

Advisory Commission on Childhood Vaccines (ACCV)
Teleconference and Adobe Connect
September 4, 2020

Members Present

John Howie, JD, Vice Chair (2020)
Karen Kain (2022)
Barbara Pahud, MD (2022)
William Spiegel, JD (2023)

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 March 6 and May 18, 2020 ACCV Meeting Minutes, Mr. John Howie, Vice-Chair, ACCV

Mr. Howie called the meeting to order and did a roll call that confirmed Ms. Kain, Mr. Spiegel and the ex-officio members were present. Ms. Pahud joined the call a few moments later. Mr. Howie welcomed Mr. William Spiegel, a new ACCV commissioner attending his first meeting. Next, Mr. Howie invited public comments on the day's agenda.

Public Comment Ms. Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC), noted that the minutes of recent meetings were not posted online. She also commented that the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) assured consulting organizations of the opportunity to comment on proposed Vaccine Information Statement (VIS) revisions and noted that it had been over a year since that opportunity was available.

Ms. Overby noted that the ACCV meeting minutes are not published on the ACCV website until the ACCV votes to approve them in a public meeting.

With no more public comments, Mr. Howie moved on to approving the March 6, 2020 and May 18, 2020, ACCV meeting minutes. On motion duly made and seconded, the ACCV unanimously approved the minutes for both meetings.

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, reports from the Department of Justice (DOJ), the U.S. Court of Federal Claims (CFC), 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), an update from the ACCV Work Group and VIS reviews.

Beginning with the VICP update, Ms. Overby reported on the number of VICP petitions filed in fiscal year (FY) 2020. In FY 2020, 1,037 petitions have been filed as of September 1, 2020. Of those petitions, 940 are for adults and 97 are for children. She added that funding for administration of the program in FY 2020 is \$10.2 million, 11% higher than FY 2019.

Currently, there are 970 petitions awaiting VICP medical review. Of these petitions, 936 are for adults and 34 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, for FY 2020, as of September 1, 2020, the VICP has paid about \$175 million in awards to petitioners and \$27.6 million for attorneys' fees and costs.

Adjudication Categories	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020*
Compensable	544	641	618
Concession	192	237	238
Court Decision	30	45	40
Settlement	322	359	340
Not Compensable	199	181	180
Total	743	822	798

*October 1, 2019 through September 1, 2020

Ms. Overby reported that the balance of the Vaccine Injury Compensation Trust Fund (Trust Fund) stands at about \$4 billion. In FY 2020, as of July 31, 2020, the Trust Fund has earned nearly \$225 million in income. This income includes over \$165 million from excise taxes and about \$60 million from investment income.

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

- 90% of petitions were filed for adults in the last 2 FYs
- Over 54% of petitions filed in the last 2 FYs allege shoulder injury related to vaccine administration (SIRVA)
- 73% of petitions filed in the last 2 FYs 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 13-month wait for petitions to be reviewed by a HRSA physician

Finally, Ms. Overby announced that the Notice of Proposed Rulemaking (NPRM), titled National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table (VICP NPRM), which proposes to remove SIRVA and syncope from the Vaccine Injury Table (Table) was published; it is available for viewing on the VICP website and ACCV commissioners were

provided a copy. The VICP NPRM is currently available for public comment, which ends on January 12, 2021. There will be a public hearing for the VICP NPRM. A notice announcing the public hearing will be published in the Federal Register and posted on the VICP website. Ms. Overby concluded her presentation and invited questions from the ACCV.

Ms. Kain began her comments by reminding the commission that the Vaccine Act intended the VICP to be a no-fault process that compassionately and expeditiously provides compensation for vaccine injury claims. Ms. Kain commented that during her first year on the ACCV she has felt a bias toward opinions and commissioners who are medical professionals, attorneys or scientists. The ACCV was designed to include opinions from representatives of all stakeholders, including the vaccine-injured and people who have been through the VICP process. Ms. Kain described her VICP experience with her daughter, who suffered a severe brain injury following a diphtheria-tetanus-pertussis (DTP) vaccine. Ms. Kain expressed that her experiences are valuable and her appointment on the commission is appropriate. She further expressed her gratitude for the opportunity to serve on the ACCV and said she looks forward to working with the new members.

Ms. Kain next discussed her desire for the commission designate the next ACCV meeting on December 3, 2020, as a science based meeting that would focus on presentations of evidence related to the VICP NPRM. She noted that during the ACCV Meeting on May 18, 2020, the commission heard public comments, but did not have the opportunity to hear substantive presentations of evidence for or against the recommendation or have the opportunity to ask questions and have discussions with the public commenters.

Ms. Kain objected to two places in the VICP NPRM that challenged the ACCV's recommendations. First, that comments from Cody Meissner, then Chair of the ACCV, were not timely in their receipt, and second, that the recommendations of the ACCV were not persuasive enough to reject the proposed changes to the Table. Ms. Kain stated that she did not have sufficient information to make a more informed decision or recommendation, because HHS did not give the ACCV enough time to properly educate themselves and review evidence. She made a motion to establish a workgroup in the near future to decide whom to invite to the December 3, 2020, meeting to present evidence and information about the VICP NPRM.

Ms. Kain observed that the VICP NPRM also proposed to remove item XVII from the Table. Item XVII on the Table includes the vaccine category "Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage." Ms. Kain stated that this is a significant change to the Table, which the ACCV has not addressed but should discuss in a forum open to the public.

Mr. Howie thanked Ms. Kain for the comments and asked for clarification about her motion. He supported the idea to have presentations related to the VICP NPRM at the December 3, 2020 ACCV meeting and determining a potential list of speakers in a work group meeting. Mr. Howie suggested that the current work group could undertake this task and forming a new work group is not necessary. Ms. Kain agreed to this arrangement.

The members arrived at consensus to hold a workgroup meeting to identify individuals to invite to the December 3, 2020 ACCV meeting to make presentations about the proposed Table changes in the VICP NPRM. Then, if necessary, follow the work group meeting with a brief special public ACCV meeting where the work group could present the list of potential speakers for the December ACCV meeting to the full commission for a vote.

Next, Ms. Overby, responding to a request for information about ACCV vacancies told the commission that:

1. Mr. Howie fills the slot for the attorney representing petitioners;
2. Ms. Kain fills one of two slots for the parent of vaccine-injured individuals (the second slot is currently vacant);
3. Dr. Pahud fills one of two slots for pediatricians (second slot remains vacant); and
4. Mr. Spiegel fills the slot for an unaffiliated attorney.

The current vacancies on the Commission are: (1) an attorney representing a vaccine manufacturer, (2) a second parent of a vaccine-injured child, (3) a general health professional, (4) a second pediatrician, and (5) a member of the general public.

Dr. Pahud inquired about the status of the ACCV's 2018 recommendation to the Secretary of HHS (Secretary) about increasing funding for the VICP and asked if it was permissible to submit another recommendation on the same subject to the Secretary. Ms. Overby explained that this is solely up to the commission and they could send another recommendation at any time of their choosing. After further discussion among the commissioners, there was a unanimous vote to re-send the ACCV recommendation sent to the Secretary in 2018 about increasing operating funding for the program, with appropriate updates.

Report from the Department of Justice, Ms. Heather Pearlman, Assistant Director, Torts Branch

Ms. Pearlman referenced the Department of Justice (DOJ) PowerPoint materials as part of her presentation for the six-month reporting period from February 16, 2020 through August 15, 2020. (DOJ PowerPoint (PP) at 2.) She noted that DOJ's reporting period is different from the HHS and CFC reporting periods. Ms. Pearlman stated that during DOJ's reporting period, 567 petitions were filed, 47 (8%) of which were filed on behalf of minors and 520 (92%) of which were filed by adults. (DOJ PP at 2.)

Ms. Pearlman stated that 476 petitions were adjudicated during this reporting period. (DOJ PP at 3.) Three hundred and seventy-two of the adjudicated cases were compensated. (DOJ PP at 3.) Of the 372 compensated cases, 164 cases were conceded by the government, sixteen of which had decisions awarding damages and 148 of which had decisions adopting proffers. Two hundred and eight of the compensated cases were not conceded by the government, the majority of which (201 cases) involved settlements. One hundred and four cases were not compensated. (DOJ PP at 3.) Ten petitions were voluntarily withdrawn. (DOJ PP at 4.)

Ms. Pearlman discussed recently decided and pending cases in the U.S. Court of Appeals for the Federal Circuit (CAFC). (DOJ PP at 5-7.) She stated that during the reporting period, the CAFC affirmed two entitlement decisions appealed by petitioners, affirmed in part and remanded in part one entitlement decision appealed by a petitioner, remanded two entitlement decisions appealed by petitioners, dismissed one appeal of an entitlement decision by a petitioner, and affirmed one entitlement decision appealed by respondent. (DOJ PP at 5.) She further noted that eight appeals by petitioners were pending, four of which were filed since the last reporting period (entitlement decisions), and no appeals by respondent remain pending before the CAFC. (DOJ PP at 6-7.)

Ms. Pearlman next discussed appeals at the Court of Federal Claims (CFC). (DOJ PP at 8-11.) She noted that the CFC affirmed five entitlement decisions appealed by petitioners during this reporting period and affirmed in part and remanded in part one attorneys' fees and costs decision appealed by a petitioner. (DOJ PP at 8.) She further noted that the CFC denied one motion to recuse filed by a petitioner, and one petitioner withdrew an appeal of an interim attorneys' fees and costs

decision. (DOJ PP at 8.) Ms. Pearlman noted that the CFC affirmed one attorneys' fees and costs decision appealed by respondent and reversed one entitlement decision appealed by respondent. (DOJ PP at 9.) Ms. Pearlman stated that there were fourteen appeals pending before the CFC filed by petitioners, twelve of which were filed since the last reporting period (eleven entitlement decisions and one interim attorneys' fees and costs decision). (DOJ PP at 10-11.) She further stated that there were no appeals by respondent pending before the CFC. (DOJ PP at 12.)

Ms. Pearlman noted that oral argument was held at the CAFC in *E.J. v. HHS* on September 3, 2020, and no oral arguments were scheduled at the CFC. (DOJ PP at 13.)

Ms. Pearlman provided a list of cases that were settled during the reporting period, which are listed in the DOJ PowerPoint presentation in order of the time they took to resolve. (DOJ PP at 14-32.) She noted that most of the cases involved alleged SIRVA injuries occurring after influenza vaccination, and many cases settled within two years of filing with the CFC. Ms. Pearlman also provided the usual appendices, which include a glossary of terms and diagrams to help commissioners understand the appeals process.

Ms. Pearlman concluded her report and invited questions from the commissioners. Mr. John Howie asked whether citations for appellate cases and decisions could be included in the DOJ ACCV presentation in the future. Ms. Pearlman stated that the CFC published those citations on its website, but DOJ would consider adding the citations to the list of cases included in its presentations.

Report from the Office of the Special Masters (OSM), CFC, Mr. Brian H. Corcoran, Chief Special Master.

Chief Special Master Corcoran explained that he would talk about the OSM caseload, the new pre-assignment review (PAR) process, functions of the Special Processing Unit (SPU), and changes in his office's procedures as they have been affected by the pandemic.

Vaccine injury claims increased steadily from 2012 through 2017, leveling off at more than 1,200 claims since then. There are 2,932 open cases on the OSM's docket. To date, in calendar year 2020, there has been a slight decline of about 13% in petitions filed.

The purpose of PAR, which began in September 2019, is to ensure that sufficient documents are filed with a petition to allow completion of a meaningful review of the claim. All cases in PAR are assigned to the Chief Special Master. Once PAR finds the claim is in order (that the required records have been submitted and are certified as accurate), the Activation and Reassignment Order, which allows the claim to proceed, is issued. Additionally, a new questionnaire that Petitioner's counsel must complete assists the court in determining the completeness of the record.

The SPU, which was created in 2014 to expedite decisions in more straight-forward cases (for example, SIRVA injuries), assesses the viability of a claim and its likelihood of resolution through settlement (such as Vaccine Injury Table claims), or the opposite, addresses claims involving a vaccine that is clearly not covered under the Vaccine Program and must be dismissed. Cases meeting the SPU criteria are assigned to the Chief Special Master's docket after the PAR review. The majority of vaccine cases currently being filed in the CFC are assigned to SPU, with the more complicated cases, or ones that appear less likely to settle quickly, assigned to the special masters and not the SPU.

Chief Special Master Corcoran commented on new initiatives he has begun in the SPU since becoming chief, including the "one year rule" to encourage claims' movement. Claims should not remain in SPU for more than one year, unless the parties establish that they are highly likely to reach an agreement on entitlement and need additional time to resolve damages or

compensation. He also has established a “motions day” practice during which four to six cases can be scheduled for expedited hearings on the same day that the Special Master can resolve after hearing the counsel’s arguments on the record with an immediate oral ruling. This process allows for more expeditious decisions to be issued.

Finally, the CFC, in conjunction with the Federal Circuit Court, has issued an order (which has been renewed several times) related to COVID-19 restrictions. No non-court personnel can be present in the Court, and live/in-person hearings are not favored, resulting in the special masters having mostly all-video proceedings since the start of the pandemic. However, the OSM is able to obtain permission to hold small in person proceedings with very few present. Any in-person proceeding includes the usual pandemic precautions of face masks, distancing requirements; OSM has a temperature screening station, and has also taken steps to make its courtroom safer for in-person proceedings. Chief Special Master Corcoran concluded that, despite the pandemic interference, productivity is similar to that of the same period last year, and his goal is to continue OSM operations with little change in productivity.

Mr. Howie asked about how long a case can remain in PAR, and if the time limit had changed in response to COVID-19. Chief Special Master Corcoran stated that there are exigencies imposed by the pandemic that could allow a claim to remain in PAR for a longer period of time, with the extension of time depending on attorneys making reasonable efforts to complete the retrieval and filing of medical records. But as a general matter, the Chief Special Master does not want cases to sit in PAR too long, since different types of records have different importance at different stages of the litigation; it will depend on what is outstanding.

Update from the Immunization Safety Office (ISO), CDC, Dr. Jonathan Duffy

Dr. Duffy said that in his presentation he would review several recent publications, and then talk about COVID-19 vaccine activities.

1. **Order of live and inactivated vaccines and risk of non-vaccine-targeted, infection in U.S. children 11-23 months of age**, Newcomer SR, et al. Order of Live and Inactivated Vaccines and Risk of Non-vaccine-targeted Infection in U.S. Children 11-23 Months of Age. *Pediatr Infect Dis J.* 2020 Mar;39(3):247-253.
It discusses the premise that receiving live vaccines may be associated with decreased non-vaccine targeted infection (NVTI) risk. The researchers focused on data from the Vaccine Safety Datalink to estimate the risk of NVTIs based on most recent vaccine type received in children 11-23 months of age. Electronic health records and immunization data were reviewed from children born between 2003 and 2013. Some observational studies suggest that receiving live vaccines may be associated with decreased non-vaccine targeted infection (NVTI) risk.
2. **Age inappropriate influenza vaccination in infants less than 6 months old, 2010-2018**; Suragh TA, et al. Age inappropriate influenza vaccination in infants less than 6 months old, 2010-2018. *Vaccine.* 2020 May 6;38(21):3747-3751.
This study concerned inappropriate administration of influenza vaccine in children under 6 months of age, which is not recommended and is considered a vaccine error if it occurs. A study of adverse events (AEs) reported in VAERS revealed that in 114 reports, 25 were linked to such vaccine error. The AEs were mainly fever, irritability and diarrhea. Errors occurred when 1) individuals getting vaccinated in groups

resulted in patient mix-ups, 2) healthcare providers not verifying the patient information, and 3) provider confusion due to similarities in vaccine packaging.

3. **Risk of subdeltoid bursitis following influenza vaccination: A population-based cohort study**, Hesse EM, et al. Risk of subdeltoid bursitis following influenza vaccination: A population-based cohort study. *Ann Intern Med.* 2020 Jun 23.
This study looked at the risk of subdeltoid bursitis following flu vaccination. Relying on data from seven Vaccine Safety Datalink sites, involving 2.9 million individuals who received the vaccine during the 2016-2017 flu season, for the period up to 60 days after the injection there were an estimated 7.78 additional cases of bursitis per one million people vaccinated, which is considered a small risk.
4. **Determining Which of Several Simultaneously Administered Vaccines Increase Risk of an Adverse Event**, Wang SV, et al. Determining Which of Several Simultaneously Administered Vaccines Increase Risk of an Adverse Event. *Drug Saf.* 2020 Jul 1.
This study developed a process to determine which of several simultaneously administered vaccines increase risk of an adverse event in children. This study created simulation scenarios using observed data from two Vaccine Safety Datalink (VSD) sites. Researchers developed a systematic process to determine which of the simultaneously administered vaccine(s) would be most likely to have caused an observed increase in risk of an adverse event. From the five scenarios simulated, the process determined which vaccines contributed to the simulated excess risk. This process method could be used again in the future to provide valuable information on the potential risk of adverse events following individual and simultaneous vaccinations.
5. **Monitoring the safety of high-dose trivalent inactivated influenza vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2011-2019**, Moro P, et al. Monitoring the safety of high-dose trivalent inactivated influenza vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2011-2019. *Vaccine.* 2020 Aug 18;38(37):5923-5926.
This study looked at 12,320 VAERS reports filed between 2011 and 2019. The study did not identify any unexpected risk patterns or new safety concerns.

Turning to COVID-19, Dr. Duffy briefly reviewed the recent history of the COVID-19 pandemic, including when it was determined that the coronavirus disease was caused by the SARS CoV-2 virus, and when the World Health Organization (WHO) declared COVID-19 a pandemic. With more than 5.6 million cases reported by August 23, 2020, the government-initiated Operation Warp Speed that set a goal of producing 300 million doses of a COVID-19 vaccine with initial deliveries by January 2021. The Advisory Committee on Immunization Practices (ACIP) normally meets three times a year, but increased meetings to a monthly schedule to support the COVID-19 emergency. The ACIP established a COVID-19 workgroup. The COVID-19 workgroup will:

1. Review safety and immunogenicity data for COVID-19 vaccines,
2. Review the epidemiology of COVID-19 disease and identify potential target populations for vaccination,
3. Discuss potential vaccine prioritization plans in the event of insufficient

- early COVID-19 vaccine supply,
4. Identify areas where additional data are needed to inform COVID-19 vaccine recommendations, and
 5. Develop COVID-19 vaccine policy options that ACIP may consider for recommendations.

Dr. Duffy described the vaccine development efforts currently under way. The technologies being pursued include vaccines with recombinant protein with or without adjuvant; a vaccine based on an RNA platform; and viral vectors which work with a live attenuated virus to include the COVID-19 antigens. There are six manufacturers funded by Operation Warp Speed working on COVID-19 vaccine candidates. Moderna, AstraZeneca and Pfizer have begun Phase III clinical trials in the US. The ISO is preparing to perform surveillance roles through VAERS, VSD and the CDC Clinical Immunization Safety Assessment (CISA) network if and when the vaccines are approved by the FDA. Dr. Duffy concluded his presentation and invited questions.

After Dr. Duffy's presentation, there was a brief discussion about the definitions of adverse events. Dr. Duffy clarified that there are non-serious and serious adverse events. Serious adverse events are life-threatening reactions, reactions requiring hospitalization, or death. Dr. Duffy also explained the difference between solicited adverse events, which is when the vaccine protocol specifies a specific event-reporting requirement versus non-solicited adverse events, which are voluntarily submitted.

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

Ms. Schuster specified that part of NIAID's charge is responding to emerging health threats and the COVID-19 pandemic is a challenge that fits that description. In April 2020, NIAID launched a strategic plan to advance COVID-19 research, including how to diagnose, treat, and prevent the virus. One aspect of the strategic plan is managing the response with the challenge that SARS-CoV-2 infections are mild in some cases and very serious in others. Another aspect is developing rapid diagnostics and assays, which includes assays to distinguish SARS-CoV-2 infections from other virus-based infections, as well as serologic assays to identify antibodies to the virus. Antibodies can also help identify individuals who have recovered from a previous SARS-CoV-2 infection. The plan also prioritizes the development of treatments and vaccines for COVID-19.

In February 2020, NIAID launched the first clinical trial in the U.S. to look at an experimental treatment for COVID-19. The study, the Adaptive COVID-19 Treatment Trial (ACTT), includes hospitalized adults who have been diagnosed with COVID-19. There are multiple studies under the umbrella of ACTT. The first iteration, ACTT-1, assessed an antiviral, remdesivir developed by manufacturer Gilead Sciences. ACTT-1 enrolled more than 1,000 patients. The results of the study revealed that patients who received remdesivir had a 32% faster time to recovery than those who received placebo and suggested a survival benefit. The second iteration (ACTT-2) began in May and is looking at remdesivir plus an anti-inflammatory, baricitinib, which is used to treat moderately to severely active rheumatoid arthritis (RA). The third iteration (ACTT-3), which began in August 2020, is evaluating remdesivir plus an immunomodulator interferon beta-1a, which is used to treat multiple sclerosis.

The journal *Science* published a paper authored by a number of experts on COVID-19 who agreed that more than one effective vaccine approach would probably be required to meet the global need. The authors proposed harmonizing clinical testing of multiple vaccines and supporting public-private collaboration to accelerate vaccine development. In July 2020, interim results were announced for a NIAID-supported Phase I trial of an experimental SARS-CoV-2 vaccine, known as mRNA-1273. The investigational vaccine was generally well tolerated and prompted neutralizing antibody activity among healthy adults. No serious adverse reactions were reported. The vaccine was co-developed by NIAID and Moderna, Inc. The clinical trial was expanded to include adults older than 55 years of age.

Four months after the Phase I trial was launched, a Phase III trial began to determine if mRNA-1273 could prevent symptomatic COVID-19 in adults. The randomized placebo control trial will enroll about 30,000 healthy adults who will receive two doses of either mRNA-1273 or placebo.

In addition, Ms. Schuster commented that two Phase III trials are being initiated to look at whether experimental monoclonal antibodies can prevent COVID-19 infection in different settings such as nursing homes or assisted living facilities or among household contacts of individuals with SARS-CoV-2 infection. Observational studies are also being conducted to look at the impact of COVID-19 on children, who may develop multisystem inflammatory syndrome (MIS-C) as a side effect of exposure to SARS-CoV-2. NIH is also looking at the impact of COVID-19 on pregnancy outcomes with studies supported by the National Institute of Child Health and Human Development.

Finally, on a non-COVID topic, a paper published in the *Lancet* in June 2020, reported on a small Phase I trial that assessed a vaccine against mosquito-borne diseases. The investigational vaccine is designed to generate an immune response against mosquito saliva, rather than specific parasites, viruses, and bacteria that the mosquito might transmit. The results suggest that the vaccine is safe and induces a strong immune response in healthy volunteers. Ms. Schuster concluded her presentation. There were no questions from commissioners.

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

CDR Marshall articulated the FDA's commitment to supporting development of a safe and effective COVID-19 vaccine consistent with good scientific research. The agency released guidance, "Development and Licensure of Vaccine to Prevent COVID-19," which covers the FDA's requirements for chemistry, manufacturing and control, nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation. On October 22, 2020, CBER's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will conduct a virtual meeting online to discuss the development, authorization and/or licensure of vaccines to prevent COVID-19.

In June 2020, the FDA approved a supplement to the biologics license application for human papillomavirus 9-valent vaccine recombinant (GARDASIL® 9) to add prevention of oropharyngeal and other head and neck cancers caused by human papillomavirus (HPV) types targeted by the vaccine.

On September 17-18, 2020, the FDA will conduct an online symposium entitled, "Considerations for the Use of Real-World Evidence (RWE) to Assess the Effectiveness of Preventive Vaccines". The purpose of this symposium is to exchange information with

stakeholders from industry, academia, and government about the scientific, clinical, and regulatory challenges and opportunities in using RWE to assess the effectiveness of preventive vaccines. CDR Marshall concluded her report.

Update from OIDP, Dr. David Kim

Dr. Kim stated that OI DP provides leadership in the federal efforts to reduce the burden of infectious diseases, notably HIV/AIDS, antibiotic-resistance diseases, the development of strategies to combat infectious diseases that can be treated with vaccines, and hospital-associated infections. In August 2020, an effort was begun to catch up to gaps caused by the COVID-19 pandemic in the vaccination program for children. Since the pandemic emergency began, there has been a significant decrease in vaccine ordering and administration resulting in an 80% decline in vaccination coverage in some instances. In August, the third amendment of the Public Readiness and Emergency Preparedness Act (PREP) was implemented, authorizing licensed pharmacists to administer vaccines to children age 3 through 18 years, which increases access to vaccines for children.

The National Vaccine Advisory Committee (NVAC) recommends vaccine policy to the HHS Assistant Secretary for Health. NVAC has established two subcommittees, one focused on vaccine confidence and another looking at immunization equity. The National Vaccine Plan, responsible for the strategic approach to immunizing adults and children, is undergoing revision, the first since 2010. The National Vaccine Plan 2020 will undergo agency review and an opportunity for the public and others to comment, and it should be released by the end of 2020 or in early 2021.

Healthy People 2030 was launched in August with 365 core objectives and 144 developmental objectives, refining the specific objectives for various vaccines including targets for reducing the number of children who receive no vaccinations, specific dosing schedules for MMR and DTaP, programs to increase the number of adolescents who receive HPV vaccine and programs to increase the number of individuals who receive seasonal flu shots.

Dr. Kim announced that a major vaccine safety report was being prepared that would assess evidence on the safety of routinely recommended vaccines, including combination vaccines for children. The report will discuss adverse events reported since the last report was published in 2014. The Vaccine Safety Report will be available for review by stakeholders and is scheduled to be released in 2021. Dr. Kim concluded his report.

Review of VISs, Ms. Suzanne Johnson-DeLeon, CDC

Ms. Johnson-DeLeon provided a brief description of the VISs and the CDC review process, which includes review by the ACCV. She noted that the VIS contains available data and information for each vaccine, presented in understandable language and includes a brief description of the benefits and risks of the vaccine, information about the VICP and how to report an adverse event.

There are seven major sections in each VIS. The first four sections of the VIS are vaccine-specific in the discussion and therefore different from each other; the last three sections are identical. The first section, “why get vaccinated,” is unique for each vaccine and the information is taken from the individual assessments for each vaccine. The second section discusses dosage. Section 3 talks about cautions and contraindications and invites the recipient to

consult his/her health care provider if there are questions. Section 4 describes risk of vaccine reactions.

The last three sections contain the same text for all vaccines; (section 5) what to do if a serious reaction occurs; (section 6) information about the VICP; (section 7) where to get more information about vaccines in general.

There are 18 VISs for vaccines covered under the VICP, 15 of which, the ACCV has already reviewed. At this meeting, the commission will review the last three:

1. Multi-pediatric vaccine (DTaP – diphtheria-pertussis-tetanus, hepatitis B, polio, *haemophilus influenzae* type B, and pneumococcal disease-PCV13);
2. Td (tetanus-diphtheria), and
3. Tdap (tetanus, diphtheria, and pertussis).

Multi-pediatric vaccine combination

Ms. Johnson-DeLeon invited comments on the multi-pediatric vaccine VIS mentioned, noting that the vaccine-specific sections (sections 1-4) are taken from the various individual vaccine VISs. She also reminded the commissioners that the ACCV previously reviewed the individual vaccine VISs for vaccines included in the multi-pediatric vaccine combination VIS during earlier meetings.

A commissioner suggested that hyperlinks could be added to provide more detailed information about risk, dosage, etc. Ms. Johnson-DeLeon noted that the VIS is usually handed to the patient as a document, which is not compatible with hyperlinks, but she would submit the suggestions to the CDC.

There was a suggestion to include information from the vaccine package insert in some way, perhaps as a hyperlink. Ms. Johnson-DeLeon responded that the information is generally quite detailed and lengthy, that type of inclusion is discouraged in the VISs because the intent is for VISs to be brief. In addition, she noted that there might be 10-20 links for the combination vaccines.

Mr. Howie reiterated his concern, expressed during earlier VIS reviews, that the brief warning about the statute of limitations for filing of a claim is inadequate. He suggested including the statement: “there is a time limit to file a claim, which may be as short as two years from the date of vaccination.” He also recalled that in previous ACCV meetings the commissioners had decided to look at options to improve the statute of limitations language.

Ms. Overby stated that the commission had discussed some options for recommendations to change the statute of limitations language but the commission has not yet agreed on a recommendation for the VISs because the issue of the VICP NPRM had taken precedence with the commissioners.

Td and Tdap Combination Vaccine

There were no comments from the Commission members regarding Td or Tdap vaccines. Ms. Johnson-DeLeon clarified that under the second section for the Tdap vaccine, although the overall recommendation is for adults to receive a booster for Tdap every 10 years, pregnant women should receive a dose during every pregnancy. That recommendation is included in the VIS.

Ms. Johnson-DeLeon concluded the discussion, noting that additional suggestions and comments would be welcomed after the meeting.

Selection of an ACCV Chair

Noting that Dr. Cody Meissner had resigned as chair after the last ACCV meeting, Ms. Overby invited nominations for the position of ACCV Chair. Ms. Kain nominated Mr. John Howie for Chair of the ACCV; Dr. Pahud seconded the nomination. The ACCV unanimously approved Mr. Howie's nomination.

Ms. Overby, noting the need for a Vice Chair, invited nominations. Mr. Howie nominated Ms. Kain for Vice Chair of the ACCV; Mr. Spiegel seconded the nomination. The ACCV unanimously approved Ms. Kain's nomination.

ACCV Work Group Update.

Mr. Howie explained that the work group was a less formal group designed to discuss ideas and issues of interest to the commissioners and make recommendations to the full commission. The current work group consists of only two members, Mr. Howie and Ms. Kain, but Mr. Howie invited the other commissioners join the group.

The first work group topic Mr. Howie discussed was an issue documented in letter from Jody Hunt, DOJ Assistant Attorney General, submitted on May 18, 2020 in support of the proposed table changes in the VICP NPRM. In this letter, Assistant Attorney General Hunt pointed out that at least 20 VICP petitions were filed that included altered medical records, some of which changed the site of the vaccination, which puts in question the integrity of the process. The work group determined that the subject of potentially fraudulent claims required further investigation and invited comment from the OSM and the DOJ regarding these incidents. Catherine Reeves, Deputy Director, Torts Branch, DOJ responded that such fraud is addressed in the litigation process and any further comments on the subject would be inappropriate as they may be associated with ongoing litigation. The OSM responded that there have been such alterations in the past that could be interpreted as legitimate, but OSM does not tolerate fraudulent changes to records filed with a petition. In addition, the OSM does not believe that the problem is widespread or that the integrity of the program is at risk.

The work group has also been looking at how to make a recommendation to the Secretary to conduct a study comparing health outcomes among vaccinated and unvaccinated children. The work group felt that they may lack sufficient knowledge and expertise about creating scientifically credible studies, and in order to develop a recommendation about a vaccinated vs unvaccinated study, it would be helpful for Ms. Herzog or Ms. Overby to identify experts who could weigh in on the subject at an upcoming ACCV meeting.

The work group also discussed revisiting recommendations to the Secretary regarding the statute of limitations on filing VICP petitions.

Finally, the work group has begun discussing a recommendation to present to the full ACCV about appointing an independent consultant to review the processes in all phases of the program (DOJ, OSM and HHS), with the purpose of finding ways to improve efficiency. Mr. Howie ended his comments and there were no further questions or comments from the commission.

Public Comment

Mr. Howie asked the operator to open the lines for public comment. There was one public comment.

Theresa Wrangham, Executive Director, NVIC, expressed appreciation to the ACCV for looking at a process to review evidence around SIRVA and syncope. She felt it was unfortunate that the Secretary pushed the NPRM forward without a presentation of any new evidence outside of the Institute of Medicine report or clarifying their interpretation of the law concerning vaccine administration.

In Ms. Wrangham's observations, when other advisory committees, like ACIP and NVAC, establish work groups, the charge to the work group is to report to the committee, and that may include a charge like inviting speakers to present to the committee without preapproval by the full committee. Why couldn't ACCV have a similar charge and invite speakers to present to the full committee without preapproval?

Finally, while there is a NPRM under way regarding SIRVA and syncope, the ACCV is not bound to tie their investigation of evidence for use in recommendations to the NPRM. Under the law, the ACCV can conduct investigations and make recommendations to the Secretary at any time.

Mr. Howie expressed appreciation for Ms. Wrangham's comments and noted that there were no other requests for public comment.

Future Agenda Items/New Business

Ms. Kain suggested that one of the ACCV responsibilities under the Vaccine Act is to survey federal, state, and local programs and activities related to the gathering information about injuries alleged to be caused by vaccination, including adverse reaction reporting requirements. Ms. Kain stated that VAERS is underreported and asked what has been done to improve the quality and quantity of reports to VAERS at the federal and state levels. She stated that reporting vaccine adverse events is a federal requirement. What is HHS doing to raise awareness about VAERS? Ms. Kain said she would like to discuss how to improve tracking vaccine injuries in each state and ensuring that states are reporting these vaccine injuries to VAERS. Ms. Kain stated there may be a way to rely on electronic medical records to notify doctors about adverse events that should be reported to VAERS.

Mr. Howie indicated that the business of the meeting was concluded and adjourned the meeting.

Adjournment

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