Advisory Commission on Childhood Vaccines (ACCV)

5600 Fishers Lane, Room 5W07, Rockville, MD 20857

Teleconference and Adobe Connect

June 6, 2019

Members Present

Karlen E. (Beth) Luthy, D.N.P., A.R.P.N., ('19), Chair
Cody Meissner, MD, ('20), Co-Chair
Kathleen F. Gaffney, PhD, RN ('20)
John Howie, J.D., ('20)
Martha Toomey ('19)
Dino S. Sangiamo, 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., Director, DICP
Andrea Herzog, Principal Staff Liaison, ACCV

Welcome and Report of the Chair, Beth Luthy, ACCV

Ms. Luthy called the meeting to order, welcomed the commission members, DICP staff, ex officio members, and guests on the teleconference call. She noted that a quorum of ACCV members, required for a vote, was not present, but she added that sufficient members were expected. She deferred agenda items requiring a vote until a quorum was present.

Public Comment on Agenda Items, Ms. Beth Luthy

The conference operator announced the request for comments on agenda items and there were not any comments from the public.

Approval of March 2019 ACCV Minutes, Ms. Beth Luthy

Ms. Luthy suggested that approval of the minutes be deferred until 1:00 p.m. or until a quorum could be constituted. The present ACCV members agreed by consensus to delay approval of the minutes.

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

Dr. Nair outlined the meeting agenda, which included HRSA National Vaccine Injury Compensation Program (VICP) updates, a report from the Department of Justice, brief reports from ex officio members representing the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the National Vaccine Program Office (NVPO), and a report from the ACCV Work Group.

Dr. Nair reported the number of petitions filed in the VICP from Fiscal Year (FY) 2009 to date in FY 2019. During FYs 2009 through 2013, the average number of petitions filed was 427. There were significant increases in claims filed in FY 2014 (633), FY 2015 (803) and FY 2016 (1,120). FYs 2017 and 2018 had filing numbers similar to FY 2016, and FY 2019 is on track to

have a similar number of claims. So far, in FY 2019, 808 claims have been filed. Funding for HRSA to administer the program was $6.45 million in FY 2014 and increased to $7.5 million for FY 2015 through FY 2017. The funding increased in FY 2019 to $9.2 million.

During the same period (FY 2015 – present) claims filed with medical records to review increased significantly, resulting in a backlog of VICP cases awaiting medical review. There are currently 775 claims in the backlog, divided about evenly between claims filed in FY 2018 and FY 2019 (no claims filed in FY 2017 or prior years are in the backlog).

In FY 2018, petitioners' awards totaled about $200 million and attorney's fees and costs were about $27 million. To date, for FY 2019, those amounts are $144 million and $17 million respectively.

Adjudication Categories	2017	2018	2019
Concession	183	192	116
Court decision	26	29	19
Settlement	487	319	190
Non-compensable	185	189	78
Total	881	729	403

*October 1, 2018 to June 3, 2019

Dr. Nair gave a brief update on the Vaccine Injury Compensation Trust Fund (Trust Fund). The balance of the Trust Fund, as of April 30, 2019, is more than 3.8 billion. The Trust Fund pays for the administrative costs of the program, petitioners' awards, and attorneys' fees and costs. In the first 6 months of FY 2019, about $169 million was received, about $47 million from interest on the Trust Fund's balance, and over $122 million from excise tax.

Regarding significant program activities, on April 4, 2018, the Notice of Proposed Rulemaking (NPRM) to add the category of vaccines recommended for pregnant women to the Vaccine Injury Table was published in the *Federal Register*. The public comment period ended on October 1, 2018. Fifty-one comments were received and are being reviewed, and responses to the comments will be included in the Final Rule.

Additional information about the ACCV meeting is available on the VICP web site: http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.

During the discussion following Dr. Nair's presentation, there was a question about whether the substantial amount of money in the Trust Fund could be used for purposes other than those related to compensating vaccine injuries and administering the VICP. Dr. Nair commented that the statute restricts the use of the Trust Fund to the purposes discussed earlier – paying petitioners' awards, attorney's fees and costs, and administrative funding. Any change would require enactment of new legislation.

Mr. Howie asked about actions implemented to address the backlog. Dr. Nair responded that HRSA medical staff are continuing to process claims as expeditiously as possible and are continually seeking ways to reduce the backlog. Other action, such as increasing staff, has not been practical considering budget limitations. He observed that the Trust Fund balance has been increasing during the last several years (that is, income has been increasing at a slightly greater rate than outlays). Dr. Nair added the rate of increase to the backlog has been declining.

Dr. Nair announced that he will be retiring and that this is the last ACCV meeting that he would be leading. Dr. Nair expressed his appreciation to the commissioners for their participation and contributions.

Approval of March 2019 Minutes, Ms. Beth Luthy, Chair

Ms. Luthy noted a change in the agenda, moving Ms. Aikin's report of NVPO activities earlier to accommodate a scheduling conflict for Ms. Aikin. Ms. Luthy announced that Ms.

Kathleen Gaffney and Dr. Cody Meissner had joined the meeting, and now the ACCV has a quorum. She stated that the issues requiring votes should be addressed.

Dr. Meissner commented that, it appeared from the meeting materials, the terms of everyone on the Commission would expire in 2019. Ms. Herzog stated that there was a typographical error and that the terms of John Howie and Kathleen Gaffney would not expire until 2020.

Ms. Luthy invited approval of the March 2019 meeting minutes and, on motion by Dr. Meissner, seconded by Ms. Toomey, the minutes were unanimously approved.

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

Ms. Aikin reported that several years ago the NVPO awarded Kaiser Foundation Hospitals $338,425 for a project that focused on "adversomics", a term first introduced in 2009 referring to the study of vaccine adverse reactions using immunogenomics and systems biology approaches. It aimed to identify inherited, immunologic, and clinical factors that may predict the occurrence of febrile seizures in children after measles vaccination, as well as some issues associated with respiratory infections and some immunological conditions. The Principal Investigator for the project is Nicola Klein.

Principal Investigator Steven Black, at Cincinnati Children's Hospital Medical Center, was awarded $250,000 for a project that focused on maternal immunization safety. His objective was to validate the Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) maternal and neonatal outcome definitions to standardize the evaluation of the safety of vaccines.

The Rockefeller University received a grant of $161,575 to support Principal Investigator Jean-Laurent Casanova's precision medicine research analyzing the genetic determinants of the immune response following yellow fever vaccination among individuals who experience serious adverse events.

She briefly discussed the June 2019 National Vaccine Advisory Committee (NVAC) meeting and comments regarding an update of the 2016 report on antimicrobial resistance and an update on the 2015 report on vaccine confidence, which focused on children.

The NVAC will establish a working group to expand on the latter report to include adults. Ms. Aikin noted that the next NVAC meeting is scheduled for September 17-18.

Nomination for ACCV Chair and Vice Chair

There was a brief discussion about taking advantage of the quorum present to nominate the succeeding ACCV chair and vice chair. The commission agreed by consensus to allow individual members who would be willing to take on the responsibilities of chair and vice chair to volunteer for the positions. Dr. Meissner and Mr. Howie agreed to serve as chair and vice chair respectively, and those nominations were affirmed by consensus. A formal vote confirmed the nominations unanimously.

Report from the Department of Justice, 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 February 16, 2019 through May 15, 2019. (DOJ PowerPoint (PP) at 2.) Ms. Reeves stated that during this reporting period, 287 petitions were filed. (DOJ PP at 2.) Ms. Reeves further noted that the vast majority of those 287 petitions were filed by adults. She stated that of the 287 petitions filed in this reporting period, nine (3%) were filed on behalf of minors and 278 (97%) were filed by adults. (DOJ PP at 2.) Ms. Reeves commented that approximately 120 fewer petitions were filed during this reporting period than in the previous reporting period.

Ms. Reeves noted that 191 petitions were adjudicated during this reporting period. (DOJ PP at 3.) She commented that approximately 38 more petitions had been adjudicated during this reporting period than in the preceding reporting period. One hundred forty-four cases were compensated during this reporting period, which is approximately 20 more cases than in the previous reporting period. (DOJ PP at 3.) Of the 144 compensated cases, 83 cases were not conceded by the government, which is approximately the same number as those cases compensated, but not conceded, by the government in the previous reporting period. Forty-seven cases were not compensated, which is approximately 19 more cases than in the preceding reporting period. (DOJ PP at 3.) None of the compensated cases were Omnibus Autism Proceeding (OAP) cases. Five 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 three appeals by petitioners (two entitlement decisions and one attorneys' fees and costs decision) and affirmed one appeal by respondent (attorneys' fees and costs decision). (DOJ PP at 5.) She noted that nine cases remain pending before the CAFC, all of which were filed by petitioners. (DOJ PP at 6.)

Ms. Reeves next discussed appeals at the U.S. Court of Federal Claims (CFC). (DOJ PP at 7-9.) She noted that four appeals 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' entitlement decisions. (DOJ PP at 7.) Ms. Reeves stated that there are presently 14 cases pending before the CFC, all but one of which were filed by petitioners. (DOJ PP at 8-9.) Ms.

Reeves noted that the majority of these cases involve appeals of entitlement decisions.

Ms. Reeves noted that two oral arguments are scheduled at the CAFC and the CFC at this time. (DOJ PP at 10.) She stated that Thomas G. Ward, Deputy Assistant Attorney General for the U.S. Department of Justice, Civil Division, will argue Boatmon v. HHS in the CAFC on July 9, 2019. She also stated that the CFC has scheduled oral argument in Zumwalt v. HHS for June 17, 2019.

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 11-18.) Ms. Reeves stated that more than half of the settled cases during the reporting period

alleged Shoulder Injury Related to Vaccine Administration (SIRVA) injuries.

Following Ms. Reeves's presentation, she invited questions and comments. Mr. Sangiamo inquired about the vaccines at issue and the injuries alleged in the cases appealing entitlement decisions that were decided by the CAFC and the CFC during the reporting period. (DOJ PP at 5, 7.) Ms. Reeves stated that in McCollum, the petitioner alleged that the influenza (flu) vaccine caused him to develop narcolepsy. In Miles, the petitioner alleged that the flu vaccine significantly aggravated his son's pre-existing nephrotic syndrome. In Heddens, the petitioner alleged that the human papillomavirus (HPV) vaccine caused her to develop multiple sclerosis (MS). In L.M., the petitioner alleged that the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine, and other childhood vaccines, caused her daughter to suffer a significant aggravation of her underlying genetic disorder. In Maciel, the petitioner alleged that the HPV vaccine caused him to develop or significantly aggravated his pre-existing MS. In Tenneson, the petitioner alleged that he developed SIRVA, most likely, Ms. Reeves commented, as a result of a flu vaccination. Ms. Reeves noted that Tenneson was an unsuccessful appeal contesting a special master's fact finding.

Dr. Meissner referred Ms. Reeves to her presentation's second slide setting forth the number of claims filed on behalf of minors as compared to the number of claims filed by adults during the reporting period (DOJ PP at 2), and inquired as to how she defines "minor." Ms. Reeves responded that anyone under the age of 18 at the time of case filing is considered to be a minor. Dr. Meissner noted that fewer than five percent of the claims filed during the reporting period were brought on behalf of minors, and commented that this appeared to be a reversal of the initial intent of the Vaccine Injury Compensation Program (Program). Mr. Sangiamo explained that if a vaccine is recommended for routine use in children by the Centers for Disease Control and Prevention, vaccine injury claims related to its administration are encompassed by the Program, irrespective of whether the vaccine was administered to an adult.

Ms. Toomey inquired as to whether minors develop SIRVA. Dr. Meissner commented that vaccines are more typically administered into children's thighs rather than the deltoid muscle. He further stated that the bursa is smaller in a child than an adult, such that it is not as likely for the needle administering the vaccine to penetrate a child's joint. He also stated that SIRVA may follow repeat vaccine exposure through which memory cells may be recruited and exaggerate one's immune response. Ms. Reeves stated that she is aware of only one SIRVA claim that has been filed on behalf of a minor in the Program, and her recollection was that the minor was an adolescent at the time of vaccine administration.

Mr. Sangiamo inquired as to whether SIRVA claims are more quickly evaluated than other claims in the Program. Mr. Howie responded that, in his experience, SIRVA claims are more straightforward and are easier to evaluate. Ms. Reeves responded that before a claim can be evaluated, all of the documentation required to be submitted together with the petition under the Vaccine Act must be filed, something which is not always done at the time of case filing.

Mr. Sangiamo inquired as to when, after a case is filed, DOJ becomes involved. Ms. Reeves responded that even if HHS has not yet reviewed a case, some Special Masters are requiring DOJ attorneys to review the petitioner's medical records and to file a status report identifying any critical missing records based on that attorney's review.

Mr. Sangiamo inquired as to whether better compliance by petitioners' bar with the Act's filing requirements would help alleviate the current case backlog. Dr. Nair explained that, although the filing of medical records in a case triggers HHS's review, there likely would still be a case backlog.

Dr. Meissner inquired as to whether recent public education and awareness efforts have helped reduce the rate of SIRVA claims. Dr. Nair explained that that is unclear at this point in time, as claims can be filed in the Program up to three years after the first sign or symptom of the injury manifests. He also commented that although outreach efforts produce awareness about the need to prevent SIRVA, they also increase awareness about the Program and the potential to pursue a SIRVA claim.

Update on the Immunization Safety Office (ISO) Vaccine Activities, CDC, Dr. Michael McNeil

Dr. McNeil reported on recent and upcoming vaccine safety related presentations at meetings and conferences involving CDC ISO personnel. A meeting of the Advisory Committee on Immunization Practices (ACIP) is scheduled for later in the month and the update would be presented at the next ACCV meeting. The Annual Conference on Vaccinology Research was held on April 3-5 in Baltimore and there were four presentations by members of the ISO. ISO Director, Frank DeStefano, made an oral presentation on Using Large Healthcare Databases to Look for Links between Vaccines and Autoimmunity. Karen Broder, Team lead for the Clinical Immunization Safety Assessment (CISA) Project, had a poster presentation on Advancing the Evidence Base for Vaccine Safety. John Su had a poster presentation on Anaphylaxis after Vaccination Reported to the Vaccine Adverse Event Reporting System (VAERS), 1990-2016. Finally, Tiffany Suragh made an oral presentation on Cluster Anxiety-Related Adverse Events following Immunization (AEFI): An Assessment of Reports Detected in Social Media and Those Identified Using an Online Search Engine. She gave the same presentation at the June 2019, NVAC meeting.

At the annual Epidemic Intelligence Service (EIS) Conference held in Atlanta (April 29-May 2), Elisabeth Hesse, CDC, made two presentations:

- An oral presentation on Deltoid Bursitis as an Adverse Event Following Injectable Influenza Vaccine in the Vaccine Safety Datalink—United States, 2016-2017; and
- A poster presentation entitled Post-Licensure Safety Surveillance of Recombinant Zoster Vaccine, (Shingrix), Using the Vaccine Adverse Event Reporting System, United States, October 2017–June 2018.

At the American Academy of Ambulatory Care Nursing meeting (May 8-11, Palm Springs, CA), Elaine Miller, CDC, had a poster on "Four Vaccine Safety Updates: What Nurses Need to Know". She specifically covered vaccines for pregnant women, SIRVA, the Shingrix vaccine, and new adjuvanted vaccines, including FLUAD. At the Prevention 2019 meeting in Pittsburgh, Jonathan Duffy, CDC, had a poster presentation on "Safety Surveillance of Bivalent Meningococcal Group B Vaccine, as reported in VAERS, 2014-2018". Lakshmi Sukumaran, CDC, will make a presentation at the Royal College of Obstetrics and Gynecology (RCOG) World Congress 2019 in London on the "Safety of Vaccines during Pregnancy: The CDC perspective".

Dr. McNeil announced that the June 26-27 ACIP meeting in Atlanta will include two safety-related presentations: "Update: Safety Monitoring and Surveillance for Recombinant Zoster Vaccine (RZV)" and "2018-2019 Influenza Season Vaccine S-safety Update."

Dr. McNeil included the following recent publications in his presentation slides but did not discuss them during his presentation.

1. DeStefano F, Monk Bodenstab H, Offit PA. **Principal controversies in vaccine safety in the United States.** *Clin Infect Dis*. 2019 Feb 12.
   Summary of some main current vaccine safety controversies in the United States: 1) MMR vaccine and autism; 2) thimerosal and the risk of neurodevelopmental disorders; 3) vaccine-induced Guillain-Barré Syndrome (GBS); 4) vaccine-induced autoimmune diseases; 5) safety of HPV vaccine; 6) aluminum adjuvant-induced autoimmune diseases and other disorders; and 7) too many vaccines given early in life predisposing children to health and developmental problems. A possible small increased risk of GBS following influenza vaccination was identified, but the increase is less than the risk of GBS following influenza infection. Otherwise, the biological and epidemiologic evidence does not support any of the reviewed vaccine safety concerns.
   Available at https://www.ncbi.nlm.nih.gov/pubmed/30753348

2. Myers TR, McCarthy NL, Panagiotakopoulos L, Omer SB. **Estimation of the Incidence of Guillain-Barré Syndrome During Pregnancy in the United States**. *Open Forum Infect Dis.* 2019 Mar 15. Conclusions: It is reassuring that in a cohort of >1.2 million pregnancies and using validated methods to identify pregnancies and classify cases of GBS, we found very few cases of GBS occurring during pregnancy. This study helps fill a critical knowledge gap for a potential adverse event following immunization that will be of particular interest during Zika vaccine trials. Should a signal for GBS be detected during clinical trials of maternal Zika vaccination, it will warrant immediate scrutiny given the low incidence of this syndrome during pregnancy.
   Available at https://doi.org/10.1093/ofid/ofz071

3. Klein NP, Goddard K, Lewis E, Ross P, Gee J, DeStefano F. Baxter R. **Long term risk of developing type 1 diabetes after HPV vaccination in males and females.** Vaccine 2019 Mar 28;37(14):1938-1944.
   Conclusions: No increased risk for development of diabetes mellitus 1 (DM1) following HPV vaccination. Provides reassurance that during the 10-year time period after HPV vaccine was introduced, there was no substantial increased risk for DM1 following HPV vaccination.
   Available at https://www.ncbi.nlm.nih.gov/pubmed/30827738

4. Su JR, Moro PL, Ng CS, Lewis PW, Said MA, Cano MV. Anaphylaxis after vaccination reported to the Vaccine Adverse Event Reporting System, 1990-2016. J Allergy Clin Immunol. 2019 Apr;143(4):1465-1473. Conclusions: Anaphylaxis after vaccination is rare in the United States and can occur among persons with no history of hypersensitivity. Most persons recover fully with treatment, but serious complications, including death, can occur.
   Available at https://www.ncbi.nlm.nih.gov/pubmed/30654049

5. DeStefano F, Shimabukuro TT. **MMR vaccine and Autism**. *Ann Rev Virol* 2019 April 15.

   Conclusions: Autism is a developmental disability that can cause significant social, communication and behavioral challenges. A report published in 1998, but subsequently retracted by the journal, suggested that MMR vaccine might cause autism. Autism, however, is a neurodevelopmental condition that has a strong genetic component with genesis before one year of age, when MMR vaccine is typically administered. Several epidemiologic studies have not found an association between MMR vaccination and autism, including a study that found that MMR vaccine was not associated with increased risk of autism even among high-risk children whose older siblings had autism. Despite strong evidence of its safety, some parents are still hesitant to accept MMR vaccination of their children. Decreasing acceptance of MMR vaccination has led to outbreaks or resurgence of measles. Health care providers have a vital role in maintaining confidence in vaccination and preventing suffering, disability and death from measles and other vaccine-preventable diseases.

   Available at https://www.ncbi.nlm.nih.gov/pubmed/30986133

At the conclusion of his presentation, Dr. McNeil announced that this would be his last meeting as the representative from the ISO and that he appreciated the opportunity to participate. His replacement as ISO ACCV representative going forward is Dr. Akpobome (Patricia) Wodi email lgz1@cdc.gov.

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

Ms. Schuster discussed a series of articles by NIAID scientists and supported researchers describing efforts to improve seasonal influenza vaccines and to develop universal influenza vaccines. The universal influenza vaccine can provide durable protection against multiple influenza strains, including those that might cause a pandemic. The articles were published in the Journal of Infectious Diseases supplement (April 15, 2019). She also reported that NIH is conducting a clinical trial of a universal influenza vaccine candidate, H1ssF_3928, to assess its safety, tolerability, and ability to induce an immune response in healthy volunteers.

NIAID has recently announced two awards for the study of influenza immunity in children. The studies will look at how young children's immune systems respond over time to their first influenza infection and vaccination, assess how immune memory works and evaluate peoples' ability to mount an immune response to different influenza subtypes. Researchers at Cincinnati Children's Hospital Medical Center and St. Jude Children's Research Hospital are conducting these studies.

NIAID is also supporting research for development of vaccines for sexually transmitted infections (e.g., syphilis, gonorrhea and chlamydia). Recently, awards totaling $41.6 million over 5 years were announced to support four cooperative research centers to conduct that research.

Ms. Schuster stated that, on April 2, 2019, NIAID published a perspective piece on acute flaccid myelitis (AFM) in the journal mBio. AFM is a condition associated with infections (e.g., polioviruses or non-polio enteroviruses) that cause sudden muscle paralysis. There is no vaccine currently available and no specific treatment to cure AFM.

On April 29, 2019, NIAID Director, Anthony Fauci, published an article emphasizing the importance of childhood vaccines. Finally, Ms. Schuster mentioned an NIAID-supported trial of an experimental vaccine for chronic hepatitis C virus (HCV). The vaccine was ineffective in preventing chronic HCV infection in adults. The trial began in 2012. It evaluated the safety of an experimental prime boost vaccine and whether it could prevent chronic HCV infection, which is defined as persistent presence of the virus in blood for six months after initial detection of infection. The results indicated that the vaccine failed to offer increased protection against chronic HCV infection compared to placebo. Additional data analysis is ongoing.

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

CDR Marshall explained that dengue disease is a major global public health concern and is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico and the U.S. Virgin Islands. On May 1, 2019, the FDA approved Dengvaxia, a live tetravalent vaccine manufactured by Sanofi-Pasteur, for the prevention of dengue disease caused by dengue virus serotypes (1, 2, 3 and 4) in people ages 9 through 16 with laboratory-confirmed previous dengue infection and who live in endemic areas. Infection by one type of dengue virus usually provides immunity against that specific serotype. However, a subsequent infection by any of the other three serotypes of virus increases the risk of developing severe dengue disease, which can lead to hospitalization or even death. Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown.

Health care professionals should evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus. The safety and effectiveness of the vaccine was determined in three randomized, placebo-controlled studies involving approximately 35,000 individuals in dengue-endemic areas, including Puerto Rico, Latin America and the Asia Pacific region.

During this discussion, Dr. Meissner noted that the vaccine is only licensed for children 9 to 16 years of age who have already had dengue and that it is a very positive benefit for that limited population, but probably not the last development in dengue prevention.

Public Comment

Ms. Luthy invited comments from the public. Ms. Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC) noted that the Vaccine Act, when initially passed, did not include a provision for adult injuries or compensation. The commission member's comment is correct that compensation relies on language in the law that states that "injury from routinely recommended childhood vaccines" is eligible for compensation. In addition, the recommendation by a commission member that an adult with a vaccine injury be added to the commission would require a legislative change to the law. Ms. Wrangham also commended the commission for putting recommendations forward that would improve the effect of the law, adding that many of those recommendations have not been acted by the Secretary, but that is beyond the control of the commission. Some also require legislative changes.

Ms. Wrangham observed that, while the NVAC continues to meet for two days on an in-person basis, the ACCV meetings have been reduced to a single day, mainly via telephone conference. Ms. Wrangham expressed concern that this may negatively affect the effectiveness of the ACCV. There is also concern that too few children are included in the VICP

compensation system. There is a lack of public understanding of the benefits available through the VICP, which may serve to exclude some injured parties who would otherwise be eligible for compensation. She commented that there is no mechanism to assess the adequacy of VICP awards. Ms. Wrangham felt that the backlog previously discussed is affected by delays caused by the need to file claims for off table injuries. Finally, she recommended establishing a mechanism for inviting members of the public to comment on proposals to add injuries to the Vaccine Injury Table.

There were no additional comments for public comment.

Future Agenda Items/New Business, Ms. Beth Luthy, Chair

Ms. Luthy noted that the next meeting is scheduled for September 5-6, 2019. Ms. Luthy invited comment by the newly elected chair and vice chair on future agenda items and new business. Dr. Meissner suggested that the process to add pregnant women and their children to the Vaccine Injury Table might be more clearly described. Dr. Nair explained that the rule was previously proposed and published in the Federal Register, and public comments had been received. The last step is to write the final rule and publish it in the Federal Register and on the web site. There is no opportunity for public comment on final rules. Because of the process, which involves several layers of review, a timeline for that process cannot be determined. There were no other suggestions for future agenda items.

Adjournment

Noting this meeting would be her last on the commission, as it would be for Martha Toomey, Ms. Luthy expressed appreciation to those on the commission for their service and on the call for their participation. There being no further business, the meeting was adjourned.