

Advisory Commission on Childhood Vaccines (ACCV)
Adobe Connect Webinar and Telephone Conference meeting
December 6, 2018
108th Meeting

Members Present

Karlen E. (Beth) Luthy, D.N.P., Chair, ('19)
H. Cody Meissner, MD, Vice Chair, ('19)
Kathleen F. Gaffney, PhD, RN ('19)
Martha Toomey ('19)
Alexandra Stewart, J.D., ('19)
Martha Toomey ('19)
John Howie, J.D. ('19)

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

Narayan Nair, M.D., Acting Director, DICP
Andrea Herzog, Principal Staff Liaison, ACCV

Welcome and Report of the Chair, Beth Luthy, ACCV

Ms. Luthy called the meeting to order. After a roll call of the commission members present, Ms. Luthy invited public comment on the meeting agenda.

Public Comment on Agenda Items, Ms. Beth Luthy, Chair

The invitation to submit comments on agenda items was announced by the conference operator and there was one request to speak:

- (1) Theresa Wrangham, Executive Director, National Vaccine Information Center (NVIC). Ms. Wrangham noted the NVIC's interest in participating in ACCV work groups and other stakeholder engagement, an interest articulated during public comments at the last ACCV meeting in September 6, 2018. Ms. Wrangham stated that the draft minutes of the September 6, 2018 ACCV meeting did not reflect the Center's comments and NVIC's offer to participate in ACCV workgroups and other stakeholder engagement. Ms. Wrangham made additional comments regarding the review and revision of Vaccine Information Statements (VIS). She stated that the ACCV was interested in the history of the VIS. The NVIC was involved in drafting the segment of the law related to the VIS and would be interested in providing a consumer perspective. Finally, Ms. Wrangham noted an error in how her name was spelled in the draft September 6, 2018 ACCV meeting minutes.

There were no additional requests to speak.

Approval of September 2018 ACCV Meeting Minutes, Ms. Beth Luthy, Chair

Ms. Luthy invited comments and approval of the September 6, 2018 meeting minutes. Regarding procedure, Ms. Herzog noted that staff would review the audio recording of the September 6, 2018 meeting, specifically related to Ms. Wrangham’s remarks, and the minutes would be revised as appropriate, then the September 6, 2018 meeting minutes could be approved at the March 2019 ACCV meeting. Ms. Luthy confirmed that approval of the September 6, 2018 ACCV meeting minutes is deferred until the March 2019 ACCV meeting.

Report from the Division of Injury Compensation Programs, Dr. Narayan Nair, Director, DICP

Dr. Nair outlined the meeting agenda beginning with an update on the VICP, followed by a report from the Department of Justice, brief reports from ex officio members (Food and Drug Administration [FDA], Centers for Disease Control and Prevention [CDC], National Institutes of Health [NIH], and National Vaccine Program Office [NVPO]), and a report from the ACCV Work Group chair.

Dr. Nair reported that, as of November 30, 2018, the average number of petitions filed for the Fiscal Years 2009 through 2013 was 427. During FY 2018, 1,238 claims were filed and to date in FY 2019, 203 petitions were filed. Funding for HRSA administrative expenses was \$6.46 million in FY 2014 (633 claims), increased to \$7.5 million in FY 2015 (803 claims) and FY 2016 (1,120 claims), rose slightly higher to \$7.75 million in FY 2017 (1,243 claims), and increased again to \$9.2 million in FY 2018 (1,238 claims). Funding for FY 2019 will remain at \$9.2. The current backlog of claims is 694, all of these claims were filed in FY 2018 and 2019. The VICP has cleared the backlog of claims from 2017.

Petitioners’ were awarded almost \$200 million in FY 2018 and attorney’s fees and costs were nearly \$27 million. To date in FY 2019 those amounts are \$41 million and almost \$5 million respectively. Adjudications in FY 2018 totaled 719 (530 were compensable, 189 were dismissed). In FY 2019, to date, those numbers are 50 adjudications (41 compensable and 9 dismissed). The breakdown by adjudication category for the last three fiscal years:

Adjudication category	FY 2017	FY 2018	FY 2019 (to date)
Compensable	187	183	17
Court decision	47	63	0
Settlement	462	285	25
Not compensable	183	189	14
Total	879	720	56

Dr. Nair reported that the Vaccine Injury Compensation Trust Fund (Trust Fund) stands at approximately \$3.86 billion. Total revenues for FY 2018 were about \$378 million, which includes about \$304 million from excise taxes, \$4.7 million from prior year refunds, and \$69 million from interest income (18.32% on total income).

Regarding other activities, a Notice of Proposed Rulemaking published in the Federal Register on April 4, 2018, to add the category of vaccines recommended for pregnant women to

the Vaccine Injury Table. The comment period ended on October 1, 2018; 49 comments were received and are being reviewed. Responses to comments will be included in the Final Rule.

In the discussion following Dr. Nair's report, Ms. Luthy asked for clarification of the decrease in petitioners' awards from FY 2013 to FY 2014. Dr. Nair explained that awards are determined by the U.S. Court of Federal Claims (Court) and the decrease could have been related to a temporary delay in the claims review process or a decrease in the number of claims filed during that period. He added that the majority of claims filed relate to influenza vaccine injury in adults. Ms. Luthy also asked about whether there were educational efforts to reduce the number of claims for Shoulder Injury Related to Vaccine Administration (SIRVA) injuries. Dr. Nair responded that within the last year his office provided an update on SIRVA to the National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP) in public meetings and both groups were very interested in preventing SIRVA injuries and in educating the public. CDC has also added educational information to its web site with the catch phrase "Know the site, get it right." A commissioner commented that the American Academy of Pediatrics has a public outreach effort to inform the public.

Ms. Toomey asked about statistics on children versus adults in the queue on adjudicating claims. Dr. Nair explained that pediatric claims are filed and reviewed as soon as possible, so most of the claims pending review are for adults. He noted that he did not have data on the number of pediatric claims that are pending after they are assigned and reviewed at VICP. Asked about the "prior year refunds" to the Trust Fund, Dr. Nair explained that part of it is the result of a recipient who may not be able to receive the full amount of an award because of death or an authorized amount is made available for award, but for various reasons some of the funding is not required. An award amount is authorized, but is returned.

Report from the Department of Justice, Ms. Catharine Reeves, Deputy Director, Torts Branch

Ms. Reeves referenced the Department of Justice (DOJ) PowerPoint materials as part of her presentation for the three-month reporting period from August 16, 2018 through November 15, 2018. (DOJ PowerPoint (PP) at 2.) Ms. Reeves noted that during this reporting period, 375 petitions were filed. (DOJ PP at 2.) Ms. Reeves further noted that the vast majority of those 375 petitions were filed by adults. She stated that of the 375 petitions filed in this reporting period, 23 were filed on behalf of minors and 352 were filed by adults. (DOJ PP at 2.)

Ms. Reeves noted that 181 petitions were adjudicated during this reporting period. (DOJ PP at 3.) She commented that this number was slightly less than the number of petitions adjudicated during the preceding reporting period. One hundred forty-four cases were compensated during this reporting period, the majority of which were resolved by settlement. (DOJ PP at 3.) Thirty-seven cases were not compensated. (DOJ PP at 3.) Six petitions were voluntarily withdrawn. (DOJ PP at 4.)

Ms. Reeves discussed recently decided and pending cases in the U.S. Court of Appeals for the Federal Circuit (CAFC). (DOJ PP at 5, 6.) She noted that during the reporting period, the CAFC affirmed two cases that had been appealed by petitioners. (DOJ PP at 5.) She noted that nine cases remain pending before the CAFC, including Boatmon v. HHS. (DOJ PP at 6.) Ms. Reeves stated that the majority of those nine cases are appeals by petitioners of entitlement decisions.

Ms. Reeves next discussed appeals at the U.S. Court of Federal Claims (CFC). (DOJ PP

at 7-9.) She noted that four appeals by petitioners were decided by the CFC during this reporting period. (DOJ PP at 7.) She further noted that in all four cases, the CFC affirmed the special masters' decisions. (DOJ PP at 7.) Ms. Reeves stated that there are presently a number of cases pending before the CFC, the majority of which are appeals by petitioners of entitlement decisions. (DOJ PP at 8-9.)

Ms. Reeves noted that no oral arguments are scheduled at the CAFC or the CFC at this time. (DOJ PP at 10.)

Ms. Reeves provided a list of cases that were settled during the reporting period, which are listed in the DOJ PowerPoint presentation in order of the time they took to resolve. (DOJ PP at 11-19.) Ms. Reeves noted that most cases that were resolved by settlement during the reporting period took two years or less to resolve from the date of case filing. Ms. Reeves stated that the majority of settled cases during the reporting period alleged Guillain-Barré Syndrome (GBS) or Shoulder Injury Related to Vaccine Administration (SIRVA) injuries. Ms. Reeves further stated that most cases currently filed in the Vaccine Injury Compensation Program (Program) are filed by adults alleging SIRVA claims.

Following Ms. Reeves's presentation, she invited questions and comments. In response to a question concerning appeals, Ms. Reeves confirmed that no special master decisions were reversed on appeal during the reporting period. A follow-up question concerned whether, when a case is appealed, attorney's fees and costs related to the appeal are covered by the Program or if a petitioner must incur fees and costs related to the appeal. Ms. Reeves responded that the Vaccine Act prohibits a petitioner's attorney from billing a petitioner for fees and costs related to proceedings on a petition for vaccine compensation, including an appeal, and that those costs are generally compensated by the Program. She noted instances in which the appeal may raise the issue of the reasonable basis for the petition, in which case fees may be denied, but she noted that even in that circumstance, a petitioner would not be responsible for the costs of the appeal.

In response to a question concerning why no oral arguments are scheduled before the CAFC or CFC, Ms. Reeves explained that oral arguments have simply not been scheduled by the Courts and that some appeals are decided on the parties' written briefs without oral argument. Ms. Reeves further explained that oral argument is not required by the CFC. She noted that oral arguments are typically scheduled in appeals pending before the CAFC unless both parties waive said argument.

Finally, a question was raised related to the issue of whether a parent whose child's case is resolved by mediation can later serve as an ACCV member. Ms. Reeves explained that if mediation results in a settlement of the child's case—such that the case is not resolved via a court adjudication—then the child's parent cannot later serve as an ACCV member.

ACCV Work Group Update, Martha Toomey, Work Group Chair

Ms. Toomey announced that there was unfinished business at the end of the September 6, 2018 ACCV meeting, a deferred vote on a recommendation to the Secretary for increased funding to support additional special masters, and staffing resources for the HRSA and DOJ. She invited comment, if any, or a vote to approve the recommendation. Ms. Stewart recommended adding FY 2018 statistics to the supporting documents for the recommendation since there are final figures available now. Commission members expressed consensus that the recommendation should be updated to reflect FY 2018 information. Asked about whether the

letter would have to be reviewed after those revisions were made, Tamara Overby stated that the revised letter would be sent to the ACCV Chair and Co-Chair for final review and verification that the changes were made. Ms. Luthy made a motion to approve the recommendation with the date changes discussed.

On motion duly made and seconded, the Commission approved by verbal roll call vote the recommendation to increase funding to support additional special masters and staffing resources for the HRSA and the DOJ.

There was a question about strengthening the delivery of the recommendation, and there was agreement that the forwarding letter could request a response from the Secretary by the March ACCV meeting.

Ms. Toomey next provided a work group update, noting that at the last meeting, there was a productive effort to look at various options for getting feedback from petitioners on their experience with the program. The work group identified a number of options, one of which was developing an exit interview with petitioners at the conclusion of the claims process. The commission had a lengthy discussion about how such a survey could be designed and executed that would result in an assessment of the experience from the petitioner's earliest investigation of the availability of the Program, to filing the claim, through fulfilling the requirements for information and records and working with the court, to the outcome.

Ms. Stewart suggested that the first step might be to determine if the full commission believes a survey of VICP petitioners is necessary. If so, there should be an effort to identify other surveys conducted within the federal system that might provide guidance in the development of a VICP exit survey. There should also be a clear definition of the purpose of the survey and a description of the of the survey's audience. There was a suggestion that the basic purpose of the survey should be to determine how individuals who complete the court process found out about the compensation program.

There was a comment that during the work group discussion there was agreement that the ACCV might not have the resources to effectively conduct a major survey and that the support of the Secretary should be pursued. The work group decided that the ACCV should request that the Secretary support the development of the survey.

Moving on, Ms. Toomey discussed clarifying the qualifications for appointed as a member of the commission. She felt that an individual with a vaccine-related injury should be eligible as a specific ACCV member category, and not just as a member of the general public. Tamara Overby clarified that commission membership is defined in the legislation and that a particular change would require a legislative amendment, which would begin with a recommendation to the Secretary. Mr. Howie agreed that the pool of parents with vaccine-injured children, who would qualify for the "parent of a vaccine injured child," is limited and their responsibilities for caring for their children further exacerbates the challenge of enlisting their voluntary service. Expanding the definition to include vaccine-injured individuals should alleviate that situation.

There was agreement that the work group should draft a recommendation about adding and injured person category to the ACCV membership. Then, the work group will forward it to the full commission for review, revision and approval, before sending it on to the Secretary.

Ms. Stewart brought up another issue the work group discussed related to public education about vaccine safety, especially when an individual obtains a vaccination from a retail outlet, such as a pharmacy. In some of instances of vaccination at a retail outlet, the vaccine recipient may not receive a Vaccine Information Statement (VIS), which incidentally is a way to

learn about the VICP (the VICP is described in some VISs). If the individual asks about the vaccination, typically he or she is referred to the retail outlet's web site. Since it appears to be an inconsistent policy on the part of the retailer, it was suggested, that recommendation to the Secretary to establish a formal education program to encourage distribution of the VIS could be considered by the work group. There was a brief discussion on how the VISs are distributed under different circumstances and by different organizations.

Noting that the ACCV work group update exceeded the time allotted, Ms. Stewart summarized the discussion:

1. The work group approved the draft recommendation to the Secretary,
2. Approved the proposal to develop a letter of recommendation about the survey, and
3. Agreed on the proposal that the work group address the issue of expanding the eligibility for appointment to the commission to include a vaccine-injured individual.

Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC), Vaccine Activities, Dr. Michael McNeil, CDC

Dr. McNeil stated that he would discuss the presentations at the October 2018 meeting of the Advisory Committee on Immunization Practices (ACIP), followed by brief comments about selected recent publications. At the October ACIP meeting, there was a unanimous vote to approve the use of hepatitis A vaccine for routine vaccination of the homeless over the age of one, which would reduce both the hepatitis A infection risk in the vulnerable homeless population and the general risk of large-scale outbreaks.

Dr. McNeil discussed a report on administration of human papillomavirus (HPV) vaccine related to primary ovarian insufficiency (POI) and adolescent vaccination. The study was conducted at the Kaiser Northwest Vaccine Safety Datalink (VSD) site from August 2006 to December 2014. The study looked at 199,078 female vaccine recipients between the ages of 11-34 years old. Of the female patients enrolled at the VSD site during the period of the study, 58,871 were administered the quadrivalent HPV vaccine (4vHPV). Three additional vaccines were looked at as well, Tdap, MenACWY, and IIV. There was no evidence of increased risk of POI after any of these vaccinations. There was data in the report supporting expanding the age range for administration of 4vHPV vaccine through 45 years of age. Although HPV incidence decreases with age, new infections can occur; many adults have already been exposed to a 9-valent HPV type. Studies from six countries have revealed that 4vHPV vaccine effectiveness decreases with age. Because three U.S. models have not resulted in conclusive benefits of 9vHPV vaccine, ACIP is conducting an ongoing review.

Dr. McNeil told the ACCV that at the October 2018 ACIP meeting, there was a session on influenza vaccine effectiveness at which the PREVENT Network was discussed. The network collected data on acute respiratory or febrile illness in pregnant women 18 to 50 years of age that resulted in hospitalization and determined that, between 2010 and 2016, influenza vaccination had the potential to prevent 40% of those flu-associated admissions. During the ACIP flu session, Sanofi Pasteur presented data on safety and immunogenicity of quadrivalent Fluzone, comparing 0.5 ml (full dose) and the approved half dose (0.5 ml versus 0.25 ml). The Phase IV randomized, observer-blinded, multicenter study in 2,190 children (6-35 months of age) indicated that the safety of each dose was similar, but the efficacy of the larger dose may have been more immunogenic. There were other studies reported in the literature with similar

findings. A biologic license application (BLA) has been submitted to the FDA to permit use of the 0.5 ml dose in children as young as 6 months.

The ACIP also convened a pertussis vaccines work group to consider repeat Tdap vaccinations, which would result in a label change to remove the “single use” language. One of the manufacturers has submitted a BLA that would probably complete review by January 2019. The move would allow the use of Tdap for the decennial Td (tetanus and diphtheria) booster.

Dr. McNeil concluded his report. He displayed, but did not discuss, eight PowerPoints describing recent publications:

1. Suragh TA, Lamprianou S, MacDonald NE, Loharikar AR, Balakrishnan MR, Benes O, Hyde TB, McNeil MM. Cluster anxiety-related adverse events following immunization (AEFI): An assessment of reports detected in social media and those identified using an online search engine. *Vaccine* 36 (40). 2018 Sept.5949-5954
2. Grohskopf LA, Sokolow LZ, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2018–19 Influenza Season, *MMWR RecommRep* 2018 Aug 24; 67(3):1-20
3. Naleway AL, Mittendorf KF, Irving SA, Henninger ML, Crane B, Smith N, Daley MF, Gee J. Primary Ovarian Insufficiency and Adolescent Vaccination. *Pediatrics* 2018 Sept, 142(3) Epub2018 Aug 21
4. Walker WL, Hills SL, Miller ER, Fischer M, Rabe IB. Adverse events following vaccination with inactivated, Vero cell culture-derived Japanese encephalitis vaccine in the United States, 2012-2016 *Vaccine*. 2018 Jul 5;36(29):4369-4374.
5. Groom HC, et al (CDC co-authors: Natalie McCarthy and Lakshmi Sukumaran). Uptake and safety of Hepatitis B vaccination during pregnancy: A Vaccine Safety Datalink study. *Vaccine*. 2018 Oct;36(41):6111-6116.
6. Moro PL, Lewis P, and Cano M. Adverse events following purified chick embryo cell rabies vaccine in the Vaccine Adverse Event Reporting System (VAERS) in the United States, 2006–2016.October 2018.*Travel Medicine and Infectious Disease*
7. Fortner KB, Swamy GK, Broder KR, Jimenez-Truque N, Zhu Y, Moro PL, Liang J, Walter EB, Heine RP, Moody MA, Yoder S, Edwards KM. Reactogenicity and immunogenicity of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant and nonpregnant women. *Vaccine* 2018 Oct 8; 36(42):6354-60.
8. Suragh T et al. Safety of bivalent human papillomavirus vaccine in the U.S. Vaccine Adverse Event Reporting System (VAERS), 2009-2017.*Br J Clin Pharmacol*.2018 Sep 19. (Epub ahead of print)

There was no discussion or questions related to Dr. McNeil’s presentation.

Ms. Luthy announced that Dr. Meissner, who had lost his connection to the conference call, had returned, and she invited him to make a comment. He expressed appreciation for the opportunity to comment on an agenda item completed earlier in the meeting. He stated that, although the VIS is usually provided to patients receiving a vaccination, most do not read the VIS. Nonetheless, if an individual suffers an adverse reaction, his health care provider should inform him of the process to report the reaction to the FDA. Finally, he observed that the

suggestion that the provider spend time discussing potential adverse reactions with each person receiving a vaccination does not seem to be practical or economically viable, especially since adverse reactions are often very rare occurrences. Ms. Stewart agreed that a discussion of a very rare adverse event is not practical or legally required.

Asked about ways to more effectively inform the public about the program, Dr. Nair commented that, because of limited resources for such an effort, there has been a recent effort to revamp the web site to make it more accessible, and to take advantage of opportunities to make presentations at events that make participation possible without incurring travel expenses. Dr. Meissner suggested making a presentation to the Redbook Committee for the American Academy of Pediatrics.

Following Dr. Meissner's comments and the brief related discussion, Ms. Luthy moved the meeting along and invited a report from the ex officio member representing NIH.

Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities, Ms. Claire Schuster, NIAID, NIH

Ms. Schuster reported that NIH is conducting a Phase 1 trial to assess whether imiquimod cream enhances immune response in combination with H5N1 influenza vaccine, an inactivated vaccine developed with partial NIAID support and manufactured by Sanofi Pasteur. The immune-enhancing potential of imiquimod could help extend the supply of the H5N1 vaccine because it reduces the number of vaccine doses needed to achieve sufficient immune responses in recipients. This approach would allow more people to be vaccinated in pandemic outbreaks. This NIAID-funded study is enrolling 50 adults aged 18 to 45 years and is being conducted at the NIAID-supported Vaccine and Treatment Evaluation Unit (VTEU) at Baylor College of Medicine.

NIAID is also testing the safety and immune-stimulating properties of an experimental nasal influenza vaccine in children and adolescents at a VTEU site at Saint Louis University. The vaccine developed by FluGen, is made from a seasonal flu virus, H3N2. Half of the participants will receive the vaccine; the other half, an inactive saline solution delivered as a nasal spray. All participants will receive a licensed quadrivalent seasonal influenza vaccine three months later.

There are videos that describe the 1918 influenza pandemic posted on the NIAID Now blog. More information is available at <https://www.niaid.nih.gov/news-events/blog>.

Ms. Schuster also announced that, in 2017, NIAID and Children's National Health System launched a clinical research partnership to treat and prevent allergic, immunologic, and infectious diseases in children. The institutions offer joint training opportunities for physicians interested in caring for affected children. There was an inaugural symposium on September 17, 2018.

On November 13, 2018, NIAID hosted an informational webinar entitled "New NIAID Infectious Diseases Clinical Trial Funding Opportunities." The webinar provided an overview of the Leadership Group for an Infectious Diseases Clinical Research Consortium and a new VTEU funding opportunity.

Finally, Ms. Schuster announced that on November 13, 2018, CDC Director, Dr. Robert Redfield, delivered The Joseph Kinyoun Lecture at the NIH campus in Bethesda, MD. The lecture was entitled "Opioids: Epidemic of our Time and Impact on Infectious Diseases." The talk looked at the impact of unprecedented use of opioids on the management of infectious

diseases. Although overdose is the main cause of death in opioid users; viral hepatitis, bacterial endocarditis and HIV disproportionately affect opioid users. The webinar may be viewed at <https://videocast.nih.gov/> (search for: Kinyoun Lecture). Ms. Schuster concluded her report.

Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities, CDR Valerie Marshall, CBER, FDA

CDR Marshall reported that, in October 2018, following a review of efficacy and safety data, the FDA approved a supplement to the BLA for Afluria and Afluria quadrivalent influenza vaccine for Types A and B virus, to extend the pediatric age range to person 6 months of age to 59 months of age. The vaccine was previously indicated for persons 6 years of age and older.

CDR Marshall also reported that, in October 2018, following an extensive review of safety and efficacy data, the FDA approved a supplement to the BLA for human papillomavirus 9-valent vaccine, Gardasil, to extend the use of the vaccine to include women and men from 27 to 45 years of age. The vaccine was previously indicated for girls and women 9 through 26 years of age, and boys and men 9 through 26 years of age. According to the CDC, HPV vaccination prior to becoming infected with the HPV virus types covered by the vaccine has the potential of preventing more than 90% of cancers, or more than 31,000 cases every year.

Update from the National Vaccine Program Office, (NVPO), Ms. Ann Aikin, NVPO

Ms. Aikin reported that the last National Vaccine Advisory Committee meeting focused broadly on vaccine innovation and included panel presentations on three different vaccine technologies. There was also a panel presentation on Cytomegalovirus vaccines that are being developed in the pipeline, a presentation on the new shingles vaccine, Shingrix, and another session on the unmet needs projects that NVPO recently funded. Finally, the meeting concluded with a series of presentations highlighting opportunities to prevent HPV-related cancers, agency and liaison updates, and public comments. The next meeting will be a virtual meeting on February 5, 2019.

Ms. Aikin described action in the regional HHS offices to implement the National Adult Implementation Plan (NAIP) that was published in 2016. To spark action on the plan, in 2018, NVPO worked with HHS Regional Offices to hold six meetings across the country that discussed adult immunization topics like financing, quality improvement, and communications strategies. Four meetings are also planned for 2019 at the remaining four regions. Lessons learned during the first year of the NAIP initiative included:

1. Despite operating within resource-constrained environments, stakeholders across the country are eager to improve adult immunization rates through collaboration and coordination.
2. Inter-regional knowledge sharing helped stakeholders in other regions enhance their initiatives.
3. There was value in encouraging remote participation, especially for last minute travel changes and for areas with geographical boundaries.
4. Meeting participants reported increased visibility of NVPO and the NAIP.

We were able to engage new and existing partners from a variety of sectors. This allowed us to maximize and leverage opportunities and work already being conducted by stakeholders.

5. Regional offices are a powerful tool for Office of the Assistant Secretary for Health and should be an integral part of our work

Ms. Aikin concluded her report. Ms. Luthy invited public comments.

Public Comment

Ms. Wrangham, Executive Director, National Vaccine Information Center, commented on the discussion about SIRVA, which was previously added to the Vaccine Injury Table. She noted there was a comment that SIRVA is less a vaccine injury than a vaccine administration error, which is related to education for providers and the ACCV may have a need to revisit that conversation as the ACCV discusses membership. Concerning the issue of recruitment of commissioners, she wanted to remind the commission that the reason there was no slot for a vaccine-injured adult was that originally the program focused on childhood injuries. Ms. Wrangham suggested that there could be consideration of expanding the number of commissioners rather than changing the eligibility requirements of an existing member slot. Ms. Wrangham thanked the ACCV work group for considering some of the NVIC concerns that are also concerns of other stakeholders. Finally, she noted that gaps in vaccine safety science, identified by the Institute of Medicine report, might present obstacles for petitioners when they try to enlist medical experts to support their petitions to benefit from the safety net that the VICP was supposed to provide. Ms. Wrangham added that using the Trust Fund as a potential resource for closing the science knowledge gap should not be considered since it was developed to help the vaccine injured. Finally, she stated that more public awareness was important and perhaps a presentation by the Banyan Group that was made to NVAC should be considered by the ACCV. She added that Ms. Toomey has indicated that looking into social media as a powerful force for increasing public awareness, would be appropriate.

There were no other requests to make comments, and no recommendations for future agenda items. Ms. Luthy announced that there were potential new commission members being reviewed and some may be available by the time of the next meeting. The tentative date for the next meeting is March 7, 2019.

Adjournment

There being no further business, on motion duly made and seconded, the Commission unanimously approved adjournment.