

Advisory Commission on Childhood Vaccines (ACCV)

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

Teleconference and Adobe Connect

September 6, 2019

Members Present

H. Cody Meissner, M.D. ('20) Chair

John Howie, J.D. ('20) Co-Chair

Kathleen F. Gaffney, PhD, RN ('20)

Dino S. Sangiamo, J.D., ('19)

Tina Tam, M.D., ('19)

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 June 2019 Minutes, Dr. Cody Meissner, ACCV

Dr. Meissner called the meeting to order, welcomed the commission members, DICP staff, ex officio members, and guests and invited public comment on the agenda. The meeting operator confirmed there were no request to comment. Dr. Meissner deferred approval of the June 6, 2019 ACCV meeting minutes because there were not enough members present for a quorum to vote to approve the minutes. Mr. Sangiamo arrived later in the meeting, establishing a quorum and, on motion duly made and seconded; the ACCV approved the June 2019 meeting minutes unanimously.

Dr. Meissner invited Tamara Overby, Acting Director DICP, to report.

Report from DICP, Ms. Tamara Overby, Acting Director

Ms. Overby announced that Dr. Narayan Nair, the previous director of the DICP, retired during the summer and that she is currently serving as Acting Director of DICP. She expressed appreciation to Dr. Meissner and Mr. Howie for agreeing to serve as Chair and Co-Chair respectively of the ACCV. Finally, she recognized new member, Karen Kain, who joined the Commission as representative of a vaccine-injured child.

Ms. Overby reviewed the day's 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), 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), a report from the ACCV Work Group, and an opportunity for the commissioners to review updates to eight Vaccine Information Statements (VISs). Ms. Overby reported the number of petitions filed in the VICP from Fiscal Year (FY) 2009 to date in FY 2019. During FYs 2009 through 2013, the average number of petitions filed was 427. There were significant increases in claims filed in FY 2014 (633), FY

2015 (803) and FY 2016 (1,120). FYs 2017 and 2018 had filing numbers similar to FY 2016, and FY 2019 is on track to have a similar number of claims. So far, in FY 2019, 1,131 claims have been filed.

Concerning claims awaiting review, the VICP has cleared the backlogs for 2017 and 2018. There are no pending cases for those years. There are 818 claims awaiting review for FY 2019, suggesting the current wait time for an adult claim review is about 10 months.

Funding for HRSA to administer the program was \$6.45 million in FY 2014 and increased to \$7.5 million for FY 2015 through FY 2017. The funding increased in FY 2019 to \$9.2 million.

In FY 2018, petitioners' awards totaled about \$200 million and attorney's fees and costs were about \$27 million. To date, for FY 2019, those amounts are approximately \$180 million and \$26 million respectively.

Adjudication Categories	Fiscal Years (FY)		
	FY 2017	FY 2018	FY 2019*
Compensable			
Concession	183	192	186
Court decision	24	29	35
Settlement	488	319	291
Non-compensable	185	189	125
Total	880	729	637

*October 1, 2018 to September 3, 2019

Ms. Overby reported that the balance in the Vaccine Injury Compensation Trust Fund (Trust Fund), as of June 30, 2019, is more than was approximately \$3.9 billion. Excise tax revenue accounted for \$160 million, and interest on Trust Fund investments contributed about \$61 million, for a total income of \$221 million.

Finally, a significant activity of the program is the continuing process of implementing the Maternal Immunization Provisions. The Notice of Proposed Rulemaking (NPRM) to add the category of vaccines recommended for pregnant women to the Vaccine Injury Table (Table) was published in the Federal Register on April 4, 2018. The period for public comment ended on October 1, 2018, and VICP received and are reviewing 51 comments. Responses to comments will be included in the Final Rule.

Ms. Overby provided a web link to access information about ACCV meetings: <https://www.hrsa.gov/advisory-committees/vaccines/index.html>. She added contact information for Ms. Annie Herzog, the ACCV Principal Staff Liaison. Ms. Overby concluded her report.

During discussion, Mr. Howie asked how to determine the number of covered vaccinations administered since the initiation of the program. Ms. Overby responded that the Department of Treasury web site began posting information on the number of VICP covered vaccine units sold, therefore taxed, about ten years ago. She stated that she would try to locate more information, but she added that the specific number of vaccines administered could not be determined from the Department of Treasury information because that information generated is from the excise tax revenue from vaccines sold and there is likely a disparity between vaccines sold and administered.

Ms. Kain noted that 92% of vaccine compensation went to adults in 2019 for flu vaccinations. She wondered why such a large proportion of the compensation went to adults in a

program originally developed for children. Ms. Overby explained that when a vaccine recommended for routine use in children by the CDC, then it is covered by the VICP; adults become eligible for compensation if they are administered that vaccine. There is no legislation or regulation that prohibits adults from filing claims if they believe they suffered an injury as the result of being administered a VICP covered vaccine. The seasonal flu vaccine is a VICP covered vaccine and more adults receive that vaccine than children do. Seasonal flu vaccine is also the most widely distributed vaccine in the country. Because of that and the high rate of receipt of the vaccine in the US adult population, adult injuries related to flu vaccinations represent the majority of injury claims.

Dr. Meissner commented that the 10-month delay in reviewing claims seems to be an improvement. Ms. Overby explained the delay is actually increasing over time. At one point, the delay was six months, and it has increased to the present 10-month delay. She added that there are no pediatric cases in the backlog. She also clarified the definition of a backlog case, which does not include cases removed from the queue for various reasons not related to the medical review process. The backlog represents cases that are ready for medical review, but have not had a review by a VICP medical officer.

Dr. Meissner also asked about the accuracy of the 27% interest income on slide 10 of the presentation, which discusses the balance and earnings in the Trust Fund. Dr. Meissner thought 27% was a very high interest rate. Ms. Overby acknowledged the question and told Dr. Meissner she would follow up on it for him.

During the discussion following Ms. Pearlman's presentation, Ms. Overby referred back to a question posed about the Trust Fund. Ms. Overby clarified that the reference to 27% interest is not the interest rate that the money in the Trust Fund earns (the VICP does not report this information). The 27% references the percentage of the quarterly income (about \$221 million in the reported quarter) that is attributed to interest (about \$61 million), rather than other sources of income such as excise tax. Dr. Meissner thanked her for the clarification.

Report from DOJ, Ms. Heather Pearlman, Assistant Director, Torts Branch

Ms. Pearlman referenced the Department of Justice (DOJ) PowerPoint materials as part of her presentation for the three-month reporting period from May 16, 2019 through August 15, 2019. (DOJ PowerPoint (PP) at 1.) Ms. Pearlman stated that during this reporting period, 307 petitions were filed. (DOJ PP at 2.) Ms. Pearlman further noted that of the 307 petitions filed in this reporting period, seven (2%) were filed on behalf of minors and 300 (98%) were filed by adults. (DOJ PP at 2.)

Ms. Pearlman stated that 228 petitions were adjudicated during this reporting period. (DOJ PP at 3.) One hundred and seventy-nine of the adjudicated cases were compensated. (DOJ PP at 3.) Of the 179 compensated cases, 86 cases were conceded by the government, three of which had decisions awarding damages, 82 of which had decisions adopting proffers, and 1 of which had a decision adopting a settlement. Ninety-three of the compensated cases were not conceded by the government, 87 of which involved settlements. Forty-nine cases were not compensated. (DOJ PP at 3.) Seven 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 noted that during the reporting period, the CAFC affirmed one appeal by petitioner and reversed one appeal by petitioner (both entitlement

decisions). (DOJ PP at 5.) She noted that nine appeals by petitioner remain pending and one appeal by respondent remains pending before the CAFC. (DOJ PP at 6-7.)

Ms. Pearlman next discussed appeals at the U.S. Court of Federal Claims (CFC). (DOJ PP at 8-11.) She noted that nine appeals by petitioner were decided by the CFC during this reporting period (seven entitlement decisions and two attorneys' fees and costs). (DOJ PP at 8.) She further noted that the CFC affirmed the special masters' decisions in all but one of petitioners' appeals (entitlement decision). (DOJ PP at 8.) Ms. Pearlman noted that the CFC affirmed one appeal by respondent (entitlement decision), and respondent has appealed to the CAFC. (DOJ PP at 7, 9.) Ms. Pearlman stated that there are presently 10 appeals pending before the CFC filed by petitioners (six entitlement decisions and four attorneys' fee and costs). (DOJ PP at 10.) She further stated that there are 2 appeals by respondent pending before the CFC (one entitlement and one attorneys' fees and costs). (DOJ PP at 11.)

Ms. Pearlman noted that no oral arguments are scheduled at the CAFC, and oral argument was held on September 5, 2019, in Dupoch-Carron v. HHS at the CFC. (DOJ PP at 12.)

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 13-20.)

Following Ms. Pearlman's presentation, she invited questions and comments. Dr. Meissner inquired as to whether attorneys' fees were paid in the 49 dismissed cases, noting an interest in ensuring that there was sufficient incentive for representation of injured petitioners. Ms. Pearlman stated that attorneys' fees are often awarded even if a case is dismissed or no compensation is awarded and that there are many different attorneys representing petitioners in the program. Dr. Meissner inquired whether most attorneys are filing claims on behalf of adults in SIRVA and GBS cases or on behalf of children. Ms. Pearlman noted that based on the number of cases filed on behalf of adults versus children, most attorneys are representing adults but, to Ms. Pearlman's knowledge, do not do so at the exclusion of representing children. Ms. Tamara Overby referenced Tab 4, p. 8-9 of the meeting book for information from DICP regarding the dollar amounts paid in attorneys' fees in dismissed cases.

Update on ACCV Work Group Activities, John Howie, Chair

Mr. Howie reported that work group had been inactive because several members of the workgroup have rotated off the Commission. Mr. Howie told the commission he had a brief discussion with Dr. Meissner. They agreed that the members should discuss new issues for the work group to address, and plan for a future conference call to give the members an opportunity to bring up ideas and projects. Ms. Kain stated her interest in conducting a study comparing vaccinated and unvaccinated individuals. She also expressed interested in a review of the recommendations to the HHS Secretary. Ms. Overby commented that the Secretary has been considering candidates to fill the vacancies on the commission. She added that the terms of commission members should overlap so that the terms of all the commissioners would not end at the same time, which would assure some continuity as membership changed.

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

CDR Marshall reported that the FDA approved supplements for the biologics license applications (BLA) for seasonal influenza vaccines to include the 2019-20 United States formulation and associated labeling revisions. Vaccine lots released by the FDA are available for distribution by the manufacturers.

CDR Marshall announced an upcoming workshop on September 16-17, 2019. CBER, the NIH, National Institute of Allergy and Infectious Diseases (NIAID), and the Coalition for Epidemic Preparedness Innovations (CEPI) will hold a public workshop entitled, “Identification and Use of Biomarkers to Advance Development of Preventive Vaccines.” The public workshop will bring together government agencies, academia, industry, and other stakeholders to discuss the scientific, clinical, and regulatory challenges encountered in the identification, characterization, and qualification of biomarkers for preventive vaccines for infectious diseases indications. The workshop will include discussions on exploring the use of biomarkers to inform the clinical development of preventive vaccines and in regulatory decision-making.

Finally, FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session on November 8, 2019 to discuss and make recommendations on the development of chikungunya vaccines. CDR Marshall concluded her report.

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

Dr. Wodi stated that she would discuss the June 2019 Advisory Committee on Immunization Practices (ACIP) meeting, followed by a brief discussion recent publications by the CDC Immunization Safety Office.

The ACIP agenda included a review of 9vHPV (Gardasil 9) vaccine for adults, and a look at the health economic models for Human Papillomavirus (HPV) vaccination of mid-adults and the Evidence To Recommendations framework. The ACIP voted to recommend harmonization of catch-up vaccination through age 26 for males and females who are not adequately vaccinated. There was also a recommendation to vaccinate adults 27 years to 45 years (the vaccine is not licensed for adults over 45 years of age) based on shared clinical decision-making.

The ACIP reviewed the current outbreak of hepatitis A in the US that began in 2016, involving 20,512 cases with 11,776 hospitalizations (57%). The ACIP also looked at hepatitis A and pregnancy from a safety standpoint. There is no identified increased risk of maternal or infant mortality after hepatitis A vaccination in pregnancy. There has been no concerning pattern of adverse events after hepatitis A vaccination during pregnancy that has been reported to the Vaccine Adverse Event Reporting System (VAERS). From an ongoing study, the Vaccine Safety Datalink (VSD) has reported a potential signal for small gestational age (SGA) births (preliminary results should be released by the end of the year).

The ACIP recommended routine hepatitis A vaccination of individuals 12 through 18 years of age if not previously vaccinated. The ACIP also recommends vaccination for all individuals with HIV aged one or over, and pregnant women identified as being at risk for hepatitis A infection during pregnancy or having a severe outcome from hepatitis A infection. The high-risk population ACIP recommends for hepatitis A vaccination now excludes persons with clotting factor disorders.

The ACIP discussion of meningococcal B (MenB) vaccines focused mainly on the importance of a booster vaccination one to two years following the primary vaccination. There

was a recommendation for a MenB booster for persons aged ten and older with complement deficiency, complement inhibitor use, asplenia and microbiologists. ACIP recommended booster vaccination one year after primary vaccination and then every 2-3 years as long as increased risk persists. For individuals aged 10 years and older determined by public health officials to be at increased risk during an outbreak, ACIP recommended a one-time MenB booster dose if it has been more than one year since completion of a MenB primary series.

Dr. Wodi described a new combination vaccine (DTaP, IPV, Hib, hepatitis B) developed jointly by Merck and Sanofi Pasteur, Vaxelis, approved by FDA in December 2018, which will become commercially available in 2021. The Vaxelis license is for a three-dose series for children at 2, 4, and 6 months (no birth dose). ACIP agreed that the vaccine series should be included in the Vaccines for Children (VFC) program. ACIP is considering if this vaccine should be preferential recommended for the American Indian/Alaskan Native population.

Dr. Wodi noted that there was significant discussion of the 2018-2019 influenza activity, which presents a moderate severity risk for all age groups. The overall effectiveness is about 30%, and the vaccine probably prevented up to 90,000 hospital admissions. VAERS did not indicate new safety concerns, although the VSD found an increased risk for Bell's palsy in 4 – 17 year olds, and increased risk for febrile seizures in children 6 months to 59 months.

Concerning Tdap, a recent change in the labeling allows a second dose of Sanofi Pasteur's Adacel eight or more years after the first dose and a booster dose for wound management if five years has elapsed since the previous receipt of a tetanus-toxoid containing vaccine. Although not recommended in any other labeling, there is evidence that there is widespread administration of a second dose. ACIP will be discussing whether the current recommendation that non-pregnant adults receive a single lifetime dose of Tdap with Td boosters every 10 years be changed to allow any Td-containing vaccine (Tdap or Td) to be used for the decennial Td booster. ACIP will also consider whether any Td-containing vaccine (Tdap or Td) should be allowed for tetanus prophylaxis in the setting of wound management; and should the catch-up immunization schedule for Tdap/Td be changed for those seven years of age and older.

Dengue fever is a significant disease burden globally – 390 million infections, 500,000 hospitalizations and 20,000 deaths annually. In May 2019, the FDA approved the Dengvaxia vaccine only for high-risk seropositive persons age 9 to 16. ACIP is considering three doses (0, 6, 12-month schedule) of vaccine administered routinely to persons aged 9-16 years with laboratory-confirmed previous dengue infection who live in endemic areas.

Finally, Dr. Wodi also provided information from the ACIP meeting on the measles outbreak in 2019 when 1,077 cases were reported in 28 states. CDC has responded by providing onsite assistance, including educational resources and technical assistance. Nevertheless, the United States remains in elimination status, although there are prolonged outbreaks in close-knit communities. Vaccination coverage remains high, but communities with low vaccination coverage are at risk for outbreaks. Dr. Wodi added that she had information that most of the measles cases involved individuals who had not received, or at least completed, the MMR vaccine series. Dr. Wodi commented on several recent publications:

1. Hesse EM et al, in MMWR, 2019 June 24 – an analysis of VAERS reporting that during the 2018-2019 flu season, VAERS received 125 reports (192 patients) following expired inactivated influenza vaccine, although reported adverse events were consistent with adverse events following administration of non-expired seasonal IIV, suggesting no additional safety issues associated with receipt of expired IIV.

2. DeStefano F et al, in *Clinical Infectious Diseases*, 2019 Feb 12 – that summarized the key evidence on some of the main current U.S. vaccine safety controversies.
3. Moro PL et al, in *Vaccine*, 2019 May 30 -- More than three-fourths of reports of an excess dose of vaccine did not describe an adverse health event (AHE). Among reports where an AHE was reported, no unexpected conditions or clustering of AEs was observed.
4. Edwards K et al, in *Biologicals*, 2019 May 23 – described that increased risk of narcolepsy was consistently observed after Pandemrix (AS03-adjuvanted) vaccine, but similar associations following other vaccines were not observed, recommending additional studies to determine whether other issues could be the cause.
5. Su JR et al, in *Journal of Allergy and Clinical Immunology*, 2019 Apr – looked at anaphylaxis after vaccination, which is rare in the United States and can occur among persons with no history of hypersensitivity.
6. Klein NP et al, in *Vaccine*, 2019 March – verified no increased risk for development of diabetes mellitus type 1 (DM1) following HPV vaccination.
7. Kochhar S et al, in *Vaccine*, 2019 May 31 – looked at important prerequisites for the successful introduction of new vaccines for immunization in pregnancy.

Dr. Wodi concluded her report.

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

Ms. Schuster reported on acute flaccid myelitis (AFM), a rare but often serious condition that causes muscle weakness and paralysis. Since the CDC began tracking AFM in August 2014, there have been 570 confirmed cases. CDC received reports of outbreaks in 2014, 2016 and 2018. Spikes in the disease, primarily in children, have coincided with outbreaks of non-polio enteroviruses, such as EV-D68 and EV-A71. The viruses typically cause mild respiratory illness and most people fully recover. Despite the link between AFM and enterovirus, circulation, evidence of direct causality has not been found.

A new NIAID-supported study of patients with and without AFM provides additional evidence of an association between AFM and infection with non-polio enteroviruses. Looking at cerebrospinal samples from 14 patients diagnosed with AFM, researchers detected enterovirus-specific antibodies in 79% of the cases. Of those, six samples were positive for EV-D68, strongly suggesting that enterovirus had been in the central nervous system. Investigators at Columbia University’s Center for Infection and Immunity, and investigators from the CDC conducted this study. Their findings are reported in the August 13, 2019, issue of the online journal, *mBio*. In addition, NIAID has awarded the University of Alabama Birmingham (UAB) about \$10 million over five years to study AFM. As part of this contract, UAB will organize and implement an international multi-site study to learn more about the incidence and distribution of AFM and to increase understanding of how the disease develops and progresses in children.

Ms. Schuster also reported on respiratory syncytial virus (RSV), a leading cause of respiratory illness in the very young and in the elderly. RSV infections account for about 57,000 hospitalizations and 2 million outpatient clinic visits among US children younger than five years old each year. A novel investigational vaccine has shown promise in a Phase I clinical trial conducted at the NIH Clinical Center in Bethesda. Participants in the trial are healthy adult volunteers. The vaccine candidate, DS-Cav1, was developed by NIAID scientists guided by their atomic-level understanding of the shape of an RSV protein. An interim analysis from the first 40 participants showed that one dose of the investigational vaccine prompted large increases in RSV-neutralizing antibodies sustained for several months. These findings were reported in the August 2, 2019, issue of *Science*, and final results from the study are expected next year.

NIH and partners announced a Phase III HIV vaccine trial at multiple clinical research sites in North America, South America and Europe. It will assess whether an investigational vaccine regimen designed to induce immune response against a variety of global HIV strains will safely and effectively prevent HIV acquisition among men who have sex with men and transgender individuals. It will enroll 3,800 participants. In 2017, a complementary study in women began in five southern African countries. All participants will be offered a comprehensive HIV prevention package plus either the investigational vaccine or a placebo. The study will begin enrolling in the US later in the year.

In other trials, Ms. Schuster stated that NIH is supporting a Phase I clinical trial to assess, the safety and immunogenicity of two licensed seasonal influenza vaccines, Flublok and Fluzone, administered with or without one of two novel adjuvants, *AF03* or the Advax-CpG55.2. Adjuvants are designed to enhance a vaccine's immune response.

Ms. Schuster concluded her presentation.

Vaccine Activities Update from OIAP, Ann Aikin

Ms. Aikin reported on two national vaccine plans released by the OIAP (formally NVPO). The National Vaccine Plan was released in 2010 and is being revised. The National Adult Immunization Plan was released in 2016. The goals of the National Vaccine plan are:

1. Develop new and improved vaccines
2. Enhance the vaccine safety system
3. Support communications to enhance informed vaccine decision-making
4. Ensure a stable supply of, access to, and better use of recommended vaccines in the US
5. Increase global prevention of death and disease through safe and effective vaccination

The goals of the National Adult Immunization Plan are:

1. Strengthen the adult immunization infrastructure
2. Improve access to adult vaccines
3. Increase community demand for adult immunizations
4. Foster innovation in adult vaccine development and vaccination-related technologies

Ms. Aikin explained that NVPO developed the National Adult Immunization Plan in response to the low rates of and stark disparities in vaccination among adults. The updated plan, currently in development, will consolidate these two immunization plans. OIAP should release the new consolidated plan in 2020 and it will be effective for 3-5 years. The Assistant Secretary for Health at HHS charged the National Vaccine Advisory Committee (NVAC) with looking at

the current goals from the two national immunization plans and creating a report, to include recommendations, on how to address these goals during the next 3-5 years.

In addition, NVAC has two other charges and are developing reports on immunization equity and vaccine confidence. Finally, OIHP hosted a series of regional stakeholder meetings that concluded in August, which involved all ten regional health offices. The discussions during those meeting covered a variety of adult immunization topic areas and a final report is being prepared.

During discussion following the OIHP update, Ms. Aikin commented on the differences between adult and childhood immunization as the Vaccines for Children program has contributed to the vaccination rate of children, with adults we see much lower rates of immunization across the board. Dr. Meissner added that the vaccination is an integral part of pediatric health care and a significant aspect of pediatric care in the early years of life.

Review of Vaccine Information Statements (VIS's), Suzanne Johnson-DeLeon and Skip Wolfe, CDC

Dr. Gaffney recused herself from the discussion of the vaccine information statements. Ms. Johnson-DeLeon established that the CDC has primary responsibility for development and periodic revision (updating) of VIS's as required by 42 USC, including the requirement to disseminate a VIS for all vaccines listed on the Vaccine Injury Table. The VIS must include a concise description of the benefits of the vaccine, the risks associated with the vaccine, and a statement of the availability of the National Vaccine Injury Compensation Program. Also included are information about contraindications and precautions, and a statement that additional information is available on the CDC web site.

Ms. Johnson-DeLeon explained that eight of the VIS's are under review, in part because there has been feedback that stakeholders want standardization and simplification, and a reading level that benefits the majority of users. The content focuses on the patient, not the provider, but there is always a recommendation that the patient consult his or her health care provider. Each review is approved by subject matter experts at CDC and have been reviewed by FDA.

Review discussion section by section:

1. **Influenza vaccine (inactivated or recombinant).** There were no comments from the commissioners regarding Section 1: Why get vaccinated? There were no comments on Section 2 consists of a brief description of the CDC vaccine specific recommendation.

In Section 3: "Talk with your health care provider," Ms. Johnson-DeLeon explained that earlier reviews had determined that the terms "health care provider" or "vaccine provider", most accurately described the provider, and are used in all VIS's. Dr. Meissner noted that the reference to Guillain-Barré syndrome (GBS) in the flu VIS was slightly different from that in the second VIS on live intranasal flu (the former includes "has ever had GBS" and the latter includes "has had GBS within six weeks after a previous dose of flu vaccine."). He felt the former was more appropriate. There was also a recommendation to emphasize the paragraph beginning "People with minor illnesses" by making it a bullet in Section 3. Ms. Johnson-DeLeon indicated that the revision should apply to every VIS. There was a comment

that in earlier VIS reviews it had been determined that the definition of “severely ill” in the same section should be agreed on by the patient and the provider.

In Section 4, concerning the risk of fainting after vaccination, there was a suggestion to ask about prior syncope episodes before administering a vaccine.

Ms. Johnson-DeLeon noted that sections 5, 6 and 7 are the same on all VIS’s so that any revisions discussed would apply to all. There was a suggestion that, since allergic reactions usually occur within hours of a vaccination, especially anaphylaxis, a timeframe might be added to the instructions about allergic reactions.

There were no revisions suggested for Sections 6 and 7. It was observed that links to other informational resources are included on the online versions of the VIS’s, which is not practical because of space limitations on the printed VIS.

2. **Influenza (flu) vaccine (live, intranasal).** Ms. Johnson-DeLeon noted that Section 1 was the same as the previous VIS. There was one comment that it would not be appropriate to administer live attenuated influenza vaccine (LAIV) to an immunosuppressed patient with, for example, a cancer patient.

Ms. Johnson-DeLeon observed that Section 3 lists more topics to discuss with providers, and that the suggestion to revise the paragraph about minor illnesses with a separate bullet would be addressed. It was also observed that GBS was not included in Section 4, probably because it has not been reported as a side effect and because it was not included in the ACIP recommendations.

Finally, Sections 5, 6, and 7 are the same in all VIS’s and any earlier revisions would be included in the LAIV VIS.

3. **Meningococcal ACWY vaccine.** Section 1 is basic information about the vaccine. There was a comment that the information about the virus being fatal to 10 to 15 affected individuals per hundred cases sounds alarming, considering the very low incidence of the disease. The seemingly dramatic impact of the statement could be softened perhaps by deleting the statistics. Section 2 contains the vaccine regimen and a list of individuals who should be vaccinated, and Section 3 is encouragement to consult a health care provider about precautions or contraindications to the vaccine, including warnings to pregnant or breastfeeding mothers. Section 4 covers vaccine reaction and Sections 5, 6 and 7 are the same as in other VIS’s.

4. **Meningococcal B vaccine.** Section 1 is the same as for Meningococcal ACWY and the previous recommendations about deleting the statistic for mortality would also apply.

Section 2, information about the vaccine, includes the target population and the fact that more than one dose is needed in most cases, and that the same product should be administered in a series of vaccinations, (there are two vaccines available). There was an observation that the admonition to use the same product for serial vaccinations is valid but probably directed more at the health care provider.

There was also an observation that, although licensed for children at age 10 for high-risk individuals, the ACIP recommended the vaccine for anyone 16 through 23, whether or not at high risk for Men B, which could be confusing. Ms. Johnson-DeLeon agreed that the sentence needs clarification.

Section 3 is the advice to consult with a provider. There were no comments. Section 4 defines risks, and the previously recommended wording for syncope will be applied. As before, Section 5 through 7 are the same as for other VIS's.

5. **Hepatitis B Vaccine.** Ms. Johnson-DeLeon stated that there is a new licensed Hep B product, which is included in this VIS. Section 1 is longer than others at the request of the subject matter experts, who wanted to include more information than appears on the other VIS's. Dr. Meissner commented that the risk of complications can be very serious if Hep B is contracted as an infant, for example, which is not fully explained in the VIS. However, he added a reservation about the impacts of trying to convince the patient about serious complications. Ms. Johnson-DeLeon agreed, stating that the approach is to provide enough information to inform the patient, including the effects of the disease and whether, in consultation with the provider, the patient would be able to make a decision based on risk and benefit. Ms. Kain interjected that the decision is often moot when a state mandates that for a child to attend school he or she must be vaccinated. Nonetheless, the information is needed so that the parent can make an informed decision about whether to withdraw a child from the state school system or home school the child. Dr. Meissner commented that, given those options, fully describing the negative aspects of the infection, particularly in neonates, is very important.

Ms. Johnson-DeLeon described the content of Section 2 and Section 3 and there were no comments from the commission.

In Section 4, Dr. Meissner commented that, regardless of the perhaps overly cautious recommendation of the lawyers involved with the review, the Hep B vaccine is so safe that including the risk of death seems inappropriate. Ms. Johnson-DeLeon stated that, as with the other VIS's Sections 5, 6 and 7 are the same.

6. **MMR vaccine without varicella vaccine.** Section 1 reviews measles, mumps and rubella and the rationale for vaccination, and the schedule for vaccination. Dr. Meissner expressed the opinion that the risk of arthritis is transient, usually in the small joints and it usually resolves quickly. However, the teratogenic complications of rubella during pregnancy never disappear and may be significantly life-changing for the child. He felt that the contrast in level of risk should be explained. There was also a comment to clarify that up to half of teenage and adult women get rubella, not half experience arthritis. Noting the reference to one or two vaccinations, Ms. Johnson-DeLeon said that to explain the rationale would be too detailed for the VIS and that parents and patients should consult with their provider when this arises.

There were no comments about Section 2. In Section 3, Dr. Meissner commented that the description of the risk of immune insufficiency was not clear. It could imply that the vaccine could cause that problem. Ms. Johnson-DeLeon agreed that the wording has been problematic and invited suggestions to improve it.

Continuing, she referred to Section 4, a list of risks of a vaccine reaction including the warning about syncope and the risks of severe allergic reactions. Sections 5, 6 and 7 are identical to other VIS's.

7. **MMRV (with Varicella).** Ms. Johnson-DeLeon stated that the VIS contained added information about varicella vaccine, including the age range reduction to age 12 (adults are not licensed to receive the varicella vaccine). There is also a recommendation to inform the provider if the patient is taking salicylates, such as aspirin.

A description of risks of rash and shingles on this MMRV VIS is not on the MMR VIS. Ms. Kain inquired about whether the fact that most reactions become evident on the ninth day should be included in the VIS and Ms. Johnson-DeLeon said she would follow up on that concern.

8. **Varicella (Chickenpox) vaccine.** Ms. Johnson-DeLeon noted that most of the previously discussed revisions were in this VIS. There were no comments on this VIS, except that Ms. Kain suggested that, in Section 6, the time limit for filing an injury claim should be described. Ms. Overby observed that since the time limit varies with the type of injury there was a decision earlier to keep the wording simple and not specify time limits. Mr. Howie suggested adding the words “this could be as soon as two years from the date of vaccination,” period. Ms. Overby said that the time limit begins with the recognition of the first symptoms of injury and she stated that revised language can be developed and presented to the commission. If the timeline needs to be included, it would require development of more detailed, but simple, wording. Ms. Johnson-DeLeon agreed to recommend additional discussion.

Public Comment

Dr. Meissner invited public comment.

Theresa Wrangham, Executive Director of the National Vaccine Information Center, stated that it was not clear if the publications discussed at the end of CDC’s presentation were all epidemiological studies. Evidence base for the Table is both epidemiological and mechanistic information. She also expressed concern about the measles outbreak and whether or not the CDC tracks vaccine strain infections since that is on the Table and may lead to complications in attaining to VICP awards. She added her interest in hearing about how many children are in the VICP system and how many received compensation. She encouraged the commission to look at shifts in provision, qualification, and age definitions within the Table that could result in exclusion of some childhood vaccine injuries, and what actions could ensure focus on the original goal of compensating childhood vaccine injuries. It is unlikely that only adults are injured.

There continues to be a lack of awareness about the VICP that results in uncompensated injuries. The Work Group could consider how to increase awareness of VICP without primarily relying on health care professionals. NVIC regularly receives phone calls from the public about the program. A review of previous studies/reports on this topic would benefit the program as well as awareness discussions and ensuring VIS and VAERS reporting are addressed in the Adult Immunization Vaccine Plan and the National Vaccine Plan.

There should be ongoing mechanisms to assess the adequacy of compensation awards and the level of information consumers would like on vaccine injury, as noted in the Banyan and Altarum reports as well as the effect of vaccine injury research deficits on the backlog.

The NVIC supports the ACCV in making a statement on informed consent and the need for voluntary choice, particularly given the continued attacks on vaccine exemption laws. Concerning the discussion of the VIS revisions, the original intent of the law was to provide as much information as possible about vaccine risks. There is nothing in the law about brevity or limiting the VIS to two pages, which results in the sacrifice of important information needed to make vaccination decisions. Concerning the use of the word “rash” as a risk of MMR and varicella vaccines, she felt it was not accurate. It is important for the public to know that vaccine strain infection is a known complication as are other serious injuries and death.

In closing, with regard to statute of limitations, Ms. Wrangham stated that NVIC previously recommended language that gives an indication of the timeframe. Clearer wording may improve public awareness of this deadline. She expressed appreciation for the opportunity to comment. There were no additional requests to make comments.

Future Agenda Items/New Business

Dr. Meissner stated that the next meeting would be on December 5-6. He invited suggestions for future agenda items or new business. There were none.

Adjournment

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