Advisory Commission on Childhood Vaccines (ACCV)

Teleconference

June 2, 2022

Members Present

Karen Kain, Vice Chair (2022)
Albert Holloway, Jr. MD (2024)
Dana DeShon, DNP, APRN, CPNP-PC. (2024)
Daniel Boyle (2024)
Timothy Thelen (2024)

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

CDR Reed Grimes, MD, Director, DICP, Temporary Chair, ACCV
Andrea Herzog, Principal Staff Liaison, ACCV
Pita Gomez, Principal Staff Liaison, ACCV

Welcome Remarks and Chair Report, CDR Reed Grimes, MD, Chair, ACCV

Dr. Grimes called the meeting to order and welcomed everyone. Dr. Grimes announced that all current active commissioners were present and constituted a quorum. In addition, all ex officio members were present. Dr. Grimes noted with appreciation the service of Karen Kain, whose three-year term ends July 2022. DICP staff is actively involved in the review of potential replacements for current vacancies on the Commission.

Public Comment on Agenda Items

Dr. Grimes invited public comments on the agenda. There was one request for public comment.

1. Theresa Wrangham, Executive Director, National Vaccine Information Center (NVIC)
   The NVIC, which worked with Congress in passing legislation establishing the ACCV in 1986, made the first comment. Theresa Wrangham commented that Karen Kain would present on conducting research using the Vaccine Safety Datalink (VSD) to study vaccinated/unvaccinated populations. Theresa Wrangham noted that in 2005, the Institute of Medicine commented on the use of the VSD and asserted that independent researchers should have access to the data.

There were no additional comments.

Approval of the December 2, 2021, Meeting Minutes, CDR Reed Grimes, MD, Chair, ACCV

On motion duly made and seconded, the ACCV voted and unanimously approved December 2021 ACCV Meeting Minutes.

Discussion and Vote Regarding Revising December 2020 Minutes, Karen Kain, Vice Chair, ACCV

Dr. Grimes invited discussion of the proposed revision of the December 2020 Meeting Minutes, which were previously approved. The ACCV members needed to vote to determine if they wanted to discuss revising the December 2020 ACCV Meeting Minutes. On motion duly made and seconded, the proposal to discuss revision of the minutes was approved three in favor and two abstentions from members who were not members of that ACCV when the December 2020 ACCV Meeting occurred. Therefore, Karen Kain explained that during the December 2020 meeting, four commissioners were present and unanimously approved inviting Dr. Mawson to make a presentation at the March 2021 meeting. The vote was not included in the meeting minutes to which Karen Kain took exception. Next, a motion was made and seconded to vote on revising the minutes to reflect the December 2020 vote. ACCV members voted to approve the revision to the December 2020 minutes - two in favor, one opposed, and two abstentions.

Karen Kain's three-year term ends in July and Dr. Grimes thanked Karen for serving as the ACCV Vice Chair and a member.

Report from the DICP, CDR Reed Grimes, MD, Director, DICP, and Chair, ACCV

Dr. Grimes 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 Diseases and HIV/AIDS Policy (OIDP).

The number of VICP petitions filed in Fiscal Year (FY) 2022 as of May 1, 2022 was 529. Of those petitions, 461 were filed for adults and 68 were 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 1,443 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 May 1, 2022, the VICP has paid about $94 million for petitioners' awards and nearly $20 million for attorneys' fees and costs.

Adjudication Categories for VICP Petitions as of May 1, 2022			
Adjudication Categories	**Fiscal Year 2020**	**Fiscal Year 2021**	**Fiscal Year 2022**
Compensable	**711 (100%)**	**754 (100%)**	**524 (100%)**
Concession	265 (37%)	336 (45%)	237 (45%)
Court Decision	48 (7%)	18 (2%)	6 (1%)

Settlement	398 (56%)	400 (53%)	281 (54%)
Not Compensable	**217**	**253**	**148**
Total	**928**	**1,007**	**672**

The balance in the Vaccine Injury Compensation Trust Fund as of March 31, 2022, was approximately $4.3 billion. Income so far for FY 2022 includes about $167 million from excise tax revenue and $24 million from investments, for a total of about $191 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 two FYs allege Shoulder Injury Related to Vaccine Administration (SIRVA).
- 75% of petitions filed in the last two 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

Dr. Grimes concluded by noting that DICP staff continues to seek nominations for all vacant ACCV positions. HRSA always invites nominations. Dr. Grimes ended the presentation and invited questions.

Timothy Thelen asked a question regarding the doubling number of petitions filed between FY 2020 and FY 2021. They asked if this increase in number of petitions could be from petitions wrongfully filed into VICP, for example a product or vaccine that is not covered, like COVID-19. Dr. Grimes clarified that the increase from FY 2020 to FY 2021 was based on SIRVA claims. There was a notice that SIRVA would be possibly removed from the Vaccine Injury Table (Table), so there was an increase in the number of petitions filed prior to the removal of that condition from the Table. Subsequently, this removal was rescinded and SIRVA remained on the Table. Dr. Grimes mentioned that DICP does not anticipate doubling of claims every year, but wanted to note that as claims have increased, the funding and resources have not increased in a commensurate manner. Dr. Grimes shared that there is a current backlog of about 1,400 claims and it takes almost 13 months to review a claim after the PAR is activated.

During discussion, Timothy Thelen made a motion to submit a recommendation to the Secretary to increase the administrative resources for the VICP. Dr. Grimes invited a second, which provided by Dr. Holloway. Tamara Overby clarified that the intent of the motion was to approve Timothy Thelen's suggestion as an agenda item for the next ACCV meeting planned for September, before which DICP staff would prepare proposed wording of the recommendation to the Secretary. All commissioners present approved this motion.

Karen Kain also had a question regarding the VICP Petitions line graph and why data is captured starting in FY 2010. They wondered if we looked prior to FY 2010, could we see when the trend changed to close to 95% of petitions filed by adults, instead of children. Dr. Grimes clarified that this line graph is meant to represent the significant increase in adult claims.Tamara Overby shared that this slide was also meant to show a 10-year trend of VICP petitions filed.

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

Heather Pearlman, referencing the DOJ PowerPoint materials as part of their presentation, stated that their presentation covered the period February 16, 2022 through May 15, 2022, which is a different time period than presented in the DICP update. Heather Pearlman stated that 205 petitions were filed in the U.S. Court of Federal Claims (CFC), 178 filed by adults and 27 on behalf of minors.

Heather Pearlman stated that the VICP adjudicated 292 petitions during this reporting period. Of the 292 petitions adjudicated, 241 were compensated and 51 were not compensated. HHS conceded 102 cases, mostly resolved by accepting a proffer, and 139 of the compensated cases were not conceded. Thirty-seven petitions were voluntarily withdrawn resulting in no judgment. In May, the U.S. Court of Appeals for the Federal Circuit decided one case, affirming Webb v. HHS. Three cases were pending, all appeals by the petitioner.

In the CFC, six cases appealed by petitioners were decided and all were affirmed. Two cases were appealed by respondent and decided, and both were vacated and remanded. There were seven appeals pending, all filed by petitioner, none by respondent. Finally, there were no oral arguments pending at either the U.S. Court of Appeals for the Federal Circuit or the CFC. During the reporting period there were 127 settlements adjudicated, with an average time to resolution of 2.5 years. Most cases involved SIRVA and/or influenza vaccine.

Heather Pearlman provided a list of cases settled during the reporting period, listed in the DOJ PowerPoint presentation in order of the time they took to resolve. Heather Pearlman also provided the usual appendices, including a glossary of terms and diagrams to help commissioners understand the appeals process. Additional information is available on the CFC's website. Heather Pearlman concluded their report and invited questions from the commissioners.

Daniel Boyle asked if there is any process where the adjudicated cases, the settlements, or the decisions are tracked and look at how they line up with injuries on the Table. They believe this could be helpful in terms of identifying new trends that might need to be added to the Table. Heather Pearlman stated there is not a direct correlation between what is settled and what is added to the Table. On the CFC's website, there are more specific details on cases that are settled.

Karen Kain asked DOJ for information regarding the time period of November 16, 2021 and February 15, 2022, since this would have been reported at the ACCV March 2022 meeting that was postponed. Heather Pearlman excluded this information to be consistent with the time periods reported to ACCV, but agreed to email this information after the ACCV June 2022 meeting.

Update on the ISO, CDC Vaccine Activities, Dr. Jonathan Duffy, Medical Officer, National Center for Emerging and Zoonotic Infectious Diseases, CDC

Dr. Duffy stated that CDC has recommendations for three COVID-19 vaccines : Pfizer-BioNTech, Moderna, and J&J/Janssen vaccines. Everyone age 5 and older should get vaccinated against COVID-19, and those 12 and older who have been vaccinated should receive a booster -- 5 months after the two-shot regimen for the first two formulations (Pfizer-BioNTech and Moderna) or 2 months after the initial J&J/Janssen vaccine. As of May 12, 2022, 257 million Americans had received at least one dose, 220 million are fully vaccinated, and 11 million had received a second booster.

The Advisory Committee on Immunization Practices (ACIP), which usually meets three

times a year, has held additional meetings to discuss COVID-19 related topics in December 2021 and in January, February, April, and May 2022. There have been reports of thrombosis with thrombocytopenia syndrome and Guillain-Barré Syndrome after the Janssen vaccine; the ACIP recommendations now state that the Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination.. Dr. Duffy stated that the ACIP COVID-19 Vaccine Safety Technical (VaST) Work Group provided an assessment of COVID-19 booster dose safety on April 20, 2022..

Dr. Duffy listed a number of COVID-19 vaccine-related publications on vaccine safety, surveillance, and adverse reactions that can be found on the CDC website. Dr. Duffy then briefly described several non-COVID-related publications on vaccine safety, surveillance, and adverse effects that can be found on the CDC website:

1. "A Decade of Data: Adolescent - 2007 to 2016 Vaccination in the Vaccine Safety Datalink 2007, provides a historical look at the subject.
2. Another study, Association of COVID-19 Pandemic with routine Childhood Vaccination Rates, compared trends in pediatric vaccination before and during the pandemic and found that vaccination rates are lower than they were prior to the pandemic.
3. Another retrospective study of children born between 2004 and 2014 showed that the recommended vaccination schedule is not positively associated with the incidence of Type 1 diabetes.
4. Another study looked at risk of Guillain-Barré in Medicare patients 65 and older after recombinant zoster vaccination (RZV or Shingrix) and identified a slight increased risk following RZV vaccination.
5. Because patients and clinicians expressed concern about adminitering influenza vaccine during hospitalization for orthopaedic surgery, a study was done which showed no evidence of a substantial increased risk of infection-related outcomes associated with influenza vaccination during hospitalization for orthopaedic surgery.
6. A paper about Safety surveillance of meningococcal group B vaccine (Bexsero®) in the Vaccine Adverse Event Reporting System did not reveal any safety concerns.
7. Post marketing safety surveillance of high dose quadrivalent influenza vaccine (Fluzone) indicated that 95% of the reactions (injection site irritation, fever, headache, and nausea) were non-serious and most had been observed in the prelicensure clinical trial.

Dr Duffy summarized non-COVID-19 vaccine topics which had been discussed at the ACIP meetings in January and February of 2022:

1. ACIP approved a recommendation for Lyophilized CVD 103-HgR for cholera in children and adolescents aged 2-17 years traveling to an area with active cholera transmission.
2. In February 2022, ACIP voted on recommendations for a tick-borne encephalitis (TBE) vaccine for lab workers who might be exposed to TBE; and for individuals who may be visiting a TBE endemic area; and for individuals entering such areas who might be engaged in outdoor activities.
3. Regarding influenza vaccines, there is evidence of benefit favoring HD-IIV, aIIV, and RIV (enhanced influenza vaccines, or EIVs) either individually or collectively compared to standard unadjuvanted flu vaccines,
4. The ACIP looked at a 3-Antigen Hepatitis B Vaccine (PreHevbrio) which is included in

the existing Hep B recommendations.

5. ACIP established a work group to look at vaccines for respiratory syncytial virus for children age 18 and under.
6. ACIP discussed a measles-mumps-rubella (MMR) vaccine, Priorix, not yet licensed in the U.S.
7. Finally, the ACIP discussed policy questions for pneumococcal vaccines, specifically whether PCV15 should be routinely recommended for children under two, and for children aged 2 to 18 with underlying medical conditions.

Dr. Duffy concluded the presentation and invited questions. Daniel Boyle commented on VSAFE and VAERS being an important development and a step forward. They believe it aligns with the requirements of ACCV duties to survey federal, state, and local programs related to gathering of information on injuries. Currently, VSAFE is not being used for childhood vaccines because its focus is on COVID-19 vaccines. Daniel Boyle said it would be within the scope of ACCV duties to recommend that systems like VSAFE be used for other vaccines. Dr. Duffy said VSAFE was specifically developed for COVID-19 and decisions about its use for other vaccines in the future has not been made, but will share this suggestion with CDC staff.

Daniel Boyle pointed out that there is an opportunity to research a large number of claims from influenza vaccines and individuals on Medicare. They were unsure if there is any research being done on Medicare data and tracking vaccine-related injuries. Dr. Duffy mentioned that the Medicare data is a data source available and often FDA takes the lead in using this data for different analyses regarding influenza vaccines or for this specific age group.

Timothy Thelen referenced the study with positive increase in childhood vaccines leading up to 2016 and then referenced study that showed a decrease in 2020, presumably COVID-19 related. They asked if Dr. Duffy knew the order of magnitude of this decrease in 2020 and if there was a follow-up study for the number of childhood vaccinations in 2021. Dr. Duffy referred Timothy Thelen to the publication for more specific information.

Update on the NIAID, NIH, Vaccine Activities, Claire Schuster, Communications Team Lead for NIAID Division of Microbiology and Infectious Diseases

Claire Schuster announced that NIH had launched an early-stage clinical trial to evaluate the safety and immune response of an investigational vaccine for Epstein Barr virus (EBV). It is the primary cause of infectious mononucleosis and is associated with some cancers and autoimmune diseases. This Phase I study is one of two studies that will test an investigational EBV vaccine in more than a decade. The study will enroll 40 healthy volunteers between 18 and 29 years of age, half of whom have evidence of prior EBV infection. The vaccine includes an adjuvant developed by Novavax.

NIAID has launched a new study to better understand enterovirus D68 (EV-D68) which may cause a polio-like neurological disease in children. The pilot study is enrolling children 10 and younger and will continue for at least three years. The study is part of an NIH initiative known as PREMISE (Pandemic Response Repository through Microbial and Immune Surveillance and Epidemiology). Through the EV-D68 pilot study, researchers hope to demonstrate that it is possible to select a virus; develop an understanding of how the virus infects, replicates and mutates; and identify characteristics of individual susceptibility and

immunity. If successful, this approach could be applied to other viruses, such as hantaviruses, coronaviruses, influenza and hemorrhagic fever viruses.

Claire Schuster provided a brief update on the NIH Researching COVID to Enhance Recovery (RECOVER) initiative to enhance understanding of the long-term effects of COVID-19. The adult study protocol is available at recoverCOVID.org. The protocol ensures consistency in research methods and the types of data collected. If changes are made to the protocol, updates will be posted on the RECOVER website. Claire Schuster also described the pediatric COVID-19 vaccine study, KidCove, which is testing the safety and efficacy of Moderna's mRNA-1273 vaccine for children aged 6 months to less than 12 years of age. In March, Moderna announced early results from children 6 months to 6 years of age, who received two 25 µg doses of mRNA-1273 and the result was a robust neutralizing antibody response similar to adults. The vaccine was generally well tolerated. In April, Moderna announced submission of a request for emergency use authorization (EUA) in this age group. In addition, a paper reporting KidCove results among children 6 to 11 years of age was published in the New England Journal of Medicine on May 11. Two 50-µg doses of the mRNA-1273 vaccine were found to be safe and effective in inducing immune responses in this age group.

Claire Schuster stated that NIAID committed approximately $577 million to establish nine Antiviral Drug Discovery Centers for Pathogens of Pandemic Concern. The centers will conduct research and develop candidate COVID-19 antivirals, especially those that can be taken in an outpatient setting, as well as antivirals targeting specific viral families with high potential to cause a pandemic in the future. Claire Schuster also described NIAID's SARS-CoV-2 Assessment of Viral Evolution (SAVE) Program. The objective is to generate data in a coordinated way to further understand SARS-CoV-2 variants and support public health decision-making. The data, involving early detection and analysis as well as *in vitro* and *in vivo* studies, are shared with the HHS SARS-CoV-2 Interagency Group.

In March, NIAID began a Phase II trial (COVAIL) to evaluate COVID-19 booster shots to understand if different regimens can broaden immune response in vaccinated adults. The trial will look at immune responses induced by prototype vaccines and variant vaccine candidates—including bivalent vaccines, which target two SARS-CoV-2 variants—to inform booster shot recommendations. Claire Schuster concluded their remarks and invited questions.

Update on the CBER, FDA Vaccine Activities, Jay Slater, MD, Medical Officer,

Dr. Slater stated that, in December 2021, FDA authorized a single booster for individuals 16 and 17 years of age at least 6 months after completing the primary series of the Pfizer BioNTech COVID-19 vaccine. On December 14, 2021, FDA announced revisions to the COVID-19 Fact Sheet, including a Janssen COVID-19 contraindication for administration to individuals with a history of thrombosis thrombocytopenia. On January 7, 2022, FDA amended the EUA to receive the booster after a delay of five month after completing the primary Moderna vaccine series. Finally, on January 11, 2022, FDA announced minor revisions to the Janssen vaccine Fact Sheet.

On January 31, 2022, FDA approved a Moderna vaccine, Spikevax, consisting of two doses one month apart, to prevent coronavirus disease caused by SARS-CoV-2, and on March 29, authorized a second booster of the Pfizer-BioNTech or Moderna vaccines for older people and others at higher risk. There were changes in the use of the Janssen vaccine and the content of

the Fact Sheet, and in May, FDA authorized use of a single booster of the Pfizer-BioNTech vaccine for children 5 to 11.

Dr. Slater concluded their presentation by announcing that June would be a busy month for the Vaccines and Related Biological Products Advisory Committee (VRBPAC), with four meetings about COVID 19 on the calendar. Dr. Slater added that FDA maintains a website dedicated to COVID-19 that is updated regularly. Dr. Slater concluded their remarks and invited questions.

Update on the OIDP, Sean Dade, Public Health Analyst

Sean Dade explained that the OIDP mission is to achieve optimal prevention of human infectious diseases through immunization. Specific goals including building partnerships with federal agencies to provide strategic leadership and coordination to support activities within the National Vaccine Plan, and to support initiatives and policies that support and increase immunization rates. OIDP provides guidance to the National Vaccine Advisory Committee (NVAC), which meets three times a year. Since the last meeting in December, NVAC held one meeting on February 10-11. The meeting addressed how vaccines are being used to protect populations through immunization, the effectiveness of the COVID-19 vaccines, and HHS guidance on prohibiting discrimination in COVID-19 vaccination programs. The agenda for the second day addressed correlates of protection and the expansion of immunization information exchange. The meeting concluded with a presentation on vaccine safety. The next two NVAC meetings will be held on June 15-16 and September 22-23.

Sean Dade briefly discussed the status of the Vaccines Federal Implementation Plan, which is a companion document to the five-year Vaccines National Strategic Plan (VNSP) released in January 2021. The Implementation Plan highlights federal agencies' vaccine activities that will be conducted over the next five years to advance the VNSP. It was published in the Federal Register in March to permit a 30-day public comment period. The Implementation Plan should be completed and released in the summer of 2022.

Sean also discussed an initiative entitled, "Promoting Vaccine Confidence in Local Communities through Partnership with Regional Health Offices." Six grantees were awarded funds to expand traditional immunization partnerships to plan, implement, and evaluate evidence-based practices and develop novel approaches to increase confidence in vaccines in local communities, particularly partnerships with minority-serving or other advocacy organizations that work with populations with low vaccination rates. OIDP staff is meeting with awardees on a monthly basis to ensure they are making progress in implementing activities in accordance with agreed upon timelines.

COVID-19 disrupted life-saving vaccination at a global level, putting millions at risk for catching diseases like measles, meningitis, and whooping cough. OIDP launched a campaign to help those who missed vaccinations because of the pandemic. There are several specific efforts to support this catch-up program, including a program to encourage parents to keep up with childhood vaccination schedules. The program will include print, digital, and multi-media tactics, and is slated to begin in July.

HHS is supporting the HHS Immunization Action Coalition's call to action focused on increasing adult vaccinations. Finally, the National Vaccine Program is working to establish national objectives for Healthy People 2030.

Sean Dade concluded their presentation and invited questions.

Discussion of Formation of Vaccinated vs. Unvaccinated Epidemiological Health Outcomes Assessment Workgroup, Karen Kain, Vice Chair

After a brief recess, Dr. Grimes invited Karen Kain to lead the discussion. Karen Kain noted the ACCV charter's charge to ensure vaccine safety and efficacy, and the related importance of valid studies that covered vaccinated and unvaccinated individuals. Karen Kain stated that no vaccine on a childhood schedule has ever been tested comparing the vaccine to an inert sterile saline and they are compared with other vaccines that have already been approved. In 1980, childhood chronic health was 12% with ten vaccines on the schedule. When the 1986 Act was passed, pharmaceutical companies were protected against liability for vaccine-related injury. Currently children receive 69 doses of vaccine before age 5 and chronic health is now 54%.

Karen Kain recommended creation of a workgroup to discuss working with an outside group to look at VSD data regarding vaccinated children versus unvaccinated. The Institute of Medicine (IOM) made that recommendation several years ago. They said it is a recommendation that the ACCV should support and promote. One question to consider is whether the proposed workgroup falls under ACCV's statutory obligations.

The ACCV charter permits the formation of subcommittees with the approval of the Secretary of HHS to perform specific functions for the ACCV. The subcommittee must report its activities to the ACCV. The ACCV must provide for reasonable participation by members of the public subject to existing regulations and agency guidelines. Similar advisory committees, like ACIP and NVAC, have formed subcommittees/workgroups with outside public participants under those guidelines. Karen Kain stated that the proposed workgroup falls under ACCV statutory obligations.

The 2011 NVAC White Paper acknowledged vaccine safety gaps, noting that 11 reviews completed by the IOM were "all hindered by inadequate understanding of potential biologic effects elicited by immunization." The paper stated that since 60% of IOM causality assessments found inadequate evidence to make a determination, further research might lead to more definitive assessments. Inadequate evidence is interpreted to mean lack or absence of quality research. In 2012, the largest IOM review to date included 158 commonly reported adverse events (AEs) for eight childhood vaccines. Causality determinations could not be made because of "inadequate evidence." Karen Kain reviewed the guiding principles, which were adopted to guide making recommendations for additions to the Table, acknowledging the role of the IOM in providing causality statements the ACCV needed to make changes to the Table. In considering changes to the Table, ACCV should favor adding or retaining proposed injuries.

Karen Kain stated that vaccine safety research gaps exist that require ACCV to better advise on implementation of the VICP and the Secretary's responsibilities. They also noted that a 2016 CDC study affirmed that the VSD is currently the best available system for studying the safety of the immunization schedule for the United States. The VSD has been previously used to identify the under vaccinated, including those not vaccinated.

- Karen Kain also noted that a 2016 CDC study affirmed that the VSD is currently the best available system for studying the safety of the immunization schedule in the United States. The VSD has been previously used to identify the under vaccinated, inclusive of zero vaccinated, for research purposes. Karen Kain commented that high

quality data is available that compares health outcomes of children vaccinated in conformance with the federally recommended schedule to the health outcomes of unvaccinated children. They added that, in 1991, the IOM confirmed the importance of replicated studies to confirm the legitimate conclusions of published research. The National Academy of Science reviewed the VSD design in 2005 to assess compliance of the VSD Data Sharing Program with data sharing standards of practice and determined that independence minimizes biases and conflicts of interest.

- Transparency ensures development of processes, practices and policies that are clear and in the spirit of openness.
- Fairness assures that all processes, practices, and policies are evenly implemented.
- Protection is available such that design and implementation protects individually identifiable information.

Karen Kain noted that the IOM recommended federal agencies seek legal advice on the applicability of federal law to VSD data and public access to the data. Applicable laws include the Shelby Amendment (1999), which has the force and effect of law, that assures public access to published research produced by a federal agency; and the Information Quality Act (2000) that contains guidelines to ensure the objectivity, utility, and integrity of information disseminated to the public by federal agencies.

In summary, the ACCV should comply with its statutory responsibility to establish a work group to assess studies of health outcomes in a vaccinated/unvaccinated study, and to make recommendations based on the study. The IOM has confirmed that such a study has not been conducted. Use of VSD data to determine the childhood vaccination schedule has been recommended by the IOM. The CDC has confirmed IOM's findings that the VSD is the best resource to study that schedule and that such a study is feasible. It is unknown if legal advice has been obtained by federal agencies on the applicability of the Shelby Amendment and the Information Quality Act. Nor is it known what access has been made available to independent external researchers related to IOM data sharing recommendations.

Karen Kain proposed the formation of the vaccinated/unvaccinated epidemiological health outcomes assessment workgroup. The charge of the workgroup would be to assess epidemiological studies conducted since the IOM's 2013 report on the safety of the childhood schedule that compare the short- and long-term health outcomes of vaccinated and unvaccinated children, inclusive of the VSD; and report findings and make recommendations for the ACCV's consideration.

Dr. Grimes invited discussion, and there were several comments: Dana DeShon suggested that there have been some studies of vaccines and normal saline. They noted that the IOM report presented on was released over a decade ago and there are studies that are more recent. Dana DeShon commented that the childhood vaccine schedule protects children from 14 pathogens. Delaying vaccinations has led to outbreaks of vaccine-preventable diseases, particularly for people under-immunized or who were never immunized. The IOM committee found no evidence that the present schedule is unsafe nor is there any indication that there are any links to autoimmune disease, asthma, seizures, child development disorders, learning disorders, or attention deficit disorder. Another comment on the study suggested it would require a large study population to properly permit randomization and that a compromised unvaccinated group from a general population would introduce many variables that could confound the results. Dana DeShon expressed concerns with the proposed workgroup, since they firmly believe in the

studies of vaccine safety and effectiveness.

Dr. Grimes interrupted the discussion to correct an oversight that the public comment should have occurred before the general commission discussion. Dr. Grimes invited public comment.

Public Comment on Formation of Workgroup

1. Carolyn Dimitri (ph.), Employee, Wayne State University – Developmental Disabilities Institute
   Carolyn Dimitri made a comment. They described their 30-year-old son who is vaccine injured. They suggested there was a prejudicial aspect of the committee composition, since there has not been a parent of a vaccine-injured individual, with the exception of Karen Kain. This is contrary to the 1986 Act, which requires that such an individual be a member. There is also an apparent lack of transparency that could be addressed by the creation of the proposed workgroup. Carolyn Dimitri expressed concern that there may be data missing from the meeting reports and materials because there is no indication of how many injured individuals have died, and very little information about the demographics of the vaccine-injured population. They expressed that this workgroup could increase transparency of the committee. To maintain a balance on the committee, they suggested that a motion might be made to retain Karen Kain on the committee until some of the vacancy issues are resolved. They commended Karen Kain's demeanor and their contribution of reports and data for the commission's consideration. Carolyn Dimitri expressed her concern about the current VICP backlog.
2. Theresa Wrangham, Executive Director, NVIC
   Theresa Wrangham suggested that it would be appropriate to look at the trends in childhood and adult petitions and Table changes that may have affected those trends. Initially the childhood petitions were higher than what has been the case until 2010. The lack of research creates a more adversarial environment. The IOM is charged with defining causality and has not been able to do that because of the lack of quality science. This inhibits the ability of the ACCV to revise the Table. The IOM also recommended that independent researchers have access to data from the VSD to be able to replicate research by federal agencies and/or to propose alternative hypotheses. The proposed workgroup would not look at vaccine safety specifically, which is not under its purview. It would only explore the reports and studies to understand the deficits that may exist and to consider the potential impact of ACCV recommendations. Theresa Wrangham noted that the Federal Advisory Committee Act (FACA) provides for verification of the minutes since audio recordings are maintained that enable ensuring that minutes reflect the proceedings of any meeting. It should be relatively easy to verify. Concerning the appointment of members to vacancies, the ACCV should be updated on the progress of that process. Regarding the data submitted to the ACCV to support the Table revision process, there should be a transparent process that explains the development of the data.
3. Jo Rezino
   Jo Rezino (ph), stated that their nonprofit organization is an alliance of practicing

nurses that focuses on the vaccine injured patient population and their families. The organization serves both nurses and patients. They noted that not all of the presentations made at the meeting were available on the ACCV website, making it difficult to follow the statistics mentioned, particularly regarding current VICP claims. The second point is the extensive review of COVID-19 vaccine information. The vaccine is not covered by the VICP, but rather the Countermeasures Injury Compensation Program (CICP), which is not under the purview of the ACCV. The time spent earlier discussing that issue, since not relevant to the ACCV, might have been better spent considering the more than two million vaccine injuries recorded on VAERS. Jo Rezino(?) expressed the opinion that the information regarding vaccine injury claims published on the website is incomplete in that many claims are not mentioned on the site and information available is very limited. They responded to Dana DeShon's comments regarding vaccine studies with saline and referred committee to Institute for Autism Science et al v. Centers for Disease Control and Prevention. Finally, they agreed that it would be important to add a representative of parents of vaccine injured children and attorneys to the commission to ensure that it is balanced.

Vote on Formation of Workgroup

Dr. Grimes closed the public comment period and invited ACCV members to discuss the formation of a workgroup and vote on it. Dr. Holloway referred to the earlier comment about the decline in vaccination rates, which they felt were the result of a decline in well child visits to doctors and clinics during the pandemic, rather than an issue of trust. In addition, the increase in chronic pediatric disorders is partly the result of adding new disorders to the chronic disease list, including mental health issues.

Timothy Thelen commented on the previous statement that vaccines on the Table are not placebo-controlled studies is inaccurate. The study designs are publicly available and do not support that contention. They stated that negative results and data should be published to enhance public trust in vaccines, but felt the workgroup might not be the best approach. They proposed reaching out to sister agencies, who are better equipped with scientific expertise, to answer a few questions proposed from the ACCV to get information that is more comprehensive. Dr. Holloway suggested that the NVAC White Papers mentioned by Karen Kain are probably obsolete and it might be appropriate to suggest updating them.

Daniel Boyle commented on the traumatic aspect of vaccine injury, and the lack of research makes it difficult to make decisions related to the Table. There is not research or active surveillance to help those injured. Although the VSD link is the best available system currently, Daniel Boyle felt that it was not enough to resolve the related issues. They felt an active surveillance system would be an improvement. Making the VSD completely public and available to the scientific community is an appropriate objective. Daniel Boyle felt the issue of restrictions on release of personally identifiable information should be examined. They recommended researching the recurring cases that were adjudicated or settled to update the Table. The ACCV duty to survey federal, state and local programs and activities related to the gathering of information on injuries associated with childhood vaccines is a commendable goal, but the overall mission should be larger in scope.

Karen Kain referred to the previous vote on Dr. Mawson coming to answer many of these questions for the committee. They reiterated the importance of testing vaccines against saline, and that this continues to deserve extended discussion. In addition, Karen Kain proposed another study to look at unvaccinated children and if they are dying from sudden infant death syndrome (SIDS). The proposed workgroup should be established with a balanced membership and the ability to invite independent experts, as well as representatives of the CDC and other representatives of the scientific community, to ensure a fair and balanced conversation. This should include both sides of any issue, such as a vaccinated versus unvaccinated study population.

Dr. Holloway recalled the effects of contagious diseases before the availability of childhood vaccinations, and the risks related to being unvaccinated. There is also an ethical issue related to research that includes an unvaccinated population. Karen Kain added that it is difficult to introduce unvaccinated studies into the discussion at ACCV meetings, although they believed there are a number of those studies that would be helpful to consider. They would like the study to be done, without fear of the findings. Karen Kain shared personal experience as parent of vaccine-injured child, who was treated horribly and was delayed payment from VICP. They stated that the VICP process is exceptionally contentious and expensive.

Timothy Thelen emphasized the need for ACCV positions to be filled for balanced discussion and needing to rectify the transparency in the ACCV appointment process. It is critical to tap into additional vaccine safety resources, but believes the proposed workgroup is not the solution and doubts controlled trials of vaccinated and unvaccinated populations is an option. However, the exploration of this scientific question should be done and possibly advised by NVAC.

Dr. Grimes invited a motion concerning the establishment of a workgroup. Timothy Thelen moved to defer action on the workgroup and invite the NVAC to provide advice on the design and function of the working group discussed, including the vaccinated versus unvaccinated study proposed. They clarified that it was a two-part motion; first is the decision to ask questions to NVAC and secondly, decide on the questions ACCV would like NVAC to provide technical assistance on regarding the viability of vaccinated and unvaccinated studies. The motion failed for lack of a second. Dr. Holloway made a motion to establish a workgroup as described by Karen Kain in their prior presentation. Karen Kain seconded. Dr. Grimes invited a vote on the motion, the result was two in favor, and three opposed. The motion failed. Timothy Thelen requested a second on their prior motion. The motion failed for lack of a second.

Future Agenda Items/New Business

Dr. Grimes invited recommendations for future agenda items. Daniel Boyle asked that a discussion on different tools that the ACCV might utilize to meet its mission, including the scope of workgroups. Dr. Grimes invited public comment.

Public Comment

1. Jo Rezino
   Jo Rezino agreed that active surveillance for all vaccines rather than passive

surveillance would be a good topic to address. They added that, in their experience of more than 28 years as a practicing nurse, they have never received any information in any patient population or in any studies, about what the appropriate things to watch for would be for a vaccine injury, how to report one, or whether there is mandated reporting. That issue might be avoided if reporting was actively mandated. Jo Rezino referred to Dr. Holloway's previous comment that described their extensive support and care for vaccine injured children. They mentioned the effects of childhood illness related to vaccine injury, including children who have suffered permanent disability or died. Jo Rezino added there are children whose only real care and support came from their parents. Jo Rezino would like to make sure that both sides are continuously being addressed. They emphasized the important role of the ACCV to ensure vaccine safety for all vaccinated children.

2. Theresa Wrangham, Executive Director, NVIC
   Theresa Wrangham expressed appreciation to Karen Kain who included in their presentation the role of the ACCV in making recommendations to the VICP. The workgroup Karen Kain proposed is a place to conduct conversations about subjects that are in the ACCV's purview under federal laws, including changes to the Table. Those conversations will not take place if the workgroup is not established. They strongly endorsed the idea of the proposed workgroup and others that might be formed in the future.

There were no additional public comments and Dr. Grimes invited a motion to adjourn. On motion duly made and seconded, the meeting adjourned.