeframes in which they must occur after the varicella vaccine is administered:

Anaphylaxis or anaphylactic shock; 4 hours
Encephalitis or encephalopathy; 5 to 30 days
Cerebellar ataxia; 5 to 30 days
Thrombocytopenia; 7 to 30 days
PCR-confirmed vaccine strain viral infection, including but not limited to Herpes zoster, in a non-immunodeficient or immunodeficient recipient; Non-applicable

The ACCV recommends that the Secretary take the appropriate steps to add to the Table the following injuries or conditions and the timeframes in which they must occur after the hepatitis A vaccine is administered:

Anaphylaxis or anaphylactic shock; 4 hours

**03/22/2006 to Secretary Mike Leavitt from Don Wilber, MD, ACCV Chair**

The ACCV recommends that: **Vote: 7 for; 1 against; 1 abstention**

- a standing scientific panel of recognized medical and scientific experts, each of whom has been screened for conflicts of interest, be established to review periodically the Table, and recommend any changes, including proposed additions to the injuries listed, to the ACCV based upon current, available scientific and medical knowledge;

- the scientific panel include, but not be limited to representation in the following disciplines: medical ethicist pediatrics, infectious diseases, neurology, immunology, toxicology, epidemiology and/or statistics; and

- the charter of the scientific panel require the panel members to consult with the ACCV when prioritizing the issues to be reviewed and the data sources to be consulted.

**03/23/2007 to Secretary Mike Leavitt from Don Wilber, MD, ACCV Chair**

The ACCV supported the following recommendations:

- Allowing Payment of Interim Fees and Costs to Petitioners' Attorneys by allowing a petitioners' attorney to seek and award for reasonable fees and cost incurred in the proceeding after the special master or court has determined that a petition is entitled to compensation. **Vote: Unanimous**

- Allowing the special master or court to order attorneys' fees and cost awarded be made payable solely to the petitioner's attorney if the petitioner expressly consents or the special master or court determines that (i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees and costs expeditiously, or (ii) there are other exceptional circumstances and good cause for paying such fees and costs solely to the petitioner's attorney. **Vote: Unanimous**

- Increasing the $250,000 benefit cap for death and the $250,000 benefit cap for pain and suffering to account for inflation. Both benefit caps would be retroactively increased since 1988 to account for inflation and would increase annually to account for inflation using the Consumer Price Index - All Urban Wage Earners (CPI-U), as envisioned by Congress in the original National Childhood Vaccine Injury Act of 1986. **Vote: Unanimous**

- Allowing compensation for reasonable and necessary, non-reimbursable expenses that have been or will be incurred for (a) family counseling determined to be reasonably necessary and that results from the vaccine-related injury and/or death for which the petitioner seeks compensation; and (b) compensation for reasonable and necessary non-

reimbursable expenses, including attorneys' fees, that have been or will be incurred to establish and maintain a guardianship, conservatorship, or trust, approved by the U.S. Court of Federal Claims, for the benefit of an individual who has suffered a vaccine-related injury. **Vote: Unanimous**

- Amending the Act to permit, but not require, the Secretary to appoint an adult who has personally suffered a vaccine-related injury, or the guardian or family member of such an adult, to one of the two ACCV posts reserved for the legal representative of a child who has suffered a vaccine-related injury or death.
  **Vote: Unanimous**

- Amending 42 USC § 300aa-15(a)(2): In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased, in addition to the injury benefits provided in Sections 15(a)(1), 15(a)(3) and 15 (a)(4). **Vote: Unanimous**

- Extending the statute of limitations (SOL) for vaccine-related injuries from 3 to 8 years, but make the Program the exclusive remedy for any petitioner who files during the extended period (no opt out). There would be no change in the current 3 year SOL, including the right to opt out. However, the Program would be the exclusive remedy for any petition filed during the extended 5-year period (year 3-8). **Vote: Unanimous**

- Extending the SOL for vaccine-related deaths from 2 to 8 years following a death, with the Program being the exclusive remedy for the extended 6-year period (no opt out); and extend the SOL from 4 to 8 years from injury, with the Program being the exclusive remedy from year 4-8 (no opt out). **Vote: Unanimous**

- Amending the Act to require parent or other third party to file a petition in the Program before filing or maintaining a civil action against a vaccine manufacturer or administrator in a Federal or State court for damages relating to a vaccine-related injury or death, including but not limited to damages for loss of consortium, society, companionship or services, loss of earnings, medical or other expenses, and emotional distress, and no court may award damages in such an action unless the action is joined with a civil action brought by the person whose vaccine-related injury is the basis for the parent's or other third party's action. **Vote: 8 for; 1 against**

- Adding a definition of the word "vaccine" to 42 USC § 300aa-33 that includes all components and ingredients listed in the vaccines' product license application and product label. **Vote: 8 for; 1 against**

- Enlarging the current definition of manufacturer (42 USC § 300aa-33(3)) to include any corporation, organization, or institution (public or private) which manufactures, imports, processes, or distributes *any component or ingredient* of any vaccine set forth in the Vaccine Injury Table. **Vote: 7 for; 2 against**

- Clarifying that a component or ingredient approved for use in a Table vaccine by the FDA is not to be considered an adulterant or contaminant for purposes of the Act. (42 USC § 300aa-33(5)) **Vote: 7 for; 1 against; 1 abstention**

New Definition: Vaccine-related injury or death means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine. For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.

**05/07/2009 to Secretary Kathleen Sebelius from Jeffrey Sconyers, JD, ACCV Chair and Tawny Buck, ACCV Co-Chair**

The ACCV proposed a set of recommendations to improve the National Vaccine Injury Compensation Program (VICP) and requested a response from the Secretary. The ACCV voted unanimously to support the following set of recommendations at its meeting on March 6, 2009.

- **Increase Benefits Caps for Death and Pain and Suffering.** Increase the $250,000 benefit cap for death, and the $250,000 benefit cap for pain and suffering to account for inflation since 1988, when these limits were established. Both benefit caps should be increased to account for inflation since 1988, and should thereafter be adjusted annually to account for inflation using the Consumer Price Index – All Urban Wage Earners (CPI-U), as envisioned by Congress in the original National Childhood Vaccine Injury Act of 1986.

- **Extend the Statute of Limitations.** Extend the existing statute of limitations (SOL) under the Program as follows, so that the SOL corresponds to the eight years of retroactive coverage provided under the Act when a new vaccine or injury is added to the Table:
    - For vaccine-related **injuries**, extend the SOL from its current 3 years to a total of 8 years, but make the Program the exclusive remedy for any petition filed during years 3 – 8. Currently, the SOL for injuries is 3 years from the date of the first symptom of the injury, even if unknown to the petitioner. The ACCV proposes to extend the SOL an additional 5 years, to a total of 8 years after the first symptom of injury, but for petitions filed more than 3 years after the first symptom, the Program would be the exclusive remedy, and petitioners could not opt out of the Program to pursue a tort claim in state or federal court.

    - For vaccine-related **deaths**, extend the SOL to 8 years following a death, but make the Program the exclusive remedy for any petition filed during the extended period. Currently the SOL for deaths is 2 years after the death or 4 years after the date of the first symptom of the injury. The ACCV proposes to extend the SOL to a total of 8 years in cases involving death. For petitions filed more than 2 years

after the death, or more than 4 years after the first symptom of injury, the Program would be the exclusive remedy, and petitioners could not opt out of the Program to pursue a tort claim in state or federal court.

| **Proposed SOL Changes** | **Current Law** | | **Proposal** | |
|---|---|---|---|---|
| Injuries | 3 years after 1st symptom | Opt-out available | 8 years after 1st symptom | No opt-out for claims brought from 3-8 years after 1st symptom |
| Death | 2 years after death | Opt-out available | 8 years after death | No opt-out for claims brought from 2-8 years after death |
| | 4 years after 1st symptom | | 8 years after 1st symptom | No opt-out for claims brought from 4-8 years after 1st symptom |

- **Allowing Compensation for Family Counseling Expenses and Expenses of Establishing and Maintaining Guardianships, Conservatorships or Trusts**. Permit compensation under the Act for reasonable and necessary, non-reimbursable expenses that have been or will be incurred for (a) family counseling determined to be reasonably necessary and that result from the vaccine-related injury or death for which the petitioner seeks compensation, and (b) compensation for reasonable and necessary non-reimbursable expenses, including attorneys' fees, that have been or will be incurred to establish and maintain a guardianship, conservatorship or trust, approved by the U.S. Court of Federal Claims, for the benefit of an individual who has suffered a vaccine-related injury.

- **Appointment of Adult with Vaccine-Related Injury to ACCV**. Permit (not require) the Secretary to appoint an adult (or the guardian or family member of such an adult) who has personally suffered a vaccine-related injury, to one of the two ACCV posts reserved for the legal representative of a child who has suffered a vaccine-related injury or death.

- **Clarification that a Petitioner Who Establishes a Vaccine-Related Injury and Death is Entitled to Both Death and Injury Benefits**. Amend 42 U.S.C. §300aa-15(a)(2): In the event of a vaccine-related death, an award of statutory amount for the estate of the

deceased, *in addition to the benefits provided in Sections 15(a)(1), 15(a)(3) and 15(a)(4).* (New text in *italics*.) The ACCV recognizes that the Federal Circuit has decided one case supporting this approach to payment of benefits, and recommends that the Act be amended to assure that the approach is made a permanent part of the law.

- **Parent Petitions for Compensation**. Permit a parent or legal guardian to seek compensation for benefits under the Act for damages for loss of consortium, society, companionship or services, loss of earnings, and medical or other expenses (derivative claims), and require the parent or legal guardian to seek compensation for benefits under the Program as part of the injured person's petition, before filing or maintaining a civil action against a vaccine manufacturer or administrator in a federal or state court for damages relating to a vaccine-related injury or death. Such derivative claims would be subject to the same exclusivity provisions under the Act, and any subsequent civil actions must include both the underlying injury or death and the derivative claim. Congress should establish a reasonable cap on such damages.

- **Clarification of Definition of Manufacturer**. Enlarge the current definition of manufacturer (42 U.S.C. §300aa-33(3)) to include any corporation, organization or institution, public or private, that manufactures, imports, processes or distributes *any component or ingredient* of any vaccine listed on the Vaccine Injury Table.

- **Clarification of Definition of Vaccine-Related Injury or Death**. Clarify that a component or ingredient that is approved by the FDA for use in a vaccine listed on the Table is not to be considered an adulterant or contaminant for purposes of the Act (42 U.S.C. §300aa-33(5)). New definition (new text in *italics*):

  > Vaccine-related injury or death means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine. *For purposes of the preceding sentence, any component or ingredient listed in a vaccine's product license application or product label is not an adulterant or contaminant.*

- **Add Definition of Vaccine**. Add a definition of the term "vaccine" to the Act, 42 U.S.C. §300aa-33. The Act currently contains no definition of this term. The new definition should provide that the term "vaccine" includes all components and ingredients listed in the vaccines' product license application and product label.

- **Allowing Payment of Interim Fees and Costs to Petitioners Attorneys**. After the Court has determined that it has jurisdiction over the petition and that the petition was brought in good faith and upon a reasonable basis, allow the petitioner's attorney to seek an award for reasonable fees and costs incurred in the proceeding, including petitioner's expert witness costs. This interim award of fees and costs shall be paid promptly by the Secretary from the Vaccine Injury Compensation Trust Fund on entry of the special master or court's determination, without need of a final disposition of the case. The ACCV recognizes that the Federal Circuit has decided one case supporting this approach

to the interim payment of fees and expenses, and recommends that the Act be amended to assure that the approach is made a permanent part of the law. The ACCV encourages an early payment of interim fees and costs to reimburse petitioners' incurred expenses, if possible within 12 to 18 months of filing.

- **Procedure for Paying Fees and Costs Solely to Petitioner's Attorney**. When a special master or the court awards attorneys' fees or costs, it may order them payable solely to the petitioner's attorney if the petitioner expressly consents, or if the special master or court determines that (a) the petitioner cannot be located or refuses to respond to a request the special master or court for information, and there is no practical alternative to ensure the attorney will receive the fees and costs expeditiously, or (b) there are other exceptional circumstances and good cause for paying such fees and costs solely to the petitioner's attorney.