Advisory Commission on Childhood Vaccines (ACCV)

5600 Fishers Lane, Room 5W07, Rockville, MD 20857

Teleconference and Adobe Connect

December 5, 2019

Members Present

H. Cody Meissner, M.D. (2020) Chair
John Howie, J.D. (2020) Vice Chair
Kathleen Gaffney, Ph.D., R.N. (2020)
Karen Kain (2022)
Dino Sangiamo, J.D. (2019)F

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 September 2019 Minutes, Dr. Cody Meissner, ACCV

Dr. Meissner was temporarily delayed connecting to the teleconference and the public comment period was handled by Mr. Howie, Vice Chair, ACCV. Mr. Howie called the meeting to order, welcomed the commission members, DICP staff, ex officio members, and guests and invited public comment on the agenda. There was one request for public comment.

Public Comment:

Ms. Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC), commented on the review of Vaccine Information Statements (VIS) agenda item. Ms. Wrangham noted that NVIC had previously consulted with the Centers for Disease Control (CDC) on vaccine-related issues including reviewing VISs. She expressed concern that it has been more than a year since the CDC invited comments from organizations like NVIC, and in that time, the number of VISs the CDC is updating has increased. She also expressed the opinion that the current length of a VIS, restricted to two pages, has resulted in the elimination of important information previously made available. Ms. Wrangham stated that two federal reports, the Banyan and Altarum reports released in 2009 and 2010, discussed in previous ACCV meetings, identify the public's interest in information that addresses vaccine safety and risk. She recommended that CDC review those reports. These reports also included information that doctors are sometimes reticent to proactively distribute the VIS material to patients and sometimes do not provide opportunities for patients to discuss the vaccines.

Ms. Wrangham also recommended introducing hyperlinks in the online VISs to allow individuals to access much more information when interested. She noted that the VIS section entitled "Why vaccinate" has become a vaccine marketing promotion, rather than an objective information discussion. She also commented that the section originally entitled "Who should not get the vaccine", has become a statement that patients should "talk to their health care provider," which Ms. Wrangham stated was inappropriate. The statement should specifically indicate that

certain individual should not receive the vaccine and include a list of individuals who should not be vaccinated. In conclusion, she stated that there is nothing in the legislation to prohibit any of the suggestions previously mention or providing educational information that would help individuals make an informed decision about vaccination.

Approval of the September 2019 ACCV Meeting Minutes:

Dr. Meissner restored his connection to the meeting, Ms. Andrea Herzog confirmed a quorum, and he invited approval of the September 2019 ACCV meeting minutes. On motion duly made and seconded, the ACCV unanimously approved the minutes of the September 6, 2019 meeting.

Office of Special Masters (OSM), United States Court of Federal Claims (CFC), Mr. Brian Corcoran, Chief Special Master

Mr. Corcoran stated that he began his tenure as Chief Special Master about a month prior to this meeting. A speedy resolution to vaccine injury claims is the objective of the OSM in spite of the delays caused by the increased caseload and temporary interruptions resulting from the appellate process. On November 7, 2018, the OSM established a task force, which included representatives of the petitioner's bar from the five firms who have had the most claims in the National Vaccine Injury Compensation Program (VICP). The goal of the task force was to develop initiatives to address the increase in caseload, with the limited available resources. The task force also solicited comments from a wide range of stakeholders and ultimately arrived at two approaches that may improve the situation.

Mr. Corcoran, continued by giving an overview of two new initiatives, the Pilot-100 (P-100) Program and Pre-Assignment Review (PAR) process.

The P-100 Program's objective is to reduce the length of time and resources in the settlement process by sending petitions eligible for settlement to a third party neutral for evaluation. On September 23, 2019, the OSM initiated a test group of 25 petitions for the P-100 program. The test group includes five petitions from each of the five law firms participating in a Task Force. The intent of the program, when fully operational, is to achieve a substantial increase in annual petition resolutions via referral of a significant number of appropriate petitions to a neutral party for evaluation. If successful, CFC expects to refer 100 petitions to P-100 for each round of neutral evaluations.

Beginning on September 3, 2019, the OSM initiated a PAR process for all newly filed petitions. The objective of PAR is to increase efficiency in processing petitions by deferring case assignments to a special master until the record is substantially complete and ready for medical review by HHS/HRSA. The CFC initially assigns all petitions to the Chief Special Master's docket, and then staff in the OSM reviews the case filings to determine if the record is substantially complete as required by Section 11(c) of the National Childhood Vaccine Injury Act of 1986 (the Act), as amended.

The initial PAR review will result in either an Activation Order if the medical records and other evidence are substantially complete or a PAR Scheduling Order setting forth the filings required to complete the PAR process if the medical records are not substantially complete. The CFC issues follow-up scheduling orders as necessary until the record is substantially complete. If at the end of 30 days of the filing of the Statement of Completion there is no Activation Order or PAR Scheduling Order, a petitioner may move for an assignment of the case.

In order to expedite the processing of a petition through PAR, petitioners are strongly encouraged to file a complete set of certified medical records, including a Statement of Completion, as soon as possible after filing the petition. Beginning on January 1, 2020, completion of the PAR process will require the filing of the PAR Questionnaire Form (signed by petitioner) and certified medical records. PAR should ultimately result in the faster overall processing of petitions.

Finally, Mr. Corcoran commented that he oversees the SPU. Although set up to expedite the handling of all claims, the majority of SPU claims are for SIRVA and the SPU has become very focused on rulings related to those cases. He commented that in the future the focus is moving all cases through the process.

During discussion, Mr. Corcoran observed that the neutral evaluators were typically retired Special Masters or petitioner's attorneys familiar with the claims process, or individuals experienced in mediation. Most neutral evaluators are aware that vaccines are generally safe, although they may not be as knowledgeable about vaccine safety as an individual who is in the business of vaccine injury. He emphasized that the intent of the recommendations from a neutral evaluator are to move the parties to an agreement and are not binding on the parties involved in the claim and even referring a case to the P-100 is voluntary, not mandatory.

Asked about whether PAR is effective, Mr. Corcoran conceded that PAR was too new for a definitive evaluation. He noted that, although the Act specifies a 240-day limitation to conclude the case, the parties might agree to extend that time indefinitely. PAR does not have a time limit.

Report from the DICP, Ms. Tamara Overby, Acting Director

Ms. Overby reviewed the day's remaining agenda, which included 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), CDC, the National Institutes of Health (NIH), and the Office of Infectious Diseases and HIV/AIDS Policy (OIDP), an opportunity for the commissioners to review updates to VISs and a proposal of new VIS language to provide more information about the statute of limitations.

Ms. Overby informed the ACCV that the DICP updated its presentation and it now includes numbers of petitions filed by adults and children separately, as well as total petitions filed since 2010. The VICP defines children as less than 18 years of age. For the last three years, adult petitions have been level at around 1,250, and petitions for children have slowly declined from 171 in 2016 to 113 in 2019. Funding has also remained stable at $9.2 million for the last two years.

Currently, there are 898 adult petitions awaiting review including 106 that do not contain complete medical records. Of these petitions awaiting review, eight are petitions filed on behalf of children, all of which lack complete records. Awards for FY 2019 were about $196 million to petitioners and $26 million to attorneys for fees.

Adjudication Categories	Fiscal Years (FY)		
	FY 2018	**FY 2019**	**FY 2020***
Compensable	539	633	82
Concession	191	232	30
Court decision	29	44	2
Settlement	319	357	50
Non-compensable	189	143	24
Total	728	776	106

*October 1, 2019 – December 3, 2019

There were 633 compensable claims and 143 claims dismissed in 2019, and in 2020 to date, there were 82 compensable claims and 24 claims dismissed. The number of compensable claims increased in FY 2019 from 539 to 633, and the compensable claims went from 191 (35%) to 232 (37%). Ms. Overby presented the following additional information in response to ACCV member inquiries in previous meetings:

- The trust fund has a balance of $9.8 billion as of October 31, 2019, tax revenue was $9.8 million for the same period, plus $6.6 million from interest income, for a total income of $16.5 million (40%).
- Approximately, 90% of petitions were filed in the last two year were for adults.
- Over 54% of petitions filed in the last 2 fiscal years allege shoulder injury related to vaccine administration (SIRVA).
- Approximately, 73% of petitions filed in the last 2 fiscal years allege an injury from the influenza vaccine.
- Since FY 2006, about 70% of petitions filed are compensated via negotiated settlement (56% in FY 2019).
- There is nearly a 10-month wait for medical reviews by a HRSA physician for adult petitions.

Finally, on April 4, 2018, the Notice of Proposed Rulemaking (NPRM) to add the category of vaccines recommended for pregnant women to the Vaccine Injury Table, was published in the *Federal Register*. The comment period ended on October 1, 2018; the HHS received 51 comments, which are under review.

During the discussion following the presentation, a commissioner requested clarification on some of the terminology in the presentation. Ms. Overby clarified that in this presentation adjudications referred to all cases with an outcome (sett led, conceded, compensation via court decision or dismissed). Ms. Overby also clarified that when to DICP reports not compensated, that refers to court dismissals. Dr. Meissner asked for the average award for shoulder injury claims. Ms. Overby did not have that information on hand but would follow up and provide it at the next ACCV meeting.

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

Ms. Reeves announced that there were 376 petitions filed in the CFC during the reporting period 8/16/19 through 11/15/19. Of those petitions, 33 claims are for minors and 343 for adults, a slight increase in both categories over the last reporting period. The total number of petitions adjudicated during this reporting period are 214. The outcomes of the adjudicated cases are 66 claims conceded by HHS, 115 claims not conceded and resolved by settlement or proffer, and 33 claims not compensated/dismissed. During this reporting period, petitioners voluntarily withdrew seven petitions.

The U.S. Court of Appeals for the Federal Circuit (CAFC) handed down decisions in two appeals during this period, one of which was significant, Boatmon v. HHS, involving allegation that the vaccine caused sudden infant death syndrome (SIDS). The Court affirmed the Court of Claims reversal of the Special Master's decision on entitlement. Currently ten appeals by petitioner are pending in the CAFC, three of which are new claims filed since the last report to the Commission.

The CFC handed down six decisions on appeals by petitioners; there were no decision on appeals by respondent. Currently, there are nine appeals by petitioners pending in the CFC, four filed since the last report to the commission; and four appeals by respondent, two since the last report.

Oral arguments were heard in Cottingham v. HHS on December 3, 2019 and in Faup v. HHS on December 4, 2019.

Ms. Reeves presented data on adjudicated settlements for the reporting period, showing that the claim that took the longest, 5 years and 6 months, involved Hepatitis A, MMR and flu vaccines. The case adjudicated in the shortest time, one year, involved SIRVA related to Pneumococcal vaccine. Most of the cases adjudicated involved the injuries SIRVA or Guillain-Barré syndrome. Most of the cases were resolved in less than two years.

Ms. Reeves concluded her presentation by briefly discussing the Appendix slides, which included a glossary of terms, and flow charts illustrating the paths taken by claims from filing to resolution.

In the discussion following Ms. Reeves' presentation, a commissioner asked for more information on the SIDS case. Ms. Reeves responded that the first Special Master sided with the petitioner and the subsequent appeals reversed the original decision.

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

Dr. Wodi stated that her report would focus on the presentations made at the October 2019 Advisory Committee on Immunization Practice (ACIP) meeting. The first presentation was on pertussis-containing vaccines. The FDA approved a label change for Sanofi's Tdap product, Adacel. The changes are:

1. The 2nd dose of Adacel may be administered ≥8 years after the first dose of Tdap
2. Wound management: A booster dose of Adacel may be administered if ≥5 years since a previous receipt of a tetanus toxoid containing vaccine.

There are no FDA changes to the label for GSK's Tdap product, Boostrix.

There is evidence that repeat Tdap vaccination is widespread but there is limited data on safety of multiple doses. During the ACIP meeting there was a discussion of the safety of closely spaced (less than 12 months) Tdap vaccines, which are addressed in two papers, one by Theeten et al (Current Medical Research and Opinion), and the other by Fortner et al (Vaccine, October 2018). There were no adverse events or contraindications noted in either report.

There was a brief report on closely spaced Tdap vaccine in the Vaccine Adverse Event Reporting system (VAERS). Of the 88 reports of closely spaced doses of Tdap, 21 described an adverse event, mainly local reactions. In the Vaccine Safety Datalink (VSD) there were no increased adverse events in individuals who received either Tdap or Td, and in 187 pregnant women who received multiple Tdap doses during the same pregnancy, only one reported limb pain and swelling (unclear if related). In summary, published data on closely spaced Tdap vaccinations revealed no increase in adverse events. Safety data on such vaccine regimens is limited but the data available is reassuring. ACIP arrived at three recommendations for pertussis-containing vaccines:

1. A decennial Td booster to ensure continued protection against tetanus and diphtheria, booster doses of either Td or Tdap should be administered every 10 years throughout life.
2. Tetanus prophylaxis in the setting of wound prophylaxis for nonpregnant persons with documentation of previous vaccination with either Td or Tdap should be used if a tetanus toxoid–containing vaccine is indicated.
3. For either Td or Tdap additional doses of the catch-up schedule for persons ≥ 7 years should be used.

In the October 2019 meeting, the ACIP also discussed childhood immunization schedules. The ACIP approval of childhood immunization schedules is required prior to the schedule's publication in *MMWR*, February 2020. The ACIP voted to approve the following updates to the Child and Adolescent Immunization Schedule:

1. Influenza vaccination (June 2019)
   2019–20 influenza vaccine recommendations
2. Hepatitis A vaccination (June 2019)
   Recommendation for routine catch-up vaccination for all children and adolescents aged 2 through 18 years
3. Meningococcal B vaccination (June 2019)
   Recommendation for booster doses for those ≥ 10 years and at increased risk of infection
4. Tdap vaccination (October 2019)

Concerning the ACIP recommendations for influenza vaccines; Influenza activity remains low in the United States overall. So far, influenza A(H3N2) viruses are predominant in the US. The vaccine components selected for the 2019-20 Northern Hemisphere vaccine look appropriate.

The ACIP discussed the measles outbreak in New York in 2018-2019, which contributed, in part, to a global increase in reported measles cases, importation into the US of cases, and vaccine and vaccine hesitancy and targeted anti-vaccine activity.

The ACIP also discussed a planned review of flu vaccines for older adults that will look at the efficacy of vaccines currently recommended, and safety (systemic and injection site adverse events, Guillain-Barré syndrome, serious adverse events including anaphylaxis).

During the ACIP meeting, a brief presentation that described the three main CDC vaccine safety-monitoring programs: VAERS, VSD and the Clinical Immunization Safety Assessment Project (CISA). VAERS, a collaboration between the FDA and CDC, is the frontline repository for reporting suspected adverse events from vaccinations, and serves to provide an early warning of vaccine adverse events. The VSD is a collaboration between the CDC and eight integrated

health care systems covering more than 12 million members. It is the system most relied on to track vaccine-related adverse events. CISA is a smaller system, with links to seven academic centers, that provides individual clinical vaccine assessments and conducts research and analysis to support various health care providers in the U.S.

To conclude her presentation, Dr. Wodi briefly commented on several recent publications:

1. Moro PL et al. described "Challenges in evaluating post-licensure vaccine safety: observations from the CDC" in *Expert Rev Vaccines*. 2019 Oct. The researchers looked at selected challenges for conducting pharmacovigilance and epidemiologic studies of adverse events after vaccination. The paper relied on post-licensure safety surveillance data.
2. McNeil MM et al. looked at adverse events following adenovirus type 4 and type 7 vaccine, live, oral in the Vaccine Adverse Event Reporting System from 2011 through 2018. Data was for vaccines for use in military personnel 17 through 50 years of age. The data identified no unexpected or concerning pattern of adenovirus vaccine AEs.
3. Christianson MS, et al, looked at primary ovarian insufficiency and human papilloma virus vaccines: A review of the current evidence, in Am J Obstet Gynecol. 2019 Aug 31. The vaccines prevent cervical cancer and anogenital cancers caused by human papilloma virus infection. Vaccine coverage rates lag behind the other vaccines. Public concerns are related to the notion that the vaccine causes primary ovarian insufficiency. However, that was not supported in a recently published epidemiologic study of approximately 60,000 females. Current evidence is insufficient to suggest or support a causal relationship between human papilloma virus vaccination and primary ovarian insufficiency.
4. Grohskopf LA, et al published a study of prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2019–20 Influenza Season, in Recommendations and Reports - *MMWR*. August 23, 2019.
5. Donahue JG, et al, inactivated influenza vaccine and spontaneous abortion in the Vaccine Safety Datalink in 2012-13, 2013-14, and 2015-15. *Vaccine*. 2019. The researchers found no association between IIV and SAB, including among women vaccinated in the previous season.
7. Groom HC, et al, published a paper on uptake and safety of hepatitis A vaccination during pregnancy (Vaccine Safety Datalink study) in Vaccine, Volume 37, Issue 44, 16 October 2019. They found that the rate of maternal HepA vaccination adverse events was low and rarely due to documented risk factors for vaccination. HepA vaccination during pregnancy was not associated with an increased risk for a range of adverse events examined among pregnancies resulting in live births.

In the discussions following Dr. Wodi's presentation, several commissioners had questions. Referencing the Tdap study (slide 6 of the CDC update), Ms. Kain asked how long the study followed the pregnant women after the vaccination. Dr. Wodi said that particular study the followed the participants for 8 days. However, other pregnancy outcome studies, some published and some unpublished, followed participants for serious adverse events up to 6 months after delivery.

Regarding the measles outbreak, Ms. Kain asked what percentage of people effected by the measles outbreak were hospitalized, if they were fully vaccinated and if there were any

particular strains of measles that were involved. Dr. Wodi was unable to answer those specific questions but offered to direct Ms. Kain, via email, to people in CDC that may be able to provide answers. Mr. Sangiamo asked what the age distribution is for people who contracted measles during this outbreak; again, Ms. Wodi offered to follow and directed Mr. Sangiamo to MMWR, which is a CDC publication on the measles outbreak. Dr. Meissner asked for clarification on whether the CDC has decided that the measles outbreak in New York is over. Dr. Wodi was not sure on the accuracy of this.

Dr. Meissner also asked if what the CDC plans were to address issue of small gestational age (SGA) infants from women who received the HepA vaccine in pregnancy and would there be a study. Dr. Wodi responded that she would follow up on this question.

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

Ms. Schuster discussed an NIAID-sponsored human influenzas challenge study in which human adults will be intentionally infected with flu virus under carefully controlled conditions. The study will take place at four major academic medical centers and look at how existing antibodies in the subjects affect the course of flu symptoms. The healthy volunteers will receive a nasal application of seasonal flu virus, which will result in mild to moderate flu disease. In earlier similar trials, researchers observed no significant safety issues or complicated cases of flu and there were no cases of flu outside the clinic.

NIAID recently initiated a program called CIVICs, to involve a new network of research centers that will work together in a coordinated multidisciplinary effort to develop more durable and longer lasting influenza vaccines, targeting a wide variety of flu viruses. The program will also explore the advancement of seasonal vaccines. NIAID will provide up to $51 million for the program. The program will support three vaccine centers, a manufacturing and toxicology core, two clinical cores, and a statistical, data management and coordination center.

Ms. Schuster announced that NIAID has funded a large program to advance tuberculosis (TB) immunology and vaccine research. First year funding is $30 million. TB, caused by Mycobacterium tuberculosis (MTB), spreads by airborne transmission, and is the world's largest cause of death. The program will provide a seven-year grant for three immune mechanisms of protection against MTB developed by three research institutions.

Ms. Schuster continued her presentation by discussing new findings in NIH funded research. Antibiotic treatment research, funded by the NIH, found evidence of antibiotic-resistant gut bacteria. The study used high-speed DNA sequencing and advanced computational analysis to study stool samples from 58 infants who received prolonged antibiotic treatment. The samples from these infants had less diverse bacterial populations in the gut, compared to the other infants, and the bacteria in their stool samples contained more antibiotic-resistant genes. The research suggests that early life antibiotic treatment may reduce the diversity of microbial communities in the gut, encourage the growth of harmful bacteria, and perhaps suppress the growth of beneficial microbes. Ms. Schuster clarified that prolonged antibiotic treatment is not defined as continuous treatment but may be in a series of treatments separated by time intervals.

Ms. Schuster reported that investigators, partly supported by the NIH, have reported positive results from a Phase III trial of a triple-drug therapy for individuals with cystic fibrosis. Vertex Pharmaceuticals developed the drug and the FDA recently approved it. The drug would benefit about 90% of individuals with cystic fibrosis.

Finally, Dr. Ian Wilson (Scripps Research Institute) delivered the NIAID's 2019 Joseph J. Memorial Kinyoun Lecture on November 19, 2019, in the Lipsett Amphitheater. The lecture was on structure-assisted design of universal vaccines and therapeutics against influenza virus.

During the discussion, Ms. Kain, asked if the participants in the antibiotic study were breastfed. Ms. Schuster was unsure and said she would need to look back at the study and that she would send a link to the study around to commissioners. Regarding the same study, Mr. Sangiamo asked if treating any or all pre-term infants with antibiotics was the standard treatment. Ms. Schuster deferred to the physicians in the group. Dr. Meissner, most infants in neo natal ICU end up on prolonged antibiotics; however, doctors make efforts to reduce infants' exposure to antibiotics. Dr. Meissner stated that the 20-month period of antibiotics seemed too long and was perhaps a misprint and asked if Ms. Schuster would distribute the link to that study as well.

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

CDR Marshall presented a brief discussion of a smallpox and monkey pox vaccine, approved in September 2019. The vaccine, Jynneos, is a live, non-replicating vaccine for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. Although naturally occurring smallpox disease is no longer a global threat; however, the intentional release of this highly contagious virus could have a devastating effect. Approval of this vaccine reflects the U.S. government's commitment to emergency preparedness. The vaccine will be stored in the Strategic National Stockpile.

CDR Marshall announced that, on November 8, 2019, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss and make recommendations on the development of Chikungunya vaccines. Chikungunya is a viral disease transmitted to humans by infected mosquitoes. It causes fever and severe joint pain. Other symptoms include muscle pain, headache, nausea, fatigue and rash. Epidemiologists and vaccine manufacturers made presentations at the VRBPAC meeting covering a number of approved chikungunya vaccines and vaccines currently in development. The committee also discussed the challenges of randomized trials since chikungunya outbreaks are irregular and unpredictable.

In the discussion following Ms. Marshall's presentation, an ACCV member, Ms. Gaffney, asked what areas are seeing Chikungunya. Ms. Marshall responded that the first reported case of chikungunya was in Tanzania but there have been cases throughout Africa and Asia and more recently, cases in France, Italy, the Caribbean, South and Central America and the United States. Ms. Marshall clarified this disease is seen in both children and adults.

Update from the OIDP, Dr. David Kim

Dr. Kim discussed the National Vaccine Plan 2020, noting that the objective of the plan is to update the 2010 plan and combine it with the National Adult Vaccine Plan that was published in 2015. The updated plan will be concise and combine the childhood and adult vaccination policies and programs, with a goal to develop a five-year outlook for immunization across the lifespan – children, adolescents and adults, including older adults. In developing a simplified National Vaccine Plan, OIDP conducted stakeholder interviews individually and in

small focus groups. Additionally, over a 30-day public comment period over 38,800 comments were received. The plan will have five objectives:

1. To support vaccine innovation
2. Increase vaccine safety
3. Increase vaccine confidence
4. Optimize access to vaccines physically and financially
5. Promote global immunization as a citizen of the world. The timeline includes release of the National Vaccine Plan in the fall of 2020.

Dr. Kim reported on the National Vaccine Advisory Committee (NVAC), a federal advisory committee that convenes three times a year to develop advice and recommendations for the HHS Assistant Secretary for Health (ASH), who is designated as director of the National Vaccine Program. NVAC's goal is to provide the ASH with information to continue his work on vaccine development, safety, efficacy and supply. The ASH charged NVAC with drafting reports, due by September 2020, on vaccine confidence, and immunization equity to eliminate disparities among different populations.

OIDP is revising the Healthy People 2020 initiative for 2030 to both simplify it and to expand certain areas. The initiative provides science-based, 10-year national objectives for improving the health of Americans. OIDP is developing two new objectives for Healthy People 2030. The first is the adult immunization composite measure, which includes several routinely recommended immunizations for adults specifically based on age, vaccination for influenza, pneumococcal pneumonia, Tdap and shingles. The second developmental objective is the immunization information system (IIS), vaccine registry. The objective is to ensure that the IIF is capable to capturing immunization data across the lifespan of the constituents in a jurisdiction. The two developmental objectives are awaiting the Secretary's approval.

During discussion following Dr. Kim's report Dr. Meissner asked how long the revision has been going on and who is drafting it. Dr. Kim clarified that the revision of Healthy People 2030 has been ongoing for several years and the OIDP is drafting the plan under the ASH. The goal is to release the Healthy People 2030 plan in Spring 2020. Ultimately Healthy People 2030 will be approved by the Secretary and it is not open for public comment.

Ms. Kain asked for more information about data capture by IIS, Dr. Kim stated that in the past data capture for childhood vaccinations had been relatively easy and effective. However, adult immunization involves a number of different programs and capturing data has been more challenging. For example, in one state that collects detailed childhood immunization records, when an individual becomes an adult, he or she must opt in to continue the data collection program. If an adult does not opt in, after a short period those data records are deleted from the system and lost to further access. The developmental objective for adult data collection is to improve that process.

Proposed Filing Deadline Language for VISs, Ms. Tamara Overby, Acting Director, DICP

Ms. Overby explained that at the September 2019 ACCV meeting there were concerns that the timeframes for filing a vaccine injury claim were unclear. Currently the VIS states there is a time limit to file a claim for compensation. Replacement language is submitted for ACCV consideration for review and recommendations, after which CDC would be responsible for final

approval. The proposed wording is, "Please note that, with limited exceptions, all petitions must be filed within three years after the first symptom of the alleged vaccine injury, or within two years of the death, and four years after the first symptom of the alleged vaccine injury that resulted in death. For information about additional requirements that must be met in order to pursue compensation visit the VICP web site." The web site url is provided. Ms. Overby invited discussion.

Mr. Sangiamo observed that if the CDC accepts the recommended language, and incorporates it in all VISs, an amendment to the time limits in the original legislation could result in significant logistical problems and the possibility that outdated VISs could remain in circulation. He added that relying on the individual to interpret the language and possibly miss the deadline might be less preferable than including in the VIS a recommendation to consult an attorney. For example, an individual might not understand the "limited exceptions" or the difference between first symptoms and first manifestation of onset. There was also mention of the fact that initial symptoms might not be easy to define.

Asked about the significance of the date of vaccine administration, Ms. Overby clarified that the legislation specifically points to the onset of first symptom and is silent on the date of vaccination. Mr. Howie observed that a warning that claims should be filed within three years of the date of the vaccination would be appropriate. That would eliminate all of the exceptions. Even more simply, the wording could say that the deadline could be as soon as two years and the individual should consult a lawyer before that time limit, which covers all variables. Mr. Howie suggested tabling the discussion and referring the question to the work group.

Dr. Kim agreed that the first sentence was complex and could be confusing. He suggested editing the statement to improve clarity. For example, he felt the exceptions could be explained early on. On motion duly made and seconded, the commission unanimously approved referring the discussion of the revised wording concerning the statute of limitations to the standing work group.

Review of VISs, Ms. Suzanne Johnson-DeLeon and Mr. Skip Wolfe, CDC

Referring to the previous discussion, Ms. Johnson-DeLeon noted that she and Mr. Wolfe were also concerned about individuals either not receiving the VISs or not reading them when they do receive them. That is the purpose of this extensive review, to try to improve the VISs so that they are more easily understood and more concise. Ms. Johnson-DeLeon added that she assembled the recommendations from previous ACCV reviews and those will be considered as future revisions are made, although commission members are welcome to reiterate any that they consider important.

The headings for all VISs are the same (except for rotavirus, explained below)

1. Why get vaccinated;
2. Vaccine description
3. Talk with your health provider;
4. Risks of vaccination;
5. What if there is a serious problem;
6. The National Vaccine Injury Compensation program;
7. How can I learn more?

Ms. Johnson-DeLeon began the reviews with Hemophilus influenzae type b (Hib). A commissioner asked why there was not a list of vaccine ingredients that could initiate an allergic reaction. Ms. Johnson-DeLeon stated that the caveat to consult a health care provider would give the potential vaccine recipient an opportunity to mention serious allergies or other potentially life-threatening conditions at that time. A commissioner suggested including links to the package inserts in the VIS. Ms. Johnson-DeLeon responded that links to the package inserts are not included in the VISs, in part because the links can be lengthy and complicated to add to the online VIS, especially if the vaccine has a number of different options that could multiply the number of links required. The CDC has stated that these documents are not the appropriate place to insert links.

There was a comment that Section 1 states that before the vaccine was available, Hib was the leading cause of bacterial meningitis among children under five, but it was also the leading cause of acquired mental retardation, which should also be included in the VIS. There were no comments on Section 2, 3 and 4. Ms. Johnson-DeLeon stated that the last three sections, 5 through 7 would be the same for all VISs.

Ms. Johnson-DeLeon invited comments for human papillomavirus vaccine (HPV). It was noted that oropharyngeal disease, the most common type of cancer that is prevented by the vaccine, is not mentioned in Section 1. Ms. Johnson-DeLeon stated that it was originally in the VIS, but FDA felt it was not an approved indication for the vaccine, to prevent oropharyngeal cancer. Dr. Meissner commented that was interesting since that is the main reason that men were included in the vaccine recommendation. There was a question about why the symptom of genital warts was not mentioned in Section 1.

In Section 2, Ms. Johnson-DeLeon noted that the recommendation concerning HPV for individuals over 26 years of age is intentionally left to the health care provider by the recommendation of the ACIP. She also explained that the omission of a recommendation to wait (rest) 15 minutes after vaccination was considered more in the purview of the heath care provider's counsel. Asked about the omission of the caveat about individuals who should not get the vaccine (previously included as a separate section), Ms. Johnson-DeLeon explained that when precautions and contraindications were added to the VIS under that section, there was concern that individuals might interpret them as tacit recommendations to avoid receiving the vaccine. It was felt that this decision should rely on the advice of the health care professional. There was a comment by Ms. Kain, a commission member that the vaccine was one of the most dangerous on the list and that the VIS should include the section providing information about contraindications and the decision not to accept the vaccine. Dr. Meissner commented that, to the contrary, a recent paper in Pediatrics cited studies that identified very few adverse events and that the vaccine appeared to be very safe.

Ms. Johnson-DeLeon continued to Pneumococcal Conjugate Vaccine (PCV13), noting that in Section 1 the ACIP had changed the recommendation for providing the vaccine to adults 65 and older with a recommendation to rely on the counsel of a health care provider, which is reflected in new wording in the proposed draft. The recommendation to consult a health care provider in Section 3 has been expanded to include a caution concerning any allergic reaction to an earlier pneumococcal conjugate vaccine known as PCV7, or to any vaccine containing diphtheria toxoid. In Section 4, a difference from other VISs is that children may be at increased risk for seizures caused by fever after PCV13 if it is administered at the same time as inactivated influenza vaccine. As for earlier VISs, Sections 5, 6 and 7 are identical to other VISs.

Turning to Polio vaccine, Ms. Johnson-DeLeon noted that the word "inactivated" has been deleted since there is only one polio vaccine approved for use. Asked about whether a warning about anaphylaxis should be added, Ms. Johnson-DeLeon explained that the symptoms described in the first paragraph of Section 5 are those for an anaphylactic response to a vaccine. There were no other comments on the Polio VIS.

Continuing to Rotavirus vaccine, Ms. Johnson-DeLeon mentioned that it was different from other vaccines in that it is a live activated vaccine and there is a recognized risk of intussusception. The vaccine is also only for infants so there is no mention of risk exposure to children or adults. Ms. Johnson-DeLeon pointed out the very dense url related to the reference to porcine circovirus. The subject matter experts agreed that the description of that virus should remain in the VIS. Dr. Meissner observed that porcine circovirus is a nonissue because it does not infect individuals and it may not be a viable virus. He asked if the subject matter experts provided a rationale since, in his opinion, the issue is irrelevant. He offered a brief explanation that several years before, there were hybridization assays completed on several vaccines, of which this pig virus was one. Porcine circovirus nucleic acid was identified rotavirus vaccine and there was an indication that it contaminated the vaccine, which could be a cause for concern. However, subsequent studies showed that the porcine circovirus does not affect humans, who get exposure to it in a variety meat sources.

In Section 3, intussusception is mentioned because it is a serious life-threatening condition often requiring a surgical intervention, and because the individuals involved are infants who may not be able to express how they are feeling. There was a recommendation to provide more information on how to recognize the onset of the disorder, including how prevalent the condition is in the general U.S. population. There were no additional comments or questions on the Rotavirus VIS.

Ms. Johnson-DeLeon stated that the VISs for DTaP and Hepatitis A are in early draft form and properly formatted, like other VISs. Ultimately, they will conform to the same format as the other VISs. There were two comments on the DTaP VIS. First, that unlike other VISs describing Guillain-Barré Syndrome, there is no time-limiting condition; and second, in Section 4, the reference to swelling of the entire arm or leg should be modified to allow patients to continue the vaccine series if the symptoms resolve in a reasonable time.

Turning to the final VIS, Hepatitis A, there was a comment that the statement in Section 1, that "Most children less than 6 years of age do not have symptoms," should be revised to begin "Most children with hepatitis A" and end with "but may still be contagious and could spread the disease." In Section 2, there was a question about the phrase "usually need 2 doses" and Mr. Wolfe stated he would confirm the phrase. There were no additional comments on the VIS.

Mr. Wolfe expressed appreciation for the extensive participation and the recommendations.

Public Comment

Dr. Meissner invited public comment. Ms. Theresa Wrangham, Executive Director, NVIC, stated that Mr. Corcoran's comments were encouraging in that his suggestions could expedite case resolutions and reduce the current backlog. However, as there is no equitable polling allowed in the VICP, and the PAR pilot program is not mandatory, she expressed

concern about the readiness of plans to move forward. There is little awareness of the program and petitions are often filed late. That begs the question of how to promote the program so that there is adequate time to properly prepare a claim.

Ms. Wrangham mentioned the NVIC's continuing concern about the existing gaps in vaccine safety research. Closing the existing research gaps would help meet the intent of the law to settle claims quickly and establish a more expeditious process to settle successful claims. Regarding the 2020 National Vaccine plan, the plan does not address closing these acknowledged research gaps and continues to focus on vaccine innovation and development. The same is true of the Healthy People 2030 goals.

There is also a lack of privacy and permission opportunity for consumers to participate in vaccine information systems. Sensitive data is used for other purposes without permission of the consumers who provide the data, mainly to state data systems. These serious privacy concerns are not being addressed.

Ms. Wrangham commended Dr. Meissner's reference to developing a breakdown of compensation by alleged injury, a longstanding request by NVIC. That information would provide guidance on the type of research needed to understand the mechanisms of vaccine injury. That data is being gathered but not published.

Given the original purpose of the Act to provide generous no fault compensation for vaccine injury, Ms. Wrangham expressed her confusion about why the DOJ would reverse the Special Master's decision to award compensation in the SIDS case mentioned in Ms. Reeves' presentation. She said the reversal seems unnecessarily aggressive and adversarial.

Concerning the review of the VISs, the NVIC's position and recommendation is that the public wants more information about vaccine safety and that the arbitrary limitation on VISs of two pages is not productive to that end. A congressional report on HPV stated that 90% of the infected population resolves the infection without any complication or adverse event. The same is true of polio, but the VIS did not mention that fact. Epidemiological information on each VIS condition should be included in the VIS.

With regard to rotavirus, intussusception is a life-threatening condition and should be explained.

Ms. Wrangham expressed appreciation for being able to comment. There were no other requests to comment.

Adjournment

Dr. Meissner thanked the commissioners, ex officio members and staff who participated in the meeting. On motion duly made and seconded, the meeting was adjourned.