



April 16, 2021

U.S. Department of Health & Human Services (DHHS) &  
Department of Health Resources and Services Administration (HRSA)  
c/o Ms. Tamara Overby, Acting Director  
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Official Comment Submission: [Regulations.gov](https://www.regulations.gov)

Re: Federal Register 86 FR 14567; Docket HRSA-2021-001 – National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Withdrawal of Final Rule Published January 21, 2020 in FR 6249

The National Vaccine Information Center (NVIC) submits this additional written public comment in support of the proposal to withdraw the above noted final rule, which removed syncope and shoulder injury related to vaccine administration (SIRVA) from the federal vaccine injury table (VIT).

As previously noted in our public comments relating to this rule,<sup>1 2</sup> NVIC co-founders are parents of DPT vaccine injured children who went on to establish the charitable non-profit educational organization, Dissatisfied Parents Together (DPT) in 1982, now known as NVIC. NVIC's co-founders worked with Congress to secure vaccine safety informing, recording, reporting and research provisions in the Act, as well as had input into development of the VIT for the federal Vaccine Injury Compensation Program (VICP) included in the Act, which gives our organization unique standing to provide comment.

The retaining of these injuries on the VIT is consistent with the Act's intent of expanding the VIT based on scientific evidence through the engagement of the National Academy of Medicine, formerly the Institute of Medicine (IOM)<sup>3</sup> and the previously robust process initiated by the U.S. Department of Health and Human Services (DHHS) to add these injuries to the VIT.<sup>4 5 6</sup>

NVIC additionally notes that, the federal compensation mechanism of the Act was specifically created to provide support to children who were injured or died after receiving federally recommended childhood vaccines. The majority of VICP claims were supposed to be administratively awarded without contest by DHHS and the Department of Justice, which is why a VIT providing guidelines for awarding compensation was included in the Act.

At the inception of the VICP, 74 percent of injury claims were for children with acknowledged vaccine injuries listed on the VIT. However, by 2015 these "on-table" vaccine injury claims had drastically decreased to just two percent of total claims with a corresponding increase in the number of off-table vaccine injury claims being 98 percent.<sup>7</sup> These

increases in lengthy, off-table vaccine injury claims contested by DHHS, which require adjudication in the U.S. Court of Federal Claims, is largely due to systematic narrowing of the VIT by DHHS through rule-making authority and the continuing lack of federal funding of high quality bench science to inform the VIT.

Reports by the General Accounting Office (GAO) have noted that the impact of narrowing the VIT creates a more adversarial process by shifting the burden to the petitioner. This defeats congressional intent of providing families with a less adversarial, less traumatic, expedited administrative alternative to a vaccine injury lawsuit and makes it much harder for petitioners to be justly compensated for vaccine injuries.<sup>8 9</sup> DHHS should responsibly address the legitimate high caseload concerns in more appropriate ways than punishing plaintiffs by further narrowing the VIT.

The impact of long standing, significant gaps in knowledge about vaccine safety, especially inadequate understanding of the biological mechanisms of vaccine injury and death, is a big reason why “off-table” claims continue to increase. Since the claims in the VICP began to be processed three decades ago, multiple reports authored by IOM committees between 1991 and 2013 noted the lack of high quality vaccine safety science research and published studies designed to explain the biological mechanisms of and genetic, epigenetic and environmental risk factors for vaccine injury and death.<sup>10 11 12</sup> This lack of scientific knowledge about individual susceptibility<sup>13</sup> to adverse responses to vaccination has consistently compromised the operation of the VICP and the integrity of the VIT, which serves as a guide for the awarding of federal compensation.

NVIC makes the following additional recommendations:

- Review previous changes to the VIT that have had the effect of narrowing the table and have made the VICP highly adversarial<sup>14 15</sup> and inconsistent with IOM findings,<sup>16</sup> with consideration for similar withdrawals of previous rules;
- Address inherent conflicts of interest at DHHS that inhibit the funding of methodologically sound vaccine safety research and contributes to the erosion of public trust in federally recommended vaccines.<sup>17</sup>

Recently, the government has prioritized the addressing of “vaccine hesitancy.”<sup>18 19</sup> The withdrawal of this rule, which makes it much harder for those who have suffered syncope and brachial neuritis after receiving federally recommended vaccines to be compensated, is a step toward restoring public trust in a federal program that was supposed to instill trust in the vaccine system.

Sincerely,



Barbara Loe Fisher  
Co-founder & President



Theresa Wrangham  
Executive Director

## References

<sup>1</sup> Fisher BL, Wrangham TK. [NVIC Written Public Response - Proposed Rule-Change to Remove SIRVA and Syncope from the federal Vaccine Injury Table](#). NVIC Jan. 12, 2021.

<sup>2</sup> Fisher BL, Wrangham TK. [NVIC Public Response - Delay of Rule on Proposed Removal of SIRVA and Syncope from the federal Vaccine Injury Table](#). NVIC Feb. 16, 2021.

<sup>3</sup> Institute of Medicine Committee (IOM). [TABLE 12-1 Summary of Epidemiologic Assessments, Mechanistic Assessments, and Causality Conclusions for Injection-Related Adverse Events](#). In: Adverse Events of Vaccines: Evidence and Causality. *The National Academies Press* 2012.

<sup>4</sup> HRSA. [\(10\) Shoulder injury related to vaccine administration \(SIRVA\)](#). In: Vaccine Injury Table. Mar. 21, 2017; Pg. 8.

<sup>5</sup> Johann-Liang R. [Updating the Vaccine Injury Table following the 2011 IOM Report on Adverse Effects of Vaccines](#). *Health Resources & Services Administration (HRSA)* Mar. 8, 2012.

<sup>6</sup> Advisory Commission on Childhood Vaccines (ACCV). [ACCV Meeting Transcript](#). HRSA Mar. 8, 2012; Pg 148.

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- <sup>7</sup> Holland M. [Liability for Vaccine Injury: The United States, the European Union, and the Developing World](#). *Emory Law Journal* 2018; 67(3).
- <sup>8</sup> U.S. General Accounting Office (GAO). [Vaccine Injury Compensation - Program Challenged to Settle Claims Quickly and Easily](#). December 1999.
- <sup>9</sup> GAO. [Vaccine Injury Compensation - Most Claims Took Multiple Years and Many Were Settled through Negotiation](#). November 2014.
- <sup>10</sup> Institute of Medicine. [Appendix D Table 1: Causality Conclusions Organized by Chapter and Adverse Event](#). In: Adverse Effects of Vaccines: Evidence and Causality. *The National Academies Press* 2012.
- <sup>11</sup> Institute of Medicine. [Afterword on Research Needs](#). In: Adverse Effects of Pertussis and Rubella Vaccines. *The National Academies Press* 1991; Pg. 206.
- <sup>12</sup> Institute of Medicine. [Executive Summary](#). In: Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. National Academies Press 1991; Pg. 17.
- <sup>13</sup> Institute of Medicine Committee (IOM). [Increased Susceptibility](#). In: Adverse Events of Vaccines: Evidence and Causality. *The National Academies Press* 2012; Pg. 82.
- <sup>14</sup> U.S. General Accounting Office (GAO). [Vaccine Injury Compensation - Program Challenged to Settle Claims Quickly and Easily](#). December 1999.
- <sup>15</sup> GAO. [Vaccine Injury Compensation - Most Claims Took Multiple Years and Many Were Settled through Negotiation](#). November 2014.
- <sup>16</sup> Fisher BL, Wrangham TK. [NVIC Referenced Public Comment Re: Proposed Rule by U.S. Health & Human Services Department – National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table – Encephalopathy](#). *NVIC* Jan. 25, 2016.
- <sup>17</sup> NVIC. [National Vaccine Information Center Calls for Removal of Vaccine Safety Oversight from U.S. Department of Health and Human Services](#). Sept. 2, 2014.
- <sup>18</sup> U.S. Department of Health and Human Services. [Featured Priority: Vaccine Confidence](#) In: Vaccines & Immunizations. Aug. 6, 2019.
- <sup>19</sup> CDC COVID-19 Response Vaccine Task Force. [Building Confidence in COVID-19 Vaccines Among Your Patients – Tips for the Healthcare Team](#). *Centers for Disease Control* January 2021; Slide 15.