



May 14, 2020

Tamara Overby, Acting Director
Division of Injury Compensation Programs
Healthcare Systems Bureau
Health Resources and Services Administration
Executive Secretary, Advisory Commission on Childhood Vaccines
5600 Fishers Lane, Room 08N146B
Rockville, MD 20857

Dear Acting Director Overby:

On behalf of the American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA), we are writing to oppose the Health Resources and Services Administration's (HRSA) proposal to remove vasovagal syncope and shoulder injuries related to vaccine administration (SIRVA) from the Vaccine Injury Table. Our organizations are very concerned that such a move will put a significant damper on vaccine research and development, as well as the willingness of health providers, including pharmacists, to administer vaccines without the liability protections provided by the National Vaccine Injury Compensation Program (NVICP). As our nation is preparing for COVID-19 vaccination and reducing restrictions on the provision of routine immunizations, now is not the time to make the proposed changes. **In order to encourage COVID-19 and other vaccine R&D and robust vaccine administration programs, it is imperative that the Advisory Commission on Childhood Vaccines (ACCV) vote to maintain vasovagal syncope and SIRVA on the Vaccine Injury Table.**

Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 60,000 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 stand ready to assist in the nationwide vaccination effort. HRSA, in sync with other national and state efforts, needs to encourage – not

discourage -- the engagement of manufacturers and providers in increasing the availability of vaccines to protect the public health.

Process Concerns

In 2017, HRSA conducted extensive literature reviews, consultations, and public deliberations that resulted in the decision to add vasovagal syncope and SIRVA to the Vaccine Injury Table. Unfortunately, with less than three years of experience with the inclusion of vasovagal syncope and SIRVA on the Vaccine Injury Table, HRSA's proposal to now remove them represents an abrupt about-face in policy without the opportunity for similar public input and discussion. A move that would potentially threaten our nation's vaccine R&D and vaccine administration efforts, particularly in the midst of the COVID-19 pandemic, is bad public policy and should not be implemented. At the very least, such an ill-advised change should not be undertaken without the benefit of appropriate public deliberations.

Medical Concerns

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." 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)."¹ 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.² As injection technique was not concluded as the primary cause of injury, additional review is warranted before any policy changes are made.

Conclusion

By seeking to remove vasovagal syncope and SIRVA from the Vaccine Injury Table, HRSA's NPRM threatens patient access to COVID-19 and other critical vaccinations. Rather than encouraging vaccination, this proposal could severely impact our nation's ability to research, develop, and widely administer life-saving vaccines due to concerns about potential liability. Pharmacists are trained immunizers, and collectively have the ability to vaccinate and provide care to patients across the country. In order to preserve widespread access to vaccines, APhA and NASPA urge ACCV to vote to maintain vasovagal syncope and SIRVA on the Vaccine Injury Table. In addition, we encourage HRSA to continue to work with pharmacy and other healthcare professional associations to educate vaccine providers regarding proper immunization technique and reporting of any adverse reactions to VAERS.

¹ Atanasoff, S., Ryan, T., Lightfoot, R., & Johann-Liang, R. (2010), *Vaccine*, 28(51), 8049-8052, p. 8052.

² Hesse EM, Atanasoff S, Hibbs BF (2020), *Vaccine*, 38(5), 1076-1083.

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 Director, Health Policy, at kbolte@aphanet.org or by phone at (301) 648-0673.

Sincerely,

/S/

Thomas E. Menighan, BSPHarm, MBA,
ScD (Hon), FAPhA
Executive Vice President and CEO
American Pharmacists Association (APhA)

/S/

Rebecca Snead, RPh CAE, FAPhA
Executive Vice President and CEO
National Alliance of State
Pharmacy Associations (NASPA)