



November 24, 2020

Advisory Commission on Childhood Vaccines

Division of Injury Compensation Programs
5600 Fishers Lane, 08N146B
Rockville, MD 20857

RE: *Health Resources and Services Administration (HRSA) Notice of Proposed Rulemaking (NPRM);
December 3, 2020 ACCV Meeting*

Members of the Advisory Commission on Childhood Vaccines (ACCV):

In anticipation of the May 18, 2020 ACCV meeting, the Vaccine Injured Petitioners (VIP) Bar Association submitted a letter for the ACCV's consideration, dated May 14, 2020, opposing HRSA's NPRM.

During the ACCV's May 18, 2020 meeting,¹ members heard from interested parties and deliberated HRSA's NPRM, before voting to unanimously oppose the Vaccine Injury Table changes proposed in the NRPM.² During that meeting, questions about when and how SIRVA and syncope were added to the Vaccine Injury Table arose. Outlined below, please find a condensed timeline of HRSA's public efforts to add *and* remove SIRVA and syncope to and from the Vaccine Injury Table.

Addition of SIRVA and syncope to the Vaccine Injury Table

In **September 2010**, Dr. Rosemary Johann-Liang, Chief Medical Officer at the Division of Vaccine Injury Compensation (DVIC), first presented on SIRVA and introduced recent research to ACCV members. Dr. Atanasoff described his case series study, involving thirteen (13) claims filed in the National Vaccine Injury Compensation Program (NVICP) from 2006 to 2010, involving SIRVA. Factors considered in the development of SIRVA included needle length, improper administration of the injection, injection of a vaccine antigen into the synovial space, prior exposure to the vaccine antigen, and an immune-mediated inflammatory response to the vaccine.³

¹ ACCV, Meeting Minutes, May 18, 2020, <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-may-meeting-minutes.pdf>.

² ACCV Recommendations, May 20, 2020, <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/reports/accv-recommendation-may-2020.pdf>.

³ ACCV, Meeting Minutes, September 2-3, 2010, <https://www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2010/Sept%202-3/20100902-minutes.pdf>.

In **December 2011**, Dr. Tom Ryan with the Secretary of Health and Human Services presented on proposals to add SIRVA and syncope to the Vaccine Injury Table, with specific reference to the medical literature that supports the addition of these two injuries.⁴

In **March 2012**, the first draft proposal for the revised Vaccine Injury Table was presented to the ACCV for members' consideration. The draft includes SIRVA and syncope as added injuries following injected vaccinations.⁵ The ACCV unanimously approved the addition of SIRVA and syncope to the Vaccine Injury Table.⁶

During the **September 2014** ACCV meeting, revisions to the proposed Vaccine Injury Table changes were presented.⁷

On **July 29, 2015**, HRSA published a NPRM in the Federal Register, proposing changes to the Vaccine Injury Table, including the addition of SIRVA and syncope as injuries following injected vaccinations. The open public comment period ran through January 25, 2016, and a public hearing was held during that timeframe, on January 13, 2016.⁸

Throughout **2016**, HHS reviewed public comments and formulated its final rule.⁹

On **January 19, 2017**, the final rule adding SIRVA and syncope to the Vaccine Injury Table was filed in the Federal Register.¹⁰ The Vaccine Injury Table was subsequently revised.

⁴ ACCV Meeting Minutes, December 8-9, 2011,

<https://www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2011/Dec%208-9/20111209-minutes.pdf>. Power Point Slides, presented by Dr. Tom Ryan, on behalf of the Injection-Related Work Group,
<https://www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2011/Dec%208-9/20111209-mmrrreportsirva.pdf>.

⁵ Draft Proposal for ACCV Consultation: Vaccine Injury Table and Qualifications and Aids to Interpretation,

<https://www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2012/March%208-9/20120308-drafttablechanges.pdf>.

⁶ ACCV Meeting Minutes, March 8-9, 2012,

<https://www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2012/March%208-9/20120308-minutes.pdf>.

⁷ Clarification on Proposed Changes to the Vaccine Injury Table, September 4, 2014,

<https://www.hrsa.gov/sites/default/files/advisorycommittees/vaccines/2014/Sept%204-5/20140904-vaccineinjurytablepresentaton.pdf>

⁸ NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS TO THE VACCINE INJURY TABLE A Proposed Rule by the Health and Human Services Department, July 29, 2015,

<https://www.federalregister.gov/documents/2015/07/29/2015-17503/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table>.

⁹ ACCV Meeting Minutes, September 20, 2016, <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2016/20160920-meeting-minutes.pdf>; ACCV Meeting Minutes,

<https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2016/20161202-minutes.pdf>.

¹⁰ NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS TO THE VACCINE INJURY TABLE A Rule by the Health and Human Services Department, January 19, 2017,

<https://www.federalregister.gov/documents/2017/01/19/2017-00701/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table>.

NPRM to remove SIRVA and syncope from the Vaccine Injury Table

Shortly before the **March 2020** ACCV meeting, HRSA's draft NPRM was circulated amongst ACCV members and then briefly discussed at the March 6, 2020 ACCV Meeting.¹¹

The NPRM was discussed extensively during the **May 2020** ACCV meeting, concluding with the ACCV's unanimous vote to oppose HRSA's NPRM.¹²

HRSA's NPRM was filed in the federal Register on **July 20, 2020**.¹³ A public hearing was held on November 8, 2020, and the public comment period runs through January 12, 2021.

HRSA specifically proposed that SIRVA be added to the Vaccine Injury Table in 2017 after years of deliberating the supporting science and medical literature. The timeline above demonstrate that HRSA publicly considered the *addition* of SIRVA and syncope to the Vaccine Injury Table over a period of at least (4) years before filing its NPRM in the Federal Register. In contrast, HRSA publicly considered the *removal* of SIRVA and syncope from the Vaccine Injury Table over a period of at least four (4) months before filing its NPRM to do so in the Federal Register.

As you know, the ACCV established "Guiding Principles for Recommending Changes to the Vaccine Injury Table" which two basic tenets: (1) the Table should be scientifically and medically credible; and (2) if there is evidence to either support and/or reject a proposed change, the change should whenever possible, be made to benefit the petitioners.

As outlined in the Bar's May 18, 2020 letter to the ACCV members, HRSA's NPRM does not rely upon medically or legally sound arguments for the removal of SIRVA and syncope from the Vaccine Injury Table, and complete removal from the NVICP. Furthermore, it will undoubtedly limit, if not extinguish, viable legal options for vaccine injured individuals, and irreparably damage the NVICP.

Thank you for your consideration,

Christina Ciampolillo
President, Vaccine Injured Petitioners Bar Association

¹¹ ACCV Meeting Minutes, March 6, 2020, <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-march-meeting-minutes.pdf>.

¹² ACCV Meeting Minutes, May 18, 2020, <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/meetings/2020/accv-may-meeting-minutes.pdf>; ACCV Recommendations, May 20, 2020, <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/reports/accv-recommendation-may-2020.pdf>.

¹³ NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS TO THE VACCINE INJURY TABLE A Proposed Rule by the Health and Human Services Department, July 20, 2020, <https://www.federalregister.gov/documents/2020/07/20/2020-15673/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table>.