

## **Advisory Commission on Childhood Vaccines (ACCV)**

### **Teleconference and Adobe Connect**

**May 18, 2020**

#### **Members Present**

H. Cody Meissner, MD, Chair (2020)

John Howie, JD, Vice Chair

Karen Kain (2022)

Barbara Pahud, MD (2022)

#### **Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)**

Tamara Overby, Acting Director, DICP

Andrea Herzog, Principal Staff Liaison, ACCV

#### **Discussion of the Draft National Vaccine Injury Compensation Program (VICP) Notice of Proposed Rulemaking (NPRM)**

Dr. Meissner called the meeting to order and announced that HHS submitted proposed changes to the Vaccine Injury Table (Table) in a draft NPRM. The National Childhood Vaccine Injury Act of 1986, as amended, (Vaccine Act) among other provisions, requires the Secretary of HHS (Secretary) to provide the ACCV a copy of the proposed revision and request the commission's recommendations and comments. Per the Vaccine Act, the Secretary must provide the ACCV at least 90 days to submit their recommendations.

Dr. Meissner stated that the purpose of the meeting was for the ACCV to hear public comments about and discuss the draft VICP NPRM. The ACCV will hear 17 public comments from speakers who contacted HHS with their requests prior the meeting today. These comments will be heard in the order they were received. After these comments, there will also be a public comment period for people who wish to comment but did not contact HHS in advance. The ACCV also received written public comments. These written comments will not be read aloud at this meeting; however, they are posted on the ACCV website for the public to view. [Written comments were received from the following.

- 1) Joseph Hunt, Assistant Attorney General, Department of Justice
- 2) John Murphy, Biotechnology Innovation Organization
- 3) Keri Steckler
- 4) Mike Milmoie, Law Office of Leah Durant
- 5) Thomas Menighan, BSPHarm, MBA, ScD (Hon), FAPhA, American Pharmacists Association and Rebecca Snead, RPh CAE, FAPhA, National Alliance of State Pharmacy Association (Joint Letter)
- 6) Steven C. Anderson, FASAE, CAE, IOM, National Association of Chain Drug Stores
- 7) Theresa Wrangham, National Vaccine Information Center
- 8) Christina Ciampolillo, Vaccine Injured Petitioners Bar Association
- 9) Uma Srikumaran, MD, MBA, MPH, Johns Hopkins School of Medicine

10) Uma Srikumaran MD, MBA, MPH, Johns Hopkins School of Medicine, Response to the AAOS position statement: Rotator Cuff Tendinopathy, Adhesive Capsulitis, and Arthritis Can Not be Caused by Vaccine Administration]

After the public comments, the ACCV will discuss the Table revisions proposed in the draft VICP NPRM and may decide to vote and make recommendations to the Secretary. Each public comment will be limited to ten minutes.

Dr. Meissner invited the first presenter to comment.

## **Public Comments**

### **1. Ms. Theresa Wrangham, Executive Director, National Vaccine Information Center (NVIC)**

Ms. Wrangham began by saying that she was not making a presentation; rather she is making a public comment, as the short notice of the option to present at this meeting did not allow the NVIC enough time to prepare a presentation. She stated the NVIC's mission is to prevent vaccine injury death through education and to defend the informed consent ethic.

Early on, the NVIC worked with Congress, by invitation, to develop the National Childhood Vaccine Injury Compensation Act of 1986, which created the VICP. The NVIC's cofounders came together through their shared experience of inoculating their children with the diphtheria, pertussis and tetanus (DPT) vaccine in the 1980s then seeing a regression of health in their children following the airing of the Emmy award winning documentary – DPT: Vaccine Roulette. This documentary aired similar stories of regression of health and vaccine reactions in children, interviewed public health and health care professionals on both sides of the debate, and noted that serious vaccine injuries such as brain damage from the DPT vaccine were documented in the medical literature for 40 years.

Ms. Wrangham noted that NVIC's cofounders and organizational mission were not anti-vaccine, but instead NVIC's cofounders advocated for inclusion of:

- informed consent protections to require the disclosure of disease and vaccine risks prior to vaccination,
- an ongoing vaccine safety research mandate to assure Americans that the safest vaccines were in use,
- changes in health post vaccination were recorded in the permanent medical record,
- the creation of a no-fault, generous and expeditious vaccine injury compensation program with the right of the injured to sue vaccine makers if unhappy with VICP outcomes;
- the creation of a centralized vaccine adverse event reporting system; and
- that federal agencies would make the public widely aware of the VICP and VAERS .

Ms. Wrangham noted that DHHS has failed to support the informed consent ethic, due to the informed consent protections being largely gutted from the 1986 Act in 1995. She referenced a study by the Altarum group, commissioned by the VICP, which found that parents and guardians want more information on vaccine safety and that even knowing the risks, they would still likely chose to vaccinate their children, while doctors continued to have an agenda of not

disclosing vaccine risks out of fear of vaccine refusal – similar to the FDA statement in the 1982 DPT: Vaccine Roulette documentary.

Continuing, Ms. Wrangham also noted that since the passage of the 1986 Act, DHHS has systematically narrowed the scope of the vaccine injury table and VICP process, such that it no longer meets the spirit and intent of the law, to expeditiously compensate vaccine-injured individuals. Additionally, Ms. Wrangham stated that HHS had also failed to widely inform the public about VAERS and the VICP, which results in underreporting of vaccine reactions and the ability to identify safety signals, as well as limiting vaccine injury compensation. In addition, an Institute of Medicine (IOM) report on adverse events following vaccination stated that there is a lack of quality science to permit identification of causality, which prevents the Table and VICP from keeping pace with new information about vaccine injury and death. This finding from the IOM makes HHS's positions on the safety of vaccines inaccurate. Ms. Wrangham expressed the opinion that the HHS has never attempted to implement the intent of the Vaccine Act, nor acted to eliminate research deficits as highlighted in IOM reports.

Finally, Ms. Wrangham cited this draft VICP NPRM only the latest example of DHHS's attempts to move further away from the original intent and spirit of the 1986 Act to compensate those harmed by vaccines. She stated that during her over 15 years of monitoring of the Commission that this current attempt to narrow the vaccine injury table without a presentation of evidence by HHS to the ACCV was unprecedented. Ms. Wrangham thanked the chair for the opportunity to provide comment and stated that NVIC submitted additional comments on its position on this draft VICP NPRM in writing to the ACCV.

## **2. Mr. Mike Milmoie, JD, Law Office of Leah Durant**

Mr. Milmoie began his comments by introducing himself. He was a Department of Justice (DOJ) attorney, representing the government in VICP claims for 30 years. Because of his work with the DOJ and now as a petitioners' attorney, he is personally invested in the outcomes in the VICP. Mr. Milmoie noted that HHS chose not to send a representative to the meeting who could explain the rationale behind HHS's recommendation to remove Shoulder Injury Related to Vaccine Administration (SIRVA) from the Table. He suggested that HHS is avoiding a discussion about the recommended Table revisions and that HHS should have a representative who can discuss the draft VICP NPRM present at this meeting.

Mr. Milmoie stated that an advisory council within the U.S. Court of Federal Claims (CFC), which hears vaccine compensation cases, added a discussion of this draft VICP NPRM to its April 2020 agenda. The advisory council includes members from HHS and the DOJ. At that meeting, a representative for HHS stated that neither agency, HHS or DOJ, would be commenting on the draft VICP NPRM, nor did either agency submit any information about the recommendation or agree to send a representative to discuss it in the future. Mr. Milmoie contacted the Advisory Committee for Immunization Practices (ACIP), the HHS National Vaccine Advisory Committee (NVAC), the National Foundation for Infectious Disease (NFID), and the Institute for Vaccine Safety at Johns Hopkins University. All four confirmed that HHS never consulted them about the proposed Table revisions in this draft VICP NPRM. Since that time, each of these organizations has made plans to review HHS's proposed Table revisions.

Mr. Milmoie referred to the HHS Final Rule, published in the Federal Register in January 19, 2017, that added SIRVA, syncope and Guillain-Barrè Syndrome to the Table. These revisions to the Table were predicated on a 2012 IOM report, "Adverse Effects of Vaccines:

Evidence and Causality’’. HHS spent five years deliberating and developing the Final Rule. The recommendation to add SIRVA and syncope to the Table was thoroughly vetted by nine work groups, included public comment periods, and was debated in open public meetings. The current proposal would negate the provision of the 2017 HHS Final Rule without the same or a comparable level of scrutiny.

Mr. Milmoie emphasized that, the current law requires HHS to solicit and consider the recommendations of the ACCV before making any changes to the Table and discussed the ACCV’s responsibility regarding revisions to the Table. First, there is an ethical obligation established in the ACCV’s Guiding Principles for Recommending Changes to the Vaccine Injury Table (Guiding Principles), drafted in 2006, requiring the Commission to review all information related to proposals to change the Table. Second, the ACCV’s Guiding Principles indicate that expertise from HHS should be available in guiding the development of the proposals. Third, changes to the Table should, whenever possible, be made for the benefit of the petitioners. Finally, ACCV members should tend toward retaining injuries already on the Table. Mr. Milmoie said that, although the HHS stated in the draft VICP NPRM that the Department is not legally bound by the ACCV’s Guiding Principles, the ACCV is so bound. Further, since none of the conditions from the ACCV’s Guiding Principles is satisfied, Mr. Milmoie strongly urged the ACCV to vote against the proposed Table revisions in the draft VICP NPRM unanimously.

The letter from Mr. Hunt, submitted after the close of business on Friday before Monday morning’s meeting, states that DOJ supports the removal of SIRVA from the Table because SIRVA cases have increased the workload of DOJ staff. However, Mr. Milmoie stated that this is not a valid reason or scientific reason to remove SIRVA from the Table. Mr. Milmoie expressed frustration and concern that neither Mr. Hunt nor anyone from HHS was present to defend the draft VICP NPRM.

SIRVA is not just a needle injury. As Dr. Srikumaran states in his letter, SIRVA is an injury caused by a needle and a vaccine antigen. Even an article written by Dr. Meissner makes this very important point.

### **3. Mr. Kevin Nicholson, Vice President, National Association of Chain Drug Stores (NACDS)**

Mr. Nicholson explained that the NACDS represents 40,000 pharmacies in traditional drug stores, supermarkets, and mass merchants employing nearly three million individuals, including 155,000 pharmacists who fill over three billion prescriptions a year. He recommended that that ACCV oppose the HHS proposal to remove syncope and SIRVA from the Table, especially considering the current health care crisis of the COVID-19 pandemic.

Mr. Nicholson discussed the relationship between the pharmacy industry and improvements in public health due to increased vaccination. The adult vaccination rate in the US is below recommended levels. Retail availability of vaccines could improve the adult vaccination rate. Patients visit their pharmacies ten times more than they visit their health care providers. All fifty states have approved the administration of most vaccines by trained pharmacy personnel. Studies have indicated that in addition to vaccinations administered in health care providers’ offices, pharmacies administer an additional 6.2 million flu vaccinations and 3.5 million pneumococcal vaccinations. In 2018, the Center for Disease Control and Prevention (CDC) reported that pharmacies administer almost one-third of all flu vaccinations. A

2019 study revealed that the community pharmacy vaccination program increased the pertussis vaccination rate to 74%.

Additional studies focused on cost, showing that the average direct cost paid for vaccination in pharmacies was 11% to 26% lower than in other locations. For example, analysis showed that the cost of pneumococcal vaccinations was about \$66 in a physician's office and \$72 in other medical settings versus about \$55 in a pharmacy. Finally, a 2018 study showed that community-based vaccine resources could prevent 16.5 million influenza cases and 146,000 deaths at a savings of \$4 billion to \$12 billion.

Accepting the draft VICP NPRM could result in enormous added costs to vaccine providers for liability claims, which could discourage pharmacies from providing vaccination services. Additionally, the suggestion that pharmacy personnel do not have an incentive to administer vaccines properly because of their VICP protections is not valid. Vaccine administrators in pharmacies are highly trained professionals who provide quality care to patients.

#### **4. Ms. Amy Pisani, Executive Director, Vaccinate Your Family**

Ms. Pisani commented that former First Lady Rosalyn Carter and Former First Lady of Arkansas Betty Bumpers founded Vaccinate Your Family in 1991, originally called Every Child by Two. The mission expanded in 2015 from advocating for vaccinating toddlers to now advocating for vaccinations in individuals of all ages, reflected in a new name, Vaccinate Your Family. The liability protections provided by the Vaccine Act encouraged vaccine manufacturers to develop effective vaccines for meningitis, hepatitis A and B, rotavirus, pneumonia and the human papillomavirus. The Vaccine act also created the VICP, a compassionate alternative to the civil tort system.

Ms. Pisani discussed the draft VICP NPRM recommendation to remove SIRVA and syncope from the Table, noting that some medical experts and the IOM, report evidence that those adverse reactions are caused by the administration of the vaccine, the injection process, and not the vaccine itself. However, she added, more research on the causes; underlying issues and recommendations to reduce instances of SIRVA, from the CDC and independent researchers is forthcoming. Therefore, Ms. Pisani stated, Vaccinate Your Family recommends that the ACCV defer making a decision on the draft VICP NPRM recommendations until the publication of this research and all the current research is available to review.

#### **5. Naveed Natanzi, DO, The Regenerative Sport and Spine Institute**

Dr. Natanzi began his presentation by stating that his goal for participating in this meeting is to share information and education on SIRVA. Dr. Natanzi has reviewed hundreds of SIRVA cases during the last two years and had treated SIRVA patients. He said that current research supports the theory that the vaccine antigen, injected erroneously in or around the synovial structure can cause a serious inflammatory reaction which results in long-term disability that can last months and even years. The key research question is whether the needle, the antigen or both cause the inflammatory reaction. Dr. Natanzi explained that many non-vaccine materials (e.g., steroids, lidocaine, platelet-rich plasma, which is often inflammatory, stem cells) injected into the glenohumeral joint or the subacromial space, do not appear to result in SIRVA-like

injury when using the same size needle at the same injection site as a vaccine. The only variable is the medication, which may indicate that the vaccine antigen is causally related to SIRVA.

Dr. Natanzi addressed the effect of injecting various sites, including those that have a synovial structure such as the knee and wrist, versus the standard injection into subcutaneous tissue. The vaccine antigen injections into the synovial sites result in a significantly higher immune (inflammatory) reaction than injections in the usual subcutaneous sites. This suggests that the vaccine antigen caused the reaction, not the needle. The effects of non-antigen injections usually clear in a short time, unlike the long-lasting negative effects of SIRVA.

Dr. Natanzi concluded with the comment that every medical procedure, including vaccinations, carries with it a chance of an adverse reaction, albeit adverse reactions to vaccination are rare. He stated his belief that SIRVA is a rare reaction to a vaccine antigen injected into the wrong place. SIRVA is rare. More training and education of all health care providers who administer vaccines will further reduce incidence of SIRVA.

## **6. Mr. John Murphy, Deputy General Counsel and Vice President, Biotechnology Innovation Organization (BIO)**

Mr. Murphy explained that BIO is the largest international biotechnology trade association in the world, representing a broad range of organizations that are involved in biotechnology innovation, including vaccine development. He noted that vaccines are clearly important in world health, evidenced by the data in a 2014 CDC report that stated vaccines were estimated to have prevented 21 million hospitalizations and 732,00 child deaths in a 20-year period. BIO believes that the VICP process is far more efficient at adjudicating vaccine claims promptly and fairly, than traditional litigation.

Mr. Murphy stated that BIO does not support the proposed Table changes in the draft VICP NPRM. The rationale put forth by HHS in 2017 to add the two conditions has not substantially changed. Convincing legal arguments from several past VICP cases have cited broad coverage parameters, including vaccine administration errors. Finally, concerning the arguments in the draft VICP NPRM related to the financial claims data, BIO contends that the public and the ACCV need much more information before they can make an informed decision.

## **7. Marko Bodor, MD, Interventional Spine and Sports Medicine Private Practice**

Dr. Bodor commented that he was the first to describe vaccination-related shoulder injury in 2007, subsequently named SIRVA. He added that SIRVA is uncommon, affecting perhaps 1 in 100,000 individuals who receive vaccinations. He cited three requirements for SIRVA to occur. First, the needle is inserted too high on the arm, specifically in the upper part of the deltoid muscle and goes too deep, penetrating into the bursa, rotator cuff or bone. Second, the injection must include vaccine antigen. Third, there likely is a genetic or previous environmental exposure component.

Dr. Bodor stated that recently he has been able to alleviate chronic pain associated with SIRVA in five patients by identifying the location of the vaccine deposition, most commonly the teres minor or infraspinatus tendons, followed by an ultrasound-guided ultrasonic aspiration and debridement. He has written up his results in paper which is undergoing peer review. He took exception to the idea that the SIRVA and syncope claims are needlessly depleting VICP funds.

Dr. Bodor reiterated that SIRVA is a response to vaccine antigen and erroneous injection, and that SIRVA is a real and sometimes debilitating injury.

### **Ramon Rodriguez, MD, JD, Vaccine Injured Petitioners Bar Association**

Dr. Rodriguez stated he is a licensed primary care physician in family medicine and an attorney who represents petitioners in the VICP. He is a Board Member (Treasurer) of the Vaccine Injured Petitioners Bar Association, established in 2010, and consisting of attorneys who represent petitioners in VICP cases. He stated that the association strongly opposes the recommendations contained in the draft VICP NPRM. First, he noted that the draft VICP NPRM discusses the concern that the VICP funding is being needlessly depleted because of SIRVA claims. Dr. Rodriguez contested and stated that the fund is healthy and its balance has been increasing for the past four years. Second, the draft VICP NPRM suggests that removing SIRVA from the Table would reduce processing time for more complicated cases. Dr. Rodriguez refuted that contention, noting that the SIRVA cases are resolved in an expedited way in a special processing unit, to reduce their effect on the workload and the time it takes to process other types of VICP cases. Third, Dr. Rodriguez said removing SIRVA from the Table would require processing these claims in the traditional way involving litigation, which would increase cost and delay resolution. In closing, Dr. Rodriguez pointed to the principle that the decision should favor the vaccine claim petitioner. He stated that the ACCV should not support this draft VICP NPRM.

### **8. Ms. Amy Jordan**

Ms. Jordan explained that she acquired SIRVA and began to experience serious discomfort after a flu shot. After six months, magnetic resonance imaging (MRI) confirmed bone damage and her treatment included antibiotics, two surgical procedures and several rounds of physical therapy. The treatment regimen interfered with her normal activities. In the downtime during her recovery, she developed a survey that focused on SIRVA and recruited 246 volunteers. The data gathered in the survey was mainly anecdotal, although some statistics were developed. The findings from this survey show 36% of respondents who received a flu vaccination from a pharmacy developed SIRVA, and more than 50% of respondents who received the vaccine in a physician's office or similar health care setting developed SIRVA. The predominant symptom of SIRVA for the respondents was shoulder pain or other muscle discomfort. An overwhelming number described an indifference or disbelief in their symptoms from their healthcare providers.

The survey identified a long list of activities affected by having SIRVA – driving, dressing, grooming, simple daily activities, changing body position (sitting, reaching, lifting, etc.), and especially sleep-related situations (rolling over, finding a comfortable position, managing covers). Daily activities that require use of arms are often very difficult. Finally, 71% of respondents mentioned mental health issues, such as depression, equally distributed in a range from mild to severe.

Ms. Jordan recommended the ACCV oppose the draft VICP NPRM and recommend that SIRVA remain on the Table.

### **9. Mr. David Smith**

Mr. Smith explained that his wife is a cancer patient on a drug regimen that suppresses her immune system. As a precaution, her oncologist requires family members to have an annual influenza vaccination. After one of these vaccinations, Mr. Smith experienced the symptoms of SIRVA, specifically shoulder pain.

He described his disability related to the pain and the course of his medical treatment, which initially was for bursitis and rotator cuff tear and involved the possibility of surgery. After more than six months of disabling pain, he underwent the surgery. During the surgery the surgeon discovered that a previous MRI returned a false positive showing damage to the rotator cuff. In fact, the rotator cuff was fine, but there was adhesive capsulitis (frozen shoulder) with significant inflammation, which the surgeon treated. Following the surgery there was little improvement in the level of his discomfort, which negatively affected all aspects of his life including his ability to sleep, take care of his wife, travel for medical and leisure purposes and socialize with family and friends. He went to 27 physical therapy sessions, which required significant travel. Then at the end of the treatment, the surgeon certified that Mr. Smith had a permanent 10% loss of motion in his shoulder. Mr. Smith stated that, after 19 months, there had been sufficient improvement and he could lie on his back without serious pain and has some pain free days. As evidenced by his own experience, SIRVA can have a severe negative effect on the quality of life for the patient.

Mr. Smith added that he has a Master's degree in Biomedical Engineering and Mathematics, and worked in research and quality assurance in a scientific setting. He stated that after reviewing the draft VICP NPRM he is disappointed that the quality of the document was not as good as expected. He felt that the analysis of the cause of the injury was incomplete because the draft VICP NPRM addressed the mechanical injury caused by a misdirected needle, but did not mention the possibilities related to the vaccine antigen injected in the shoulder. Mr. Smith stated that to argue that SIRVA is not a vaccine related injury is disingenuous.

#### **10. Uma Srikumaran, MD, Associate Professor of Orthopedic Surgery, Johns Hopkins Shoulder and Sports Medicine**

Dr. Srikumaran began his presentation by stating that he is only speaking on behalf of himself and his remarks only represent his views. He also strongly supports vaccination efforts and believes SIRVA is a rare event. Dr. Srikumaran, an orthopedic surgeon, has treated a number of patients with shoulder dysfunction after vaccination and based on his own clinical experience and his review of the scientific literature, he believed that vaccine antigen injected into or near the bursa or synovium is the cause of the injury known as SIRVA. He said the placement of the needle alone is not the cause of SIRVA, and that vaccine antigen causes bursitis and synovitis. Shoulder practitioners inject various medications or blood products into the bursa or joint via needles and their patients do not experience SIRVA-like injuries.

Addressing a position statement from the American Academy of Orthopedic Surgeons (AAOS) stating that vaccine administration is unlikely to cause SIRVA, Dr. Srikumaran observed that this statement does not reflect the opinions of the majority of the AAOS but is more accurately a description of opinions of the authors. In addition, this position statement from the AAOS was not peer-reviewed and the authors failed to identify several papers, which are prominent in the scientific literature about SIRVA. The literature cited in the position statement

does not meet the medical and scientific standards relied on to make valid conclusions on SIRVA causation.

Finally, Dr. Srikumaran, contested arguments made in the draft VICP NPRM to remove SIRVA from the Table and suggested that there would be significant negative impacts on public health resulting from removing SIRVA from the Table. He stated that regardless of the skill of the vaccine administrator, a vaccination could result in an adverse reaction. It is a little outrageous to suggest that vaccine administrators may be less careful because of the liability protections offered through the VICP. Clinicians are first motivated to do no harm. It is not practical or cost effective to adopt procedures that would guarantee that the needle would not penetrate the bursa or synovium because that would require ultrasound imaging for every vaccination. There are not enough nurses, pharmacists and physicians trained in this procedure to maintain necessary levels of vaccination and the cost would be prohibitive.

Removal of SIRVA and syncope from the Table would significantly increase tort liability the cost of liability insurance for practitioners and vaccine manufacturers. In addition, vaccination costs would increase for patients. A result of these cost increases could be clinicians may be less likely to offer vaccines, there may be less research and development in vaccines and increased vaccine hesitancy among the public. In summary, Dr. Srikumaran maintained that it is clear to him that the vaccine antigen is required to develop SIRVA and removing the VICP protection could have a significant negative impact on healthcare.

#### **11. Ms. Charyl Wojtaszek**

Ms. Wojtaszek read from a prepared statement. She acquired SIRVA following a seasonal flu vaccine in 2016 at a CVS Pharmacy. Ms. Wojtaszek described the administration of this flu vaccine and the provider. Her vaccination was painful, her arm was sore and she experienced increasing shoulder pain in the weeks following the vaccine. Eventually the pain she experienced was so bad she lost use of her right arm. She consulted multiple medical professionals who determined that she had an 80% rotator cuff tear. She was sent for physical therapy, which did not sufficiently resolve the issue. Her medical provider told her she was not a candidate for surgical repair because of her age. In her case, surgery would likely make her condition worse.

Ms. Wojtaszek's disability continues in the form of an inability to raise her arms to a shelf, a medical prohibition on lifting anything weighing more than ten pounds, uncomfortable sleeping positions to avoid pain and the inability to work because of pain when typing or writing. She also cannot do routine housework or engage in leisure activities she used to enjoy.

Ms. Wojtaszek added that her healthcare providers doubting that her condition resulted from the flu vaccine added to frustration on top of her injury. To her shock, her providers had never heard of this type of vaccine injury.

Ms. Wojtaszek attempted to seek compensation from CVS for the poorly administered flu vaccine, the only attorney she could find that was willing to take her case required a \$10,000 retainer win or lose, saying that the fee was typical of most other liability lawyers. The retainer was more than she could afford. She emphasized the importance of the compensation provided by the VICP and urged the Commission to reject the HRSA recommendation to eliminate SIRVA from the Table.

#### **12. Mr. Scott Everhart**

Mr. Everhart began his presentation stating that he is a SIRVA petitioner and he is opposed to the draft VICP NPRM removing SIRVA from the Table. He described his experience with SIRVA acquired after a November 2017 tetanus vaccine required by his employer. He described the various tests and treatments that he experienced, including surgeries and 2½ years of physical therapy, most of which were and continue to be painful. He admitted he was beginning to doubt that he would ever be pain free. Prior to his 2017 tetanus vaccine, he was healthy, very active in outdoor sports, and a full-time sheriff's deputy in Colorado. SIRVA significantly and negatively affected his entire lifestyle and livelihood.

The shoulder pain that accompanied the inflammation after the tetanus shot was excruciating, worse than he had ever experienced. He now realizes how pain induces serious stress and affects physical and mental abilities, appetite, libido, damages relationships with family and others, and results in financial strain due to the inability to work. He stated that perhaps it is hard for people who have never dealt with SIRVA to understand the enormous impact it has on all aspects of a SIRVA patient's life.

Mr. Everhart's associates in the sheriff's department did not take his injury seriously. He described the loss of support and ridicule he endured as a result. After several years without enough improvement in his symptoms, Mr. Everhart said that he had to resign from the sheriff's department because he felt he could not reliably perform his law enforcement duties. Despite workmen's compensation, which did help, he experienced a significant reduction in total income, and had to move his family from the home they loved to a new more affordable neighborhood.

Mr. Everhart stated that even though a vaccination caused his injury, he is still a strong supporter of vaccines. He is opposed to removing SIRVA from the Table. He stated that the costs of treating SIRVA is much more than most people could afford on their own and the VICP has given him hope in his situation. Mr. Everhart added that he would prefer that the focus be on improving vaccine administration skills to reduce the incidence of SIRVA.

### **13. Ms. Mindy Lawson**

Ms. Lawson shared information about herself. She is 39-years-old, and has been a nurse since 2009. She has worked in several different settings, including cardiology, endocrinology and currently she is a clinical coordinator on a medical surgical floor. She received her regular annual flu vaccine in November 2016 from a nurse co-worker. Following her vaccination, she experienced shoulder pain so severe that she could not lift her arm. Her vaccine injury has severely affected her physical, mental and financial health.

Workmen's compensation denied Ms. Lawson's injury claim and after five months without improvement, she questioned her employer about her medical care. Following this conversation, Ms. Lawson's employer fired her.

Since September 2016, Ms. Lawson has had five rounds of physical therapy, five steroid injections, three surgeries, one recently, and spent thousands of dollars on her treatments. Over time, her shoulder discomfort has improved, but achy pain persists. In addition, she has had to make changes to her job duties and lifestyle to accommodate her injury and she will have to live with some level of shoulder pain for the rest of her life.

Ms. Lawson suffered financially paying for her treatments and insurance after losing her job so, she looked for an attorney to file an injury claim against her former employer. She had trouble finding an attorney to help her. Eventually, an attorney from out of town agreed to take

her case and informed her about SIRVA and the VICP. The VICP has allowed her to seek compensation for her injury without suing her provider. For her, this is a preferable option. She believes her former employer did not permit staff to give the seasonal flu vaccine to employees because of their knowledge of her pending vaccine injury legal case, instead they had an outside vendor provide vaccines to staff.

In conclusion, Ms. Lawson affirmed her support for SIRVA not to be removed from the Table. She also questioned whether other providers would stop administering flu vaccine and how difficult seeking legal recourse would be for SIRVA patients if protections for SIRVA were removed from the VICP.

#### **14. Mr. Mustafa Hersi, Vice President and General Counsel, National Community Pharmacists Association (NCPA)**

Mr. Hersi explained that the NCPA represents 21,000 community pharmacies across the country that provide access to health care, particularly medicines and vaccinations. The pharmacies employ 250,000 individuals who provide health care services to millions of patients every day. Many of these patients are in underserved areas. NCPA members are mainly small business owners who are among America's most accessible health care providers. Pharmacists can administer most available vaccines in all 50 states, playing a vital role in public health. The proposed changes in the draft VICP NPRM could significantly upset the availability of vaccines within the areas that these community pharmacies operate. The changes proposed in the draft VICP NPRM would expose these small pharmacies to tort liability, which would discourage them from providing vaccinations, thereby reducing the availability of vaccines to the public and in particular, people in underserved communities.

Two public commenters listed on the agenda, Ms. Janet Olch and Ms. Kerri Steckler, did not make public comments.

#### **Additional Public Comments**

##### **1. Mr. Jesse Hecht**

Jesse Hecht introduced himself and stated he is an individual unaffiliated with any organization. He commented that the present inclusion of SIRVA and vasovagal syncope on the Table is contrary to the text of the Vaccine Act and to the purpose of the statute, declared by congressional report at the time of the passage of the Vaccine Act, and subsequently supported by the Supreme Court. The definition of vaccine according to recognized references is a substance (antigen) introduced in the individual to induce or increase resistance to a disease. The statute refers to the vaccine, not vaccination, and the law recognizes a vaccine injury as an illness, condition, injury, or death associated with one or more of the vaccines set forth in the Table.

Mr. Hecht referred to House Report 99-908 of 1986, published prior to passage of the Vaccine Act, which discussed the purposes of the law, and years later, a Supreme Court case, *Bruesewitz v. Wyeth* (562 U.S. 223, 2011), which was intended to stabilize the vaccine market and facilitate compensation for those injured by a vaccine. Mr. Hecht submitted that it was not the intention of Congress that the Act cover malpractice by

physicians or other health care professionals administering the vaccine. The civil court tort process should handle vaccine administration errors.

## **2. Mr. Michael Milmo**

Mr. Michael Milmo spoke again and took exception to the suggestion that the Vaccine Act does not include protection for vaccine administrators and stated there are 17 places in the Vaccine Act that reference the term “administration of a vaccine”. He stated that the Vaccine Act has a subrogation clause which permits the Federal government to seek recompense if the VICP awards compensation, but later determines that a vaccine company or administrator was negligent. Specifically, he read an excerpt from the HHS Health Resources and Services (HRSA) website that describes protection for vaccine administrators.

Mr. Milmo argued that the idea that processing SIRVA claims will slow down the compensation process for children’s claims is false, because HHS policy places children’s cases at the head of the line. Additionally, a special processing unit designed to expedite resolution of SIRVA claims and reduce their burden on the Court processes SIRVA claims.

Finally, he observed that removing SIRVA from the Table would not prevent attorneys from pursuing claims in the VICP as causation in fact claims, which will likely increase the workload at the DOJ and the Court, rather than reduce it.

## **3. Ms. Theresa Wrangham**

Ms. Theresa Wrangham spoke again and commented that there was testimony and evidence presented from public comment at the beginning of the meeting that supported the that the vaccine antigen could be responsible for the SIRVA injury. She expressed deep concern at the lack of any presentation to the ACCV by HHS to justify ACCV recommending to the Secretary the removal of SIRVA and syncope from the vaccine injury table. Lastly, she felt a more complete discussion of the subject should be undertaken at a future ACCV meeting, which should include a presentation of evidence from HHS, and renewed NVIC’s long-standing request that when ACCV consider petitions to change the vaccine injury table that equal time given to members of the public to present additional evidence to the ACCV in addition to HHS presentations.

With no more public comments, Dr. Meissner ended the public comment period.

## **ACCV Comments/Recommendations on the Draft VICP NPRM**

Dr. Meissner invited a motion to discuss the draft VICP NPRM. Mr. Howie made a motion to that effect, Dr. Pahud seconded the motion, and the commission unanimously approved.

Mr. Howie made the first comment, noting that ACCV commissioners received this draft VICP NPRM in February, at that time commissioners were told it was privileged, confidential document that could not be discussed. It was not on the agenda for the March 6, 2020 meeting. However, during the meeting, a discussion did occur about the draft VICP NPRM despite the

fact it was not on the agenda. Mr. Howie stated that he has repeatedly asked through emails, phone calls and letters that HHS follow federal law and give the commission the opportunity to discuss the draft VICP NPRM and provide evidence to support the proposed changes, in order for the commissioners to make an informed decision.

Mr. Howie continued, stating that commissioners believed HHS would be present at the meeting. However, no one from HHS attended this meeting, which is indicative of how important this is to the department. Mr. Howie reiterated that to date, HHS has not provided the commissioners any evidence to evaluate the draft VICP NPRM. The ACCV must follow their Guiding Principles when considering changes to the Table. The Table should be scientifically and medically credible. When there is reliable scientific evidence to support a change, it should, whenever possible, be made to benefit the petitioner.

Mr. Howie continued, in 2012, the IOM studied evidence and concluded that SIRVA and syncope were caused by vaccination. A few years later, HHS extensively reviewed the evidence and agreed with IOM. HHS concurred that vaccination can result in SIRVA and syncope and recommended adding these injuries to the Table, which they were. Mr. Howie added that nothing has changed since 2017 except for the fact that a lot of SIRVA claims were filed. Mr. Howie noted that the Guiding Principles do not say that an abundance of claims and the associated increase in workload and expense justify removing an injury from the Table.

He noted that he was the only current ACCV commissioner ever to have filed a claim or litigated a claim for a vaccine injury. However, during the discussions about the proposal to remove SIRVA from the Table, no one asked him about the effect of such a decision on his clients. He would have welcomed that discussion.

Mr. Howie described the special processing unit, established to handle SIRVA and other table claims, more efficiently. Removing SIRVA as an injury from the Program would send SIRVA cases through a lengthier and more expensive tort process.

Mr. Howie stated that the draft VICP NPRM is a bad idea and HHS handled the process for consulting the ACCV about the Table changes badly.

Dr. Pahud asked for clarification of the role of the commission in addressing the issues created by the overwhelming number of SIRVA cases. She agrees SIRVA should remain on the Table. She noted that the evidence presented earlier in the meeting suggests that the injury is related to more than just the needle and the injection process, but to the antigen as well.

Dr. Pahud acknowledged that there is a large backlog of SIRVA claims, but understood there is sufficient money available in the Vaccine Injury Compensation Trust Fund to pay for additional personnel. However, accessing this funding will require an act of Congress. So what can the ACCV do to facilitate a solution to the increased workload? What should be the ACCV's next steps?

Asking procedural questions, Ms. Kain requested assurance that there was a quorum present, and for an explanation of the voting process. Ms. Overby confirmed a quorum. She also explained that the ACCV commissioners determine how to handle the draft VICP NPRM by means of a formal vote. Ms. Overby further explained the role of the commission is to make recommendations to the Secretary. The commission could make a recommendation stating whether the ACCV opposes or supports the draft VICP NPRM. She added that regarding the need for additional resources, the commission has, in the past, submitted recommendations to the Secretary about increasing funding, not only for HHS but also the DOJ and the Court. She confirmed that such additional funding for the VICP does require Congressional approval.

Ms. Kain expressed her disappointment that HHS sent no representative to the meeting to support the draft VICP NPRM, and that the introduction of the draft VICP NPRM came with little information or evidence, and no opportunity for discussion of the recommendations with agency personnel. She endorsed the principle that changes to the Table should be made to benefit the petitioners.

Dr. Meissner expressed his appreciation to all who participated in the public comment session during the meeting. Next, he made comments about the way the draft VICP NPRM was handled during the March 6, 2020, ACCV meeting. Explaining that shortly before the meeting, he received a call advising him that the ACCV had received clearance to discuss it.

Dr. Meissner admitted difficulty in making the decision about the draft VICP NPRM. Specifically, he expressed concern about the lack of scientific and medical evidence and the absence of participation in the meeting by the HHS. Dr. Meissner stated there is no question that the VICP is critical for those who are injured and for the success of the vaccination program in the country. Wide public acceptance of vaccines is important, despite the fact that there are unexpected and rare adverse reactions to vaccinations. The VICP should compensate legitimate vaccine injuries. It is also important to maintain some constraint on the claims, to ensure that they are, in fact, a vaccine injury. Anecdotally, he described receiving hundreds of letters describing SIRVA injuries, some of which are consistent with the science and some are not. He expressed concern about compensating claim under the category of SIRVA that are not, in fact, SIRVA. He also referred to the potential paradox of removing SIRVA and syncope from the Table, which could cause a decrease in vaccine acceptance, and leaving it on the Table, which could have the same result because anti-vaxers could use the large number of claims and high payout as a scare tactic to suggest that vaccines are dangerous.

Dr. Meissner said that he was not convinced that the initial decision to add SIRVA and syncope to the Table was justified based on the data he has seen. However, now that SIRVA and syncope are on the Table, he has concerns about removing them before developing a greater understanding of the injuries. His suggestion is to recommend HHS table the draft VICP NPRM until the publication of forthcoming research on these injuries.

Dr. Meissner added that, most of the SIRVA injuries are from seasonal flu vaccine and new technology to administer the flu vaccine, like the micro needle patch placed on the skin and oral vaccines, are in the research and development stage. These forms of vaccine administration could reduce incidences of SIRVA and syncope.

Mr. Howie referred to Dr. Meissner's concerns regarding possibly compensating illegitimate SIRVA claims. Mr. Howie explained that filing a Table case does not automatically make it compensable. Compensation still relies on a review by a VICP medical officer, a subsequent review by a DOJ attorney, the petitioner attorney's argument, and finally, a decision by a Special Master.

Mr. Howie added that guidance by the Federal government on the conduct of advisory committee meetings states, in a handbook available online, that the commission should not discuss subjects that are not on the agenda. Mr. Howie stated that he felt that the previous comments by Dr. Meissner regarding the March 6, 2020 ACCV meeting did not comply with that policy.

Dr. Meissner responded that his comments began with a concern about the HHS methods used to put this draft VICP NPRM forward. He also commented that 70% of all VICP claims are settled, suggesting that the HHS did not necessarily agree with the petitioners' claims, but reached some kind of agreement with the petitioners' attorneys. He reiterated that the ACCV

should therefore gather more information to understand the injury and to make it easier for the court to make a decision.

Mr. Howie made a motion that the ACCV, in accordance with the Guiding Principles, vote on whether to send a recommendation about the draft VICP NPRM to the Secretary. The motion was seconded by Ms. Kain and unanimously passed. However, both Drs. Meissner and Pahud advised that the commission must carefully word any recommendation to the Secretary. Ms. Overby explained that the wording of the recommendation to the Secretary could be developed after the vote, and subsequently approved.

There was a discussion among the commissioners about what the recommendation should be. Dr. Meissner began by confirming with the group that it sounded like there were three recommendation options for consideration, the ACCV could: (1) concur with the draft VICP NPRM, (2) oppose the draft VICP NPRM, or (3) recommend HHS table the draft VICP NPRM.

Next, Dr. Pahud summarized the opinions that she heard the commissioners express during the meeting. First, the ACCV would like HHS to come to a meeting and explain the process for adding SIRVA and syncope to the Table. Second, there are some articles that apparently are coming out soon that are going to shed more light on SIRVA, and the ACCV commissioners need to review this information before they can make an informed decision on whether to remove this injury from the Table. Finally, the commissioners are concerned about making sure that the VICP continues to cover SIRVA, and that SIRVA protections are not abused. Dr. Pahud suggested that recommending HHS table the draft VICP NPRM until HHS addresses the commissioner's concerns might be the best solution, but invited opinion from the group.

Mr. Howie expressed his concern that if the ACCV recommends tabling the draft VICP NPRM, the Secretary has given his 90-day deadline, and may proceed anyway without bothering to address the ACCV concerns. He recommends opposing the draft VICP NPRM now as it is written, and stating that the ACCV would be willing to reconsider the Table revisions later, if HHS wants to bring another proposal forward.

Ms. Kain stated her strong opposition to the draft VICP NPRM. She referenced the testimonies she had heard during the meeting from SIRVA patients, medical professionals, and other presenters who, in her opinion, made very strong cases to keep SIRVA on the Table. She noted that HHS had not provided any sufficient evidence to justify removing SIRVA from the Table.

After a brief discussion, the ACCV commissioners agreed to send a recommendation to the Secretary opposing the draft VICP NPRM with a letter explaining the specific reasons commissioners had for their decisions. The rationale for the opposition differed among the commissioners but the recommendation was the same. On a motion duly made by Dr. Meissner and seconded by Dr. Pahud, the ACCV unanimously voted to oppose the proposed changes to the Table. The ACCV further agreed to reiterate its previous recommendations that the Secretary support an increase in the number of special masters and an increase in the amount of staffing and funding resources for the VICP.

Ms. Overby confirmed that the ACCV support staff would draft the recommendation and letter and circulate them for review and editing from the commission. The goal would be to have the recommendation and letter signed by the ACCV Chair and Vice Chair and then delivered to the Secretary by the May 21, 2020. Finally, Mr. Howie made a motion to end the meeting.