Advisory Commission on Childhood Vaccines (ACCV)

Teleconference

March 1, 2023

Members Present

Albert Holloway, Jr. MD (2024)
Daniel Boyle (2024)
Timothy Thelen, JD (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, Chair, ACCV
Pita Gomez, Principal Staff Liaison, ACCV

Welcome and Chair Report, CDR Reed Grimes, MD, MPH Director, Division of Injury Compensation Programs (DICP) and Chair, ACCV

Dr. Grimes called the meeting to order and welcomed everyone. Dr. Grimes announced that three of our four current commissioners and all ex officio members were present which constituted a quorum.

Public Comment on Agenda Items, CDR Reed Grimes, MD, MPH Director, DICP and Chair, ACCV

Dr. Grimes invited public comment on the meeting agenda and there were none.

Approval of the December 1, 2022, and December 2, 2022 Meeting Minutes, CDR Reed Grimes, MD, MPH, Director, DICP and Chair, ACCV

Dr. Grimes invited approval of the December 1, 2022 Meeting Minutes. On motion duly made and seconded, the ACCV voted and unanimously approved the December 1, 2022, ACCV Meeting Minutes.

Dr. Grimes invited approval of the December 2, 2022 Meeting Minutes. Dan Boyle noted there was a typographical error, that a comment attributed to Dr. Broder was actually made by Dr. Stratton. With that correction, on motion duly made and seconded, the ACCV voted and unanimously approved the December 2, 2022 ACCV Meeting Minutes.

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

Dr. Grimes previewed the updates for March 1st Meeting: 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

(NIH), 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).

Dr. Grimes also previewed the presentations from March 2nd Meeting, which included scientific presentations from both NIH and CDC.

The number of VICP petitions filed in Fiscal Year (FY) 2023 as of February 1, 2023, was 390. Of those petitions, 342 were filed for adults and 48 were filed on behalf of children. There had been a minor but steady increase year to year, with a bolus in 2021 for petitions filed for adults because of an increase in claims for shoulder injury related to vaccine administration (SIRVA). Petitions filed for children has been relatively stable and did not experience this increase in 2021. Administrative funding for processing claims has not increased at the same rate as claims filed, which has resulted in a backlog of 1,374 petitions for adults awaiting review. Additionally, 101 of the 102 claims for children in the backlog have not yet been activated by Pre-Assignment Review (PAR).

During FY 2019 to FY 2022, petitioners' awards of about $200 million per year and attorneys' fees of about $34 million were paid annually. In FY 2023, as of February 1, 2023, the VICP has paid about $46 million for petitioners' awards and nearly $20 million for attorneys' fees and costs.

Adjudication Categories for VICP Petitions as of February 1, 2023

Adjudication Categories	Fiscal Year 2020	Fiscal Year 2021	Fiscal Year 2022	Fiscal Year 2023
Compensable	**711 (100%)**	**754 (100%)**	**932 (100%)**	**272 (100%)**
Concession	264 (37%)	335 (45%)	426 (45%)	138 (51%)
Court Decision	48 (7%)	18 (2%)	16 (1%)	4 (1%)
Settlement	399 (56%)	401 (53%)	490 (54%)	130 (48%)
Not Compensable	**217**	**259**	**262**	**116**
Total	**928**	**1,013**	**1,194**	**388**

The balance in the Vaccine Injury Compensation Trust Fund as of December 31, 2022, was approximately $4.4 billion. Income includes about $27.5 million from investments and $42 million from excise tax income. Recent trends in the VICP include:

- 92% of petitions filed were filed for adults in the last two FYs;
- Over 63% of petitions filed in the last 2 FYs allege SIRVA;
- 74% of petitions filed in the last two FYs allege an injury from the influenza vaccine;
- About 58% of petitions filed are compensated by negotiated settlement; and
- There is nearly a 13-month wait for petitions to be reviewed by a HRSA physician after the (PAR) activation.

At the December 2022 ACCV meeting, the National Academies of Sciences, Engineering, and Medicine (NASEM) Committee was still being formed. The Committee was formed and held their first multi-day meeting from January 25 – February 1, 2023. In late March, the Committee will have an open scientific session with a public comment period. Dr. Grimes concluded by noting that DICP staff continues to seek nominations for all vacant ACCV positions.

Dr. Grimes ended the presentation and invited questions. Daniel Boyle requested clarification on Slide 3 regarding the number of petitions filed in FY 2023 as of February 1, 2023. Dr. Grimes confirmed that these numbers are reflective of the fiscal year beginning in

October and therefore, these numbers cover a four-month period. Daniel Boyle followed up and asked about the projection of claims for the remainder of the FY, and Dr. Grimes responded that the rate of incoming claims appears to be similar to the previous year. Tim Thelen asked about the recruitment efforts to fill vacancies on the ACCV. Dr. Grimes responded that there are nominations being considered and processed. Dr. Grimes encouraged additional nominations to be submitted to continue filling vacancies.

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

Heather Pearlman, referencing the DOJ PowerPoint materials, stated that her presentation covered the period of November 16, 2022, to February 15, 2023, which is a different time period than reported in the DICP update. Ms. Pearlman reported that 277 claims were filed in the U.S. Court of Federal Claims (CFC), 39 on behalf of minors and 238 filed by adults.

The VICP adjudicated 282 petitions during this reporting period; 217 were compensated and 65 were not. HHS conceded 96 cases, mostly resolved by accepting a proffer, and 121 of the compensated cases were not conceded. Twenty-eight cases were voluntarily withdrawn resulting in no judgment.

In the U. S. Court of Appeals for the Federal Circuit (CAFC), only one case was decided/affirmed, *Loyd v. HHS*, an entitlement case brought by petitioner. Eight cases were pending, seven involving entitlement and one attorneys' fees and costs.

In the CFC, six cases were decided, three brought by petitioner and three by respondent. All were affirmed except one brought by respondent which was vacated and remanded. There were nine petitioner appeals and two respondent appeals pending. At the time the DOJ PowerPoint was prepared, one case was scheduled for oral argument at the CFC.

Ms. 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. During the reporting period, there were 96 adjudicated settlements, most involving SIRVA or Guillain-Barré Syndrome. Most were resolved in less than four years, and three lasted for six to seven years.

The usual appendices were provided, which includes a glossary of terms and diagrams of the appeal levels and processes involved.

Ms. Pearlman concluded her report and invited questions. During discussion, Daniel Boyle asked if all conceded cases meet the Vaccine Injury Table (Table) criteria and if all settlements are for non-Table cases. Heather Pearlman explained that settled cases do not meet the Table criteria. Mr. Boyle wanted to see a breakdown of concessions and injuries going forward.

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

Dr. Duffy discussed recent publications on vaccine safety that can be found on the CDC website:

1. *Safety Monitoring of JYNNEOS Vaccine During the 2022 Mpox Outbreak – United States, May 22 – October 21, 2022.*
    a. Nearly a million doses were administered, and the vaccine profile was similar to the prelicensure studies. Injection site reactions were among the most common adverse health events reported and there were no serious adverse events (AEs) among those under 18 years of age.

2. *Safety of co-administration of mRNA COVID-19 and seasonal inactivated influenza vaccines in the Vaccine Adverse Event Reporting System (VAERS) during July 1, 2021 – June 30, 2022.*
    a. The objective was to describe reports to the VAERS after co-administering mRNA COVID-19 and seasonal inactivated influenza vaccines. VAERS received 2,449 reports of adverse events, and the reports did not reveal any unusual or unexpected patterns of AEs.

Dr. Duffy listed several COVID-19 vaccines-related publications on vaccine safety that can be found on the CDC website.

1. Reports of Guillain-Barré Syndrome after COVID-19 vaccination in the United States.
2. The v-safe after vaccination health checker: Active vaccine safety monitoring during CDC's COVID-19 pandemic response.
3. A broad assessment of COVID-19 vaccine safety using tree-based data mining in the Vaccine Safety Datalink.
4. Tree-based data mining for safety assessment of first COVID-19 booster doses in the Vaccine Safety Datalink.
5. A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination.
6. Reactions following Pfizer-BioNTech COVID-19 mRNA vaccination and related healthcare encounters among 7,077 children aged 5-11 years within an integrated healthcare system.

Dr. Duffy discussed recent CDC vaccination coverage publications. This work is done by a different part of CDC (not ISO), and they publish annual updates. Dr. Duffy provided a CDC web link for additional information to be accessed. CDC uses several national surveys to measure vaccine uptake, including the (1) National Immunization Survey (NIS) of children through 35 months, (2) School Vaccination Assessment Reports for vaccinations required for enrollment in kindergarten, the (3) NIS-Teen for vaccinations given to preteens and teens, (4) the Behavioral Risk Factor Surveillance System (BRFSS) for adult vaccinations, and (5) NIS - Flu of influenza vaccinations given to individuals six months to 17 years of age.

Dr. Duffy also highlighted a few recent MMWR annual updates.

1. *Vaccination Coverage by Age 24 Months Among Children Born During 2018–2019 — National Immunization Survey–Child, United States, 2019–2021.*
    a. The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination against 14 diseases during the first 24 months of life. Vaccination coverage has remained high among children, even during the COVID-19 pandemic.
2. *Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2021–22 School Year.*
    a. Vaccination coverage with state-required vaccines among kindergarten students declined in the past two years, from 95% to 93% and the exemption rate remained low. Despite widespread return to in-person learning, COVID-19 related disruptions affected vaccination coverage and prevented a return to pre-pandemic coverage levels.

3. *National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2021.*
    a. Tetanus, diphtheria, and acellular pertussis vaccine (Tdap), meningococcal conjugate vaccine (MenACWY), and human papillomavirus (HPV) vaccine, are routinely recommended for adolescents. Among adolescents aged 13–17 years in 2021, HPV vaccination coverage of more than one dose increased, and coverage with more than one dose Tdap and MenACWY, remained high. When considering COVID-19 impact on adolescents born in 2008, there is a concerning decrease in more than one MenACWY and one Tdap dose coverage.

Dr. Duffy concluded his report and invited questions. Daniel Boyle asked for clarification that there was a decrease in the vaccination coverage trend by 1% each year. Dr. Duffy confirmed this. Additionally, Daniel Boyle asked for clarification of the term, "tree-based data mining." The tree refers to the International Classification of Diseases, Tenth Revision, or commonly known as ICD-10 codes' structure in a hierarchical way, which allows medical conditions to be grouped into different levels of categorization. This is used for a broad look at the occurrence of any potential outcomes and allows for potential associations to be identified.

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

Claire Schuster began with providing a few updates regarding advancements with influenza vaccine. One NIH-funded team is working on developing a universal vaccine that would protect against all 20 known viral subtypes. This vaccine is in early stages of development, but has shown promise in preclinical studies. Researchers don't expect that this would prevent infection, but rather that it should help prevent severe illness and death. Researchers report that they are moving towards clinical trials to continue evaluating this approach.

Claire Schuster discussed controlled human infection models (CHIMs), which involve infecting healthy adults under carefully controlled conditions. CHIMs, in use since 1930s, are used to advance understanding of infection natural history, clinical characteristics, and immune responses. The paper shown describes a CHIM study on influenza virus among healthy adults through NIAID's Vaccine and Treatment Evaluation Units (VTEUs). This is a first step to help assess the safety, immune responses and clinical outcomes generated by influenza viral challenge. CHIMs are essential to NIAID's strategic plan to develop universal influenza vaccines, as they provide another way to evaluate promising vaccine candidates.

Claire Schuster described two NIAID-supported clinical trials evaluating three different Ebola vaccine strategies in adults and children. The researchers found that all the regimens were safe and generated immune responses in both age groups. The study enrolled volunteers at sites in Guinea, Liberia, Sierra Leone, and Mali to identify optimal vaccination strategies to curtail Ebola virus disease outbreaks.

An independent Data and Safety Monitoring Board (DSMB) determined that an investigational HIV regimen tested among men who have sex with men and transgender people was safe, but did not provide protection from HIV acquisition. A Phase III trial known as "Mosaico" began in 2019 and involved 3,900 volunteers aged 18 to 60 years old. Based on the DSMB recommendations, the study is being discontinued.

Claire Schuster briefly discussed two studies of long COVID focusing on health disparities. Black and Hispanic Americans appear to experience more symptoms and health problems related to long COVID, than white Americans, but are not as likely to be diagnosed with the condition. In one analysis, researchers looked at health records of over 62,000 adults who tested positive for COVID-19 and found that Black and Hispanic patients with severe COVID-19 were more likely than White adults to be diagnosed with health problems like headaches, chest pain, and joint pain. Additionally, researchers found that in comparison to people who did not have COVID-19, those who did were more likely to experience conditions affecting their nervous system, respiratory function, and circulation. In another study, researchers examined electronic health records of more than 33,000 adults and children. The team found that most patients with long COVID had mild to moderate symptoms of acute infection. For long-term symptoms, children and teens were more likely to experience gastrointestinal and upper respiratory problems, including stomach aches and coughing.

Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare condition that can occur a few weeks after a COVID-19 infection and can result in organ failure. The cause of MIS-C is unknown, but medications can be given to decrease the inflammation that can damage organs. An NIH-supported study has examined COVID-19 vaccination among children and adolescents with prior MIS-C. There were reports of no serious complications. About half of participants experienced mild and typical vaccine reactions, such as arm soreness and fatigue.

NIH has initiated a clinical trial of an investigational oral treatment for COVID-19. The antiviral was discovered by Hokkaido University and the pharmaceutical company, Shionogi. This trial is evaluating the antiviral among patients who are hospitalized with COVID-19 and will enroll approximately 1,500 people at sites worldwide.

Researchers recently reported results from an NIAID-supported COVAIL trial looking at the immunogenicity of the BA.1 and BA.4/5 Bivalent Boosts. Neutralizing antibody levels against all Omicron subvariants were lower than against an earlier SARS-CoV-2 strain known as D614G. They noted that the breadth of antibody response from current vaccines is still not optimized for the pace of virus evolution.

Claire Schuster also reviewed a recent article that discussed next-generation vaccines for respiratory viruses, including coronaviruses and influenza viruses. These viruses share characteristics that enable them to cause repeat infections. Researchers explored challenges that have impeded development of effective mucosal vaccines and outlined approaches to developing next-generation vaccines. Finally, to provide broad protection against multiple coronaviruses, NIAID is supporting the development of pan-coronavirus vaccines with grants to seven academic institutions to advance research in this area.

Claire Schuster concluded their report and invited questions. There were no questions or comments from the Commission members.

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

Dr. Slater provided updates on FDA CBER activities from December 2022 through the end of February 2023. On December 8, 2022, CBER amended emergency use authorizations for the Moderna and Pfizer-BioNTech COVID -19 bivalent vaccines to include the use in children down to six months of age. The Moderna COVID-19 vaccine, bivalent is authorized for administration as a single booster dose at least two months following completion of a primary series for children 6 months through 5 years of age. The Pfizer-BioNTech COVID-19 vaccine,

bivalent is authorized as a third dose of the three-dose primary series for children 6 months through 4 years of age.

On January 9, 2023, CBER approved Adacel (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed) for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than two months of age.

Dr. Slater announced that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on January 26, 2023, to consider whether and how the composition and schedule of primary and booster doses of the COVID-19 vaccine. On February, 28, 2023, VRBPAC developed recommendations on the safety and efficacy of the ABRYSVO (Respiratory Syncytial Virus [RSV] Vaccine), with a requested indication for immunization for the prevention of acute respiratory disease and lower respiratory tract disease caused by RSV in adults 60 years of age and older.

On March 1, 2023, VRBPAC is meeting to discuss and make recommendations on the safety and effectiveness of AREXVY (RSV Vaccine Recombinant, Adjuvanted), with requested indication for active immunization for the prevention of lower respiratory tract disease caused by RSV-A and RSV-B subtypes in adults 60 years of age and older. FDA continues to maintain and update its COVID-19 web site and the link was provided on the slide deck.

Dr. Slater concluded his report and invited questions. Daniel Boyle asked for clarification on the addition of COVID-19 vaccines to the list of childhood vaccines and Dr. Slater confirmed that the CDC made that decision.

Update on OIDP, Sean Dade, MPA

Sean Dade described the mission of the National Vaccine Program (NVP), which includes supporting efforts to achieve optimal prevention of human infectious diseases through immunization. NVP has three overarching goals. First goal is to establish and strengthen partnerships to bring awareness to immunization best practices. For example, we currently co-lead the National Influenza and Immunization Summit with CDC and Immunization.Org to share best practices to increase vaccine rates. The second goal is to provide strategic leadership and coordination among federal agencies to support activities within the national vaccine plan, including coordinating the National Vaccine Advisory Committee (NVAC) meetings throughout the year. The third goal is to support initiatives and policies that support the increase of immunization rates. To accomplish this goal, there is currently a three-year cooperative agreement that supports six projects to increase vaccine competence in local communities. NVP provides leadership and guidance to the NVAC, which includes 15 members and meets three times a year, to develop recommendations for the Assistant Secretary for Health (ASH). NVAC held a meeting on February 1-2, 2023 to discuss innovative science and future vaccines, prevention of long COVID, the outbreak response to the measles outbreak in central Ohio, addressing gaps in immunizations for the LGBTQI+ communities, to consider actions to improve adult immunization rates, and an overview of the Federal Vaccines Implementation Plan. The next NVAC meetings are scheduled for June 15-16, 2023, and September 21-22, 2023.

During the last NVAC meeting, the ASH issued two charges to the committee. The first charge is dedicated to Vaccine Innovation. They are being asked to develop a report of recommendations outlining a vaccine innovation agenda and describe priorities and actions for advancing development of new vaccines to help optimize public health and reduce disease burden in the US. The second charge is for Vaccine Safety. The goal is to develop a vaccine

safety report to address current challenges, minimize preventable vaccine-related adverse events, and enhance coordination and stakeholder input into the timely detection and assessment of vaccine safety signals. In February 2023, NVP released the Vaccines Federal Implementation Plan, which accompanies and aligns with the Vaccines National Strategic Plan. It outlines the roles of federal agencies in achieving vaccine goals.

NVP builds partnerships with other vaccine partners through the National Adult and Influenza Immunization Summit (NAIIS). NAIIS is a coalition of 130 organizations and 700 immunization professionals, dedicated to addressing and resolving adult and influenza immunization issues and improving the use of vaccines recommended by CDC's Advisory Committee on Immunization Practices. NAIIS resumed their in-person annual meeting, which was held in Atlanta on November 2-3, 2022. The next meeting will be May 9-11, 2023, in Atlanta. The Summit theme will include improving data gathering and access; new adult vaccine recommendations and adult vaccine implementation strategies; new vaccines and monoclonals; updates on influenza, COVID-19, and mpox; and celebrating COVID-19 successes.

NVP also works closely with the communications team to promote and bring awareness to various organization activities across the nation. They are currently promoting the newly released Vaccines Federal Implementation Plan through various social media platforms. February is National Cancer Prevention Month, so there were recent efforts to promote young adults getting the HPV vaccine to protect against HPV-related cancers.

Sean Dade remarked that a Healthy People 2030 webinar will be held on March 21, 2023. It will explore three objectives: increasing the proportion of persons who are vaccinated annually against flu; increasing the proportion of pregnant women who receive early and adequate prenatal care; and reducing congenital syphilis.

Sean Dade concluded their presentation and invited questions. During discussion, referring to the mission discussed, Daniel Boyle asked if the new charge to the NVAC from the ASH to "minimize preventable vaccine-related adverse effects" includes shoulder injuries related to vaccine administration, since data suggests there is an increased number of VICP claims filed alleging that injury. OIDP responded that this is a recent charge, with a meeting held February 1-2, 2023; hence, the committee is just starting to discuss next steps.

Future Agenda Items/New Business, CDR Reed Grimes, MD, Director, DICP and Chair, ACCV

Dr. Grimes invited suggestions for future agenda items. Daniel Boyle requested additional information regarding the process for the ACCV to petition the Secretary to amend the Vaccine Injury Table (Table) for influenza vaccines. For example, they shared that the 2012 Institute of Medicine report identified several conditions after the administration of influenza vaccines that did not have enough scientific evidence to be added to the Table; however, that report was published over a decade ago. This member highlighted brachial neuritis for consideration since it has shown to be more prevalent than previously thought. Another member requested additional information to be presented to determine if scientific literature is currently available. Dr. Grimes replied that the process to submit a petition to the Secretary can be discussed at the next ACCV Meeting on March 2, 2023. Tim Thelen suggested including a discussion or presentation about potential legislative changes in future agendas. Dr. Grimes noted no legislation has been enacted adding new vaccines for VICP coverage, but updates can be provided.

Public Comment

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