



April 16, 2020

Advisory Commission on Childhood Vaccines (ACCV) Commissioners,
Ms. Tamara Overby, Designated Federal Officer (DFO) for the ACCV
Division of Injury Compensation Programs (DICP)
5600 Fishers Lane, 08N146B
Rockville, MD 20857
Email: toverby@hrsa.gov
Commission Email – Andrea Herzog: aherzog@hrsa.gov

Re: Closed Door Discussions on Possible Removal of Syncope and Shoulder Injury Related to Vaccine Administration (SIRVA) from the Federal Vaccine Injury Table (VIT)

Dear Commissioners and Ms. Overby,

During the March 6, 2020 ACCV meeting, the chair, Dr. Cody Meissner, opened a discussion by referencing “confidential” correspondence mailed to all ACCV commissioners by the U.S. Department of Health and Human Services (DHHS) which included a proposal to modify the Vaccine Injury Table (VIT) by removing syncope and shoulder injury (SIRVA).

SIRVA is currently one of the leading compensated injuries by VICP. A 2018 report found that half of the claims filed for compensation under the National Childhood Vaccine Injury Act (“The Act”) involved SIRVA.¹ Removing two of the few additions made to the VIT since the VICP’s inception may have the effect of denying the majority of claims currently compensated by the program.

DEPARTURE FROM PROCESS

Syncope and SIRVA were originally added to the VIT during regularly scheduled ACCV meetings open to the public, which included presentations from agencies on scientific evidence and commission discussions.^{2 3 4} It follows that the same procedure should be implemented if ACCV is considering removing these two vaccine-related adverse events from the VIT.

However, in a departure from the process in place to modify the VIT, DHHS officials sent the ACCV commissioners confidential correspondence that proposed the removal of two key injuries from VIT and solicited their separate opinions prior to the March meeting of the ACCV. The proposal to remove syncope and SIRVA from the VIT did not appear on the ACCV’s March meeting agenda and no presentation of evidence was made. Further, ACCV commissioners were only given 90 days to provide feedback to the Secretary’s request for comments, which is before to their next public meeting in June.

Deliberations for all previous changes to the VIT were conducted in public sessions over a period of many months.⁵

It is further cause for concern that this proposed modification to the VIT, which could significantly alter the number of compensation awards, has been secretly pushed by DHHS when four of the nine seats on the committee are vacant and three of the five sitting members are medical professionals.⁶

Discussion and votes on changes to the VIT should be conducted in meetings by the ACCV as a whole, which are required to be public per the National Childhood Vaccine Injury Act of 1986 (Act),⁷ ACCV charter,⁸ Federal Advisory Committee Act (FACA),⁹ and Government in the Sunshine Act.¹⁰

LEGAL REQUIREMENTS HAVE NOT BEEN MET

The National Childhood Injury Act: Section §300aa–14. Vaccine Injury Table of the National Childhood Vaccine Injury Act sets forth;

“(c) Administrative revision of 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 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.”¹¹

Under Section §300aa–14(c) of the Act, the Secretary must provide for notice and opportunity for a public hearing and a minimum of 180 days of public comment when promulgating any modification to the VIT.

Section §300aa–14(d) requires that prior to the notice of a hearing and soliciting of public comments the Secretary provide a copy of the proposed modification to ACCV, request recommendations and comments from ACCV and give them at least 90 days to make recommendations.

In this instance, it appears that the Secretary has circumvented the requirements of the Act as set forth above by sending a confidential letter to members of the ACCV individually.

The Federal Advisory Committee Act: FACA sets forth that the ACCV’s role as a federal advisory committee is to provide information and advice on childhood vaccines to federal officials and the nation giving the public, “*an opportunity to provide input into a process that may form the basis for government decisions.*”¹²

By soliciting the opinions of individual ACCV members privately through the mail, the Secretary is thwarting the ACCV’s role in helping to shape government policy. The transparency demanded by federal advisory committees such as ACCV is further supported by FACA requiring that meetings be:

- published with adequate advance notice;
- open and reasonably accessible to the public;
- held at convenient times and locations; and
- all papers and records including, but not limited to, detailed minutes of all meetings be available to the public subject to the Freedom of Information Act.¹³

Guiding Principles For Changes to The Vaccine Injury Table: The ACCV established overarching guiding principles for making modifications to the VIT when it adopted *The Guiding Principles For Recommending Changes to the Vaccine Injury Table* on March 9, 2006. These guidelines stipulated that when changes are made to the VIT, they should be made to benefit the petitioners when there is credible scientific and medical evidence supporting a proposed addition to or deletion of an injury to the table.¹⁴

Removing two key injuries from the VIT does not benefit petitioners and is contrary these ACCV guidelines.

NVIC submits the following requests to ACCV’s DFO relating to possible changes to the VIT:

- A copy of the confidential correspondence sent to ACCV commissioners by DHHS relating to the aforementioned proposed modifications the VIT.
- Any and all other deliberative materials and additional correspondence that were made available to, prepared for, the ACCV in relation to the proposed changes to the VIT. Pursuant to Public Access to Records under FACA, the materials requested shall include records, reports, transcripts, minutes, appendixes, working papers, drafts,

studies, agenda, or other documents that were made available to or prepared for or by each advisory committee and shall be provided to the public and interested parties without the need to request disclosure under FOIA.¹⁵

- Clarification on what federal law supports the individual soliciting of ACCV member opinions via “confidential” correspondence outside of regular committee meetings on matters within their charter meant to be addressed as a commission in a public meeting.

Process Requests - ACCV

Should ACCV consider the potential removal of syncope and SIRVA from the VIT at an upcoming ACCV meeting, NVIC maintains and requests that:

- ACCV should abide by the established procedures that have been followed by all previous ACCV’s;
- ACCV should follow the legal requirements set forth in the above-referenced Federal Statutes;
- Any and all materials including records, reports, transcripts, minutes, original presentations,¹⁶ appendixes, working papers, drafts, studies, agenda, or other documents that were made available to or prepared for or by each advisory committee member and any other informative materials that were presented to, used or seen by the previous ACCV, which approved the additions of syncope and SIRVA to the VIT, shall be made available to the ACCV for public review and discussion;
- Any evidence presented for the removal of syncope and SIRVA from the VIT be duly noted and assessed in accordance with ACCV’s evidence hierarchy guidelines, which state *“To the extent there are data sources other than an IOM report, ACCV members should make an effort to assess the relative strength of those data sources.”*¹⁷
- New evidence for consideration is assessed based on how it differs from previous evidence presented and used by the previous ACCV’s deliberations to add these injuries to the VIT; and
- Funding source(s) of new evidence presented to remove syncope and SIRVA be noted, in accordance with ACCV guidelines,¹⁸ to inform the committee about any industry funding of research, researcher conflicts of interest and potential bias.^{19 20 21 22}

HISTORY OF THE ACT AND VIT

NVIC has a long history with the VICP and ACCV. NVIC’s co-founders worked with Congress to help draft the 1986 Act and secure vaccine safety and research provisions in the legislation, which created the VICP.

To protect the childhood vaccine supply and maintain public trust in the national vaccine program, Congress created a federal no-fault, less adversarial, expedited administrative compensation alternative to a lawsuit in the Act for those injured by CDC recommended childhood vaccines.²³ The VIT was included in the Act to allow petitioners with injuries listed on the table to be awarded quick and adequate compensation without opposition from DHHS or the Department of Justice (DOJ). Claimants with off-table injuries must hire an attorney to

prove that the vaccine caused an injury because DOJ attorneys representing the Secretary of HHS argue that a petitioner's injury was not caused by the vaccine.²⁴

Congress designed the VICP to give the benefit of doubt to petitioners, i.e., causation was to be presumed and an award was to be made in the absence of a more biologically plausible explanation for the injury. The spirit and intent of the VICP was for the government to err on the side of the petitioner by awarding generous and expedited compensation, not to require absolute proof of causation in order to receive compensation. However, over time, the VIT has been narrowed rather than expanded, and standards for obtaining compensation have been raised, resulting in substantially fewer children being administratively compensated for on-table vaccine injuries or compensated for off-table injuries.²⁵

Removing injuries from the VIT also makes it more difficult for petitioners to recover compensation under the program. In a 1999 report, the U.S. General Accounting Office stated:

“HHS’ recent changes to the vaccine injury table will make the process easier for some people to obtain compensation, but will make it more difficult for a larger number to do so. This is because far more claims have historically been associated with injuries HHS removed from the table than with injuries HHS added to it. For example, about half of the awards made since the program’s inception have been for neurological injuries that HHS later removed from the table in 1995 and 1997. Removing these injuries shifts the burden of proof to the petitioner, making it more difficult to qualify for compensation under VICP.”²⁶

When the VICP was first implemented, 74 percent of injury claims were for children with recognized injuries listed on the VIT. However, today 98 percent of claims are for off-table injuries,²⁷ with the majority of claims being filed for vaccine injuries in adults.²⁸ This trend should be cause for concern and serve as a call to action by the ACCV and the VICP, particularly as the trust fund continues to grow and funds are available for compensation.

Lack of Safety Studies:

The expansion of the federally recommended childhood vaccine schedule without an equal investment in methodologically sound vaccine safety studies, as well as removal of injuries from VIT, has led to an increase in off-table claims and raises the bar for petitioners being required to prove vaccine injury “by a preponderance of the evidence,” rather than presumption in the absence of a more biologically plausible explanation.²⁹ As a result, two out of three petitioners are denied compensation, including most child petitioners.^{30 31}

As stipulated in the 1986 Act, physician committees appointed by the Institute of Medicine (IOM) in 1991³² and 1994³³ extensively reviewed medical evidence for 75 vaccine adverse events related to nine childhood vaccines. The IOM was unable to make causality statements for about two-thirds of these events due to lack of sound scientific evidence.³⁴

In 2009, the Health Resources and Services Administration (HRSA) engaged the Institute of Medicine to again convene a physician committee to review the epidemiologic, clinical, and biological evidence regarding adverse health outcomes reported to be associated with nine

CDC recommended childhood vaccines. Published in 2012, the report stated that, once again, the IOM was prevented from making causality statements for 135, or 85 percent, of the 158 vaccine adverse events due to a lack of evidence.³⁵

A 2000 report to Congress on the VICP's trust fund noted that median awards for off-table claims were significantly lower than awards for on-table claims, due to lack of medical evidence.³⁶

There is an absence of medical evidence because the vaccine safety studies that were mandated in the 1986 Act have not been conducted, which makes it even more important for ACCV to adhere to ACCV process guidelines for changing the VIT, retain existing injuries on the VIT, and use more expansive interpretations of injuries to fulfill the spirit and intent of the Act. Syncope and SIRVA occur as a direct result of individuals being given CDC recommended vaccines and should remain on-table injuries in the VICP.

NVIC urges the ACCV to retain syncope and SIRVA on the VIT and abide by the procedures as set forth in federal laws when modifications to the VIT are considered, as well as respectfully requests the above-referenced documents.

Sincerely,

/S/

Barbara Loe Fisher,
Co-founder & President

/S/

Kathryn Williams,
Co-founder & Vice President

/S/

Theresa K. Wrangham,
Executive Director

/S/

Carolyn Hendler,
Director of Legal Affairs & Public Outreach

References:

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