Advisory Commission on Childhood Vaccines (ACCV)
Teleconference
September 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, Temporary Chair, ACCV
Andrea Herzog, Principal Staff Liaison, ACCV
Pita Gomez, Principal Staff Liaison, ACCV

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 June 2, 2022, Meeting Minutes, CDR Reed Grimes, MD, Director, DICP and Chair, ACCV

With the inclusion of corrections for a minor typographical error, and Dana DeShon's credentials, on motion duly made and seconded, the ACCV voted and unanimously approved June 2, 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). Dr. Grimes noted the addition of a discussion and vote on the recommendations that would be submitted to the Secretary.

The number of VICP petitions filed in Fiscal Year(FY) 2022 as of August 1, 2022 was 776. Of those petitions, 645 were filed for adults and 91 were filed on behalf of children. There had been a minor but steady increase year to year, with a bolus in 2019 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 1,493 petitions for adults awaiting review. All 75 claims for children in the backlog have not yet been activated by Pre-Assignment Review (PAR).

In FY 2022, as of August 1, 2022, the VICP has paid about $140 million for petitioners' awards and nearly $27 million for attorney's fees and costs.

Adjudication Categories for VICP Petitions as of August 1, 2022			
Adjudication Categories	**Fiscal Year 2020**	**Fiscal Year 2021**	**Fiscal Year 2022**
Compensable	**711 (100%)**	**756 (100%)**	**739 (100%)**
Concession	264 (37%)	337 (45%)	333 (45%)
Court Decision	48 (7%)	18 (2%)	9 (1%)
Settlement	399 (56%)	401 (53%)	397 (54%)
Not Compensable	**216**	**257**	**215**
Total	**927**	**1,013**	**954**

The balance in the Vaccine Injury Compensation Trust Fund as of July 31, 2022, was approximately $4.2 billion. Income so far from FY2022 includes about $46 million from investments and $218 million from excise tax income. Total income was about $264 million.

Recent trends in the VICP include:

- 95% of claims were filed for adults in the last two FYs;
- Over 64% of petitions filed in the last two FYs allege 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; and
- 12-month wait for petitions to be reviewed by a HRSA physician after PAR activation date.

Dr. Grimes followed up on interest in informal workgroups. Some business may be conducted by informal workgroups that make suggestions to the full ACCV. The creation and operation of these workgroups must be approved by the ACCV. Informal workgroups can gather information, develop work plans, draft reports and recommendations, and discuss preliminary findings. 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 mentioned that he noticed the affiliations listed in an article he read recently and wondered if there is any way to know what kinds of studies are being investigated with the "Department of Injury Compensation" and if this could be reported

at the ACCV meetings to know what kind of studies are being looked at. He clarified that it was with CDC staff and thinks it was related to SIRVA, possibly in the Journal of Vaccines. Dr. Grimes responded that DICP is not a research division, since DICP reviews the petitions for medical merit, and makes recommendations to the DOJ attorneys. Research is not a primary goal for DICP medical staff, so there are no continuous ongoing research projects in the division. Dr. Grimes clarified that this does not mean research is not done at the Department of Health and Human Services (HHS), but cannot speak to research done within the department.

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 of May 16 to August 15, 2022, which is a different time period than reported in the DICP update. Heather Pearlman reported that 240 petitions filed in the U.S. Court of Federal Claims (CFC), 214 filed by adults and 26 on behalf of minors.

The VICP adjudicated 260 petitions during this reporting period. Of the 260 petitions adjudicated, 210 were compensated and 50 were not. HHS conceded 78 cases, mostly resolved by accepted a proffer, and 132 of the compensated cases were not conceded. Twenty-three petitions were voluntarily withdrawn resulting in no judgment.

The U.S. Court of Appeals for the Federal Circuit decided one case, *Sanchez v. HHS*, an entitlement case that was reversed and remanded. Four cases were pending, all by petitioners, three involving entitlement and one attorney's fees and costs.

In the CFC, six cases appealed by petitioners were decided and five affirmed, while the sixth case was affirmed in part, vacated in part, and remanded to the Special Master. There were no appeals by respondent that were decided in this reporting period. There were five appeals by petitioner 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, but *Heller v. HHS* and *Doles v. HHS* had both since been scheduled for oral argument before 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 116 settlements. Of these cases, about 76% involved a claim alleging SIRVA, and most also involved influenza vaccine.

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

Discussion and Vote on Secretary Recommendation for VICP Resources, CDR Reed Grimes, MD, Director, DICP and Chair, ACCV

Dr. Grimes explained that the discussion would relate to two recommendations to the Secretary regarding approval of adequate resources to support HRSA, the DOJ, and the Office of the Special Masters (OSM). Currently, there is support for no more than 8

special masters. The first recommendation would remove that cap on the number of special masters, but rather provide a minimum number to operate. The second recommendation is to increase the annual appropriations for HRSA, DOJ and the OSM, to more timely and efficiently implement the VICP.

Dan Boyle stated that there were attempts made and shown from 2016 to present. They asked about progress in responding to this type of recommendation prior to 2016. Tamara Overby stated that the recommendation letter includes that history, which affirmed that 2016 was the first request sent to the Secretary. That recommendation anticipated and immediately preceded the first indication of the beginning of the claims backlog that started in 2017.

Dan Boyle commented that most of the responses were that the Secretary received and reviewed it, but they did not have an affirmative response or action and would like action to be taken on this recommendation. Tamara Overby noted that various administrations have supported additional resources and significant increases, but Congress has not necessarily appropriated or supported those budget requests. Tamara Overby noted that the President publishes his budget request and makes it publicly available. The proposed written recommendation and the DICP Update does include VICP appropriations by Congress. There has been incremental budget increases, but they have not been comparable to the increases in workload. With the inclusion of a correction for a minor typographical error, on motion duly made and seconded, the recommendations were unanimously approved. Dr. Grimes noted that this recommendation will be sent to the Secretary.

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

Dr. Duffy summarized non-COVID-19 vaccine topics, which had been discussed at the Advisory Committee on Immunization Practices (ACIP) meeting in June 2022.

1. ACIP affirmed updated recommendations for the 2022-2023 influenza season. All flu vaccines available will be quadrivalent formulations. There were strain changes in the influenza A (H3N2) and influenza B (Victoria) components, as compared to the vaccines used last year.
2. ACIP recommended that adults over 65 should receive an adjuvanted or higher dose influenza vaccine, if available.
3. ACIP recommended that PCV15 may be used as an option for pneumococcal conjugate vaccination for children aged less than 19 years of age, according to the currently recommended PCV13 dosing and schedule.
4. The MMR vaccine (Priorix, manufactured by GSK) is recommended according to currently recommended schedules and off-label uses as an option to prevent measles, mumps, and rubella.

Dr. Duffy briefly described several non-COVID-related publications on vaccine safety, surveillance, and adverse effects that can be found on the CDC website:

1. “Safety of Live Attenuated Influenza Vaccine in Children with Asthma”

A randomized controlled trial of live attenuated influenza vaccine (LAIV) enrolled 151 children with asthma, who received either LAIV or an inactivated flu vaccine (IIV). The study subjects were monitored for 42 days post-vaccination. LAIV was not associated with increased frequency of asthma exacerbations or an increase in asthma-related symptoms

2. "Safety of measles and pertussis-containing vaccines in children with autism spectrum disorders"
   This was a Vaccine Safety Datalink (VSD) study of children aged 4 to7 with a diagnosis of autism spectrum disorder and vaccination with measles or pertussis-containing vaccines. The study included 14,947 children with ASD and 1,650,041 children without ASD. Children with ASD were not at increased risk for fever or emergency department visits compared with children without ASD following measles- or pertussis-containing vaccines.
3. "Changes in incidence rates of outcomes of interest in vaccine safety studies during the COVID-19 pandemic"
   This study assessed the changes in incidence rates of 21 selected medical encounter-based outcomes during the COVID-19 pandemic at eight VSD sites from January 1, 2017, through December 31,2020. Rates of some clinical outcomes during the pandemic changed and should not be used as historical background rates in vaccine safety studies. Inclusion of telehealth visits should be considered for vaccine studies involving Bell's palsy, ITP, and narcolepsy/cataplexy.

The ACIP held three COVID-19 related meetings in June and July 2022. The CDC currently recommends the COVID-19 primary series vaccines for everyone aged 6 months and older, and boosters for everyone 5 years and older, if eligible. Dr. Duffy recommends referring to the most update to date CDC recommendations on the CDC website. Dr. Duffy noted specific new COVID-19 vaccine recommendations made since June 2022 for different ages:

1. Pfizer-BioNTech COVID-19 vaccine primary series in children aged 6 months–4 years
2. Moderna COVID-19 vaccine primary series in children aged 6 months–5 years
3. Moderna COVID-19 vaccine primary series in children aged 6-17 years
4. Novavax COVID-19 vaccine primary series in persons aged ≥18 years

Dr. Duffy listed several COVID-19 vaccine-related publications on vaccine safety, surveillance, and adverse effects that can be found on the CDC website.

1. Safety monitoring of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to Vaccine Adverse Events Reporting System and v-safe.
2. Safety Monitoring of COVID-19 Vaccine Booster Doses Among Persons Aged 12-17 Years — United States, December 9, 2021-February 20, 2022.
3. Safety of COVID-19 Vaccination in US Children Ages 5-11 Years.
4. Post-authorization surveillance of adverse events following COVID-19 vaccines in pregnant persons in the Vaccine Adverse Event Reporting System (VAERS), December 2020-October 2021.
5. Incidence of Guillain-Barré Syndrome after COVID-19 Vaccination in the Vaccine Safety Datalink.

6. Dashboard development for near real-time visualization of COVID-19 vaccine safety surveillance data in the Vaccine Safety Datalink.
7. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022.
8. Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose.

Dr. Duffy discussed the 2022 Monkeypox Outbreak. Dr. Duffy started with background information on monkeypox. Monkeypox is caused by the monkeypox virus, part of the same family of viruses as variola virus, that cause smallpox, with similar but milder symptoms. It is rarely fatal. The virus is usually found in central and western African countries. In May 2022, the first case was identified in the U.S. and the case count as of August 15, 2022, is now about 12,000. Two vaccines may be used for prevention of monkeypox disease: JYNNEOS and ACAM2000. CDC recommends vaccination for people who have been exposed to monkeypox and people who may be more likely to get monkeypox, including those identified by public health officials as a contact of someone with monkeypox, people who are aware that one of their sexual partners in the past two weeks have been diagnosed with monkeypox, people who may have been involved with several sexual partners in an area with known monkeypox, or people (i.e. laboratory workers, healthcare, or public health workers) whose jobs may expose them to orthopoxviruses. The monkeypox outbreak is an ongoing outbreak, and CDC is working with FDA and other partners to monitor the safety of the vaccine. Dr. Duffy concluded his report and invited questions.

Timothy Thelen asked if CDC is finding an increase in safety concerns of COVID-19 vaccines in children and if CDC has a risk-benefit value perspective for COVID-19 vaccines, given that they have less morbidity and mortality related to COVID-19. Dr. Duffy responded that vaccine safety and surveillance has identified several serious, but rare adverse events that are believed to be associated with COVID-19 vaccines. In collaboration with ACIP, the CDC is continuously reevaluating the risk/benefit assessment of COVID-19 vaccines as data and evidence is generated.

Dana DeShon added that there was a recent report that looked at the multi-inflammatory syndrome in children (MISC) and showed that there was protection for vaccinated children. MISC in children and those vaccinated did not lead to death or ventilation.

Dan Boyle asked if anyone is looking closer at CDC's Clinical Immunization Safety Assessment (CISA) to see what real-time information comes from healthcare providers or if there were any publicly available reports on the kind of queries that providers are turning to CISA for guidance on. Dr. Duffy shared that anyone who contacts CDC about vaccine safety would be forwarded to CISA, but did not know specifically what information is gathered and shared.

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 is supporting research to develop universal flu vaccines. In June 2022, NIH launched a Phase 1 clinical trial of a potential universal flu vaccine developed by NIAID researchers. This study will test the safety of this vaccine candidate known

as BPL-1357 and its ability to generate immune responses. The trial will enroll 100 adults at NIH who will receive placebo or the investigational vaccine intramuscularly and intranasally. Researchers aim to generate a comprehensive, immune response that mimics immunity gained through natural influenza infection.

NIH is also looking at additional strategies to prepare for flu strains with pandemic potential. To advance new vaccine strategies for H5 influenza, NIH is supporting a clinical trial to evaluate an intranasal H5 vaccine to see if the immune response against a novel flu virus can be increased by changing the route of administration and adding an immune-boosting adjuvant. These strategies may help create new vaccines for use in pandemics.

Turning to COVID-19, Ms. Schuster reported that NIAID researchers published initial results from a study seeking to better understand persistent symptoms that some people experience after having COVID-19. They reported that about half of previously infected patients experience persistent symptoms. However, this may be an overestimate since individuals with persistent symptoms were likely more motivated to enroll in this study. Most of the COVID-19 patients in the study experienced mild to moderate symptoms after COVID-19 during the acute stage of the infection. Extensive diagnostic evaluations revealed no specific cause of reported symptoms in most cases.

In NIAID's "Mix and Match" clinical trial, researchers administered COVID-19 boosters to adults who had previously received a primary COVID-19 vaccination series. Investigators evaluated immune responses over time and published a paper in Cell Reports Medicine. The team reports that although boosters generate high levels of neutralizing antibody response against Omicron, they decrease significantly within three months.

NIH is evaluating second COVID-19 booster shots, including omicron containing vaccines. This study is looking at whether different vaccine regimens can broaden immune response in adults. They found that participants who receive vaccines containing omicron produce higher levels of antibodies directed at the variant 15 days after vaccination, compared to those who received the original (or prototype) COVID-19 vaccine.

Ms. Schuster also touched on the use of the JYNNEOS vaccine for prevention of monkeypox. NIAID played a key role in the development of this vaccine. FDA recently authorized intradermal delivery of JYNNEOS, which was initially authorized to be administered subcutaneously. Intradermal delivery uses a lower dose to generate a similar response and therefore, can be a dose-sparing option to increase the number of doses available. NIAID is planning to initiate a clinical trial evaluating dose-sparing regimens of JYNNEOS. Ms. Schuster concluded their remarks and invited questions.

Timothy Thelen asked about the efficacy of boosters, specifically, for people who are fully vaccinated and have fully recovered from COVID-19, but have not received the COVID-19 booster compared to those who are fully vaccinated and received COVID-19 booster. Ms. Schuster shared information regarding papers that are being published focused on hybrid immunity. These papers describe immunity in individuals who have had COVID-19 and received COVID-19 vaccines. Dr. Duffy stated that information about vaccine efficacy is made available on the CDC website.

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

Dr. Slater stated that on June 3, 2022, the FDA approved Priorix, a new vaccine for measles, mumps, and rubella (MMR) for those 12 months and older. On June 17, 2022, the FDA approved the extension of Vaxneuvance for the prevention of invasive disease caused by 15 serotype of *Streptococcus pneumoniae* for individuals 6 weeks through 17 years of age. On June 17, 2022, the Emergency Use Authorization (EUA) of the Moderna and Pfizer-BioNTech COVID-19 vaccines was expanded to include children aged 6 months and older. In July 2022, the FDA approved eight influenza vaccines selected for the 2022-2023 influenza season. On July 8, 2022, the FDA approved Comirnaty for the prevention of COVID-19 caused by SARS-CoV-2 for individuals aged 12 through 15. On July 13, 2022, an EUA was issued for Novavax COVID-19 adjuvanted vaccine for individuals 18 and older. On August 9, 2022, an EUA was issued for the JYNNEOS vaccine to allow health care providers to use the vaccine by intradermal injection for individuals 18 and older, and by subcutaneous injection in some younger than 18, at high risk of monkeypox infection. On August 19, 2022, an EUA was issued for Novavax COVID-19 adjuvanted vaccine for individuals aged 12 through 17. On August 31, 2022, the EUAs of Moderna and Pfizer-BioNTech COVID-19 Vaccine were amended to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination. The Moderna COVID-19 Vaccine is authorized for use as a single booster in individuals 18 and older. The Pfizer-BioNTech COVID-19 Vaccine is authorized for use as a single booster dose in individuals 12 years of age and older. The FDA maintains a website dedicated to updated information about COVID-19. Dr. Slater concluded their presentation and invited questions.

Dan Boyle asked if the "Countermeasure Program" covers individuals claiming injury from vaccines with EUAs. CDR Reed Grimes clarified that the Countermeasure Injury Compensation Program (CICP) falls under HRSA/DICP. CICP covers countermeasures, including COVID-19 vaccines, that are included in Public Readiness and Emergency Preparedness (PREP) Act Declarations, which could include vaccines approved under EUAs.

Update on the OIDP, CDR Valerie Marshall, Senior Public Health Advisor

CDR Marshall explained that the mission of the National Vaccine Program (NVP), specified in legislation, is to achieve optimal prevention of human infectious diseases through immunization. The main function is to contribute, lead, and support activities that lead to the prevention of vaccine-preventable diseases by building partnerships with federal and non-federal stakeholders through coordination of interagency activities.

The National Vaccine Advisory Committee (NVAC) last met in June 2022, and addressed new adult hepatitis B recommendations, injection-free inoculations, and discussed a COVID-19 vaccine safety review. The next meeting will be on September 22-23, 2022, and anticipates a discussion of vaccine equity and monkeypox vaccines.

NVP is charged with working with federal departments and agencies to develop the Vaccines Federal Implementation plan (the Implementation Plan). The Implementation Plan outlines the roles of Federal departments and agencies and their specific contributions to achieving their vaccine functions in a coordinated fashion. The Plan will be released soon. CDR Valerie Marshall shared an example from the Implementation that focused on communication. The plan includes 19 objectives and over one hundred specific actions.

The 2022 National Adult and Influenza Summit will meet in November 2022 with

representatives from over 130 private and public organizations dedicated to improving access for adults to routinely recommended vaccines. This year's theme is entitled, "Improving Adult Immunizations and Sustaining Progress Accomplished During the Pandemic." The Summit serves as a source of information and communication around improving access to vaccines.

August was National Immunization Awareness Month, which is supported by the Office of the Assistant Secretary for Health (OASH). CDR Marshall shared multiple OASH promotional efforts, including tweets, blogs, and educational posts to promote routine and COVID-19 vaccination. CDR Marshall concluded their presentation and invited questions.

Dan Boyle asked if there was consideration of risk communication in OIDP promotional material to increase vaccination. Specifically, if OIDP included any information about VICP to encourage more vaccination, for those who could potentially experience adverse effect to routine immunizations. CDR Valerie Marshall clarified that HRSA was part of the planning of the federal implementation plan for these communications, but would have to look further into HRSA's feedback.

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

Dr. Grimes reiterated that the efforts to recruit individuals for the vacant commission slots was continuing and provided an update on current nomination packages that are currently in the process. Dr. Grimes noted that there was interest in hearing more about the CISA program. There was a consensus that the program should be included in the next agenda. There was a motion by Dr. Holloway, duly seconded that a discussion of the CISA program be added to the next agenda. Dr. Grimes invited public comment.

Public Comment

1. Theresa Wrangham, Executive Director, National Vaccine Information Center
   Theresa Wrangham stated that the ACCV would benefit from exercising a higher level of scrutiny of studies submitted relying on agency databases, such as the Vaccine Data Safetylink (VSD). The Institute of Medicine, a lead provider of information to the ACCV for Vaccine Injury Table changes, reported in 2005 that the VSD data sharing program needed significant improvements to make the program more effective. It is not clear what recommendations of the IOM were acted on. They shared that there is much needed improvement to increase transparency, agency databases should be made publicly available for independent researchers to replicate findings and close research gaps, and there should be an expansion to the Vaccine Injury Table to reduce the backlog of VICP claims.

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