Advisory Commission on Childhood Vaccines (ACCV)

Teleconference and Zoom

December 2, 2021

Members Present

Karen Kain, Vice-Chair (2022)
William Spiegel, J.D. (2023)
Albert Holloway, M.D. (2024)
Dana DeShon, DPN, APN, CPNP-PC (2024)
Daniel Boyle (2024)
Timothy Thelen, J.D. (2024)

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

Welcome and Public Comment on Agenda Items, Ms. Karen Kain, Vice-Chair ACCV

Ms. Kain called the meeting to order, welcomed everyone present, and invited public comments on the agenda. There were two requests for public comment.

1. Theresa Wrangham, Executive Director, National Vaccine Information Center (NVIC)
   The NVIC helped draft language for the 1986 legislation that created the National Childhood Vaccine Injury Compensation Program (VICP). The NVIC represents parents who have vaccine safety concerns and people who vaccines have harmed.

   Concerning the agenda, Ms. Wrangham said it is encouraging to see the planned vote to elect a chairperson. Still, she expressed concern about the vacancies on the commission, particularly the second position for the parent of a vaccine-injured child, as that vacancy has been unfilled for some time.

   Ms. Wrangham expressed an interest in the CDC presentation. She questioned whether it would cover natural immunity and if V-Safe reporting would be integrated into the Vaccine Adverse Event Reporting System (VAERS). She also asked if the CDC would explain how Comirnaty is legally distinct from the experimental Pfizer-BioNTech COVID-19 vaccine.

   Finally, Ms. Wrangham asked about the VICP's ability to handle injuries from COVID-19 vaccines currently going to the Countermeasures Injury Compensation Program (CICP) and whether there is an intention to include COVID-19 vaccines within the VICP compensation coverage.

2. Carolyn Gammicchia

Ms. Gammicchia commented that it would be helpful to allow more than five minutes for public comments related to the agenda.

Approval of the September 2021 Meeting Minutes, Ms. Karen Kain, Vice Chair

On motion duly made and seconded, the ACCV voted, four in favor, one abstained, to approve the September 2021 ACCV Meeting Minutes.

Following the vote on the September 2021 ACCV Meeting Minutes, Ms. Kain made a motion to amend the December 2020 ACCV Meeting Minutes. She noted that the minutes did not reflect a vote by the ACCV members to invite Dr. Mawson to discuss his vaccine safety research. Ms. Overby commented that, since this issue of amending previously approved minutes has not occurred before, she would need to get clarity on the procedure and protocols on the process before the commission could take a vote to amend the minutes.

Ms. Overby welcomed Mr. Tim Thelen, a new commission member filling the ACCV role of an attorney representing vaccine manufacturers. Mr. Thelen briefly introduced himself and stated that he was pleased to join the commission.

Report from the Division of Injury Compensation Programs (DICP), Ms. Tamara Overby, Acting Director, DICP

Ms. Overby previewed the day's presentations: reports from the DICP and the Department of Justice (DOJ), and updates from ex-officio members representing the Immunization Safety Office (ISO) of the Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health, the Center for Biologics, Evaluation and Research (CBER) of the Food and Drug Administration (FDA), and the Office of Infectious Disease and HIV/AIDS Policy (OIDP).

The number of VICP petitions filed in Fiscal Year (FY) 2021 was 2,058. As of December 1, 2021, petitioners have filed 180 petitions, with 161 filed by adults and 19 filed on behalf of children.

Administrative funding for processing claims has not increased at the same rate as claims filed, so there is a backlog of 1,603 petitions awaiting review. All claims for children in the backlog have not yet been activated by Pre-Assignment Review (PAR).

In FY 2022, as of November 1, 2021, the VICP has paid about $17 million for petitioners' awards and nearly $4 million for attorneys' fees and costs.

Adjudication Categories for VICP Petitions as of November 1, 2021			
Adjudication Categories	**Fiscal Year 2020**	**Fiscal Year 2021**	**Fiscal Year 2022**
Compensable	**710 (100%)**	**749 (100%)**	**69 (100%)**
Concession	265 (37%)	334 (45%)	34 (49%)
Court Decision	49 (7%)	18 (2%)	0 (0%)
Settlement	396 (56%)	397 (53%)	35 (51%)
Not Compensable	**217**	**241**	**11**
Total	**927**	**990**	**80**

The balance in the Vaccine Injury Compensation Trust Fund as of September 30, 2021, was about $4.2 billion. Income includes about $313 million from excise tax revenue, $51 million from investments, and $2 million in refunds, for a total of about $365 million.

Recent trends in the VICP include:

- 95% of claims were filed for adults in the last two FYs;
- Over 68% of petitions filed in the last 2 FYs allege shoulder injury related to vaccine administration (SIRVA).
- 75% filed in the last 2 FYs claimed an injury from influenza vaccination.
- About 55% of claims were compensated by negotiated settlement.
- 13-month wait for review by a HRSA physician after PAR

Ms. Overby assured the commission that staff continues to seek appointments for all vacant ACCV positions. HRSA always invites nominations. Ms. Overby ended her presentation.

Report from the DOJ, Ms. Heather Pearlman, Deputy Director, Torts Branch

Ms. Pearlman, referencing the Department of Justice (DOJ) PowerPoint materials as part of her presentation, reminded the commission that the DOJ's 3-month reporting period, from August 16, 2021, through November 15, 2021, is different from the DICP reporting period. Ms. Pearlman stated that during DOJ's reporting period, 300 petitions were filed, 34 of which were filed on behalf of minors, and the remaining 266 were filed by adults.

Ms. Pearlman stated that the VICP adjudicated 266 petitions during this reporting period. The VICP compensated 222 of the adjudicated cases. Of these 222 compensated cases, the government conceded 96 cases, 12 of which had decisions awarding damages, and the remaining 84 had decisions adopting proffers. The government did not concede 126 of the compensated cases; the majority, 122, involved settlements, and the remaining 4 involved decisions awarding damages. The VICP did not compensate 44 cases. Petitioners voluntarily withdrew 21 petitions.

Ms. Pearlman stated the U.S. Court of Appeals for the Federal Circuit (CAFC) did not decide any cases during this reporting period. As of November 15, 2021, CAFC had three appeals of entitlement decisions pending, two brought by petitioners and one brought by respondent.

Ms. Pearlman next discussed appeals at the U.S. Court of Federal Claims (CFC). The CFC affirmed four entitlement decisions appealed by petitioners and one entitlement decision appealed by the respondent, and one attorney's fees and costs decision appealed by the petitioner. The CFC remanded one entitlement decision and reversed one attorney's fees and cost decision, both of which were appealed by the petitioners. As of November 15, 2021, eight appeals were pending before the CFC filed by petitioners: six entitlement decisions, one damages decision, and one attorney's fees and costs decision. She further stated that there were two appeals brought by the respondent were pending before the CFC: one entitlement decision and one attorney's fees and costs decision..

Ms. Pearlman noted that as of November 15, 2021, there were no oral arguments scheduled at the CAFC. Oral arguments at the CFC included those of *Caredio v. HHS*, scheduled for November 18, 2021, and *Mager v. HHS*,scheduled for December 8, 2021. Oral argument at the CFC in *Villarroel v. HHS* was held on September 28, 2021.

Ms. Pearlman provided a list of cases settled during the reporting period, listed in the

DOJ PowerPoint presentation organized by oldest to most recent petition filing. Ms. Pearlman also provided the usual appendices, including a glossary of terms and diagrams to help commissioners understand the appeals process. Ms. Pearlman concluded her report and invited questions from the commissioners.

Mr. Thelen asked if DOJ does any post-VICP tracking of claims voluntarily withdrawn, and Ms. Pearlman responded that DOJ does not track claims post-withdrawal from the Program.

Update on the ISO, CDC, Dr. Jonathan Duffy

Dr. Duffy began his presentation with COVID-19 vaccine information, noting that these continue to be an ISO priority. There are recommendations for using three different COVID-19 vaccines in the United States (US), Pfizer-BioNTech, Moderna, and Janssen vaccines.

The Advisory Committee on Immunization Practices (ACIP), which usually meets three times a year, has held many additional meetings to discuss COVID-19 vaccines and update the COVID-19 vaccine recommendations. Recent ACIP COVID-19 vaccine recommendations are an additional primary mRNA vaccine dose (third dose) for immunocompromised persons, booster doses for everyone 18 years old and older, and the vaccinating children aged five through eleven years of age with Pfizer-BioNTech COVID-19 vaccine. The CDC lists the most current COVID-19 vaccine recommendations on its website. Dr. Duffy shared a list of CDC publications on COVID-19 vaccine safety.

1. Surveillance for Adverse Events after COVID-19 mRNA Vaccination. JAMA 2021 September 3.
2. Spontaneous Abortion Following COVID-19 Vaccination during Pregnancy. JAMA 2021 September 8.
3. Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion. N Engl J Med. 2021 September 8.
4. Safety Monitoring of an Additional Dose of COVID-19 Vaccine — United States, August 12-September 19, 2021. MMWR Morb Mortal Wkly Rep. epub 2021 September 28.

Finally, as of November 28, 2021, 196.2 million people in the U.S. have been fully vaccinated, and 37.5 million people in the U.S. have received a booster dose.

Dr. Duffy reported that the ACIP has continued to work on other non-COVID-19 vaccine-related issues. The FDA approved a Pfizer vaccine, TICOVAC, for tick-borne encephalitis. The ACIP began reviewing the vaccine in September 2020 and plans to vote on TICOVAC recommendations in February 2022.

The ACIP voted in favor of a new recommendation for the zoster vaccine.

- ACIP recommends two doses of recombinant zoster vaccine to prevent herpes zoster and its complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed due to disease or therapy.

ACIP also voted for two new recommendations for pneumococcal vaccines.

- Adults 65 years of age or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a

pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.

- Adults aged 19 years of age or older with certain underlying medical conditions or other risk factors who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.

The ACIP heard two informational presentations about influenza vaccines. The first was about a safety and immunogenicity study of the co-administration of Fluzone high dose quadrivalent influenza vaccine at the same time as a third dose of the Moderna mRNA vaccine. There were reassuring findings for immunogenicity and safety for that procedure. The second presentation was about the new availability of a cell-culture-based inactivated influenza vaccine expanding the age ranges to include those six months and older. There are now five inactivated influenza vaccines for groups six months and older.

The ACIP also voted in favor of recommendations for hepatitis B vaccines, orthopoxviruses vaccines, and Ebola vaccines.

- The ACIP recommends the following groups should receive hepatitis B vaccines:
    - Adults 19 through 59 years
    - Adults 60 years and older with risk factors for hepatitis B infection
- The ACIP recommends the following groups may receive hepatitis B vaccines:
    - Adults 60 years and older without known risk factors for hepatitis B infection
- The ACIP recommends the use of the JYNNEOS® vaccine for:
    - Persons who are at risk for occupational exposure
    - Laboratory personnel and for designated response team members
    - Healthcare personnel who administer ACAM2000 or care for patients infected with replication-competent orthopoxviruses
- ACIP recommends the use of the rVSVΔG-ZEBOV-GP vaccine for:
    - Healthcare personnel involved in the care and transport of suspect or confirmed Ebola virus disease patients at Special Pathogens Treatment Centers
    - Pre-exposure vaccination with rVSVΔG-ZEBOV-GP vaccine is recommended for laboratorians and support staff at Laboratory Response Network (LRN) facilities that handle specimens that may contain replication-competent Ebola virus (species *Zaire ebolavirus*) in the United States

Dr. Duffy concluded his presentation and invited questions.

During the discussion, Dr. Duffy confirmed that studies of heterologous boosting COVID-19 vaccines are occurring, and more information about those studies is forthcoming. Heterologous vaccination is recommended and has happened.

When asked which vaccines were authorized under Emergency Use Authorization (EUA), Dr. Duffy responded that he believed the vaccines in use for children under 16 years of age are not fully FDA approved and still under a EUA. He recommended directing questions about licensure for COVID-19 vaccines to the FDA.

In response to an inquiry by a commissioner, Dr. Duffy explained the differences between V-safe, a tool for reporting COVID-19 vaccine reactions, and VAERS. V-Safe and VAERS are two completely separate systems. V-Safe was created and is used specifically for

COVID-19 vaccines; it is also used as a prompt to encourage reporting in VAERS, which is how the two systems, although separate, are used together. Dr. Duffy added that the V-Safe data is not available to the public at this time.

In response to a question about when the VICP would cover COVID-19 vaccines, Ms. Overby commented that at this time, no COVID-19 vaccines have had an excise tax imposed which is a requirement for VICP coverage of a vaccine. Congress would impose an excise tax.

Ms. Kain asked if the CDC had done any vaccine safety studies using Vaccine Safety Datalink (VSD) data following the publication of a white paper in 2013 that outlined how vaccine schedule safety studies could be conducted using VSD data and looking at specific health outcomes. Dr. Duffy responded that several studies are already published, and more studies are underway.

Ms. Kain asked what entities have access to the VSD data. Dr. Duffy briefly explained the two mechanisms for accessing VSD data; requesting data through the National Center for Health Statistics (NCHS) or proposing to work on a study with VSD site investigators.

Ms. Kain asked if the VSD also tracked unvaccinated populations and why they were unvaccinated, as researchers could use those populations as a control group in vaccine safety studies. Dr. Duffy explained that VSD used health insurance medical records to identify vaccination status and does have information about unvaccinated populations, he briefly described a study where this type of VSD data was used. However, there is less information about why a person is unvaccinated.

Ms. Kain asked if CDC has assembled baseline data about the acute and chronic conditions that could be associated with vaccines among the unvaccinated population. Dr. Duffy said he was not aware of a comprehensive list of this baseline data specific to unvaccinated populations available.

Ms. Kain asked if Dr. Duffy knew how many unvaccinated people could be in the control group. Dr. Duffy responded that within the VSD, the number of unvaccinated people would change regularly as new people enroll into participating health plans, so that number is variable. That number would depend on the specific study timeframe.

Ms. Kain asked about the status of the vaccine safety research task force, established in section 27b of the National Childhood Vaccine Injury Act. Dr. Duffy advised that other people within HHS could answer that question, as it is out of his purview.

Update on the NIAID, NIH, Ms. Claire Schuster

Ms. Schuster presented an update for the NIH. She stated that the NIH Researching COVID to Enhance Recovery (RECOVER) Initiative seeks to determine why some individuals experience prolonged symptoms, called long COVID, or develop new or returning symptoms after the acute phase of SARS-CoV-2 infection. The NIH RECOVER Initiative awarded nearly $407 million to build a national study population of diverse research volunteers and support large-scale studies of the long-term effects of COVID-19.

The studies supported by RECOVER are expected to provide insight into many important questions, including the incidence and prevalence of long-term effects of SARS-CoV-2 infection, the range of symptoms, underlying causes, risk factors, outcomes, and potential strategies for treatment and prevention.

The RECOVER Initiative will also follow up to 1,500 pregnant women and their offspring for four years. The research teams will assess patients' symptoms periodically over four years and evaluate the offspring for neurologic and cardiovascular symptoms.
RECOVER will also include a long-term study of children with COVID-19. It will track up to 1,000 children and young adults who previously tested positive for COVID-19 and evaluate the impact of the disease on children's physical and mental health over three years. The study is expected to reveal a detailed profile of COVID-19's effect on children's health, their development and immune responses to infection, and their quality of life in the years following infection.

Ms. Schuster showed the commission an NIH website focused on COVID-19, which includes information related to COVID-19 vaccine and children, https://covid19.nih.gov/
Ms. Schuster stated that in September 2021, NIAID announced that it had awarded about $36 million to three academic institutions to research developing vaccines to protect against multiple types of coronavirus and its viral variants. The initiative aims to develop multivalent vaccine platforms that provide broad protective immunity to multiple coronavirus strains.
In October 2021, preliminary findings were announced of an NIAID-supported Phase I-II trial evaluating homologous and heterologous COVID-19 booster vaccinations. The vaccines from Moderna, Pfizer-BioNTech, and Janssen effectively produced an immune response when used as a booster dose regardless of which COVID-19 regimen the participant had initially received. Heterologous vaccines elicited similar or higher serologic responses than using the same vaccine as a booster. No safety concerns were identified in any of the combinations, and reactogenicity was similar to the primary COVID-19 vaccine regimen. Mild reactions were observed in more than half of the participants. Ms. Schuster briefly discussed data related to neutralizing antibody titer levels in the study. Across all the combinations, antibody levels increased substantially from day one before the booster to day 15 post-booster. Ms. Schuster concluded her presentation.

Mr. Thelen asked if there is ongoing research related to health outcomes and reinfection of COVID-19. Ms. Schuster responded that she wasn't sure if any of the RECOVER studies would be looking at those issues, but she would look into it and follow up.

Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities, Dr. Jay Slater, CBER, FDA

Dr. Slater stated that the most significant recent FDA action regarding COVID-19 vaccines is the FDA EUA approval of the use of the Pfizer BioNTech vaccine in children 5 to 11 years of age. The vaccine is packaged with distinctive orange caps and labels to distinguish it from the adult vaccine. The COVID-19 vaccine for children 5-11 should be administered in two doses three weeks apart. FDA convened its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on this topic on September 17, 2021.

On September 22, 2021, the FDA amended the EUA to allow the use of a single booster dose of Pfizer BioNTech COVID-19 vaccine to be administered at least six months after the administration of the primary series to specific groups of individuals (adults 65 and older, adults 18 to 64 who are at high risk of severe COVD-19, adults 18 to 64 years of age who had frequent institutional occupational exposure to the virus). In October 2021, the FDA amended EUAs to authorize booster injections of the Moderna COVID-19 and the Janssen vaccine and supported the heterologous use of any of the three approved vaccines. In November 2021, the FDA

amended the EUA for the Moderna, Pfizer-BioNTech, and Janssen vaccines authorizing the single booster dose for all individuals 18 and older.

Dr. Slater updated an earlier presentation by announcing that in July 2021, the FDA had approved Merck's VAXNEUVANCE, a pneumococcal conjugate vaccine, approved for use in adults 18 and older for invasive disease caused by streptococcus pneumonia.

Dr. Slater shared that FDA has approved a new recombinant hepatitis B vaccine, PREHEVBRIO, authorized for adults 18 and older.

Finally, Dr. Slater shared the link to an FDA website dedicated to COVID-19: https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19. Mr. Slater ended his presentation and asked for questions.

Ms. Kain asked if children could receive a Pfizer BioNTech vaccine labeled Cormiarty or if children are still receiving the Pfizer BioNTech EUA vaccine. Dr. Slater explained that the Pfizer BioNTech vaccine is licensed for use in children 16 years old and above; those children would receive the Pfizer BioNTech vaccine under its license. Children under 16 years old would receive the COVID-19 vaccine under the EUA.

Regarding the Pfizer BioNTech COVID-19 vaccine approval letter, Ms. Kain asked what the language "same formulation but legally distinct" means. Dr. Slater said he would follow up on that question and provide a response at the next ACCV meeting.

Office of Infectious Disease and HIV/AIDS Policy (OIDP), Mr. Sean Dade, OIDP

Mr. Dade provided an update regarding the National Vaccine Advisory Committee (NVAC) Meeting held September 14-15, 2021. On the first day of the meeting, there was a presentation by the Countermeasures Acceleration Group (Operation Warp Speed) on COVID-19 safety data. The second day focused on vaccine innovation, how the immune response relates to protection from disease, a discussion of mRNA vaccines for widespread use, the latest CDC flu recommendations for the upcoming flu season, and a discussion led by the vaccine confidence subcommittee.

OIDP's vaccine division is now in the process of implementing the 5-year Vaccines National Strategic Plan 2021-2025 created in January 2021. This plan and the activities within the plan sets forth a clear vision for how the United States will be a place where vaccine-preventable diseases are eliminated through safe and effective vaccination across the lifespan. In support of this vision, the Vaccine Plan includes five major goals, which frame the plan’s objectives, and strategies that articulate actions to accomplish each objective, and indicators with measurable targets to monitor progress. To ensure the National Vaccine Plan meets its goals by 2025, the Vaccine Division is collaborating with the Federal Interagency Vaccine Workgroup (IVWG), which serves as the steering committee that guides the Vaccines National Strategic plan. IVWG members reviewed the Vaccines National Strategic Implementation Plan and have provided feedback which OIDP is analyzing. After analysis of the IVWG feedback is complete, OIDP will finalize a draft of the Vaccines National Strategic Implementation Plan and solicit public comments for 30 days. The National Vaccine Implementation Plan is tentatively scheduled for publication in March 2022.

Mr. Dade announced two new OIDP grants. The first grant, Promoting Vaccine Confidence in Local Communities through Partnership with Regional Health Offices, intends to promote vaccine confidence among underserved low vaccination populations. Six organizations

were awarded 3-year funding to work with underserved communities with low vaccine uptake to implement an iterventionstrategy to reduce vaccine hesitancy while promoting vaccine products, providers, and policy.. If successful, these evidence-based practices will be replicated in other local communities throughout the Nation. .

The second OIDP grant, Enhancing Immunization Culture in Obstetric/Gynecological (OB/GYN) Care, is intended to increase maternal, childhood, and adolescent immunizations throughout a lifetime.

The OIDP is working to highlight the importance of seasonal flu vaccination and catching up on routine vaccinations that were neglected during the COVID pandemic. OIDP supports the Immunization Action Coalition's call to improve adults' uptake of routine vaccinations and boosters, particularly influenza vaccines preparing for the upcoming flu season. OIDP has developed tool kits targeted at specific populations (African-American, Latino, American Indian, Native, and Tribal Communities).

Mr. Dade shared information about OIDP partnerships and stakeholder collaborations, including collaborations with the Office of Refugee Resettlement, FDA's Vaccines and Related Biological Products, Advisory Commission on Immunization Practices (ACIP), the American Medical Group. Mr. Dade ended his presentation.

Ms. Kain asked what communities were targeted by the two OIDP grants. Mr. Dade responded that the grant to promote vaccine confidence targets underserved communities in six cities in Minnesota, Oklahoma, North Carolina, Washington State, Illinois, and Colorado. The grant for enhancing vaccine culture in OB/GYN care targets 14 underserved metro areas with low vaccination rates.

Mr. Thelen asked if OIDP was aware of increasing or decreasing trends in vaccine confidence. Mr. Dade responded that the six grantees from the vaccine confidence grant would be collecting data through community needs assessments to gauge, vaccine confidence within these communities.

Mr. Thelen then asked if the grantees would be looking at whether vaccine mandates increased or decreased vaccine hesitancy. Mr. Dade responded that the grant was drafted before there were vaccine mandates in effect; however, that could potentially be added to the scope of the grant.

Ms. Kain made a motion to rearrange the agenda such that an unscheduled presentation by Ms. Kain would be permitted before the afternoon public comment agenda item. The commission denied this motion.

Public comment

1. Aaron Siri

   Mr. Siri submitted a public comment on behalf of the Informed Consent Action Network (ICAN). ICAN frequently hears that vaccine hesitancy is affected by clinical trials that are relied on to license childhood vaccines and the post-licensure safety studies and systems in place that assess the safety of childhood vaccines. ICAN believes that an essential component to reducing vaccine hesitancy is increasing the safety profile of the literature and systems in place to ensure the safety of the childhood vaccination schedule.

   Mr. Siri commented that the clinical trials conducted to license almost all childhood vaccines do not assess the safety profile of the vaccine. He pointed out

the lack of control groups in the clinical trials and the time frames for monitoring adverse events. Regarding post-licensure safety surveillance, Mr. Siri pointed out that there had not been comprehensive health outcome studies conducted looking at adverse vaccine reactions, and ICAN believes the current vaccine safety monitoring systems are inadequate. He encouraged the commissioners to review the written comments submitted by ICAN.

2. Ms. Theresa Wrangham, Executive Director, NVIC

Ms. Wrangham expressed appreciation for the opportunity to provide public comment and discuss the VSD. Regarding comments about 13 studies that used VSD data, NVIC endorses broader access to the VSD data for independent researchers and makes existing VSD data studies more readily available to the public and independent researchers.

Concerning the vaccination plan presented by OIDP and the hesitancy report that will be released, there has been a trend not to use stakeholders' opinions from the populations that are targets of programs to improve vaccine confidence. For vaccine programs to be effective, they must engage the target populations as stakeholders.

Ms. Wrangham questioned whether V-safe will be made public, so that non-industry researchers will have an opportunity to study it. There was interference on Ms. Wrangham's line, and so she indicated she would submit a written statement about her concerns.

3. Carolyn Gammicchia

Ms. Gammicchia commented that her son, who is now 30 years old, was vaccine injured. She stated that she was also vaccine injured by the hepatitis B vaccine. She expressed concern about the current vacancies on the ACCV, particularly the appointment of another parent of a vaccine-injured child and a second attorney who represents individuals injured by vaccines. She added that her son did not have recourse within the liability standards of the VICP.

Ms. Gammicchia thanked Ms. Kain for her work on the commission. She expressed concern about transparency, citing the commission's denial of Ms. Kain's request to add discussion items to this meeting's agenda. She said that this commission is not functioning as intended in the original legislation establishing the ACCV. Ms. Gammicchia believes it would be beneficial to appoint a vaccine safety task force to support the development of recommendations to the Secretary of the U.S. Department of Health and Human Services.

Ms. Gammicchia commented that there are no studies of vaccinated versus unvaccinated populations that VICP petitioners can utilize to support their claims in the Vaccine Court. She also expressed concern about the lack of vaccine safety research of incidence of adverse vaccine reactions in people who may be predisposed to vaccine injuries, the progression of the COVID-19 vaccine program without liability protection and studies on vaccinated versus unvaccinated individuals.

Ms. Gammicchia reiterated her request that the commission establish a task force to look at vaccine safety issues.

4. James Moody, Director, National Autism Association, Attorney, Petitioner's Bar

Mr. Moody stated that he strongly endorsed public availability of the VSD data for the petitioners' bar and outside experts. He stated that the 13 studies on VSD data mentioned earlier in the meeting appear to be internal studies done by CDC researchers or researchers affiliated with the participating HMOs. Mr. Moody pointed out that the study Dr. Duffy referenced in the discussion following his presentation concluded that less vaccinated children have fewer encounters, which is consistent with other studies of vaccinated versus unvaccinated people. He suggested that it is necessary to conduct more rigorous and government-funded vaccinated versus unvaccinated studies.

Mr. Moody expressed surprise that Dr. Duffy, CDC, did not characterize the VSD as a research database. He stated the government highlights the VSD data as the gold standard in research data throughout the government's vaccine safety literature and individuals had signed research consent forms when they joined the VSD participating HMOs. He said that if the VSD is not a research-quality database, it is crucial to create one. He agreed that it was important to conduct vaccinated versus unvaccinated studies. Further, he stated that the government and its experts have access to the data and the petitioners do not, which presents a significant issue of fairness and confidence in the VICP.

Mr. Moody discussed the history of the arguments for making VSD data publicly available, including the original CDC finding of increased incidence of autism from mercury exposure in vaccines and the mission of the ACCV to reduce the incidence of vaccine injury.

5. Michael Milmoe, Petitioner's Attorney

Mr. Milmoe, stating that it was likely just an administrative error, pointed out that the DICP slides were not on the ACCV website for this meeting and the previous two meetings and asked that HRSA post the slides to the ACCV website.

With regard to the coronavirus vaccine, Mr. Milmoe said he understood that the VICP could not lobby Congress. He pointed out that over the years, dozens of vaccines have been assessed an excise tax, and added to the VICP. He asked if Ms. Overby or someone from HHS could present how, historically, vaccines were added to the VICP and discuss any role HHS played in the process.

6. Andrew Gammicchia

The speaker commented that he posted a picture of a typical meeting agenda as his profile picture in Zoom. He stated that it was inappropriate to hold public comment before Ms. Kain's presentation.

Mr. Gammicchia also asked if there was any vetting process for members of the ACCV to ascertain whether any conflicts of interest or financial interests exist that might bias or affect the commissioner's judgment.

7. Theresa Wrangham, Executive Director, NVIC

Ms. Wrangham clarified her comments because of audio issues that may have affected their accuracy and completeness. She stated that she appreciated the discussion opportunity on the VSD and agreed with Mr. Moody regarding research on the VSD data. She asked for greater transparency in the VSD because studies of VSD data are used to inform the public that vaccines are safe. She wondered if independent researchers have replicated the findings of the 13 previously mentioned studies to strengthen the validity of their results.

On vaccine hesitancy, Ms. Wrangham reiterated that NVAC reports do not include stakeholder input from vaccine-hesitant populations. In an interest in transparency and effectiveness, NVAC should be including stakeholders from the vaccine-hesitant populations.

Regarding clinical trials for vaccine licensure, Ms. Wrangham agreed with Mr. Siri's earlier comments about the studies' need for control groups.

Future Agenda Items/New Business

Ms. Kain began the future agenda items with a discussion about establishing a workgroup on the use of epidemiology in the VICP, emphasizing the VSD data.

Ms. Kain reminded the commission of Congress's two primary goals in establishing the VICP; first, to swiftly, fairly, and generously to compensate children injured by vaccines under a standard of proof where doubts are resolved in favor of compensation; and second, to make the childhood vaccine schedule safer.

She also reminded the commission of the ACCV's responsibilities to:

(1) advise the Secretary on the implementation of the Program;
(2) on its own initiative or as the result of the filing of a petition, recommend changes in to the Vaccine Injury Table;
(3) advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions;
(4) advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines;
(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program;

Ms. Kain stated that the availability of high-quality data comparing the health outcomes of children vaccinated under the CDC's childhood vaccine schedule to unvaccinated children is a core mission of the ACCV's oversight responsibility. This metric will facilitate compensation for vaccine-injured children and the goal of making vaccines safer. This data's transparency and

availability will contribute to public trust in nationwide mass vaccination programs.

Ms. Kain remarked on her own experience with a vaccine-injured child. She reiterated the importance of filling the ACCV membership vacancy for a second parent of a vaccine-injured child, a position unfilled for two years.

Ms. Kain discussed three reports published or funded by CDC and HHS that all recommended more vaccine safety research and broader access to VSD data. Ms. Kain emphasized the importance of the ACCV, noting that in her opinion, the ACCV is failing in its mission to reduce injuries, suggest studies, and have a discussion about vaccine safety which are in the ACCV's purview. Ms. Kain concluded her remarks by requesting that the ACCV vote on creating a workgroup to look at vaccinated versus unvaccinated studies and other safety studies to make informed recommendations to the Secretary.

Ms. Overby pointed out that the commissioners received the charter and supporting materials for Ms. Kain's proposed workgroup the evening before the meeting and may not have had time to review the materials before the meeting. The commissioners briefly discussed the workgroup proposal. The commissioners agreed they needed additional time to review the materials distributed by Ms. Kain.

Mr. Thelen made a motion, duly made and seconded, to discuss and vote on a workgroup at the March 2022 ACCV meeting. The ACCV passed this motion unanimously. Mr. Thelen made a second motion, duly made and seconded, to arrange the March 2022 meeting agenda so that the public comment period comes between the discussion of the potential workgroup and the vote on forming the workgroup. This motion also unanimously passed.

Selection of the ACCV chair

Ms. Overby called for nominations for an ACCV chair. On motions duly made and seconded, Ms. Kain and Ms. DeShon were nominated. The vote taken resulted in a tie, three for each nominee. Ms. Overby, noting that the situation had never occurred, stated that she would have to consult with general counsel on the procedures for a resolution. The meeting was adjourned on motion duly made, and seconded and unanimously approved.