Advisory Commission on Childhood Vaccines (ACCV)
Teleconference and Zoom

September 2, 2021

Members Present

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

Ms. Kain called the meeting to order and welcomed those present. She asked Ms. Tamara Overby to introduce new members. Ms. Overby introduced Daniel Boyle, the general public member, Dr. Albert Holloway, a pediatrician, and Ms. Dana DeShon, a nurse practitioner representing health care professionals; each introduced themselves with a brief biography. Mr. Boyle briefly described his early experience with the program as a vaccine-injured adult. Ms. DeShon explained her background, which includes a doctorate in nursing. She has been a primary care pediatric nurse practitioner for 23 years. Dr. Holloway described himself as a pediatrician in Montgomery, Alabama, with 42 years in his practice working in community health centers and mental health centers.

The existing ACCV members also introduced themselves. Ms. Kain, the parent of a vaccine-injured child, briefly shared the story of her daughter that died at 15 years of after a DPT vaccine injury. Ms. Kain has been an advocate for the program ever since. Mr. Spiegel provided a brief background as an attorney representing physicians and other health care specialists, noting that he did not litigate claims for vaccines specifically. Ms. Overby closed by noting that work is underway to add new commissioners hopefully by the next meeting.

Public Comment on Agenda Items, Ms. Karen Kain, Vice Chair

Ms. Kain invited public comments on the agenda. There were no requests for public comment.

Approval of the March 2021 meeting minutes, Ms. Karen Kain, Vice Chair

On a motion made and seconded, the ACCV members unanimously approved the March 2021 meeting minutes.

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 petitions filed as of September 1, 2021 was 1,834 filed by adults and 117 filed on behalf of children, a total of 1,951 petitions.

Administrative funding for processing claims has not increased at the same rate as claims filed, so there is a backlog of 1,561 petitions awaiting review. Of the backlogged claims, all claims for children have not yet been activated by Pre-Assignment Review (PAR).

As of September 1, 2021, the VICP has paid about $202 million for petitioners' awards and about $33 million for attorneys' fees and costs in FY 2021.

Adjudication Categories	Fiscal Year 2019	Fiscal Year 2020	Fiscal Year 2021
Compensable	**642 (100%)**	**710 (100%)**	**636 (100%)**
Concession	238 (37%)	265 (37%)	280 (44%)
Court Decision	45 (7%)	49 (7%)	16 (3%)
Settlement	359 (56%)	396 (56%)	340 (53%)
Not Compensable	**184**	**217**	**222**
Total	**826**	**927**	**858**

The balance in the Vaccine Injury Compensation Trust Fund as of June 30, 2021, was slightly over $4 billion. Income so far for FY 2021 includes about $144 million from excise tax revenue and $38 million from investments for a total of about $182 million.

Recent trends in the VICP include:

- 90% of claims were filed for adults in the last two fiscal years;
- 54% allege shoulder injury related to vaccine administration (SIRVA), and 73% claimed an injury from influenza vaccination.
- 60% of claims were compensated by negotiated settlement.
- 13-month wait for review by a HRSA physician after PAR.

Ms. Overby commented that there is a continuing search for all ACCV positions, and nominations are always welcome: three health professionals, two must be pediatricians; three from the general public, two must be representative of vaccine-injured children; and three attorneys, at least one who is representing a vaccine manufacturer, and one representing persons who have suffered a vaccine injury. Ms. Overby provided contact information for the ACCV Principal Staff Liaison, Annie Herzog, at 301-443-6634 or e-mail: accv@hrsa.gov.

During the discussion, Ms. Overby responded to a question about the record number of claims filed in FY 2021. Ms. Overby explained that the Secretary of HHS's (Secretary) proposed to remove SIRVA from the Vaccine Injury Table which (Table) stimulated that claim

increase. Ms. Overby explained that two separate teams review adult versus children petitions. The backlog in children's claims existed because the PAR had not deemed the medical records complete.

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

Ms. Pearlman referenced the Department of Justice (DOJ) PowerPoint materials as part of her presentation for the three-month reporting period from May 16, 2021, through August 15, 2021. (DOJ PowerPoint (PP) at 2.) She noted that DOJ's reporting period is different from the HHS and CFC reporting periods. Ms. Pearlman stated that during DOJ's reporting period, 342 petitions were filed, 24 (7%) of which were filed on behalf of minors and 318 (93%) of which were filed by adults. (DOJ PP at 2.)

Ms. Pearlman stated that 221 petitions were adjudicated during this reporting period. (DOJ PP at 3.) One hundred and seventy five of the adjudicated cases were compensated. (DOJ PP at 3.) Of the 175 compensated cases, 71 cases were conceded by the government, five of which had decisions awarding damages and 66 of which had decisions adopting proffers. One hundred and four of the compensated cases were not conceded by the government, the majority of which (102 cases) involved settlements. Forty-six cases were not compensated. (DOJ PP at 3.) Thirty-four petitions were voluntarily withdrawn. (DOJ PP at 4.)

Ms. Pearlman discussed recently decided and pending cases in the U.S. Court of Appeals for the Federal Circuit (CAFC). (DOJ PP at 5-7.) She stated that during the reporting period, the CAFC reversed two entitlement decisions appealed by petitioners. (DOJ PP at 5.) She further noted that one appeal of an entitlement decision by a petitioner was pending and one appeal of an entitlement decision by respondent was pending before the CAFC. (DOJ PP at 6-7.)

Ms. Pearlman next discussed appeals at the Court of Federal Claims (CFC). (DOJ PP at 8-11.) She noted that the CFC affirmed four entitlement decisions appealed by petitioners and one damages decision appealed by respondent during this reporting period, remanded one entitlement decision appealed by a petitioner and one entitlement decision appealed by respondent, and reversed and remanded one attorney's fees decision appealed by petitioner. (DOJ PP at 8-9.) Ms. Pearlman stated that there were nine appeals pending before the CFC filed by petitioners, seven of which were filed since the last reporting period (six entitlement decisions, one damages decision, and two attorney's fees and costs decisions). (DOJ PP at 10.) She further stated that there was one appeal of an entitlement decision filed by respondent pending before the CFC. (DOJ PP at 11.)

Ms. Pearlman noted that oral argument at the CAFC in *Wright v. HHS* was scheduled for October 7, 2021, and oral argument at the CFC in *Bull v. HHS* was scheduled for September 15, 2021. (DOJ PP at 12.)

Ms. Pearlman 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 13-22.) She noted that 50% of the cases resolved in two years or less, 70% involved the flu vaccine, and 62% involved an alleged SIRVA injury. Ms. Pearlman also provided the usual appendices, which include a glossary of terms and diagrams to help commissioners understand the appeals process.

Ms. Pearlman concluded her report and invited questions from the commissioners. Dan Boyle inquired whether the adjudicated settlements were cases decided by the Court or settled

cases. Ms. Pearlman explained that every case is decided by the Court, however, in settled cases the parties negotiate an agreement without conceding entitlement and present a stipulation to the Court, and the Court typically adopts the stipulation.

Update on the ISO, CDC, Dr. Jonathan Duffy

Dr. Duffy discussed the Advisory Committee on Immunization Practices (ACIP) recommendations for COVID-19 vaccines, including vaccines approved by the FDA and manufactured by Pfizer-BioNTech, Moderna, and Janssen. About 365 million doses of COVID-19 vaccines have been administered to about 202 million individuals 12 years old and older who received at least one vaccination, comprising 71% of the population. There have been four follow-up ACIP meetings to discuss COVID-19 vaccine topics in June, July, and August. A risk of myocarditis was recorded among those who received the mRNA vaccines, particularly in males 12-29 years of age, but the ACIP determined that the benefits of the vaccinations outweighed the risks. The ACIP recommended continued administration of these vaccines. Dr. Duffy also reported that the J&J/Janssen Covid-19 vaccine appeared maybe associated with a small number of cases of Guillain-Barré syndrome – about 167 cases in more than 14 million vaccinations.

Although not a safety issue, ACIP addressed the need for additional (booster) doses in individuals who are moderately to severely immune-compromised and vulnerable to COVID-19 and or at risk of serious, prolonged illness. It is anticipated that individuals will be able to receive the booster in the fall, eight months after receiving the second dose of the mRNA vaccine. There have been several vaccine safety publications related to COVID-19.

Dr. Duffy turned to non-COVID items of interest addressed at the ACIP meeting in May. The committee voted on a new recommendation for three doses of Dengvaxia, the FDA-approved dengue vaccine, for those living in endemic areas of increased risk, administered at zero, six, and twelve months to persons 9 to 16 years of age, with a lab confirmation of previous dengue infection. For the U.S. that would be Puerto Rico, American Samoa, and the U.S. Virgin Islands.

ACIP also held a session on influenza vaccine and voted to affirm the updated statement on the prevention and control of seasonal flu with vaccines recommended for the 2021-2022 influenza season. The core recommendation remains in effect for all individuals ages six months and older who do not have contraindications.

The ACIP voted on updated recommendations for rabies vaccines for persons under 18 years of age with pre-exposure prophylaxis; a two-dose rabies vaccine series for persons for whom such vaccination is indicated.

The ACIP also held a session for discussion only to provide information about the risks of herpes zoster, severe disease, and complications, especially in immunocompromised populations. More discussion on this topic will take place in future ACIP meetings.

Finally, ACIP discussed the pneumococcal vaccine, for information only, on two new vaccines approved for use in adults – PCV 15-valent and PCV 20-valent. More discussions will occur in the future. Dr. Duffy concluded his presentation.

During the discussion, Ms. Kain shared the distressing circumstances around her parents' treatment for COVID-19 infections and her stating that doctors are denying them treatments. Ms. Kain indicated her belief that Ivermectin is a safe drug that was not made available to her father. She stated that her father is dying from COVID-19, and her mother is in grave condition,

with no clear treatment plan. She asked what reasonable treatments were recommended. CDR Valerie Marshall stated that the FDA has recommended monoclonal antibodies as a treatment for COVID-19 infection and has other treatment information on its website. Dr. Duffy commented that his office was concerned mainly with vaccine safety, not treatment. The CDC has updated information daily through surveillance systems such as the Vaccine Adverse Event Reporting System (VAERS). There was a comment that the V-Safe Reporting System is a complimentary surveillance system to identify adverse events and to proactively collect details about serious adverse events through a survey process once an individual reports an incident. Claire Schuster added that NIH is actively conducting clinical trials looking at repurposed drugs as potential treatments for COVID-19.

Update on the NIAID, NIH, Ms. Claire Schuster

Ms. Schuster presented an update for the National Institutes of Health. She explained that collaborating researchers at NIAID and the University of Washington had developed an investigational nanoparticle influenza vaccine to provide long-lasting protection against multiple flu strains. A Phase I clinical trial was launched to test the safety and immunogenicity of the vaccine, named FluMos-v1. The study will enroll up to 35 healthy participants between 18 and 50 at the Clinical Center at NIH. Universal vaccines for multiple flu strains are being developed by many research groups and could one day eliminate the need for annual vaccinations.

Ms. Schuster indicated that she would focus the rest of her presentation on COVID-19, starting with the NIH Researching COVID to Enhance Recovery (RECOVER) Initiative.). Through this initiative, NIH seeks to understand, prevent and treat post-acute sequelae of SARS CoV-2 infection (PASC). More information is available at https://recovercovid.org.

NIH has issued a Notice of Special Interest (NOSI) to solicit community-engaged research to evaluate intervention strategies to facilitate vaccination uptake in clinical and community contexts. The NOSI also addresses barriers to increasing reach, access, and uptake of vaccinations among health disparity populations at high-risk who are likely to experience vaccine hesitancy. Awards were made to various institutes under this notice.

NIH supports a Phase I-II clinical trial of fully-vaccinated adults who received the three authorized or approved COVID-19 vaccines from Janssen, Moderna, and Pfizer-BioNTech vaccines and Moderna's mRNA 1273.211 vaccine candidate to assess the safety and immunogenicity of mixed boosted vaccine regimens. At least twelve weeks after receiving the initial regimen, participants will receive a single booster as part of the trial. NIAID also supports a pilot study to assess the antibody response to the third dose of an authorized COVID-19 mRNA vaccine in kidney transplant recipients who did not respond to two doses of the Moderna or Pfizer BioNTech vaccines. Research has shown that many organ transplant recipients do not develop antibodies against SARS- CoV-2 after receiving an authorized COVID-19 vaccine regimen. The purpose of the Phase II trial is to determine whether a third dose of one of the mRNA COVID-19 vaccines could overcome this problem for some kidney transplant recipients.

In May 2021, Novavax, Inc. announced an expansion of its Phase III clinical trial for its COVID-19 vaccine to evaluate the vaccine candidate's efficacy, safety, and immunogenicity in up to 3,000 adolescents aged 12 to 17. A trial crossover will ensure that all participants receive an active dose of the vaccine, even those originally assigned a placebo. An ancillary study of nasal swabs will assess asymptomatic viral shedding of SARS-CoV-2. Finally, NIAID has launched a new observational study to evaluate the immune responses generated by COVID-19

vaccines administered to pregnant or post-partum women. The research will assess the development and durability of antibodies against SARS-CoV2 during pregnancy and the first two months post-partum. Ms. Schuster concluded her presentation.

Update on the CBER, FDA, CDR Valerie Marshall

CDR Marshall stated that on August 12, 2021, the FDA amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the administration of an additional dose (as a third primary series dose) to individuals who have been determined to have certain kinds of immunocompromise.

- A third primary series dose of the Pfizer-BioNTech COVID-19 Vaccine at least 28 days following the second dose is authorized for administration to individuals 12 years of age and older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. A third primary series dose of the Moderna COVID-19 Vaccine at least one month following the second dose is authorized for administration to individuals 18 years of age and older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The FDA announced a virtual meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the administration of a booster dose of Comirnaty (COVID-19 Vaccine, mRNA) vaccine. The meeting will be held on September 17, 2021. On August 23, 2021, the FDA granted the first approval of a COVID-19 vaccine, Comirnaty, manufactured by Pfizer Inc. for BioNTech Manufacturing, for the prevention of COVID-19 in individuals 16 years of age and older. Since the approval of Comirnaty, the Pfizer-BioNTech COVID-19 Vaccine has continued to be available under the EUA as a two-dose primary series in individuals 5 years of age and older, as a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

On August 13, 2021, FDA approved Ticovac for active immunization to prevent tick-borne encephalitis (TBE) in individuals one year of age and older. TBE is a viral infection of the brain and spine, which can be transmitted to humans through the bite of an infected tick. Although TBE is not endemic in the U.S. to date, it has been identified in more than 35 countries across Europe and Asia. U.S. citizens, such as members of the U.S. military deployed to endemic regions and travelers to those regions who engage in warm weather outdoor activities, are at risk for TBE.

On July 23, 2021 FDA approved a supplement to the biologics license application for Shingrix (Zoster Vaccine, Recombinant, Adjuvanted), to expand the indication and use to include the prevention of herpes zoster (HZ) (shingles) in adults aged 18 years and older, who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy. CDR Marshall concluded her comments.

During the discussion, Mr. Boyle asked about the coverage of vaccines under the Countermeasures Injury Compensation Program (CICP) and whether they would be included in

the vaccine injury table when recommended for children. Ms. Overby commented that the CICP is under the DICP, like the VICP; however, the CICP covers COVID-19 vaccines. For a vaccine to be covered under the VICP it must be recommended for routine administration to

Update on the OIDP, Dr. David Kim

Dr. Kim began with a statement that there is no evidence of increased adverse events related to the COVID-19 vaccine in pregnant women. Additional post-marketing studies are robust, and there is evidence that the complications from the disease far outweigh the possible adverse events associated with the mRNA COVID-19 vaccine, which is a very important tool in the battle against COVID-19. The recommendation is that individuals 12 years and older receive the vaccine. He introduced Sean Dade, who will represent OIDP in the future.

Mr. Dade said that he was excited to participate in this ACCV meeting and discuss the OIDP vaccine activities. He continued his remarks with an update about the National Vaccine Advisory Committee (NVAC). In 2021, NVAC met twice and has the next meeting scheduled in September 2021. At the first meeting, February 4-5, 2021, the members discussed barriers to receiving the COVID-19 vaccine and heard a presentation about how fear of the vaccine needle can discourage individuals from being vaccinated. NVAC also discussed vaccine safety, and representatives from VRBPAC, ACIP, and ACCV gave updates.

The second NVAC meeting was held June 16-17, 2021, and Dr. Rachel Levine outlined priorities related to vaccines. During the meeting, NVAC members heard from various organizations on how they are working to address vaccine equity and vaccine hesitancy. The meeting also highlighted the need for children and adults to get up to date on routinely recommended vaccines that may have been missed due to interruptions in medical services during the COVID -19 pandemic. The NVAC also approved an immunization equity report that outlined 23 recommendations for the Assistant Secretary of Health to advance vaccine equity in the United States during the second meeting. The report addresses equity, affordability, public awareness, vaccine acceptance, and tracking.

The third NVAC meeting is September 14-15, 2021. The panel will discuss COVID-19 vaccines, including the mRNA technology for vaccines, and will hear presentations about how organizations are preparing for the upcoming proceedings.

The Vaccine Division is now implementing the 5-year vaccine plan created in January 2021 and engaging the Interagency Vaccine Work Group (IVWG), which serves as the steering committee to guide the implementation of the National Vaccine Plan. The workgroup meets on September 21, 2021. A data collection tool is also being developed to capture the agency's activities in the next five years.

Mr. Dade announced community grants to improve vaccine uptake by the public by working with local communities to increase confidence in routinely recommended vaccines, which is scheduled for release on September 30, 2021. A second grant opportunity is an innovative approach to enhance an immunization culture in OB-GYN care, targeting OB-GYN offices, family practices, and birthing classes.

Noting the shutdowns caused by the COVID-19 pandemic, Mr. Dade noted that many children fell behind in their wellness visits and, for that reason, also fell behind in their scheduled immunizations. About 26 million doses were missed by children and teens. OIDP is focusing on this problem and is working to bring awareness to this issue. There is also a toolkit to help health practitioners alleviate the problem. Mr. Dade concluded his presentation.

During the discussion, Dr. Kim responded to a question about an increase in infections in children, noting that there has been an increase, but the vaccination regimen is effective in preventing severe illness, hospitalizations, the need for ventilation therapy, and the risk of mortality.

Public comment

Ms. Kain invited comments from the public. There were no requests.

Future Agenda Items, New Business, and Adjournment

Mr. Boyle observed that some individuals, vaccine hesitancy could be related to experiencing previous adverse events related to vaccinations, particularly during the COVID-19 pandemic. He then asked about the purpose of CISA. Dr. Duffy commented that the Clinical Immunization Safety Assessment Project is one of three main projects in the ISO. It was established in 2001 as a collaboration with seven medical research centers. It conducts vaccine safety research and provides clinical consultation with health departments and individual health care providers in the United States. CISA only provides that consultation to health care professionals who provide treatment and not to individual patients.

Ms. Kain offered two items for future discussion. Ms. Kain stated that at the December 2020 ACCV Meeting she proposed inviting Dr. Mawson to the next ACCV meeting to discuss his vaccinated vs un-vaccinated study, with the goal of creating a workgroup to study the VSD and how it can be used to study vaccine safety. She further stated that at the December 2020 Meeting the four ACCV commissioners voted in favor of having Dr. Mawson present to the ACCV at the March 2021 ACCV meeting. Then, Ms. Kain stated that days before the March Meeting she was asked by Ms. Overby to postpone Dr. Mawson's presentation because there were not enough commissioners to have this conversation. Then the June 2020 ACCV meeting was also canceled so Dr. Mawson's presentation was again postponed until the September 2021 meeting. Ms. Kain states that she was informed before the September 2021 meeting that the Commission's vote and wishes, to have Dr. Mawson present to the ACCV were being rejected. Ms. Kain stated that Ms. Overby's job is to support the Commission, not override the Commission's votes and wishes. Ms. Kain said she was told on a telephone call by Ms. Overby, nine months after the Commission initially voted to hear from Dr. Mawson, that he would not be allowed to present to the ACCV because Dr. Mawson was not an specialized in his field, his article was retracted and that Ms. Kain had not given the ACCV enough time to evaluate the information. Ms. Kain further stated that the December 2020 vote to invite Dr. Mawson was removed from the December 2020 ACCV meeting minutes. Ms. Kain stated that removing the vote from the meeting minutes is shocking and irresponsible and an example of the bullying that she has been dealing with as a commissioner on the ACCV.

Ms. Kain briefly reviewed the recent history of childhood vaccines, mentioning research gaps and recommendations by the Institute of Medicine (now known as the National Academy of Medicine). She reiterated her request that the Commission establish a workgroup that utilized the Vaccine Safety Datalink and other resources to gather information to make a recommendation to the Secretary about vaccine safety.

Ms. Overby asked what specific recommendations should be addressed by the ACCV. Ms. Kain responded that vaccinated vs. unvaccinated studies should be undertaken. Dr.

Holloway asked about the specific charge in the charter that would apply to this discussion. Ms. Overby cited the charter reference to surveying federal, state, and local programs and activities related to the gathering of information on injuries associated with the administration of childhood vaccines, including adverse reaction reporting requirements, and to advise the Secretary on the means to obtain the published credible data related to the frequency and severity of adverse reactions associated with childhood vaccines. She made it clear that the ACCV does not conduct studies but could forward a recommendation to the Secretary.

Ms. Kain noted that VSD information is not available to the public, the way that data from VAERS is available. Concerning VSD information, Dr. Duffy explained that a member of the public could request collaboration with a VSD participating site to explore an inquiry.

Finally, there was an extensive discussion about Dr. Mawson's presentation and the delays in scheduling his presentation. Dr. Kim observed that his review of the documents related to the Dr. Mawson presentation revealed that they do not necessarily represent actual studies, but a summary of studies. He also observed that the references were published in a relatively new journal called *Vaccines*, plural, and not the preeminent Elsevier Journal, *Vaccine*, singular.

Ms. Kain asked Ms. Overby to hold a vote to have Dr. Mawson come to the next ACCV meeting and discuss his studies. Ms. Overby stated that it would not be reasonable to ask commissioners to vote today to hear from Dr. Mawson because the commissioners have not had a chance to review the Dr. Mawson's papers. The commission agreed to review materials Ms. Kain has distributed to the Commission and discuss vaccinated vs. unvaccinated studies at the December 2021 ACCV meeting.

Ms. Overby recommended a motion to adjourn, which was duly made and seconded, and unanimously approved. The meeting was adjourned.