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January 12, 2021

Tamara Overby, Acting Director  
Division of Injury Compensation Programs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane, Room 08N146B  
Rockville, MD 20857

**Re: HHS Docket No. HRSA– 2020–0002**

Dear Acting Director Overby:

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) are pleased to submit our comments to the Health Resources and Services Administration (HRSA) on the National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table Notice of Proposed Rulemaking (NPRM), published in the Federal Register on July 20, 2020 (85 FR 43794). APhA and NASPA strongly oppose HRSA’s proposal to remove shoulder injury related to vaccine administration (SIRVA), vasovagal syncope, and Item XVII from the Vaccine Injury Table. Our organizations are very concerned that such a move would put a significant damper on vaccine research and development, as well as the willingness of healthcare providers, including pharmacists, to administer vaccines without the liability protections provided by the National Vaccine Injury Compensation Program (VICP). Now is not the time to remove items from the Vaccine Injury Table, when we are in the midst of a major pandemic which is dependent upon an effective vaccination program to obtain vital community protection. **In order to encourage and support COVID-19 and other vaccine R&D and robust vaccination programs, as well as monitoring and reporting of vaccine adverse events, it is imperative that HRSA maintain SIRVA, vasovagal syncope, and Item XVII on the Vaccine Injury Table.**

Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use, advancing patient care, and protecting public health. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA’s membership is comprised of state pharmacy associations and

over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

As HRSA recognizes, immunizations are vital to public health, and COVID-19 vaccination is critical to our nation's ability to win the war against this deadly disease. As important members of the immunization neighborhood, pharmacists, pharmacy technicians, and student pharmacists are playing a critical role in the nationwide COVID-19 vaccination effort. HRSA, in sync with other national and state efforts, needs to encourage – not discourage -- the engagement of manufacturers and healthcare providers in increasing the availability and administration of COVID-19 and other vaccines to protect the public health.

For the reasons cited below, APhA and NASPA urge HRSA to maintain SIRVA, vasovagal syncope, and Item XVII on the Vaccine Injury Table:

In 2017, HRSA conducted extensive literature reviews, consultations, and public deliberations that resulted in the decision to add SIRVA and vasovagal syncope to the Vaccine Injury Table. Despite HRSA's contentions in the NPRM, the scientific record supporting the addition of SIRVA and syncope to the Table has not materially changed. HRSA's proposal represents an abrupt about-face in policy without sufficient scientific and medical evidence to support the proposed changes. A move that would potentially threaten our nation's vaccine R&D, vaccine administration, and adverse event reporting efforts, particularly in the midst of the COVID-19 pandemic, is bad public policy and should not be implemented.

#### SIRVA Should be Maintained on the Vaccine Injury Table

The scientific evidence does not support the NPRM's claim that "There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself."<sup>1</sup> Rather, Atanasoff et. al.'s 2010 *Vaccine* article that reviewed SIRVA for HRSA concludes that "a vaccine *antigen* injected into synovial tissue structures underlying the deltoid muscle" has "the potential for inducing a prolonged immune-mediated inflammatory reaction (emphasis added)."<sup>2</sup> In 2019, Atanasoff and Hesse published a peer-reviewed article that confirmed the 2010 study, finding that only 36.1% of the SIRVA cases they reviewed reported 'injection too high' on the arm.<sup>3</sup> As injection technique was not concluded as the primary cause of injury, HRSA's proposal to remove SIRVA from the Vaccine Injury Table is not warranted.

The May 18, 2020 Advisory Commission on Childhood Vaccines (ACCV) meeting and November 9, 2020 public hearing on this NPRM featured numerous members of the public testifying about the serious SIRVA injuries they suffered as a result of receiving routine immunizations. Many of these patients reported constant pain, restricted movement, difficulty with daily activities of living, depression, rounds of physical therapy, surgery, and other negative

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<sup>1</sup> See 85 FR 43794, p. 43795.

<sup>2</sup> Atanasoff, S., Ryan, T., Lightfoot, R., & Johann-Liang, R. (2010), *Vaccine*, 28(51), 8049-8052, p. 8052.

<sup>3</sup> Hesse EM, Atanasoff S, Hibbs BF (2020), *Vaccine*, 38(5), 1076-1083.

sequelae. SIRVA and its serious consequences are exactly the type of injuries that Congress intended to be compensable under the VICP.

### Vasovagal Syncope Should be Maintained on the Vaccine Injury Table

APhA and NASPA strongly disagree with HRSA’s conclusion in the NPRM that vasovagal syncope (fainting) is not a “vaccine-related injury” and therefore should not be included on the Vaccine Injury Table. Rather, as HRSA notes in the NPRM, the IOM found “sufficient mechanistic evidence supporting the conclusion that syncope is directly related to vaccine administration.”<sup>4</sup> The Centers for Disease Control and Prevention (CDC) has received reports of people fainting after nearly *all* vaccines.<sup>5</sup> In addition, the agency reports that fainting after vaccinations is common in adolescents.<sup>6</sup> While steps can be taken to reduce the risk of syncope from vaccination, APhA and NASPA believe that syncope is clearly a “vaccine-related injury” that should be maintained on the Vaccine Injury Table, not removed as HRSA proposes.

### HRSA’s Proposal will Not Incentivize Proper Injection Technique

APhA and NASPA strongly disagree with HRSA’s contention that removing SIRVA and vasovagal syncope from the Vaccine Injury Table will “better incentivize those who administer vaccines to use proper injection technique.”<sup>7</sup> More than 376,000 pharmacists have been trained to administer vaccines for patients of all ages.<sup>8</sup> They are educated regarding appropriate vaccination technique in accordance with CDC guidelines, and the management of potential adverse events such as syncope. Appropriate vaccination technique is reinforced through continuing education programming and other sources of information.

In addition to their technical training, through the pharmacist’s Oath, pharmacists “promise to devote [themselves] to a lifetime of service to others through the profession of pharmacy.”<sup>9</sup> In fulfilling this vow, pharmacists pledge to “apply [their] knowledge, experience, and skills to the best of [their] ability to assure optimal outcomes for [their] patients.”<sup>10</sup> Pharmacists take their responsibility to properly administer vaccines very seriously, and removing SIRVA and syncope from the Vaccine Injury Table as HRSA has proposed removes attention for all vaccinators regarding the monitoring and management of SIRVA and syncope.

### Increased Workload is Not a Valid Reason to Remove Legitimate Injuries from the Vaccine Injury Table

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<sup>4</sup> See 85 FR 43794, p. 43800.

<sup>5</sup> CDC, Fainting (Syncope) after Vaccination, available at <https://www.cdc.gov/vaccinesafety/concerns/fainting.html>

<sup>6</sup> Id.

<sup>7</sup> See 85 FR 43794, p. 43804.

<sup>8</sup> APhA 2019 Annual Report.

<sup>9</sup> APhA Oath of a Pharmacist, available at <https://www.pharmacist.com/oath-pharmacist>

<sup>10</sup> Id.

One of the reasons HRSA and the Department of Justice cite in support of the proposal to remove SIRVA from the Vaccine Injury Table is the increased workload and backlog caused by the review of SIRVA claims.<sup>11</sup> However, the solution to addressing increased workload is not to remove the legitimate vaccine injury of SIRVA from the Table, but rather for HRSA to support a request for an increase in the number of Special Masters and the amount of funding and staffing resources for the VICP, as recommended by the ACCV.<sup>12</sup>

### HRSA Should Heed the ACCV's Advice and Maintain SIRVA and Syncope on the Vaccine Injury Table

After hearing the May 18, 2020 testimony and deliberating, the ACCV voted unanimously to oppose the implementation of HRSA's proposed changes to the Vaccine Injury Table.<sup>13</sup> Most importantly, the ACCV found that "although rare, SIRVA and vasovagal syncope are injuries that can be caused by vaccination, and thus, should be eligible for compensation from the VICP."<sup>14</sup> Furthermore, citing the ACCV's "Guiding Principles for Recommending Changes to the Vaccine Injury Table," the ACCV notes that "where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, *the change should, whenever possible, be made to the benefit of petitioners*" (emphasis added).<sup>15</sup> APhA and NASPA urge HRSA to follow the ACCV's advice and that of the many commenters and vaccine injury victims and maintain SIRVA and vasovagal syncope on the Vaccine Injury Table.

### Conclusion

APhA and NASPA strongly disagree with HRSA's contention in the NPRM that SIRVA and vasovagal syncope "are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault."<sup>16</sup> By seeking to remove SIRVA, vasovagal syncope, and Item XVII from the Vaccine Injury Table, HRSA's NPRM threatens patient access to existing and new vaccines, such as the COVID-19 vaccine. During a pandemic is especially not the right time to make changes to the Vaccine Injury Table, when we are working as a nation to optimize the development, manufacturing, monitoring, and administration of vital vaccines.

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<sup>11</sup> See chart of SIRVA Claims Filed in FY 2010 – FY 2020 in 85 FR 43794, p. 43798, and Letter from Assistant Attorney General Hunt to HHS (5/15/20), available at

<https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/hunt-letter-sirva.pdf>

<sup>12</sup> See ACCV Recommendation - May 20, 2020 - (Implementation of the Draft National Vaccine Injury Compensation Program NPRM), p. 3, available at

<https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/reports/accv-recommendation-may-2020.pdf>

<sup>13</sup> Id. on p. 2.

<sup>14</sup> Id.

<sup>15</sup> Id. on p. 3.

<sup>16</sup> See 85 FR 43794, p. 43798.

In order to preserve widespread access to vaccines and provide compensation to victims of vaccine injuries, APhA and NASPA urge HRSA to maintain SIRVA, vasovagal syncope, and Item XVII on the Vaccine Injury Table. In addition, we encourage HRSA to continue to work with pharmacy and other healthcare professional associations to educate vaccine administrators regarding proper immunization technique, management of adverse events, and reporting of any adverse reactions to VAERS.

Thank you for your consideration of our organizations' views on this important topic. If you have any questions or require additional information, please contact Karin Bolte, JD, APhA's Director of Health Policy, at [kbolte@aphanet.org](mailto:kbolte@aphanet.org) or by phone at (301) 648-0673.

Sincerely,



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