



May 14, 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)*  
*May 18, 2020 ACCV Meeting*

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

As you know, since 1988, the National Vaccine Injury Compensation Program (NVICP) has served as a no-fault alternative to the traditional civil tort system for vaccine-injured individuals, and claims have involved a myriad of vaccine injuries. For decades, the NVICP has drastically reduced the number of civil lawsuits brought against any individual or entity involved in the manufacturing or administration of covered vaccines, as specifically intended by Congress in enacting the Vaccine Act.

HRSA's recent Notice of Proposed Rulemaking primarily aims to remove two injuries, syncope and shoulder injuries related to vaccine administration (SIRVA), from the Vaccine Injury Table,<sup>1</sup> asserting that such claims should be filed in civil court, in direct contrast to Congressional intent. NPRM at 9. The medical, legal and policy arguments HRSA employs in support of the NPRM are flawed, disingenuous and contradictory to HRSA's rule change that added SIRVA to the Vaccine Injury Table in 2017. Based on the reasoning set forth in this letter, the Vaccine Injured Petitioners (VIP) Bar Association strongly opposes the NPRM.

HRSA's practice of compensating syncope-related injuries for decades and SIRVA for the past ten years, and formally adding both injuries to the Vaccine Injury Table, remain sound. However, HRSA now argues that SIRVA and syncope result from improper administration technique or improper needle length selection, and, therefore, are not "no-fault" injuries. Rather, HRSA argues that only injuries resulting from the vaccine antigen,<sup>2</sup> as opposed to improper technique, should be compensable in the NVICP.

HRSA argues that the "scientific literature indicates that SIRVA likely results from poor vaccination technique, rather than an antigen." NPRM at 5. To buttress its arguments, the NPRM advances many

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<sup>1</sup> Vaccine Injury Table, <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>

<sup>2</sup> To limit compensable injuries solely to those that are affirmatively attributable to a vaccine antigen is far reaching. For example, anaphylaxis is also a compensable injury listed within the Vaccine Injury Table for each covered vaccination, but anaphylaxis may be attributed to adjuvant, preservative or another component of a vaccine. Similarly, injuries involving abscesses at injection sites have historically been compensated but may not be directly attributed to antigen in the vaccine.

misleading references to the literature that HRSA relied upon three years ago to determine that placing SIRVA on the Vaccine Injury Table was appropriate based on relevant medical literature. For example:<sup>3</sup>

- The NPRM cites to: “Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, Shoulder injury related to vaccine administration (SIRVA), *Vaccine* 28(51):8049–8052 (recommending that injections avoid the top third of the deltoid muscle to avoid shoulder injury).” NPRM at 6, n.8. A deeper reading of Atanasoff et al. reveals consideration for injection technique combined with antigen/antibody interaction to promote the inflammatory response ripe for development of SIRVA:

Even when an individual is vaccinated in the deltoid muscle with a previously administered vaccine any local injection site reaction caused by vaccine antigen–antibody interaction is expected to be relatively brief and resolve as the antigen is cleared from the soft tissues over a period of several days. If, however, a vaccine is inadvertently injected into the synovial space of the shoulder (bursa or joint), pre-existing antibody in the synovial tissues, present as a result of earlier naturally occurring infection or vaccination, may lead to a more prolonged inflammatory response. . . .

The rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon. We believe that this type of phenomenon is not due to a specific vaccine but **results from injection of a vaccine antigen** to which a person has previously been sensitized as a result of previous naturally occurring infection or past vaccination.

*Id.* at 851 (emphasis added).

- To support exclusion of the role of the vaccine antigen in SIRVA, the NPRM cites to: “Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine*, 2017; 35: 4870-4876.” NPRM at 6, n.10. However, Arias et al. directly invokes vaccine contents in the development of SIRVA:

In addition, if the vaccine (antigens and/or adjuvants) is unintentionally given into the synovial bursa or the joint junction, a strong local inflammatory response may appear, which, in turn, can cause bursitis and injuries involving the soft tissues, tendons and bone structures situated close to the shoulder. These conditions might be caused by the antigenic or adjuvants components contained in vaccines [10,31,32]. However, multiple genetic, infectious, and even environmental, factors may also play a role. These factors are likely to trigger the immune system, which, in turn, would induce the inflammatory response.

*Id.* at 4875.

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<sup>3</sup> In the interest of brevity, an exhaustive review of all medical literature involving SIRVA is not addressed in this statement. However, should the ACCV request additional comment, the VIP Bar will be happy to comply.

- The NPRM cites to: “Barnes MG, Ledford C, Hogan K. A ‘needling’ problem: shoulder injury related to vaccine administration. J Am Board Fam Med. 2012 Nov-Dec;25(6):919-22.” NPRM at 6, n.9. Barnes et al. considers injection technique combined with vaccine contents in promoting the inflammatory response ripe for development of SIRVA: “This inflammatory response may be due either to the antigenic or nonantigenic components of the vaccine (antimicrobial, preservatives, etc.)” *Id.* at 921.

Review of the medical literature overwhelmingly supports the combined role of injection technique *and* vaccine contents in the development of SIRVA, despite HRSA’s assertion to the contrary. Indeed, the definition of SIRVA in the current Vaccine Injury Table acknowledges this phenomenon:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction.

The medical support for the NPRM is skewed and has no foundation.

In advancing legal arguments in support of the NPRM, HRSA attempts to isolate, separate and dissect injuries “*associated*” with vaccines and injuries resulting from “*administration*” of vaccines within the Vaccine Act. After thirty years of adjudicating and compensating claims arising out of the administration of a vaccine, HRSA has now concocted its own interpretation, specifically “that the better reading of the Vaccine Act is that the Table should only include injuries resulting from the antigen, not the manner in which the vaccine was administered.” NPRM at 8. There is nothing in the plain language of the Vaccine Act to support such an interpretation. HRSA is seeking to write a provision into the Vaccine Act that does not exist, and effectively amend the Act without Congressional involvement. Revision of the Vaccine Act cloaked in proposed rulemaking is not within the purview of HRSA and cannot stand.

Finally, HRSA cites several questionable policy considerations central to the NPRM. HRSA incorrectly states that SIRVA claims are “depleting the pool of funds available to those injured by vaccine antigens.” NPRM at 22.<sup>4</sup> This statement is simply untrue. A review of the annual balance of the Vaccine Trust Fund<sup>5</sup> demonstrates that on-Table SIRVA claims filed since March 2017<sup>6</sup> have not, in fact, depleted the Trust Fund. Rather, the Trust Fund has continued to grow in recent years:

January 2016	\$3,638,161,199.30
January 2017	\$3,706,480,302.43
January 2018	\$3,751,709,506.68
January 2019	\$3,853,407,321.34
January 2020	\$4,013,972,370.19

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<sup>4</sup> See also NPRM at 19 (removal of SIRVA from the Table will “save limited compensation funds under the National Vaccine Injury Compensation Program”); NPRM at 9 (SIRVA claims are “draining the Trust fund.”).

<sup>5</sup> See <https://www.treasurydirect.gov/govt/reports/tfmp/vaccomp/vaccomp.htm>

<sup>6</sup> SIRVA was added to the Vaccine Injury Table in March 2017. Since that time, hundreds of SIRVA claims have been adjudicated successfully.

Even considering the compensation paid to petitioners suffering SIRVA, the Vaccine Trust Fund remains healthy and viable. HRSA next projects a decrease in the occurrence of SIRVA if the injury is removed from the Table because “it will better incentivize those administering vaccines to use proper injection technique.” NPRM at 19. Such an argument disparages the work of medical professionals, is pure conjecture and has no evidentiary support. Finally, HRSA speculates that “the proposed rule will also limit the ability of those opposed to vaccinations to misleadingly suggest that vaccines are less safe than they truly are.” NPRM at 19-20. To upend legal procedures based on sound medical research in order to pacify those opposed to vaccinations is illogical and inappropriate. The Vaccine Act charged HHS with educating the public on the NVICP. 42 U.S.C. 300aa-10(c). An appropriate and more effective way to approach those opposed to vaccination is through transparency and education, not dissection and concealment of vaccine adverse events.

HRSA refers to SIRVA claims as “dubious” and “frivolous” in an attempt to discredit valid and painful vaccine injuries. NPRM at 9. These adjectives provide insight into HRSA’s true motivations of the NPRM, which are not supported by the overall work of the NVICP. The overwhelming majority of petitioners who suffered SIRVA since 2010 have been successfully compensated.<sup>7</sup> In many instances, an award of compensation requires the Secretary of Health and Human Services (HHS), through counsel at the Department of Justice, to negotiate or proffer an adequate amount of compensation. All awards of compensation must be approved by the Office of Special Masters (OSM). Certainly, HRSA, HHS, and OSM have not been in the business of compensating hundreds, if not thousands, of “dubious” and “frivolous” claims over the past decade. HRSA’s position in the NPRM is further belied by the fact that it was HRSA specifically who proposed that SIRVA be **added** to the Vaccine Injury Table in 2017 after years of deliberating the supporting science and medical literature.

Finally, to the extent HRSA argues or implies that removing SIRVA from the Vaccine Injury Table will unburden the NVICP from adjudicating SIRVA injuries, this is simply untrue. Removing SIRVA from the Vaccine Injury Table will not prevent individuals with SIRVA injuries from pursuing off-table claims within the NVICP, which is what petitioners regularly did before SIRVA was added to the Vaccine Injury Table by HRSA in March 2017. Undoubtedly, off-Table claims that require medical expert involvement and more extensive litigation result in increased fees and costs. Furthermore, removing SIRVA cases from the Vaccine Injury Table will directly and negatively impact the Office of Special Masters as it will inevitably force the Special Masters to address and ultimately issue entitlement decisions for every SIRVA case, further burdening OSM and preventing them from conducting entitlement hearings in complex cases. In turn, the NPRM would undoubtedly preclude vaccine claims involving injured children from having a timely entitlement hearing to adjudicate their claims. The NPRM creates more problems than it attempts to solve, and even a forthright and comprehensive deliberation of the NPRM with individuals regularly involved in the NVICP would highlight that the NPRM will only irreversibly damage the NVICP.

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<sup>7</sup> See Office of Special Master’s Annual Report of September 30, 2019 (indicating that 1,329 SIRVA cases had been compensated in the collective amount of \$130,982,662.78 through the Special Processing Unit (SPU) of the OSM since its inception in July 2014), [https://74ad3064-12c4-40b7-9de7-4ea2f5193c9f.filesusr.com/ugd/384904\\_50ce4a5f04824623bb144128ca99a4a6.pptx?dn=Recent%20Developments%20in%20the%20Vaccine%20Progr](https://74ad3064-12c4-40b7-9de7-4ea2f5193c9f.filesusr.com/ugd/384904_50ce4a5f04824623bb144128ca99a4a6.pptx?dn=Recent%20Developments%20in%20the%20Vaccine%20Progr)

Thank you for your consideration,

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