Advisory Commission on Childhood Vaccines (ACCV)

Teleconference

December 1, 2022

Members Present

Albert Holloway, Jr. MD (2024)
Dana DeShon, DNP, APRN, CPNP-PC (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
Andrea Herzog, Program Analyst

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

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

Public Comment on Agenda Items

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

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

On motion duly made and seconded, the ACCV voted and unanimously approved September 1, 2022, ACCV Meeting Minutes.

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 (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).

The number of VICP petitions filed in Fiscal Year (FY) 2023 as of November 1, 2022, was 117. Of those petitions, 99 were filed for adults and 18 were filed on behalf of children. There had been a minor but steady increase year to year, with a bolus in 2021 because of an

increase in claims for shoulder injury related to vaccine administration (SIRVA). Administrative funding for processing claims has not increased at the same rate as claims filed, which has resulted in a backlog of 1,456 petitions for adults awaiting review. Additionally, 89 of the 91 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 November 1, 2022, the VICP has paid about $7 million for petitioners' awards and nearly $4 million for attorney's fees and costs.

Adjudication Categories for VICP Petitions as of November 1, 2022				
Adjudication Categories	**Fiscal Year 2020**	**Fiscal Year 2021**	**Fiscal Year 2022**	**Fiscal Year 2023**
Compensable	**711 (100%)**	**754 (100%)**	**928 (100%)**	**46 (100%)**
Concession	264 (37%)	335 (45%)	423 (45%)	26 (57%)
Court Decision	48 (7%)	18 (2%)	16 (1%)	0 (0%)
Settlement	399 (56%)	401 (53%)	489 (54%)	20 (43%)
Not Compensable	**217**	**259**	**262**	**37**
Total	**928**	**1,013**	**1,190**	**83**

The balance in the Vaccine Injury Compensation Trust Fund as of September 30, 2022, was approximately $4.4 billion. Income includes about $61 million from investments and $332 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 shoulder injury related to vaccine administration (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 12-month wait for petitions to be reviewed by a HRSA physician after the (PAR) activation.

Finally, Dr. Grimes commended the Commission for completing and submitting a recommendation to the Secretary to support providing additional funding resources for the DICP, DOJ and Office of the Special Masters of the U.S. Court of Federal Claims and increasing the number of special masters. It was sent to the Secretary on October 11, 2022, and a reply is anticipated. 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.

Tim Thelen asked about the trend in waiting time for PAR action on petitions filed. Dr. Grimes commented that the PAR response has been relatively stable at 11-13 months. The backlog is not growing but it is also not decreasing, and additional resources could reduce the backlog. Daniel Boyle asked if there was data on the breakdown of number of vaccine doses for influenza by children and adult populations. Dr. Grimes responded that there has been no

analysis of doses administered versus doses distributed and administered, so there would be need to use a proxy number. It could be helpful to show the perspective of the number of petitions versus the total number of doses distributed. Tim Thelen asked about DICP's plans to handle proposed legislative changes that would move COVID-19 vaccine claims from the Countermeasures Injury Compensation Program to the VICP. CDR Reed Grimes shared that for a vaccine to be covered under the VICP, the CDC needs to recommend that the vaccine is routinely administered to children or pregnant people, an excise tax is imposed, and the Secretary publishes a notice of coverage adding COVID-19 vaccines to the Vaccine Injury Table. Finally, Dana Deshon asked about the dengue fever vaccine. Dr. Grimes stated that the dengue vaccine is not currently covered, partly because the excise tax for that vaccine has not been established.

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

Heather Pearlman, referencing the DOJ PowerPoint materials, stated that their presentation covered the period of August 16, 2022, to November 15, 2022, which is a different time period than reported in the DICP update. Heather Pearlman reported that 392 claims were filed in the U.S. Court of Federal Claims (CFC), 57 on behalf of minors and 335 filed by adults.

The VICP adjudicated 252 petitions during this reporting period. Of the 252 petitions adjudicated, 208 were compensated and 44 were not. HHS conceded 89 cases, mostly resolved by accepting a proffer, and 119 of the compensation cases were not conceded. Thirty-nine cases were voluntarily withdrawn resulting in no judgment.

No appeals by petitioner or respondent in the U.S. Court of Appeals for the Federal Circuit had been decided during this period. Seven cases were pending, all by petitioners, one involving attorney's fees and costs and six involving entitlement.

In the CFC, five claims filed by petitioner were decided, four affirmed and one vacated in part and remanded to the Special Master. There were no appeals by respondent that were decided in this reporting period. There were 10 appeals by petitioners and two appeals by respondent that are pending. At the time the DOJ PowerPoint was prepared, there were no oral arguments scheduled at either the U.S. Court of Appeals for the Federal Circuit or the CFC.

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. During the reporting period, there were 96 adjudicated settlements. Of these cases, about 63% involved a claim alleging SIRVA, and most also involved influenza vaccine. The shortest time to resolution was 10 months 24 days (SIRVA), and the longest time to resolution was 6 years 9 months, a claim alleging that hepatitis B vaccine caused transverse myelitis.

The usual appendices were provided, which includes a glossary of terms and diagrams of the appeal levels and processes involved. Heather Pearlman concluded their report and invited questions.

During discussion, Daniel Boyle asked if details of the conceded claims are made available, and Heather Pearlman commented that they normally have not been included in the report. Heather Pearlman added that, if the Commission wanted more detail, their office could provide an expanded report.

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

Dr. Duffy summarized topics which had been discussed at the Advisory Committee on Immunization Practices (ACIP) meeting in October 2022.

1. ACIP voted to recommend PCV20 for certain adults who previously received PCV13 , including those with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak who have received both PCV13 and PPSV23 with incomplete vaccination status; shared clinical decision-making is recommended regarding administration of PCV20 for adults aged ≥65 years who completed their vaccine series with both PCV13 and PPSV23; adults who have received PCV13 only should receive a dose of PCV20 at least one year after the PCV13 dose or PPSV23 as previously recommended to complete their pneumococcal vaccine series.
2. Vaccines for Chikungunya, a mosquito-borne viral disease, are in development. An ACIP work group is looking at developing policy options for U.S. persons at risk for the infection, including travelers and residents of U.S. territories and states with, or at risk of, transmission.
3. A single case of paralytic polio occurred in New York State in June 2022 in an immunocompetent, non-immunized adult, which suggests a risk for larger populations. The current ACIP recommendation is for adults who are unvaccinated or have incomplete vaccination for poliovirus should talk to their doctor about getting vaccinated. Adults at increased risk of exposure to poliovirus may receive one lifetime booster dose. The ACIP workgroup will consider whether additional recommendations should be made.
4. Two vaccine manufacturers presented clinical trial safety and efficacy findings for respiratory syncytial virus (RSV) candidate vaccines in development. The ACIP workgroup will consider whether either vaccine should be recommended for older adults.
5. RSV is the leading cause of hospitalization in U.S. infants. Nirsevimab is an investigational antibody in development. An ACIP workgroup will consider if Nirsevimab should be recommended for all infants <8 months of age entering their first RSV season and all infants born during the RSV season. Additionally, they will consider if it should be recommended for children <24 months of age entering their second RSV season who remain at increased risk of severe disease.
6. Regarding meningococcal vaccines, the ACIP work group will be considering three issues over the next year:
    1. Incorporation of Menveo One-Vial into current Menveo recommendations;
    2. Developing recommendations for new pentavalent vaccines (MenABCWY); and
    3. considering whether to recommend MenACWY vaccination for people experiencing homelessness.
7. Regarding influenza vaccines, ACIP heard presentations on three different topics: Clinical trial to compare safety of Flublok Quadrivalent (RIV4) versus IIV4 in pregnancy; Influenza activity update; Influenza vaccine effectiveness update.
8. Regarding dengue virus, most dengue cases in US states are associated with travel to endemic areas. Dengue is considered endemic in six US territories and freely associated states.
9. A vaccine (Dengvaxia) is available for appropriate individuals. A new vaccine is under development (Takeda TAK-003).

10. An ACIP work group is reviewing available data to inform monkeypox vaccine policy, including recommendations for use of JYNNEOS vaccine during the ongoing outbreak.

At the September 1, 2022, meeting, ACIP voted to recommend use of updated (bivalent) COVID-19 boosters: Pfizer-BioNTech for people ages 12 years and older and Moderna for people ages 18 years and older. On October 12, 2022, CDC recommended use of updated (bivalent) COVID-19 boosters in people ages 5 years and older. Monovalent mRNA vaccines are no longer authorized as booster doses.

ACIP voted to approve a resolution to add vaccines for the prevention of COVID-19 to the Vaccines for Children (VFC) program, a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of the inability to pay.

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

1. *Active Post-Licensure Safety Surveillance for Recombinant Zoster Vaccine (RZV) Using Electronic Health Record Data*. A recombinant zoster vaccine was licensed in 2017 to prevent herpes zoster and its complications in older adults. This Vaccine Safety Datalink (VSD) study of adults aged 50 years and older monitored 10 pre-specified priority outcomes, including stroke, anaphylaxis, and Guillain-Barré Syndrome (GBS) from January 2018 through December 2019, and found no sustained increased risk of any monitored outcome for RZV recipients was found. Despite a large sample, uncertainty remained regarding potential association with GBS due to the limited number of confirmed GBS cases that were observed.
2. *Association Between Aluminum Exposure from Vaccines Before Age 24 Months and Persistent Asthma at Age 24-59 Months.* This observational study of 326,000 children suggests a possible association between exposure to aluminum in some childhood vaccines and development of persistent asthma in children. Further investigation is needed to explore the potential risk of aluminum exposure from routine childhood vaccines on the development of persistent asthma in children; efforts are underway.

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

1. Association between history of SARS-CoV-2 infection and severe systemic adverse events after mRNA COVID-19 vaccination among U.S. adults.
2. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States.
3. Safety of Booster Doses of Coronavirus Disease 2019 (COVID-19) Vaccine in Pregnancy in the Vaccine Adverse Event Reporting System.
4. COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months–5 Years — United States, June 18, 2022–August 21, 2022.
5. Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 2022.
6. Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination.
7. Health Care Utilization in the 6 Months Following SARS-CoV-2 Infection.
8. Menstrual irregularities and vaginal bleeding after COVID-19 vaccination reported to v-safe active surveillance, USA in December 2020 - January 2022: an observational cohort

study.

Dr. Duffy concluded his report and invited questions. Daniel Boyle referred to the recombinant zoster vaccine study and asked how the CDC decides which outcomes to analyze. Dr. Duffy stated that CDC usually makes these types of decisions based on pre-licensure studies and historical information on previous and similar vaccines. Fever and injection site reactions are usually observed in clinical trials and do not need continuous monitoring in additional studies.

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

Claire Schuster stated that clinical trial results for the new bivalent COVID-19 vaccines were reported from Moderna and Pfizer-BioNTech. Both reported that neutralizing antibodies against BA.4 and BA.5 were higher after the new bivalent vaccine compared to the original version of the vaccine. In addition, NIAID is evaluating Pfizer BA.4/ BA.5-adapted bivalent booster to determine if different vaccine regimens can broaden immune responses.

The World Health Organization recently announced changing the name of monkeypox disease to mpox to help reduce stigma against the disease. NIAID's clinical trial of the JYNNEOS mpox vaccine began enrolling participants in September to evaluate alternative strategies for administering the vaccine to increase the number of available doses. Three regimens are being evaluated in this trial – the standard FDA-licensed subcutaneous injection, a reduced dose (one fifth of the standard amount) administered intradermally, and a further reduced dose (one-tenth of the standard) intradermally. FDA recently authorized the second regimen, using one fifth of the standard dose administered intradermally. Researchers will look at the immune response as well as safety and tolerability across the different regimens.

NIAID is supporting two clinical trials to evaluate the antiviral drug tecovirimat (TPOXX) among adults and children in the United States and the Democratic Republic of the Congo. Researchers will assess safety as well as several outcomes, including but not limited to the amount of time to healed skin lesions, disease severity, and clearance of mpox virus.

NIAID highlighted select research accomplishments on social media pages for World Antimicrobial Awareness Week, which was November 18-24, 2022. .

Additionally, NIAID is supporting a trial of phage therapy among patients with cystic fibrosis to assess this novel approach for drug-resistant infections.

Claire Schuster noted the imminent retirement of Dr. Anthony Fauci after more than 50 years of government service and 38 years as NIAID Director, wishing him well in his retirement. Claire Schuster concluded her report and invited questions.

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

Dr. Slater stated that FDA approved Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine, Adsorbed [Tdap]) on October 7, 2022, for immunization during the third trimester of pregnancy to prevent pertussis (whooping cough) in infants younger than two months of age.

On October 12, 2022, FDA amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19

Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

On October 19, 2022, FDA authorized for emergency use the Novavax COVID-19 Vaccine, Adjuvanted for use as a first booster dose to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate. The booster dose may be administered six months after the completion of primary vaccination with an authorized and approved COVID-19 vaccine.

On October 6, 2022, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss the strain selection for the influenza virus vaccines that would be used for the 2023 southern hemisphere influenza season. Dr. Slater noted that FDA maintains a dedicated web site that provides updated information on COVID-19 activities. Dr. Slater concluded their presentation and invited questions.

Dana DeShon asked if there was any information on the bivalent vaccine for infants 6 months to four years of age. Dr. Slater responded that no decisions were announced publicly, and could not further comment on this. Dan Boyle asked if there was any new information available on the development of new boosters. Dr. Slater stated that he did not have any new information to offer. Dana Deshon asked if there was any additional information about safety on bivalent and booster doses that is available to the public. Dr. Slater recommended CDC website as possibly the best resource to see ongoing safety reports.

Update on OIDP, Sean Dade, MPA

Sean Dade briefly described the mission of the National Vaccine Program, which includes supporting efforts to achieve optimal prevention of human infectious diseases through immunization. The National Vaccine program has three overarching goals. First goal is to establish and strengthen partnerships to bring awareness to immunization best practices. 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.

The NVAC meets three times a year and consists of 15 members that recommend ways to achieve optimal prevention of human infectious disease through vaccine development and provides directions for an adverse reaction to vaccines. The NVAC met on September 22 and 23, 2022, to discuss progress and emerging threats in polio eradication; and boosting supply during the monkeypox emergency. The Assistant Secretary for Health also issued two charges related to vaccine innovation and vaccine safety. The NVAC discussed innovations in vaccine safety data and booster doses and strategies. The next meeting is on February 9 and 10, 2023.

The National Vaccine Program is currently finalizing the Vaccine Federal Implementation Plan, a companion document to the five-year national strategic plan created in January 2021. The plan is in the final approval process with the Executive Secretary and will then be published. This plan outlines the roles of federal departments and agencies and their specific contributions to achieving the five goals found in the Vaccines National Strategic Plan.

Sean Dade described the 2022 National Adult and Influenza Immunization Summit (NAIIS), which is dedicated to addressing and resolving adult and influenza immunization issues and improving the use of vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). The NAIIS was held on November 2–3, 2022, at the Crowne Plaza Atlanta Perimeter at Ravinia in Atlanta, Georgia. Highlights of the meeting include improving data gathering and access; developing new adult vaccine recommendations and implementation strategies; identifying new vaccines and monoclonals; and providing updates on influenza, COVID-19, and monkeypox.

NAIIS also celebrated successes of individuals within the community that demonstrated best practices to increase vaccination rates. The National Vaccine Program shared a few of their current communication campaigns regarding flu vaccination. Sean Dade noted that a goal in their office is to promote the importance of vaccine equity and dispel minority disparities as it relates to vaccine coverage rates. To accomplish this, it is important to have diversity in their marketing campaigns.

The National Vaccine Program is currently working with CDC to formalize immunization topics as a part of the Healthy People 2030 Immunization and Infectious Diseases core objectives; identifying "best practices" for COVID-19 testing and vaccination; identifying "best practices" for routine immunizations; and discussing the importance of equity and wellness for federal monkeypox response and monkeypox vaccine efficacy and availability. Sean Dade concluded their presentation and invited questions.

Daniel Boyle asked if there was any progress toward a vaccine for ongoing protection, instead of only providing a seasonal influenza vaccine. Sean Dade stated that he would need to look back at the NAIIS discussions to see if this was discussed during the summit. Dana Deshon wanted to comment that influenza data didn't show as much influenza, but will be curious to see this year's data on vaccine efficacy, since there was a higher viral load of influenza. Daniel Boyle suggested that an update about new developments in flu vaccines could be helpful to include on a more regular basis. Dr. Grimes clarified that these updates on new developments in flu vaccines could be shared through agency updates, as they are available.

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

Turning to future agenda items, Dr. Grimes noted several that had been mentioned in earlier discussion. There should be inclusion in the DICP update of alleged injuries that affect both pediatric and adult populations, including the vaccines involved. Additionally, ex officio members could include the latest information on influenza vaccinations. Dr. Grimes invited other suggestions. Tim Thelen would like to ensure that any possible administrative and legislative changes be discussed at future meetings. Dr. Grimes reassured the ACCV that if there are any new vaccines that need to be included in the Vaccine Injury Table, they will be briefed. Dana Deshon asked to see if there was a need to follow up on the ACCV's formal recommendations to the Secretary about additional resources. Dr. Grimes clarified that there are no action items at this time.

Public Comment

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