Advisory Commission on Childhood Vaccines (ACCV)
5600 Fishers Lane, Room 5N76, Rockville, MD 20857
Teleconference and Adobe Connect
March 6, 2020

Members Present

H. Cody Meissner, MD, Chair (2020)
John Howie, JD, Vice Chair (2020)
Kathleen Gaffney, PhD, RN (2020)
Karen Kain (2022)
Barbara Pahud, MD (2022)

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 and Report of the Chair and Approval of the December 2019 Minutes, Dr. Cody Meissner, ACCV

Dr. Meissner called the meeting to order and invited a voice roll call, which confirmed the presence of a quorum. He invited approval of the December 5, 2019, ACCV minutes meeting and on motion duly made by Mr. Howie and seconded by Dr. Gaffney, the minutes were unanimously approved. Dr. Meissner invited public comment on agenda items; there were no comments. Dr. Meissner asked Ms. Overby to begin her report.

Report from the Division of Injury Compensation Programs (DICP), Ms. Tamara Overby, Acting Director

Ms. Overby briefly reviewed the day's agenda items, which include HRSA National Vaccine Injury Compensation Program (VICP) updates, a report from the Department of Justice (DOJ), brief reports from ex officio members representing the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Office of Infectious Diseases and HIV/AIDS Policy (OIDP), and an update from the ACCV Work Group.

Beginning with the VICP update, Ms. Overby reported on the number of petitions filed in the VICP. Between fiscal years (FY) 2011 and 2015, there was an average of 545 petitions filed annually. Since FY 2016 about 1,200 claims are filed each year. Since FY 2010 there has been a steady increase in the number of claims filed for adults, from a few hundred filed in FY 2010 to 1,169 filed in FY 2019. The number of claims filed on behalf of children has remained below 200. Ms. Overby added that the budget allocated to HRSA to administer the VICP increased from $7.5 million in FY 2016, to $10.2 million in FY 2020.

Currently, there are 926 petitions awaiting VICP medical review. Of these petitions, 904 are for adults and 22 are for minors. The petitions filed on behalf of minors are waiting for review because they had incomplete medical records submitted with the claims.

With regard to payments, to date for FY 2020, the VICP has paid about $73 million in awards to petitioners and $11 million for attorneys' fees and costs.

Adjudication Categories	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020
Compensable	539	635	243
Concession	191	234	98
Court Decision	29	44	12
Settlement	319	357	133
Not Compensable	189	143	56
Total	728	778	299

*October 1, 2019 through March 3, 2020

Ms. Overby reported that the balance of the Vaccine Injury Compensation Trust Fund (Trust Fund) stands at about $4 billion. To date in FY 2020, the Trust Fund has earned over $123 million in income. This income includes over $97 million from excise taxes and over $26 million from investment income.

Ms. Overby concluded her presentation by presenting the following VICP statistics that may be of interest to the ACCV:

- 90% of petitions were filed for adults in the last 2 fiscal years
- Over 54% of petitions filed in the last 2 fiscal years allege shoulder injury related to vaccine administration (SIRVA)
- 73% of petitions filed in the last 2 fiscal years allege an injury from the influenza vaccine
- About 70% of petitions filed are compensated via negotiated settlement since FY 2006 (but only 56% in FY 2019)
- There is nearly a 10-month wait for petitions to be reviewed by a HRSA physician

During the discussion following the VICP update, Ms. Kain asked about injuries not listed on the Vaccine Injury Table (Table). Specifically, she wanted to know which non-Table injuries are being compensated in cases involving minors. She added that the purpose of her question was to start a discussion about whether any non-Table injuries the VICP is compensating should be researched and potentially added to the Table. Ms. Overby explained that the VICP collects data on the injuries alleged by petitioners when they file a claim, which may or may not be the actual injury that results in compensation. Ms. Overby said that some VICP data on alleged injuries in petitions filed on behalf of minors is available and she can present it at the next meeting.

Ms. Kain asked if there is documentation available about the Trust Fund expenses. She would like to see a breakdown of the Trust Fund expenses. Ms. Overby explained that the VICP, the DOJ and the U.S. Court of Federal Claims (CFC) receive funding from the Trust Fund for processing VICP claims. She also stated that the money from the Trust Fund pays compensation to injured persons and attorney's fees for petitioners' attorneys. Ms. Overby said that she is not aware of any data detailing how petitioners' attorneys allocate their resources. However, the

sums disbursed from the Trust Fund are publicly available in Trust Fund statements produced by the U.S. Department of the Treasury and she would send the website link to Ms. Kain following the meeting.

Dr. Pahud commented that since the majority of claims filed are adult claims, it might be appropriate to consider including a specialist in a field more closely associated with the predominate injuries in adult claims, SIRVA and Guillain-Barré Syndrome (GBS), like a neurologist or internal medicine physician. Ms. Overby explained that The National Childhood Vaccine Injury Act of 1986 (Vaccine Act) legislates the composition of the ACCV and a legislative change would have to occur to create or change a specific member position. However, in the past the ACCV has made recommendations regarding the composition of the ACCV.

Dr. Meissner stated that the ACCV members recently received a draft Notice of Proposed Rulemaking (NPRM) from HHS that proposed removing SIRVA and vasovagal syncope from the Table. Dr. Meissner encouraged the members of the ACCV to read the draft NPRM and take advantage of the opportunity to send in their written responses. Dr. Meissner informed the commission that HHS waived its privilege and Commissioners can discuss this proposal during today's meeting. He also expressed his belief that the ACCV would likely not come to a consensus on a response to the proposed Table changes and again suggested that everyone send their individual responses to Mr. Al Danzy, the contact in HRSA's Office of the Executive Secretariat (Exec Sec).

Dr. Meissner also noted that in 2019 there was a decrease in the number of negotiated settlements and asked if there was an explanation for this decrease. Ms. Overby responded that before SIRVA was added to the Table in 2017, many SIRVA claims were compensated as negotiated settlements. After SIRVA was added to the Table in March 2017, SIRVA claims were conceded rather than settled resulting in a decrease in negotiated settlements and an increase in concessions. Dr. Meissner followed up, asking if vasovagal syncope had contributed to the shift from negotiated settlements to concessions. Ms. Overby replied that syncope was not a significant contributor to the decrease in negotiated settlements and the increase in concessions.

Ms. Kain stated that the guidance she received about the draft VICP NPRM said it was confidential, but she had a lot of questions and concerns about the document and would like some opportunity to discuss it either today or in a future meeting. Dr. Meissner explained that the ACCV has clearance to discuss the draft VICP NPRM during this ACCV meeting and asked Ms. Overby for guidance on how to proceed. Ms. Overby responded that the guidance sent to the ACCV members asked them to send written comments about the draft VICP NPRM to Al Danzy at HRSA's Exec Sec. However, the ACCV can discuss the draft VICP NPRM at this meeting and it is up to the ACCV to determine how they want these discussion to proceed.

Mr. Howie commented that he also thought the issue needed further discussion. Mr. Howie stated that he has had two cases of vasovagal syncope occurring after vaccine administration. He said that these cases can be serious and should be compensated by the program. Mr. Howie said that he has not seen in the legislation, any language that expressly prohibits the VICP from compensating injuries that resulted from the administration of a vaccine rather than the components of the vaccine.

Mr. Howie expressed concern for the proposed changes noting, that it would be cost prohibitive for people who suffered injuries as a result of vaccine administration to file medical malpractice claims in civil court. Mr. Howie noted that most attorneys would reject cases with damages under $50,000; the cost to fight the case would leave a petitioner with little to no

compensation. In addition, state laws have made filing medical malpractice claims very difficult in the last decade.

Mr. Howie also stated that he thinks that the Vaccine Act permits the Federal government to have subrogation rights. These rights permit the Federal government to provide compensation to a petitioner, and then, seek reimbursement from the vaccine administrator or vaccine manufacturer.

Mr. Howie also stated that the ACCV does not need a consensus to make a recommendation. The ACCV could have a discussion and vote on a recommendation regarding these proposed Table changes. He also agreed that he would like to participate in a meeting to discuss the proposed Table changes.

Dr. Pahud said she would like more information and perhaps clarification or a presentation from attorneys, regarding whether the intention of the Vaccine Act is only to compensate people injured by the components in the vaccine, or from both – injuries from the components of the vaccine and the mechanism to administer the vaccine. Clarification on this question would have a significant impact on her opinion of the proposed Table changes. Dr. Pahud, also stated that she believes if the VICP is only supposed to compensate people injured by the components in the vaccine, then there should be a program set up to compensate people who suffer mechanistic injuries resulting from the administration of a vaccine. Dr. Pahud expressed concern about who then becomes responsible and whether people would sue nurses and hospitals for these injuries. Dr. Pahud said she is not sure if SIRVA and vasovagal syncope were outside of the VICP's purview, if only vaccine component injuries are supposed to be covered.

Ms. Kathleen Gaffney agreed with Dr. Pahud's assessment of the situation. Ms. Gaffney added that she believes commissioners should submit their comments and questions individually. She also agreed that there should be a meeting to discuss these changes further. However, she stated that she is unable to participate in this meeting discussing Table changes due to ethics rules.

The Commission did not resolve their questions or make a recommendation at this time and there was agreement that individual members could submit suggestions and questions individually to Mr. Danzy, but the Commission could try to develop a consensus recommendation to the Secretary. The ACCV agreed to discuss the draft VICP NPRM in a Work Group meeting via conference call and scheduled before early May 2020. The Commissioners agreed they would like someone to participate in the Work Group meeting who can respond to questions about the language in the Vaccine Act and the proposed VICP NPRM.
Ms. Overby responded that she would work with staff to arrange the conference call.

Report from the DOJ, Ms. Catharine Reeves, Deputy Director, Torts Branch

Ms. Reeves referenced the Department of Justice (DOJ) PowerPoint materials as part of her presentation for the three-month reporting period from November 16, 2019 through February 15, 2020. (DOJ PowerPoint (PP) at 2.) Ms. Reeves stated that during this reporting period, 288 petitions were filed. (DOJ PP at 2.) Ms. Reeves further noted that of the 288 petitions filed in this reporting period, 36 (12%) were filed on behalf of minors and 252 (88%) were filed by adults. (DOJ PP at 2.)

Ms. Reeves stated that 181 petitions were adjudicated during this reporting period. (DOJ PP at 3.) One hundred and forty-six of the adjudicated cases were compensated. (DOJ PP at 3.)

Of the 146 compensated cases, 67 cases were conceded by the government, two of which had decisions awarding damages and 65 of which had decisions adopting proffers. Seventy-nine of the compensated cases were not conceded by the government, the majority of which (74 cases) involved settlements. Thirty-five cases were not compensated. (DOJ PP at 3.) Eleven petitions were voluntarily withdrawn. (DOJ PP at 4.)

Ms. Reeves 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 affirmed one decision appealed by a petitioner (entitlement decision). (DOJ PP at 5.) She further noted that nine appeals by petitioners were pending, and one appeal by respondent remains pending before the CAFC. (DOJ PP at 6-7.)

Ms. Reeves next discussed appeals at the CFC. (DOJ PP at 8-11.) She noted that six decisions appealed by petitioners were affirmed by the CFC during this reporting period (four entitlement decisions, one attorneys' fees and costs decision, and one damages decision). (DOJ PP at 8.) She further noted that one appeal filed by petitioner involving a decision on attorneys' fees and costs was withdrawn. (DOJ PP at 8.) Ms. Reeves noted that four appeals of decisions by respondent were decided by the CFC during this reporting period. The CFC affirmed one attorneys' fees and costs decision appealed by respondent, reversed one attorneys' fees and costs decision appealed by respondent, and remanded two cases appealed by respondent (one entitlement decision and one damages decision). (DOJ PP at 9.) Ms. Reeves stated that there are presently seven appeals pending before the CFC filed by petitioners, four of which were filed since the last reporting period (five on entitlement and two on attorneys' fees and costs). (DOJ PP at 10.) She further stated that there are two appeals by respondent pending before the CFC (one on entitlement and one on attorneys' fees and costs). (DOJ PP at 11.) Ms. Reeves noted that oral argument was held at the CAFC in *L.M. v. HHS* on March 3, 2020, and no oral arguments were scheduled at the CFC. (DOJ PP at 12.)

Ms. Reeves 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 13-19.) She noted that most of the cases involved alleged SIRVA injuries occurring after influenza vaccination. She further noted that most of these cases were settled within two years of filing with the CFC. Ms. Reeves also provided the usual appendices, which include a glossary of terms and diagrams to help commissioners understand the appeals process.
Ms. Reeves concluded her report.

There were no questions from the ACCV.

Report from the ACCV Process Working Group, John Howie, ACCV Vice Chair

Mr. Howie reported that the Work Group is small since some of the ACCV seats are vacant. He explained that the Work Group generally tries to meet for about an hour once a month and invited new members to join the next conference call, the date and time of which will be announced when it is available. He stated that at the last work group meeting the group discussed how the language on Vaccine Information Sheets (VIS) addresses the statute of limitations in the VICP. Dr. Meissner commented that Ms. Kain had indicated an interest in bringing several issues to the work group. Ms. Kain said that to start there were three reports she would like the work group to review, the Altarum Report, the Banyan Report, which were commissioned by the VICP and released in 2010, and the Harvard Pilgrim Health Care Study, which discusses vaccine hesitancy. She suggested that, after the commissioners have an

opportunity to read the reports, they could discuss the recommendations in the reports about reducing vaccine hesitancy and improving the VICP and determine which recommendations would be appropriate for the ACCV discuss. She mentioned a VICP stakeholder survey, which the ACCV has recommended, as an example of the ACCV making a recommendation to the Secretary based on the recommendations in the Altarum and Banyan reports. Dr. Pahud noted that it was important to focus on recommendations that are within the ACCV's purview. Ms. Overby observed that reviewing the Altarum and Banyan reports would be useful information, and that the ACCV Charter provides guidance about the Commission's areas of responsibility. Several Commissioners and ACCV ex-officio members were not familiar with the Harvard Pilgrim Health Care Study. Therefore, Ms. Kain offered to send copies of the reports to the Commissioners and ACCV ex-officio members.

Update from the Immunization Safety Office (ISO), CDC, Dr. Patricia Wodi

Dr. Wodi explained that since the February 2020 Advisory Committee on Immunization Practices (ACIP) meeting had only taken place in the last few days, she would not be giving an update from the meeting at this time. An update from the ACIP meeting will be available at the next commission meeting. Dr. Wodi briefly described several recent publications of interest.

1. Havers FP et al. ***Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccines – Updated Recommendations of the Advisory Committee on Immunization Practices, United States, 2019*** MMWR Morb Mortal Wkly Rep 2020;69:77–83. Discussed the updated ACIP updated recommendation to allow the use of Tdap or Td in situations where only Td was recommended. These situations include the tetanus booster recommended for adults every 10 years, tetanus prophylaxis when indicated for wound management in people who previously received Tdap, and for multiple doses in the catch-up immunization schedule for people 7 years of age and older with an unknown or incomplete vaccination history. This recommendation update allows providers to have flexibility at the point-of-care for patients.
2. Haber P et al. ***Safety review of tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccines (Tdap) in adults aged ≥65 years, Vaccine Adverse Event Reporting System (VAERS), United States, September 2010-December 2018.*** *Vaccine*. 2020 Feb 5;38(6):1476-1480. Summary: Using the VAERS, researchers analyzed reports of adverse events (AEs) following Tdap in adults 65 years and older. Overall, the analysis did not identify any new safety concerns and is consistent with prior post-marketing observations and pre-licensure studies.
3. Su JR et al. ***Erythema multiforme, Stevens Johnson syndrome, and toxic epidermal necrolysis reported after vaccination, 1999–2017.*** *Vaccine*. 2019 Dec 20. pii: S0264-410X(19)31670-6. Summary: Erythema multiforme (EM), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and SJS/TEN after vaccination are rare. Since the last review of VAERS data for these conditions, over 37 new vaccines were approved for use in the United States. Overall, reporting of these conditions after vaccination remained rare, with no new safety concerns identified.
4. ***Reports of atypical shoulder pain and dysfunction following inactivated Influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010-2017.*** Vaccine. 2020 Jan 29; 38(5):1137-1143. Summary - Researchers reviewed reports of adverse

events (AEs) made to the VAERS following inactivate influenza vaccine (IIV) from July 2010 - June 2017. During this time, approximately 996 million flu vaccine doses were distributed in the United States. Of the 59,230 reports submitted, 1,220 met analysis criteria of atypical shoulder pain and dysfunction starting within 48 hours following IIV and continuing for more than 1 week. The analysis suggests these reports were not common, averaging 2% of flu vaccine AEs reported each year; most were females (82.6%), median age was 52 years. While the cause of these cases is unknown, vaccines given improperly might be a factor. Proper vaccine administration education and training are preventive measures.
Available at https://www.ncbi.nlm.nih.gov/pubmed/31784231

5. Hesse et al. ***Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016.*** Vaccine. 2020 Jan 29; 38(5):1076-1083. Summary: The authors reviewed alleged medical reports and VICP clinician reviewer diagnosis of SIRVA and SIRVA-like injuries in the VICP's Injury Compensation System database. Four hundred seventy-six petitioner claims recommended for concession were identified. Most claims (83%) were women, the median age was 51 years and 84% involved influenza vaccine. A suspected administration error ('injection too high') was reported in 36% of cases. Common initial diagnoses were shoulder pain, rotator cuff problems, and bursitis. Most (80.0%) cases received physical or occupational therapy, 60.1% had at least one steroid injection, and 32.6% had surgery. Most (72%) healthcare providers who gave opinions on causality considered the injury was caused by vaccination. Injection too high on the arm could be a factor due to the risk of injecting into underlying non-muscular tissues. Healthcare providers should be aware of proper injection technique and anatomical landmarks when administering vaccines. Available at https://www.ncbi.nlm.nih.gov/pubmed/31771864
6. Walter EB et al. ***Fever after Influenza, Diphtheria-Tetanus-Acellular Pertussis, and Pneumococcal Vaccinations*** Pediatrics. 2020;145(3):e20191909 Summary: A previous CDC study showed that children aged 6-23 months had an increased risk for febrile seizure after simultaneously receiving inactivated influenza vaccine (IIV), pneumococcal conjugate vaccine (PCV13) and diphtheria-tetanus-acellular pertussis vaccine (DTaP). Researchers wanted to see if administering the IIV at a separate visit reduced the risk of post-vaccination fever and potentially febrile seizure. A randomized control trial showed similar proportions of children in both groups had fever on days 1-2 after study visits. Delaying IIV4 by 2 weeks in children receiving DTaP and PCV13 did not reduce fever occurrence after vaccination.
Available at:
https://pediatrics.aappublications.org/content/pediatrics/early/2020/02/04/peds.2019-1909.full.pdf
7. Yu W, et al. ***The use of natural language processing to identify vaccine-related anaphylaxis at five health care systems in the Vaccine Safety Datalink.*** Pharmacoepidemiol Drug Saf Feb 2020 29 (2), 182-188. Summary: Natural Language Processing (NLP) uses computers to analyze large amounts of text. Vaccine Safety Datalink (VSD) researchers developed a NLP application to identify vaccine-related anaphylaxis cases from electronic medical record notes and implemented the method at 5 VSD sites. The NLP system was trained on a dataset of 311 potential anaphylaxis cases and validated on another 731 potential cases. NLP was then applied to the notes of 6.4

million vaccinated patients, and it captured eight additional true cases confirmed by manual chart review. This study demonstrated the potential to apply NLP to clinical notes to identify anaphylaxis cases and its use to improve sensitivity and efficiency in future vaccine safety studies. Available at https://www.ncbi.nlm.nih.gov/pubmed/31797475

8. Li R, et al. ***A Bayesian approach to sequential analysis in post-licensure vaccine safety surveillance.*** Pharm Stat. 2019 Dec 22. doi: 10.1002/pst.1991. Summary: In this study, researchers compare the use of a traditional (frequentist) sequential method and a Bayesian method, with simulations and a real-world vaccine safety example. The performance was evaluated using three metrics: false positive rate, false negative rate, and average earliest detection time. The authors found that depending on the background rate of adverse events, the Bayesian sequential method could significantly improve performance in terms of the false negative rate and decrease the earliest time to producing a safety signal for further analysis. Overall, the Bayesian sequential approach was found to show promise as an alternative for vaccine safety monitoring. Available at https://www.ncbi.nlm.nih.gov/pubmed/31867860

Following the CDC update there was a brief discussion among the commissioners about the value of the VAERS. Dr. Wodi summarized that VAERS is a good early warning system, but it does not provide the extensive data required to analyze the science related to epidemiology, cause and effect.

Vaccine Activities Update from the National Institute of Allergy and Infectious Diseases (NIAID), NIH, Ms. Claire Schuster

Ms. Schuster reported that the new emerging severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, has infected over 97,000 individuals worldwide as of 3/5/2020. NIAID is relying on experience with other coronaviruses, SARS and MERS, to inform COVID-19 research. The World Health Organization was alerted to a cluster of pneumonia cases in Wuhan, China on December 31, 2019, and the first case in the US was identified on January 21, 2020. Soon after the virus' genetic sequence was released, NIAID began to develop an investigational vaccine with the biopharmaceutical company, Moderna. An initial clinical trial is expected to begin within a few months, a much shorter timeframe, compared to 20 months for early clinical testing of a SARS vaccine.

Continuing her presentation, Ms. Schuster told the ACCV that the Democratic Republic of the Congo has experienced the most serious outbreak of Ebola in recent history recording more than 3,400 new cases and 2,200 deaths between August 2018 and January 21, 2020. However, the infection seems to have declined significantly recently.

NIAID has supported development of several Ebola vaccine candidates, including a promising investigational vaccine, rVSV-ZEBOV. The vaccine has been deployed using a ring vaccination strategy, which includes vaccination of the individuals in contact with confirmed cases, contacts of contacts, and frontline health care workers. In December 2019, the FDA approved this vaccine, now known as Ervebo.

Ms. Schuster told the ACCV that NIAID suspended administration of vaccinations of its HVTN 702 clinical trial when a data safety monitoring board (DSMB) determined that the vaccine did not prevent HIV or there was no significant evidence of either decreased or increased infection rates with vaccination.

Next, Ms. Schuster discussed Hepatitis B (HBV). HBV continues to be a threat even with an effective vaccine. NIH unveiled a new strategic plan to address the issue with three strategic priorities:

1. Develop a better understanding of HBV biology;
2. Develop tools and resources; and
3. Create strategies to cure and prevent HBV.

In an influenza update, Ms. Schuster said, in September 2019 the White House announced a plan to modernize and improve production of influenza vaccines to combat seasonal influenza and potential influenza pandemics . The plan focuses on promoting increased influenza vaccine immunization in the U.S, new vaccine manufacturing technologies, moving beyond egg-based production, accelerating production, and developing new vaccines.

Finally, Ms. Schuster announced the establishment of NIAID's new Infectious Disease Clinical Research Consortium (IDCRC). The IDCRC will integrate NIAID's expanded Vaccine and Treatment Evaluation Units (VTEUs).

Vaccine Activities Update, Center for Biologics, Evaluation and Research (CBER), FDA, CDR Valerie Marshall

CDR Marshall provided an update on FDA vaccine activities. In December 2019, the FDA approved Ervebo, the first FDA-approved vaccine for the prevention of Ebola virus disease (EVD), to prevent the Zaire strain EVD in individuals 18 years of age and older. Ervebo is administered as a single-dose injection, and is a live, attenuated vaccine that has been genetically engineered to contain a protein from the Zaire EVD strain. The risk of the disease within the U.S. is minimal, but while the risk of EVD in the U.S. remains low, U.S. agencies are committed to working on outbreaks in Africa, including the current outbreak in the Democratic Republic of the Congo.

Next, CDR Marshall gave an update on seasonal influenza activities. In November 2019, FDA approved a supplement to the Biologics License Application (BLA) for Fluzone to include the high dose quadrivalent formulation for persons 65 years of age and older for the prevention of influenza caused by influenza A subtype viruses and type B viruses contained in the vaccine.

CDR Marshall informed the ACCV that in December 2019, the FDA approved a supplement to the BLA for Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine (Menveo) to include safety and immunogenicity data to support revaccination of adolescent and adults. A single booster dose of Menveo may be administered to individuals 15 through 55 years of age who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine.

Finally, CDR Marshall commented on FDA activities related to the 2019 novel coronavirus (COVID-19) outbreak. She stated that the FDA is collaborating with interagency partners, product developers, international partners and global regulators to expedite the development and availability of medical products needed to diagnose, treat, mitigate and prevent further outbreaks.

As part of the FDA's ongoing commitment to prepare and respond to infectious disease outbreaks the agency is sharing updates on processes in place to help developers understand the pathways, Including Emergency Use Authorization (EUA), that may be available to make medical countermeasures available.

Update from OIDP, Ms. Ann Aikin

Ms. Aikin stated that the most recent meeting of the National Vaccine Advisory Committee (NVAC) occurred on February 13-14, 2020 and focused on vaccine confidence and vaccine innovation. The next NVAC meeting will be on June 9-10, 2020.

Ms. Aikin informed the ACCV that NVAC plans to release a number of strategic plans for 2020, including the National Vaccine Plan, an updated National Viral Hepatitis Action Plan, and the first Sexually Transmitted Infection (STI) Federal Action Plan.

Finally, Ms. Aikin briefly discussed the OIDP's increased focus on the influenza burden and the importance of seasonal vaccine inoculations, and an effort to increase awareness and acceptance of human papillomavirus (HPV) vaccines in young adults, including a faith-based program to support the effort to reduce the burden of HPV. OIDP has developed a web-based presence to enhance public communication about the important issues the office is addressing.

Public Comment

Dr. Meissner invited public comment. There were no comments.

Future Agenda Items and New Business

The next meeting is scheduled for June 4-5, which will likely be a teleconference. There was a comment that the several vacancies on the commission need to be filled, including, a member of the general public, a vaccine manufacturer's attorney, a petitioner's attorney, and a parent of a vaccine-injured child. Ms. Overby stated that an explanation of the guidelines and qualifications for each vacancy is on the ACCV web site.

Adjournment

On motion duly made and seconded, the meeting was adjourned.