

ADVISORY COMMISSION ON CHILDHOOD VACCINES
TABLE OF CONTENTS
March 8, 2019

	<u>TAB</u>
• ACCV Agenda	1
• ACCV Charter	
• ACCV Roster	
• 2019 Meeting Dates	
• Meeting Minutes	2
○ Draft Minutes – September 6, 2018	
○ Draft Minutes – December 6, 2018	
• Vaccine Injury Compensation Trust Fund Statement	3
○ Vaccine Injury Compensation Trust Fund Summary Sheet for the Period of 10/1/2018 – 12/31/2018	
• VICP Data and Statistics	4
• Meeting Presentations & Updates	5
○ Report from the Division of Injury Compensation Programs	5.1
○ Report from the Department of Justice	5.2
○ Update on the Immunization Safety Office Vaccine Activities (CDC)	5.3
○ Update on the National Institute of Allergy and Infectious Diseases Vaccine Activities (NIH)	5.4
○ Update on the Center for Biologics, Evaluation and Research Vaccine Activities (FDA)	5.5
○ Update from the National Vaccine Program Office	5.6

***ADVISORY COMMISSION ON
CHILDHOOD VACCINES***

Agenda

February 6, 2019

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)
5600 Fishers Lane Rm 5N76, Rockville, MD 20857
and
Teleconference and Adobe Connect
Friday, March 8, 2019
(10:30 am Eastern Time)

Dial-in: 888-970-4134

Passcode: 6494485

<https://hrsa.connectsolutions.com/accv/>

Time	Agenda Item	Presenter
10:30 AM	Welcome and Chair Report	Ms. Beth Luthy, Chair
10:40 AM	Public Comment on Agenda Items	Ms. Beth Luthy, Chair
10:45 AM	Approval of September & December 2018 Minutes	Ms. Beth Luthy, Chair
10:50 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Director, DICP
11:20 AM	Report from the Department of Justice	Ms. Catharine Reeves, Deputy Director, Torts Branch, DOJ
11:50 AM	ACCV Work Group Update	Ms. Martha Toomey, Work Group Chair
12:20 PM	Lunch	
1:20 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Michael McNeil CDC
1:35 PM	Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH

Time	Agenda Item	Presenter
1:50 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	CDR Valerie Marshall CBER, FDA
2:05 PM	Update from the National Vaccine Program Office (NVPO)	Ms. Ann Aikin NVPO
2:20 PM	Public Comment (follows the preceding topic and may commence earlier or later than 2:20 pm)	
2:35 PM	Future Agenda Items/New Business	Ms. Beth Luthy, Chair
2:50 PM	Adjournment of the March 8, 2019 ACCV Meeting	Ms. Beth Luthy, Chair



Charter



CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

42 U.S.C. 300aa-19, Section 2119 of the Public Health Service (PHS) Act. The Advisory Commission on Childhood Vaccines (hereinafter referred to as the "Commission") is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. App. 2), which sets forth standards for the formation of advisory committees.

Objectives and Scope of Activities

The Secretary of Health and Human Services (Secretary) is mandated under Section 2119 of the PHS Act to appoint an advisory commission to give advice regarding the National Vaccine Injury Compensation Program (the Program), which provides compensation for certain vaccine-related injuries or deaths.

Description of Duties

The Commission shall: (1) advise the Secretary on the implementation of the Program; (2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table; (3) advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; (4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of Section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; (5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program.

Agency or Official to Whom the Commission Reports

The Commission shall advise and make recommendations to the Secretary on matters related to the Program responsibilities.

Support

Management and support services shall be provided by the Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA).

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Commission, including compensation and travel expenses for members, but excluding staff support, is approximately \$34,545. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of \$233,015.

Designated Federal Official

HRSA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Official (DFO) to attend each Commission meeting and ensure that all procedures are within applicable, statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, call all of the Commission or subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Commission reports. The DFO or his/her designee shall be present at all meetings of the full Commission and subcommittees.

Estimated Number and Frequency of Meetings

The Commission shall meet no less than four times per year and at the call of the Chair, with the approval of the DFO. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

Duration

Continuing.

Termination

Unless renewed by appropriate action prior to its expiration, this charter will expire 2 years from the date the charter is filed.

Membership and Designation

The Secretary shall select members of the Commission. The members of the Commission shall select a Chair and Vice Chair from among the members. Appointed members of the Commission shall be appointed for a term of office of 3 years.

The Commission shall be composed of the following:

- (1) Nine members appointed by the Secretary as follows:
 - (A) three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians;
 - (B) three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and
 - (C) three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.
- (2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials), each of whom shall be a non-voting ex officio member.

The nine members appointed by the Secretary shall serve as Special Government Employees. The ex officio members shall be Regular Government Employees.

Subcommittees

Subcommittees may be established with the approval of the Secretary or designee. Subcommittee members may be members of the parent Commission. The subcommittee shall make recommendations to be deliberated by the parent Commission. The Department's Committee Management Officer will be notified upon the establishment of each subcommittee and will be provided information on the subcommittee's name, membership, function, and estimated frequency of meetings.

Recordkeeping

Meetings of the Committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

4 – ACCV Charter

Filing Date

July 21, 2016

Approved:

JUL 20 2016
Date



Roster

February 19, 2019

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV) ROSTER
DIVISION OF INJURY COMPENSATION PROGRAMS (DICP)**

5600 Fishers Lane, 08N146B
Rockville, MD 20857

ACCV MEMBERS

Karlen E. (Beth) Luthy, D.N.P., A.R.P.N.
(Term Expires 2019)
Chair
Associate Professor
College of Nursing, Brigham Young University
Health Professional

H. Cody Meissner, MD, FAAP (Term
Expires 2019)
Vice-Chair
Chief, Pediatric Infectious Disease Service
Tufts Medical Center
Health Professional, Pediatrician

Alexandra Stewart, J.D., (Term Expires 2019)
The George Washington University,
School of Public Health and Health Services
Attorney

Martha Toomey, (Term Expires 2019)
Parent of a Vaccine Injured Child

Kathleen F. Gaffney, PhD, RN, F/PNP-BC
(Term Expires 2019)
Professor, College of Nursing and Health
Science
George Mason University
Member of the General Public

John Howie, J.D. (Term Expires 2019)
Founder/Owner, Howie Law, PC
Attorney Representing Vaccine Injured

Tina Tan, MD (Term Expires 2019)
Professor of Pediatrics, Northwestern University
Ann and Robert H. Lurie Children's Hospital of
Chicago
Division of Infectious Diseases
Health Professional, Pediatrician

Dino S. Sangiamo, J.D. (Term Expires
2019)
Partner, Venable LLP
**Attorney Representing Vaccine
Manufacturer**

Vacant Position
Parent of a Vaccine Injured Child

EX-OFFICIO MEMBERS

Melinda Wharton, M.D., MPH
Acting Director, National Vaccine Program
Office

Barbara Mulach, PHD
National Institute of Allergy and Infectious
Diseases
National Institutes of Health

Marion Gruber, Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics, Evaluation and Research
Food and Drug Administration

Michael McNeil, M.D., M.P.H.
Immunization Safety Office
Centers for Disease Control and Prevention

DICP STAFF

Narayan Nair, M.D.
Director, DICP
Executive Secretary, ACCV

Andrea Herzog
Principal Staff Liaison, ACCV
(301)443-6634 (Direct)
(301)443-0704 (Fax)
Email: aherzog@hrsa.gov

OFFICE OF THE GENERAL COUNSEL

Andrea Davey, J.D.
Attorney



*2019 Meeting
Dates*

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2019 MEETING DATES

March 8, 2019

June 6 & 7, 2019

September 5 & 6, 2019

December 5 & 6, 2019

2

**Advisory Commission on Childhood Vaccines (ACCV)
Adobe Connect Webinar and Telephone Conference meeting
September 6, 2018**

Members Present

Karlen E. (Beth) Luthy, D.N.P., ('18), Chair
Kathleen F. Gaffney, PhD, RN ('19)
John Howie, J.D., ('19)
Tina Tan, MD, ('19)
Alexandra Stewart, J.D., ('18)

Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)

Narayan Nair, M.D., Director, DICP
Andrea Herzog, Principal Staff Liaison, ACCV

Welcome and Report of the Chair, Beth Luthy, ACCV

Ms. Luthy called the meeting to order, welcomed the commission members, DICP staff, ex officio members, and guests on the teleconference call. A roll call confirmed the presence of a quorum.

Public Comment on Agenda Items, Ms. Beth Luthy, Chair

The invitation to submit comments on agenda items was announced by the conference operator and there was one request to speak:

- (1) Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC) requested that the Process Work Group look at ways to enhance the program's interaction with the public. Ms. Wrangham discussed petitions to add injuries to the Vaccine Injury Table (the Table) and noted that they may be submitted to the ACCV by anyone. Currently HRSA responds to petitions with a PowerPoint presentation of about 20 minutes, and then responds to questions from the ACCV commissioners. However, the parties who submit petitions have no opportunity for a similar response. The NVIC recommends that members of the public who submit petitions be allowed that opportunity to make a presentation to the Commission. NVIC believes this could improve the quality of the information provided to the Commission for its consideration of the petition. Ms. Wrangham requested that this request be considered as an item for the Work Group to discuss. She added that there is nothing in the legislation to prohibit such a change in process.

Ms. Wrangham also commented that since the ACCV is part of the review process for Vaccine Information Statements (VIS), the NVIC encourages the ACCV to support expanding information in the VIS, such as including vaccine ingredients related to

allergies, encouraging the review the vaccine manufacturer's product insert that is available on the Food and Drug Administration (FDA) website, and including informed consent which was in the VIS prior to the 1995 amendments to the legislation. Ms. Wrangham stated that the regulations limit the VIS to a single page, printed on both sides. More complete information would support the public's ability to make informed vaccine decisions, although it might require permitting more than one page printed both sides.

There were no additional requests to speak.

Approval of June 2018 Minutes, Ms. Beth Luthy, Chair

Ms. Luthy invited approval of the June 15, 2018 ACCV meeting minutes. On motion duly made and seconded, the minutes of the June 2018 ACCV meeting were unanimously approved.

ACCV Work Group Update, John Howie, Member.

Mr. Howie reported that the work group was established to address some of the issues with the program for ACCV consideration. Three meetings have occurred and a mission statement was developed, as well as identification of tasks for the work group to address. The work group has agreed to submit to the full ACCV an updated recommendation to allocate more resources to Department of Justice (DOJ), Department of Health and Human Services (HHS) and the U.S. Court of Federal Claims (Court) which have roles in administering the National Vaccine Injury Compensation Program (VICP).

The work group will look at the process currently in place to present proposals for Table changes. The work group would also like to find ways to increase interaction with the community, and is working on a list of actions to accomplish that objective.

Ms. Luthy invited comments or questions. She added that the draft of the recommendation will be made available to the Commission for review and discussion. When the recommendation is finalized and approved by a vote, the letter will be sent to the Secretary. The public may request a copy by sending an e-mail to Ms. Herzog (aherzog@hrsa.gov). There was no additional discussion.

Report from the Division of Injury Compensation Programs, Dr. Narayan Nair, Director, DICP

Dr. Nair outlined the meeting agenda beginning with an update on the VICP, followed by a report from the Department of Justice, brief reports from ex officio members (FDA, Centers for Disease Control and Prevention [CDC], National Institutes of Health [NIH], and National Vaccine Program Office [NVPO]), VIS reviews for MenACWY and DTaP, and a discussion of ACCV Work Group activities (presented earlier in the meeting).

Dr. Nair presented the current VICP statistics. Regarding petitions filed, Dr. Nair noted the average number of petitions filed for FY 2008 through FY 2012 was 410. The fiscal year for the agency is October 1 through September 30 of the following year. There have been steady increases each year through FY 2017, with the petitions to date in FY 2018 at 1,090 claims. Dr.

Nair presented a five-year snapshot of claims versus administrative funding which went from \$6.48 million to \$7.75 million between 2013 and 2017. That funding increased in FY 2018, to \$9.2 million. Those amounts do not include for funding for DOJ or the Court.

With regard to the backlog of DICP cases, Dr. Nair explained that there was no backlog for FY 2017; all claims with proper medical records have been assigned for that year. In FY 2018 there are currently 612 claims with medical records awaiting review assignment. Petitioners' awards in FY 2017 amounted to \$252.2 million and attorney's fees and costs were \$29.9 million. In FY 2018, to date, those amounts are \$170.6 million and \$26.8 million respectively. In FY 2017, 879 VICP cases were adjudicated; of those cases, 696 were compensated and 183 were dismissed. In FY 2018, to date, 573 cases have been adjudicated; 417 cases were found to be compensable and 156 were dismissed.

Dr. Nair reported additional statistics where the adjudication number are slightly different because a different database was used. According to that data there have been 554 adjudications to date in FY 2018; 423 of those cases deemed compensable and 131 of these cases were dismissed. The compensable cases include 155 that were resolved by concession, 56 that were resolved by Court decisions, and 212 were resolved by settlements between the parties.

Dr. Nair reported that the balance in the Vaccine Injury Compensation Trust Fund was nearly \$3.8 billion. Excise tax contributed \$193.5 million; and interest on the fund contributed \$56.5 million, totalling \$250 million in income to date in 2018.

Finally, Dr. Nair commented on significant activities, one of which is the ongoing implementation of maternal immunization provisions. On April 4, 2018, a Notice of Proposed Rulemaking that would add the category of vaccines for pregnant women to the Vaccine Injury Table was published in the *Federal Register*. The public may comment before October 1, 2018, and a public hearing is scheduled for September 17, 2018, at which time the public may provide testimony. Dr. Nair also reported that the VICP continues to engage in outreach activities. There was a presentation to the Adult Vaccine Immunization Coalition. More information about the meeting, presentations and minutes can be found at:

<http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html>.

During discussion, in response to a commissioner's question, Dr. Nair clarified that there are 642 that have not undergone final review, for various reasons such as petitions filed without medical records. Cases, once assigned to a reviewer, are generally completed within about 90 days.

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

Ms. Pearlman noted that the reporting period for the Department of Justice (DOJ) is different from that of the Division of Injury Compensation Programs. Ms. Pearlman referenced the DOJ PowerPoint materials as part of her presentation for the three-month period from May 16, 2018 through August 15, 2018. (DOJ PowerPoint (PP) at 2.) During this reporting period, 294 petitions were filed. (DOJ PP at 2.) Of those 294 petitions, 17 were filed on behalf of minors and 277 were filed by adults. (DOJ PP at 2.)

Ms. Pearlman noted that 198 petitions were adjudicated during this reporting period. (DOJ PP at 3.) One hundred thirty-nine cases were compensated, the majority of which were

resolved by proffer. (DOJ PP at 3.) Fifty-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), including *Depena v. HHS* and *Oliver v. HHS*, the latter of which was decided after this reporting period ended. (DOJ PP at 5, 6.) In *Depena*, the CAFC affirmed the U.S. Court of Federal Claims' (CFC) determination that the special master appropriately denied compensation in a case in which the petitioners alleged that the measles, mumps, and rubella (MMR) vaccine caused their minor son to develop pneumonia. In *Oliver*, the CAFC affirmed the CFC's conclusion that the Chief Special Master did not err in dismissing a petition in which the petitioners alleged that their child developed Dravet Syndrome as a result of various childhood vaccines. Four appeals regarding entitlement (*Olson v. HHS*, *McCollum v. HHS*, *Rogero v. HHS*, and *Gaiter v. HHS*) and one appeal regarding attorneys' fees and costs (*R.K. v. HHS*) remain pending in the CAFC. (DOJ PP at 6.)

Ms. Pearlman next discussed appeals at the CFC and noted that six appeals by petitioners and five appeals by HHS were decided by the CFC during this reporting period. (DOJ PP at 7, 8.) Five of those 11 appeals involved entitlement and six involved attorneys' fees and costs. Ms. Pearlman briefly discussed *Boatmon v. HHS*, a case in which the CFC overturned a special master's determination that vaccines can cause Sudden Infant Death Syndrome (SIDS) and dismissed the petition. Ms. Luthy inquired as to the cases appealed by HHS involving attorneys' fees and costs. Ms. Pearlman explained that, in those cases, the appeals related to the amount of fees and costs awarded to petitioners by the special masters. Eleven cases remain pending at the CFC. (DOJ PP at 9.)

Ms. Pearlman noted that no oral arguments are scheduled at the CACF or the CFC at this time. (DOJ PP at 10.)

Finally, 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 11-17.) Ms. Pearlman noted that most of these settled cases alleged Guillain-Barré Syndrome (GBS) and Shoulder Injury Related to Vaccine Administration (SIRVA) injuries. Ms. Pearlman further noted that only five of these settled cases took more than three years to resolve.

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

Mr. Wolfe announced that there were two Vaccine Information Statements to review, one on meningococcal ACWY vaccine and the other on DTaP vaccine. The ACCV is responsible for review of VIS and subsequent revisions.

Meningococcal ACWY

The MenACWY vaccine prevents meningococcal infection which is effective against serogroups A, C, W and Y. These are the serogroups most commonly responsible for infection. The infection is caused by a bacteria called *Neisseria meningitidis*. A previous vaccine, MPSV4, is no longer available. This revision mainly deletes all references to that vaccine. The VIS contained the same information for the MPSV4 vaccine.

Ms. Johnson-DeLeon commented that one addition to the VIS was under Section 3, “Some people should not get this vaccine”. In addition to routine vaccination for adolescents, MenACWY vaccine is also recommended for certain groups of people, namely, people with HIV. There was also a revision to the VIS encouraging women who are pregnant or breast-feeding to be vaccinated if they are at increased risk.

It was noted that in Section 3, last paragraph, the phrase “your doctor can advise you.” After discussion of this language, there was a recommendation to maintain provider neutral language to include health care providers other than doctors. Mr. Wolfe acknowledged that this issue was longstanding and generally “health care provider” is used unless there is a specific reason to prefer the word “doctor.” He added that switching to a consistent use of health care provider in the entire VIS, as well as others, would be considered.

Ms. Johnson-DeLeon commented that this particular VIS review was intended to fast track approval to delete any references to MPSV4. She said that future submissions for review should reflect the recommendation of the ACCV to use health care provider exclusively. She noted that the next VIS to be reviewed, for DTaP vaccine, has eliminated the word doctor in favor of health care provider.

DTaP (Diphtheria, Tetanus, Pertussis) Vaccine

Mr. Wolfe stated that this VIS had been completely updated because new DTaP recommendations were recently approved by Advisory Committee on Immunization Practices (ACIP). The changes are not extensive, and are mainly format changes. Mr. Wolfe noted that only children up to age 7 receive this vaccine. Other vaccines that include diphtheria and tetanus vaccines are covered under separate VISs. He added that to strengthen the rationale for administration to children, the risks of the diseases was added to Section 1. When asked by a commissioner if it would be helpful to add a sentence about the fact that some school systems require the vaccine for admission to the school, Mr. Wolfe suggested that such a statement might be irrelevant since the parents receive the VISs after they’ve already consented to have their children vaccinated. Ms. Johnson-DeLeon added that the requirement is typically a state level issue, not a federal issue.

Mr. Wolfe moved to Section 2, which addresses the vaccination schedule, and includes one new note; the DTaP vaccine may be given alone or in combination with other vaccines. There were no comments on Section 2.

In Section 3 there were no substantive changes. The wording was changed to emphasize that parents should consult the child’s health care provider if he or she has the conditions described. This section deals mainly with precautions and underlines the importance of informing the health care provider in the event of an adverse event. Mr. Wolfe asked for comments about the last bullet under “Tell your health care provider” that states that if a child had severe pain or swelling after a previous DTaP or DT vaccination. Mr. Wolfe explained that the last bullet specifically refers to Arthus reaction, which has a variety of symptoms, including rare instances of necrosis, which would be challenging to fully explain in the VIS. This type of reaction may not be clearly recalled by the parent if it occurred. It is uncommon and localized when it occurs. There was agreement among commissioners that the present wording was sufficient.

Section 4 of the DTaP VIS discusses risks of a vaccine reaction. Mr. Wolfe explained that a section (also Section 4 in the previous VIS) was deleted because it explained that this

vaccine is not licensed for children over 7 years of age and that there are other vaccines (Tdap and TD) available for adults. It was determined that this earlier section was not relevant. The last bullet of this section in the proposed DTaP VIS under review uses the term “lowered consciousness,” which refers to the technical conditions of hypotonic, hyporesponsive episodes, which was considered too technical for a VIS. He asked if that term was acceptable. The commissioners agreed that a parent should be able to understand the term.

Mr. Wolfe continued with section 5 of the VIS. The language in Section 5, concerning problems that arise after leaving the clinic, conforms to the format currently being used in all new and revised VISs. Further, Sections 5, 6 and 7 are standard language used in all VIS.

There was a question related to informed consent, specifically, about the possibility that the VIS may be used in some areas as a consent document. Mr. Wolfe explained there is a legal definition of informed consent and that there is no federal requirement for informed consent for vaccines. If there is a state requirement and if the VIS meets the standards for that state, it may be used as an informed consent document. However, informed consent is not the purpose of a VIS; a VIS is for information purposes to meet the requirements of the National Childhood Vaccine Injury Act. Mr. Wolfe concluded his discussion.

Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities, Dr. Michael McNeil, CDC

Dr. McNeil explained that he would give an update on June 21-22, 2018 ACIP meeting, and present a brief discussion about selected publications. The influenza session at the ACIP meeting summarized the 2017-2018 flu season findings. The 2017-2018 season was a severe season dominated by Influenza A (H3N2) virus. The efficacy of the vaccine was moderate. The vaccine reduced outpatient visits for influenza-associated acute respiratory illness by 40% in persons 6 months of age and older. Among adults, vaccine efficacy estimates were similar for outpatients and inpatients, reducing influenza-associated hospitalization by 22%.

ACIP Meeting Updates

Dr. McNeil discussed an FDA presentation about a Centers for Medicare & Medicaid Services (CMS) study that showed that cell-cultured and high-dose vaccines were marginally more effective than egg-based standard dose quadrivalent vaccines for hospital outcomes among U.S. persons over 65 years of age during this season. The ISO determined that Vaccine Adverse Event Reporting System (VAERS) monitoring detected no safety concerns for vaccines given during the 2017-2018 flu season, and in a separate monitoring process, FDA detected no signal for GBS. Finally, the Vaccine Safety Datalink (VSD) conducts rapid cycle analysis (RCA), which confirmed no RCA signals for pre-specified outcomes of acute disseminated encephalomyelitis (ADEM), anaphylaxis, Bell’s palsy, encephalitis, GBS, seizures, or transverse myelitis.

Dr. McNeil described two studies undertaken and continuing by CDC’s Clinical Immunization Safety Assessment (CISA) project. One of which assessed the safety and immunogenicity of Fluvad versus Fluzone High-Dose in older adults for two flu seasons (2017 through 2019). The other study is an ongoing randomized clinical trial looking at fever incidence in children 12-16 months of age who received simultaneous vs. sequential vaccination.

The subjects were given either simultaneous (PCV13, DTaP, and IIV4) or sequential (PCV13 & DTaP, then IIV4 2 weeks later).

The safety presentation included an update of the Systematic Observational Method for Narcolepsy and Influenza Immunization Assessment (SOMNIA), an international study conducted at 14 sites. The study looked at adjuvanted 2009 pandemic influenza vaccines, Arepanrix and Pandemrix, which did not show an increased risk of narcolepsy vaccines.

At the ACIP meeting, there was a presentation by Seqirus, a manufacturer of a quadrivalent influenza vaccine (aQIV), which conducted a randomized clinical trial in children comparing aQIV with Fluzone TIV/QIV. The Seqirus vaccine showed higher rates of local and systemic reactogenicity. Most reactions began day 1 through 3, were moderate, lasted 2-3 days, and resulted in higher incidence of fever but no increase in febrile convulsions. The vaccine showed superior efficacy and immunogenicity, but in the US is it recommended only for those 65 and older. Recommendations for the 2018-2019 flu season included some changes:

- LAIV4 was again recommended after a two-year hiatus because of poor efficacy;
- Two new strains in the trivalent vaccine;
- Afluria Quadrivalent age range was changed from over 18 to over 5 years; and
- Fluarix Quadrivalent age range to infants older than six month (previously greater than 3 years).

The ACIP session on human papillomavirus vaccine (HPV) revealed that a Biologic License Application (BLA) was submitted to the FDA in April to extend the age indication for 9vHPV to age 45 years for males and females. Some countries have already approved that age range. One trial in females aged 24-48 years showed high statistically significant efficacy against persistent infection.

In October, ACIP recommended the use of a third dose of the measles-mumps-rubella (MMR) vaccine during mumps outbreaks, which have increased since 2012. The mumps work group is updating guidance on third dose implementation.

With regard to recombinant zoster vaccine, the uptake has been rapid with nearly 7,000 reports sent to VAERS. The VSD reports 37,303 doses administered by six VSD monitoring sites as of May 31, 2018. Also, there have been over 130,000 doses administered in the VSD monitoring sites, which will be conducting rapid cycle analysis. Information on short- and long-term outcomes/adverse reactions is available. A Morbidity and Mortality Weekly Report (MMWR) article published in May 2018, described some administration errors that may have been the result of confusion between the new Shingrix vaccine and the old live Zostavax. The Shingrix vaccine is administered intramuscularly, the Zostavax was one dose administered subcutaneously. More detailed information will be published in MMWR before the next ACIP meeting in October 2018.

ACIP recommended pneumococcal vaccine (PCV13) in 2014. VAERS reporting through the end of 2017 revealed no safety signals and a VSD study did not support an increased rate of adverse events following PCV13 administration versus PPSV23 (which contains capsulated polysaccharide antigens). Studies cited at the ACIP meeting strongly suggest a direct impact of PCV13 on pneumococcal-community acquired pneumonia.

Recent Publications

Dr. McNeil briefly discussed the following recent publications:

1. Haber P, Amin M, Ng C, Weintraub E, McNeil MM. **Reports of lower respiratory tract infections following dose 1 of RotaTeq and Rotarix vaccines to the Vaccine Adverse Event Reporting System (VAERS), 2008-2016.** Hum Vaccin Immunother. 2018 Jul 11:1-5.

SUMMARY: A 2018 manufacturer post-licensure safety study identified a possible association between Rotarix (RV1) rotavirus vaccine and lower respiratory tract infections (LRTI) in infants within 0-6 days following receipt of RV1 dose 1. We reviewed reports to the VAERS of LRTI occurring 0-6 days and 0-29 days post vaccination following RotaTeq (RV5) or Rotarix (RV1) vaccinations in conjunction with either Prevnar (PCV7) or Prevnar 13 (PCV13), in infants aged 6 to 15 weeks. There was no significant difference in LRTI reports to VAERS in the 0-6 days and 0-29 days following receipt of either RV5 or RV1 given with either pneumococcal vaccine Available at <https://www.ncbi.nlm.nih.gov/pubmed/29993327>

2. Kharbanda EO, Vazquez-Benitez G, Lipkind HS, Sheth SS, Zhu J, Naleway AL, Klein NP, Hechter R, Daley MF, Donahue JG, Jackson ML, Kawai AT, Sukumaran L, Nordin JD. **Risk of Spontaneous Abortion After Inadvertent Human Papillomavirus Vaccination in Pregnancy.** Obstet Gynecol. 2018 Jul; 132(1):35-44.

CONCLUSIONS: Inadvertent 4vHPV exposure during or peripregnancy was not significantly associated with an increased risk of spontaneous abortion.

Available at <https://www.ncbi.nlm.nih.gov/pubmed/29889760>

3. Su J, Ng C, Lewis PW, Cano MV. **Adverse events after vaccination among HIV-positive persons, 1990-2016.** PLOS One, Published: June 19, 2018

CONCLUSIONS: We identified no unexpected or unusual patterns of AEs among HIV positive persons. These data reinforce current vaccine recommendations for this risk group. However, healthcare providers should know their HIV-positive patients' immune status because immunocompromising conditions can potentially increase the risk of rare, but severe, AEs following vaccination with live virus vaccines.

Available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0199229>

4. Moro PL, Perez-Vilar S, Lewis P, Bryant-Genevier M, Kamiya H, Cano M. **Safety surveillance of diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccines.** Pediatrics. 2018 Jun 4.

CONCLUSIONS: No new or unexpected adverse events detected. Observed disproportionate reporting for some non-serious vaccination errors calls for better education of vaccine providers on the specific indications for each of the DTaP vaccines.

Available at <https://www.ncbi.nlm.nih.gov/pubmed/29866795>

5. Jackson ML, Yu O, Nelson JC, Nordin JD, Tartof SY, Klein NP, Donahue JG, Irving SA, Glanz JM, McNeil MM, Jackson LA. **Safety of repeated doses of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine in adults and adolescents.** *Pharmacoepidemiol Drug Saf.* 2018 Jun 3.

SUMMARY: We evaluated the safety of repeated doses of tetanus-containing vaccine in 68,915 non-pregnant adolescents and adults in the VSD population who had received an initial dose of Tdap. Compared with 7,521 subjects who received a subsequent dose of tetanus toxoid, reduced diphtheria (Td) vaccine, the 61,394 subjects who received a subsequent dose of Tdap did not have significantly elevated risk of medical visits for seizure, cranial nerve disorders, limb swelling, pain in limb, cellulitis, paralytic syndromes, or encephalopathy/encephalitis/meningitis. These results suggest that repeated Tdap vaccination has acceptable safety relative to Tdap vaccination followed by Td vaccination.

Available at <https://www.ncbi.nlm.nih.gov/pubmed/29862604>

6. Shimabukuro TT, Miller ER, Strikas RA, Hibbs BF, Dooling K, Goud R, Cano MV. **Notes from the Field: Vaccine administration errors involving recombinant zoster vaccine—United States, 2017-2018.** *MMWR Morb Mortal Wkly Rep.* 2018 May 25; 67(20):585-586.

SUMMARY: Early monitoring indicates that vaccine providers might confuse administration procedures and storage requirements of the older ZVL and the newer RZV. Failure to reconstitute the vaccine and administration of only one component of RZV also appears to be occurring, similar to errors observed for other vaccines that require mixing. Whereas RZV administered through the appropriate intramuscular route is associated with high rates of local and systemic reactions, erroneous subcutaneous injection can increase the likelihood of these episodes. Some errors could potentially affect vaccine effectiveness. To prevent RZV administration errors, vaccine providers should be aware of prescribing information, storage requirements, preparation guidelines, and ACIP recommendations for herpes zoster vaccines.

Available at

https://www.cdc.gov/mmwr/volumes/67/wr/mm6720a4.htm?s_cid=mm6720a4_w

During discussion following Dr. McNeil's presentation, Ms. Luthy asked about the wording "unexpected adverse events" and what adverse events would be unexpected? Dr. McNeil responded that short-term systemic injection site reactions would be considered expected, which would typically be listed in the VIS. The package insert also lists extensive adverse events that may be rare, which makes it difficult to assign causality to the vaccine.

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

Ms. Schuster began by discussing current NIAID research related to influenza virus. Ms. Schuster described virus-like particles (VLPs), which are protein-based structures that mimic viruses and bind to antibodies. Because VLPs are not infectious, they could serve as vaccine platforms for many viral diseases, including influenza. A team of NIAID researchers developed

a 3-D model based on the 1918 H1N1 pandemic influenza virus VLPs. A better understanding of these VLPs could help researchers find effective seasonal and universal influenza vaccines. The research could also benefit a range of other VLP vaccine projects, including for HIV, Ebola and SARS coronavirus.

As discussed at previous ACCV meetings, in February 2018, NIAID launched a strategic plan for developing a universal influenza vaccine and is actively supporting projects that are working toward development of a universal influenza vaccine that would provide durable protection against various flu strains.

NIAID announced several new funding opportunities to stimulate research community interest in vaccine research. Two such announcements occurred in July 2018 to support research aligned with focus areas from NIAID's universal influenza vaccine strategic plan, including transmission, natural history, pathogenesis, characterization of influenza immunity and correlates of protection, as well as rational design of universal vaccines. Also, in July 2018, NIAID began soliciting proposals for a new program, the Collaborative Influenza Vaccine Information Centers (CIVICs), which has the goal of improving seasonal influenza vaccines and developing universal influenza vaccines, and will include human challenge studies, in which researchers expose a person to an influenza virus under carefully controlled conditions to better characterize the course of disease and evaluate new treatments and vaccines.. Participants will be closely monitored and cared for during these studies.

NIH and CDC have jointly supported program announcements on vaccine safety research since 2008. The latest announcements were released in July 2018. The research would focus on physiological and immunological responses to vaccines and components; how genetic variations affect the responses; risk factors and biological markers; statistical methodologies; genomic technologies and systems biology; and vaccine combinations and vaccine schedules. Since 2009, NIH has funded 24 awards under these announcements.

NIH has formed the Trans-NIH Pediatric Research Consortium to coordinate pediatric research across its 27 institutes and centers, with total support of over \$4 billion in FY 2017. The consortium seeks to harmonize research activities, explore research gaps and opportunities and establish priorities.

Finally, in August 2018, NIAID announced that a first human trial of an experimental live attenuated Zika virus vaccine developed by NIAID scientists has begun at the Johns Hopkins Center for Immunization Research and at the Vaccine Testing Center at the University of Vermont. The trial will enroll 28 non-pregnant adults 18 to 50, and the Phase I Clinical trial will assess the experimental vaccine's safety and generation of an immune response. Ms. Schuster concluded her comments.

Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities, CDR Valerie Marshall, CBER, FDA

CDR Marshall reported that the FDA approved supplements for the BLA for seasonal influenza vaccines to include the 2018-2019 United States formulation and associated labeling revisions.

CDR Marshall also discussed that over the last several years, there's been growing scientific and public interest in the role of microorganisms in the maintenance of overall health and prevention and treatment of disease. To this end, the FDA will convene a workshop, co-hosted with NIH, on September 17, 2018, to exchange information with the scientific community

about the clinical, manufacturing, and regulatory considerations associated with live microbiome-based products, when administered to prevent, treat, or cure a disease or condition in humans.

Update from the National Vaccine Program Office, (NVPO), Ann Aikin, NVPO

Ms. Aikin announced that the National Vaccine Advisory Committee (NVAC) recently released a report entitled “Strengthening the Effectiveness of National, State, and Local Efforts to Improve HPV Vaccination Coverage in the United States” that focuses on four key areas:

- Additional national partners that may be interested in supporting that area of research;
- Coalitions at the state and local level;
- Ways to engage integrated health care delivery networks; and
- Ways to address provider needs in rural areas.

The report is available on the NVPO website. Future 2018 NVAC meetings are scheduled for September 12-13 at the Hubert Humphrey Building; and in 2019, February 5 (Virtual meeting); June 4-5 (In person); September 17-18 (In person).

Ms. Aikin announced that the 21st Century Cures Act required NVPO to submit a report to Congress on encouraging vaccine innovation. Main points in the report include the fact that the vaccine enterprise is well-established and has been successful in bringing new and improved vaccines to the market (over 120 vaccine candidates were under development when the report was written). The prevailing business model that prioritizes vaccine candidates is for large markets, but some of the markets may be smaller than anticipated for the vaccines that will be developed. There is a consideration that a substantial investment will be needed to address some of the complex needs of the remaining targets. There is uncertainty about public health priorities and the estimated public demand for some of the vaccine candidates, which affects the return on investment on the development of the candidates. The report is available on the NVPO website.

Ms. Aikin described the “Your Best Shot” video series, which is educational rather than promotional, and focuses on the importance of vaccines across the lifespan. Three vaccines are highlighted – shingles, pneumococcal disease and whooping cough. The videos are available online at: https://www.vaccines.gov/resources/videos_and_tools/index.html

Finally, a major content audit and refresh was completed on www.vaccines.gov, an award-winning website developed in 2011 to provide trusted and consumer-friendly information about vaccines and vaccine-preventable diseases.

Public Comment

Ms. Luthy invited comments from anyone on the teleconference call. There was only one comment from Ms. Theresa Wrangham.

Ms. Wrangham commented that NVIC has worked with ACCV and NVAC, has successfully sponsored members on both committees, coordinated vaccine safety workshops with the IOM, and has presented parent perspectives to the IOM in their reporting process. However, in recent years NVIC appears to have been excluded from some stakeholder processes. This is of concern to NVIC, given its historic standing and involvement in processes relating to vaccine injury and death, and the fact that NVIC worked with congress to pass the 1986 Act

establishing the VICP. The NVIC welcomes and requests the inclusion in the stakeholder processes related to the ACCV and what is put before the commission for their consideration. Ms. Wrangham noted that the NVIC represents the interests of those who have vaccine safety concerns and those who are injured or die as a result of adverse events following the use of vaccines.

Ms. Wrangham said that as the Process Work Group considers recommendations, NVIC requests that the Commission continue to review the 2009 Altarum and Banyan reports, and the 2014 GAO VICP report and consider their findings and recommendations relating to the need for a mechanism to gauge ongoing petitioner satisfaction within the VICP, and adequacy of the VICP awards. Ms. Wrangham recalled that in the December 2016 ACCV meeting and the DOJ's report that a successful VICP petitioner deemed their injury award inadequate. Currently there is no measure of adequacy of awards, particularly from the standpoint of the petitioner.

Ms. Wrangham noted that NVIC works in consultation with CDC, not in collaboration, with regard to VIS revisions. NVIC supports the provider-neutral language in the VIS. It worked with congress to include informed consent protections in the 1986 Act that led to the VIS, which prior to vaccination provides information on diseases and the risks and benefits of vaccines. Many of those protections were removed from the law in 1995 to simplify the VIS, which reduced transparency and information needed to make educated vaccine decisions. NVIC encourages ACCV to review those changes in the law. There is no regulatory impediment to reinstating previously-required information. The purpose of the VIS is to provide information prior to vaccination. Ms. Wrangham felt the first section, "Why get vaccinated," is a marketing statement, rather than information about vaccine risks and benefits or information about the disease. She said that NVIC supports more neutral language in the VIS. Prior to the change in 1995 more information was available on the VIS.

Ms. Wrangham continued, with regard to pregnant women mentioned in the VIS, it would be helpful to explain which vaccines are licensed for use in this population. With regard to mention of the VICP in the VIS, consumers would benefit from a statement therein that contains more specificity on the statute of limitations. The Altarum and Banyan reports stated that consumers want more detail, not less, where vaccine injuries are concerned. NVIC encourages the commission to review those reports and determine whether they would apply to VIS content and revisions.

Finally, NVIC notes that there are significant gaps in vaccine safety research, mentioned in the IOM reports. NVIC requests information on what efforts are under way to close these gaps. The concern is that vaccines are being created and mandated more quickly than research that would assure the public that they are safe and clarify the risks related to the.

Future Agenda Items/New Business, Ms. Beth Luthy, Chair

Ms. Luthy ascertained by voice affirmation that only four commission members were on the telephone conference, which is insufficient for a quorum. Therefore, all relevant votes, specifically the letter of recommendation to the Secretary, would have to be deferred until the December 2018 meeting.

Regarding future agenda items, the Commission discussed the decision to continue the current active Process Work Group or to establish a new work group to address petition issues, like impending statute of limitations that might shortstop a case and remove the VICP's obligation to pay attorney's fees and costs. Another example is the possible reticence of an

attorney to accept a complicated claim in preference to a simpler, more straightforward claim, which could be prejudicial to an injured party. There was consensus that the Process Work Group should continue to handle such issues.

Ms. Luthy referred to Ms. Wrangham's comments regarding consent and the VIS and suggested that a presentation to educate and clarify the issue would be helpful. Dr. Nair reminded the commission that consent is not a federal requirement or issue, but one that is required by some states. That issue could still be placed on the agenda for clarification. Ms. Stewart suggested assigning the issue to the Process Work Group for review before putting it on the agenda.

Mr. Howie also referred to a comment by Ms. Wrangham about how the public is permitted to make presentations about Table revisions. There was consensus that the issue was valid, but that it should be referred to the Process Work Group.

Adjournment

Ms. Luthy expressed appreciation to those on the call for their participation. There being no further business, the meeting was adjourned.

Advisory Commission on Childhood Vaccines (ACCV)
Adobe Connect Webinar and Telephone Conference meeting
December 6, 2018
108th Meeting

Members Present

Karlen E. (Beth) Luthy, D.N.P., Chair, ('19)
H. Cody Meissner, MD, Vice Chair, ('19)
Kathleen F. Gaffney, PhD, RN ('19)
Martha Toomey ('19)
Alexandra Stewart, J.D., ('19)
Martha Toomey ('19)
John Howie, J.D. ('19)

Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)

Narayan Nair, M.D., Acting Director, DICP
Andrea Herzog, Principal Staff Liaison, ACCV

Welcome and Report of the Chair, Beth Luthy, ACCV

Ms. Luthy called the meeting to order. After a roll call of the commission members present, Ms. Luthy invited public comment on the meeting agenda.

Public Comment on Agenda Items, Ms. Beth Luthy, Chair

The invitation to submit comments on agenda items was announced by the conference operator and there was one request to speak:

- (1) Theresa Wrangham, Executive Director, National Vaccine Information Center (NVIC). Ms. Wrangham noted the NVIC's interest in participating in ACCV work groups and other stakeholder engagement, an interest articulated during public comments at the last ACCV meeting in September 6, 2018. Ms. Wrangham stated that the draft minutes of the September 6, 2018 ACCV meeting did not reflect the Center's comments and NVIC's offer to participate in ACCV workgroups and other stakeholder engagement. Ms. Wrangham made additional comments regarding the review and revision of Vaccine Information Statements (VIS). She stated that the ACCV was interested in the history of the VIS. The NVIC was involved in drafting the segment of the law related to the VIS and would be interested in providing a consumer perspective. Finally, Ms. Wrangham noted an error in how her name was spelled in the draft September 6, 2018 ACCV meeting minutes.

There were no additional requests to speak.

Approval of September 2018 ACCV Meeting Minutes, Ms. Beth Luthy, Chair

Ms. Luthy invited comments and approval of the September 6, 2018 meeting minutes. Regarding procedure, Ms. Herzog noted that staff would review the audio recording of the September 6, 2018 meeting, specifically related to Ms. Wrangham's remarks, and the minutes would be revised as appropriate, then the September 6, 2018 meeting minutes could be approved at the March 2019 ACCV meeting. Ms. Luthy confirmed that approval of the September 6, 2018 ACCV meeting minutes is deferred until the March 2019 ACCV meeting.

Report from the Division of Injury Compensation Programs, Dr. Narayan Nair, Director, DICP

Dr. Nair outlined the meeting agenda beginning with an update on the VICP, followed by a report from the Department of Justice, brief reports from ex officio members (Food and Drug Administration [FDA]) Centers for Disease Control and Prevention [CDC], National Institutes of Health [NIH], and National Vaccine Program Office [NVPO]), and a report from the ACCV Work Group chair.

Dr. Nair reported that, as of November 30, 2018, the average number of petitions filed for the Fiscal Years 2009 through 2013 was 427. During FY 2018, 1,238 claims were filed and to date in FY 2019, 203 petitions were filed. Funding for HRSA administrative expenses was \$6.46 million in FY 2014 (633 claims), increased to \$7.5 million in FY 2015 (803 claims) and FY 2016 (1,120 claims), rose slightly higher to \$7.75 million in FY 2017 (1,243 claims), and increased again to \$9.2 million in FY 2018 (1,238 claims). Funding for FY 2019 will remain at \$9.2. The current backlog of claims is 694, all of these claims were filed in FY 2018 and 2019. The VICP has cleared the backlog of claims from 2017.

Petitioners' were awarded almost \$200 million in FY 2018 and attorney's fees and costs were nearly \$27 million. To date in FY 2019 those amounts are \$41 million and almost \$5 million respectively. Adjudications in FY 2018 totaled 719 (530 were compensable, 189 were dismissed). In FY 2019, to date, those numbers are 50 adjudications (41 compensable and 9 dismissed). The breakdown by adjudication category for the last three fiscal years:

Adjudication category	FY 2017	FY 2018	FY 2019 (to date)
Compensable	187	183	17
Court decision	47	63	0
Settlement	462	285	25
Not compensable	183	189	14
Total	879	720	56

Dr. Nair reported that the Vaccine Injury Compensation Trust Fund (Trust Fund) stands at approximately \$3.86 billion. Total revenues for FY 2018 were about \$378 million, which includes about \$304 million from excise taxes, \$4.7 million from prior year refunds, and \$69 million from interest income (18.32% on total income).

Regarding other activities, a Notice of Proposed Rulemaking published in the Federal Register on April 4, 2018, to add the category of vaccines recommended for pregnant women to

the Vaccine Injury Table. The comment period ended on October 1, 2018; 49 comments were received and are being reviewed. Responses to comments will be included in the Final Rule.

In the discussion following Dr. Nair's report, Ms. Luthy asked for clarification of the decrease in petitioners' awards from FY 2013 to FY 2014. Dr. Nair explained that awards are determined by the U.S. Court of Federal Claims (Court) and the decrease could have been related to a temporary delay in the claims review process or a decrease in the number of claims filed during that period. He added that the majority of claims filed relate to influenza vaccine injury in adults. Ms. Luthy also asked about whether there were educational efforts to reduce the number of claims for Shoulder Injury Related to Vaccine Administration (SIRVA) injuries. Dr. Nair responded that within the last year his office provided an update on SIRVA to the National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP) in public meetings and both groups were very interested in preventing SIRVA injuries and in educating the public. CDC has also added educational information to its web site with the catch phrase "Know the site, get it right." A commissioner commented that the American Academy of Pediatrics has a public outreach effort to inform the public.

Ms. Toomey asked about statistics on children versus adults in the queue on adjudicating claims. Dr. Nair explained that pediatric claims are filed and reviewed as soon as possible, so most of the claims pending review are for adults. He noted that he did not have data on the number of pediatric claims that are pending after they are assigned and reviewed at VICP.

Asked about the "prior year refunds" to the Trust Fund, Dr. Nair explained that part of it is the result of a recipient who may not be able to receive the full amount of an award because of death or an authorized amount is made available for award, but for various reasons some of the funding is not required. An award amount is authorized, but is returned.

Report from the Department of Justice, Ms. Catharine Reeves, Deputy Director, Torts Branch

Ms. Reeves referenced the Department of Justice (DOJ) PowerPoint materials as part of her presentation for the three-month reporting period from August 16, 2018 through November 15, 2018. (DOJ PowerPoint (PP) at 2.) Ms. Reeves noted that during this reporting period, 375 petitions were filed. (DOJ PP at 2.) Ms. Reeves further noted that the vast majority of those 375 petitions were filed by adults. She stated that of the 375 petitions filed in this reporting period, 23 were filed on behalf of minors and 352 were filed by adults. (DOJ PP at 2.)

Ms. Reeves noted that 181 petitions were adjudicated during this reporting period. (DOJ PP at 3.) She commented that this number was slightly less than the number of petitions adjudicated during the preceding reporting period. One hundred forty-four cases were compensated during this reporting period, the majority of which were resolved by settlement. (DOJ PP at 3.) Thirty-seven cases were not compensated. (DOJ PP at 3.) Six petitions were voluntarily withdrawn. (DOJ PP at 4.)

Ms. Reeves discussed recently decided and pending cases in the U.S. Court of Appeals for the Federal Circuit (CAFC). (DOJ PP at 5, 6.) She noted that during the reporting period, the CAFC affirmed two cases that had been appealed by petitioners. (DOJ PP at 5.) She noted that nine cases remain pending before the CAFC, including Boatmon v. HHS. (DOJ PP at 6.) Ms. Reeves stated that the majority of those nine cases are appeals by petitioners of entitlement decisions.

Ms. Reeves next discussed appeals at the U.S. Court of Federal Claims (CFC). (DOJ PP

at 7-9.) She noted that four appeals by petitioners were decided by the CFC during this reporting period. (DOJ PP at 7.) She further noted that in all four cases, the CFC affirmed the special masters' decisions. (DOJ PP at 7.) Ms. Reeves stated that there are presently a number of cases pending before the CFC, the majority of which are appeals by petitioners of entitlement decisions. (DOJ PP at 8-9.)

Ms. Reeves noted that no oral arguments are scheduled at the CAFC or the CFC at this time. (DOJ PP at 10.)

Ms. Reeves provided a list of cases that were settled during the reporting period, which are listed in the DOJ PowerPoint presentation in order of the time they took to resolve. (DOJ PP at 11-19.) Ms. Reeves noted that most cases that were resolved by settlement during the reporting period took two years or less to resolve from the date of case filing. Ms. Reeves stated that the majority of settled cases during the reporting period alleged Guillain-Barré Syndrome (GBS) or Shoulder Injury Related to Vaccine Administration (SIRVA) injuries. Ms. Reeves further stated that most cases currently filed in the Vaccine Injury Compensation Program (Program) are filed by adults alleging SIRVA claims.

Following Ms. Reeves's presentation, she invited questions and comments. In response to a question concerning appeals, Ms. Reeves confirmed that no special master decisions were reversed on appeal during the reporting period. A follow-up question concerned whether, when a case is appealed, attorney's fees and costs related to the appeal are covered by the Program or if a petitioner must incur fees and costs related to the appeal. Ms. Reeves responded that the Vaccine Act prohibits a petitioner's attorney from billing a petitioner for fees and costs related to proceedings on a petition for vaccine compensation, including an appeal, and that those costs are generally compensated by the Program. She noted instances in which the appeal may raise the issue of the reasonable basis for the petition, in which case fees may be denied, but she noted that even in that circumstance, a petitioner would not be responsible for the costs of the appeal.

In response to a question concerning why no oral arguments are scheduled before the CAFC or CFC, Ms. Reeves explained that oral arguments have simply not been scheduled by the Courts and that some appeals are decided on the parties' written briefs without oral argument. Ms. Reeves further explained that oral argument is not required by the CFC. She noted that oral arguments are typically scheduled in appeals pending before the CAFC unless both parties waive said argument.

Finally, a question was raised related to the issue of whether a parent whose child's case is resolved by mediation can later serve as an ACCV member. Ms. Reeves explained that if mediation results in a settlement of the child's case—such that the case is not resolved via a court adjudication—then the child's parent cannot later serve as an ACCV member.

ACCV Work Group Update, Martha Toomey, Work Group Chair

Ms. Toomey announced that there was unfinished business at the end of the September 6, 2018 ACCV meeting, a deferred vote on a recommendation to the Secretary for increased funding to support additional special masters, and staffing resources for the HRSA and DOJ. She invited comment, if any, or a vote to approve the recommendation. Ms. Stewart recommended adding FY 2018 statistics to the supporting documents for the recommendation since there are final figures available now. Commission members expressed consensus that the recommendation should be updated to reflect FY 2018 information. Asked about whether the

letter would have to be reviewed after those revisions were made, Tamara Overby stated that the revised letter would be sent to the ACCV Chair and Co-Chair for final review and verification that the changes were made. Ms. Luthy made a motion to approve the recommendation with the date changes discussed.

On motion duly made and seconded, the Commission approved by verbal roll call vote the recommendation to increase funding to support additional special masters and staffing resources for the HRSA and the DOJ.

There was a question about strengthening the delivery of the recommendation, and there was agreement that the forwarding letter could request a response from the Secretary by the March ACCV meeting.

Ms. Toomey next provided a work group update, noting that at the last meeting, there was a productive effort to look at various options for getting feedback from petitioners on their experience with the program. The work group identified a number of options, one of which was developing an exit interview with petitioners at the conclusion of the claims process. The commission had a lengthy discussion about how such a survey could be designed and executed that would result in an assessment of the experience from the petitioner's earliest investigation of the availability of the Program, to filing the claim, through fulfilling the requirements for information and records and working with the court, to the outcome.

Ms. Stewart suggested that the first step might be to determine if the full commission believes a survey of VICP petitioners is necessary. If so, there should be an effort to identify other surveys conducted within the federal system that might provide guidance in the development of a VICP exit survey. There should also be a clear definition of the purpose of the survey and a description of the of the survey's audience. There was a suggestion that the basic purpose of the survey should be to determine how individuals who complete the court process found out about the compensation program.

There was a comment that during the work group discussion there was agreement that the ACCV might not have the resources to effectively conduct a major survey and that the support of the Secretary should be pursued. The work group decided that the ACCV should request that the Secretary support the development of the survey.

Moving on, Ms. Toomey discussed clarifying the qualifications for appointed as a member of the commission. She felt that an individual with a vaccine-related injury should be eligible as a specific ACCV member category, and not just as a member of the general public. Tamara Overby clarified that commission membership is defined in the legislation and that a particular change would require a legislative amendment, which would begin with a recommendation to the Secretary. Mr. Howie agreed that the pool of parents with vaccine-injured children, who would qualify for the "parent of a vaccine injured child," is limited and their responsibilities for caring for their children further exacerbates the challenge of enlisting their voluntary service. Expanding the definition to include vaccine-injured individuals should alleviate that situation.

There was agreement that the work group should draft a recommendation about adding and injured person category to the ACCV membership. Then, the work group will forward it to the full commission for review, revision and approval, before sending it on to the Secretary.

Ms. Stewart brought up another issue the work group discussed related to public education about vaccine safety, especially when an individual obtains a vaccination from a retail outlet, such as a pharmacy. In some of instances of vaccination at a retail outlet, the vaccine recipient may not receive a Vaccine Information Statement (VIS), which incidentally is a way to

learn about the VICP (the VICP is described in some VISs). If the individual asks about the vaccination, typically he or she is referred to the retail outlet's web site. Since it appears to be an inconsistent policy on the part of the retailer, it was suggested, that recommendation to the Secretary to establish a formal education program to encourage distribution of the VIS could be considered by the work group. There was a brief discussion on how the VISs are distributed under different circumstances and by different organizations.

Noting that the ACCV work group update exceeded the time allotted, Ms. Stewart summarized the discussion:

1. The work group approved the draft recommendation to the Secretary,
2. Approved the proposal to develop a letter of recommendation about the survey, and
3. Agreed on the proposal that the work group address the issue of expanding the eligibility for appointment to the commission to include a vaccine-injured individual.

Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC), Vaccine Activities, Dr. Michael McNeil, CDC

Dr. McNeil stated that he would discuss the presentations at the October 2018 meeting of the Advisory Committee on Immunization Practices (ACIP), followed by brief comments about selected recent publications. At the October ACIP meeting, there was a unanimous vote to approve the use of hepatitis A vaccine for routine vaccination of the homeless over the age of one, which would reduce both the hepatitis A infection risk in the vulnerable homeless population and the general risk of large-scale outbreaks.

Dr. McNeil discussed a report on administration of human papillomavirus (HPV) vaccine related to primary ovarian insufficiency (POI) and adolescent vaccination. The study was conducted at the Kaiser Northwest Vaccine Safety Datalink (VSD) site from August 2006 to December 2014. The study looked at 199,078 female vaccine recipients between the ages of 11-34 years old. Of the female patients enrolled at the VSD site during the period of the study, 58,871 were administered the quadrivalent HPV vaccine (4vHPV). Three additional vaccines were looked at as well, Tdap, MenACWY, and IIV. There was no evidence of increased risk of POI after any of these vaccinations. There was data in the report supporting expanding the age range for administration of 4vHPV vaccine through 45 years of age. Although HPV incidence decreases with age, new infections can occur; many adults have already been exposed to a 9-valent HPV type. Studies from six countries have revealed that 4vHPV vaccine effectiveness decreases with age. Because three U.S. models have not resulted in conclusive benefits of 9vHPV vaccine, ACIP is conducting an ongoing review.

Dr. McNeil told the ACCV that at the October 2018 ACIP meeting, there was a session on influenza vaccine effectiveness at which the PREVENT Network was discussed. The network collected data on acute respiratory or febrile illness in pregnant women 18 to 50 years of age that resulted in hospitalization and determined that, between 2010 and 2016, influenza vaccination had the potential to prevent 40% of those flu-associated admissions. During the ACIP flu session, Sanofi Pasteur presented data on safety and immunogenicity of quadrivalent Fluzone, comparing 0.5 ml (full dose) and the approved half dose (0.5 ml versus 0.25 ml). The Phase IV randomized, observer-blinded, multicenter study in 2,190 children (6-35 months of age) indicated that the safety of each dose was similar, but the efficacy of the larger dose may have been more immunogenic. There were other studies reported in the literature with similar

findings. A biologic license application (BLA) has been submitted to the FDA to permit use of the 0.5 ml dose in children as young as 6 months.

The ACIP also convened a pertussis vaccines work group to consider repeat Tdap vaccinations, which would result in a label change to remove the “single use” language. One of the manufacturers has submitted a BLA that would probably complete review by January 2019. The move would allow the use of Tdap for the decennial Td (tetanus and diphtheria) booster.

Dr. McNeil concluded his report. He displayed, but did not discuss, eight PowerPoints describing recent publications:

1. Suragh TA, Lamprianou S, MacDonald NE, Loharikar AR, Balakrishnan MR, Benes O, Hyde TB, McNeil MM. Cluster anxiety-related adverse events following immunization (AEFI): An assessment of reports detected in social media and those identified using an online search engine. *Vaccine* 36 (40). 2018 Sept.5949-5954
2. Grohskopf LA, Sokolow LZ, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2018–19 Influenza Season, *MMWR RecommRep* 2018 Aug 24; 67(3):1-20
3. Naleway AL, Mittendorf KF, Irving SA, Henninger ML, Crane B, Smith N, Daley MF, Gee J. Primary Ovarian Insufficiency and Adolescent Vaccination. *Pediatrics* 2018 Sept, 142(3) Epub2018 Aug 21
4. Walker WL, Hills SL, Miller ER, Fischer M, Rabe IB. Adverse events following vaccination with inactivated, Vero cell culture-derived Japanese encephalitis vaccine in the United States, 2012-2016 *Vaccine*. 2018 Jul 5;36(29):4369-4374.
5. Groom HC, et al (CDC co-authors: Natalie McCarthy and Lakshmi Sukumaran). Uptake and safety of Hepatitis B vaccination during pregnancy: A Vaccine Safety Datalink study. *Vaccine*. 2018 Oct;36(41):6111-6116.
6. Moro PL, Lewis P, and Cano M. Adverse events following purified chick embryo cell rabies vaccine in the Vaccine Adverse Event Reporting System (VAERS) in the United States, 2006–2016.October 2018.*Travel Medicine and Infectious Disease*
7. Fortner KB, Swamy GK, Broder KR, Jimenez-Truque N, Zhu Y, Moro PL, Liang J, Walter EB, Heine RP, Moody MA, Yoder S, Edwards KM. Reactogenicity and immunogenicity of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant and nonpregnant women. *Vaccine* 2018 Oct 8; 36(42):6354-60.
8. Suragh T et al. Safety of bivalent human papillomavirus vaccine in the U.S. Vaccine Adverse Event Reporting System (VAERS), 2009-2017.*Br J Clin Pharmacol*.2018 Sep 19. (Epub ahead of print)

There was no discussion or questions related to Dr. McNeil’s presentation.

Ms. Luthy announced that Dr. Meissner, who had lost his connection to the conference call, had returned, and she invited him to make a comment. He expressed appreciation for the opportunity to comment on an agenda item completed earlier in the meeting. He stated that, although the VIS is usually provided to patients receiving a vaccination, most do not read the VIS. Nonetheless, if an individual suffers an adverse reaction, his health care provider should inform him of the process to report the reaction to the FDA. Finally, he observed that the

suggestion that the provider spend time discussing potential adverse reactions with each person receiving a vaccination does not seem to be practical or economically viable, especially since adverse reactions are often very rare occurrences. Ms. Stewart agreed that a discussion of a very rare adverse event is not practical or legally required.

Asked about ways to more effectively inform the public about the program, Dr. Nair commented that, because of limited resources for such an effort, there has been a recent effort to revamp the web site to make it more accessible, and to take advantage of opportunities to make presentations at events that make participation possible without incurring travel expenses. Dr. Meissner suggested making a presentation to the Redbook Committee for the American Academy of Pediatrics.

Following Dr. Meissner's comments and the brief related discussion, Ms. Luthy moved the meeting along and invited a report from the ex officio member representing NIH.

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

Ms. Schuster reported that NIH is conducting a Phase 1 trial to assess whether imiquimod cream enhances immune response in combination with H5N1 influenza vaccine, an inactivated vaccine developed with partial NIAID support and manufactured by Sanofi Pasteur. The immune-enhancing potential of imiquimod could help extend the supply of the H5N1 vaccine because it reduces the number of vaccine doses needed to achieve sufficient immune responses in recipients. This approach would allow more people to be vaccinated in pandemic outbreaks. This NIAID-funded study is enrolling 50 adults aged 18 to 45 years and is being conducted at the NIAID-supported Vaccine and Treatment Evaluation Unit (VTEU) at Baylor College of Medicine.

NIAID is also testing the safety and immune-stimulating properties of an experimental nasal influenza vaccine in children and adolescents at a VTEU site at Saint Louis University. The vaccine developed by FluGen, is made from a seasonal flu virus, H3N2. Half of the participants will receive the vaccine; the other half, an inactive saline solution delivered as a nasal spray. All participants will receive a licensed quadrivalent seasonal influenza vaccine three months later.

There are videos that describe the 1918 influenza pandemic posted on the NIAID Now blog. More information is available at <https://www.niaid.nih.gov/news-events/blog>.

Ms. Schuster also announced that, in 2017, NIAID and Children's National Health System launched a clinical research partnership to treat and prevent allergic, immunologic, and infectious diseases in children. The institutions offer joint training opportunities for physicians interested in caring for affected children. There was an inaugural symposium on September 17, 2018.

On November 13, 2018, NIAID hosted an informational webinar entitled "New NIAID Infectious Diseases Clinical Trial Funding Opportunities." The webinar provided an overview of the Leadership Group for an Infectious Diseases Clinical Research Consortium and a new VTEU funding opportunity.

Finally, Ms. Schuster announced that on November 13, 2018, CDC Director, Dr. Robert Redfield, delivered The Joseph Kinyoun Lecture at the NIH campus in Bethesda, MD. The lecture was entitled "Opioids: Epidemic of our Time and Impact on Infectious Diseases." The talk looked at the impact of unprecedented use of opioids on the management of infectious

diseases. Although overdose is the main cause of death in opioid users; viral hepatitis, bacterial endocarditis and HIV disproportionately affect opioid users. The webinar may be viewed at <https://videocast.nih.gov/> (search for: Kinyoun Lecture). Ms. Schuster concluded her report.

Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities, CDR Valerie Marshall, CBER, FDA

CDR Marshall reported that, in October 2018, following a review of efficacy and safety data, the FDA approved a supplement to the BLA for Afluria and Afluria quadrivalent influenza vaccine for Types A and B virus, to extend the pediatric age range to person 6 months of age to 59 months of age. The vaccine was previously indicated for persons 6 years of age and older.

CDR Marshall also reported that, in October 2018, following an extensive review of safety and efficacy data, the FDA approved a supplement to the BLA for human papillomavirus 9-valent vaccine, Gardasil, to extend the use of the vaccine to include women and men from 27 to 45 years of age. The vaccine was previously indicated for girls and women 9 through 26 years of age, and boys and men 9 through 26 years of age. According to the CDC, HPV vaccination prior to becoming infected with the HPV virus types covered by the vaccine has the potential of preventing more than 90% of cancers, or more than 31,000 cases every year.

Update from the National Vaccine Program Office, (NVPO), Ms. Ann Aikin, NVPO

Ms. Aikin reported that the last National Vaccine Advisory Committee meeting focused broadly on vaccine innovation and included panel presentations on three different vaccine technologies. There was also a panel presentation on Cytomegalovirus vaccines that are being developed in the pipeline, a presentation on the new shingles vaccine, Shingrix, and another session on the unmet needs projects that NVPO recently funded. Finally, the meeting concluded with a series of presentations highlighting opportunities to prevent HPV-related cancers, agency and liaison updates, and public comments. The next meeting will be a virtual meeting on February 5, 2019.

Ms. Aikin described action in the regional HHS offices to implement the National Adult Implementation Plan (NAIP) that was published in 2016. To spark action on the plan, in 2018, NVPO worked with HHS Regional Offices to hold six meetings across the country that discussed adult immunization topics like financing, quality improvement, and communications strategies. Four meetings are also planned for 2019 at the remaining four regions. Lessons learned during the first year of the NAIP initiative included:

1. Despite operating within resource-constrained environments, stakeholders across the country are eager to improve adult immunization rates through collaboration and coordination.
2. Inter-regional knowledge sharing helped stakeholders in other regions enhance their initiatives.
3. There was value in encouraging remote participation, especially for last minute travel changes and for areas with geographical boundaries.
4. Meeting participants reported increased visibility of NVPO and the NAIP.

We were able to engage new and existing partners from a variety of sectors. This allowed us to maximize and leverage opportunities and work already being conducted by stakeholders.

5. Regional offices are a powerful tool for Office of the Assistant Secretary for Health and should be an integral part of our work

Ms. Aikin concluded her report. Ms. Luthy invited public comments.

Public Comment

Ms. Wrangham, Executive Director, National Vaccine Information Center, commented on the discussion about SIRVA, which was previously added to the Vaccine Injury Table. She noted there was a comment that SIRVA is less a vaccine injury than a vaccine administration error, which is related to education for providers and the ACCV may have a need to revisit that conversation as the ACCV discusses membership. Concerning the issue of recruitment of commissioners, she wanted to remind the commission that the reason there was no slot for a vaccine-injured adult was that originally the program focused on childhood injuries. Ms. Wrangham suggested that there could be consideration of expanding the number of commissioners rather than changing the eligibility requirements of an existing member slot. Ms. Wrangham thanked the ACCV work group for considering some of the NVIC concerns that are also concerns of other stakeholders. Finally, she noted that gaps in vaccine safety science, identified by the Institute of Medicine report, might present obstacles for petitioners when they try to enlist medical experts to support their petitions to benefit from the safety net that the VICP was supposed to provide. Ms. Wrangham added that using the Trust Fund as a potential resource for closing the science knowledge gap should not be considered since it was developed to help the vaccine injured. Finally, she stated that more public awareness was important and perhaps a presentation by the Banyan Group that was made to NVAC should be considered by the ACCV. She added that Ms. Toomey has indicated that looking into social media as a powerful force for increasing public awareness, would be appropriate.

There were no other requests to make comments, and no recommendations for future agenda items. Ms. Luthy announced that there were potential new commission members being reviewed and some may be available by the time of the next meeting. The tentative date for the next meeting is March 7, 2019.

Adjournment

There being no further business, on motion duly made and seconded, the Commission unanimously approved adjournment.

3

Vaccine Injury Compensation Trust Fund

Balance as of December 31, 2018

\$3,849,055,005

Figures for October 1, 2017 to December 31, 2018

- Excise Tax Revenue: \$56,010,000
- Interest on Investments: \$20,168,764
- Total Income: \$76,178,764
- Interest as a Percentage of Total Income: 26%

Source: U.S. Treasury, Bureau of Fiscal Service (February 6, 2019)

4

Data & Statistics

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.

In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation.

What does it mean to be awarded compensation?

Being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Approximately 70 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

What reasons might a petition result in a negotiated settlement?

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition quickly

How many petitions have been awarded compensation?

According to the CDC, from 2006 to 2017 over 3.4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 6,094 petitions were adjudicated by the Court, and of those 4,172 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 20,332 petitions have been filed with the VICP. Over that 30-year time period, 17,627 petitions have been adjudicated, with 6,358 of those determined to be compensable, while 11,269 were dismissed. Total compensation paid over the life of the program is approximately \$4.0 billion.

This information reflects the current thinking of the United States Department of Health and Human Services on the topics addressed. This information is not legal advice and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Claims, which is responsible for resolving petitions for compensation under the VICP.

**VICP Adjudication Categories, by Alleged Vaccine
 For Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006
 through 12/31/2017**

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2017 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	794,777	1	0	5	6	4	10
DTaP	101,073,594	19	25	101	145	116	261
DTaP-Hep B-IPV	68,764,777	5	11	26	42	50	92
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	24,237,580	0	0	2	2	3	5
DTap-IPV-HIB	62,397,611	3	5	8	16	28	44
DTP	0	1	1	3	5	2	7
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	15,826,685	2	0	15	17	4	21
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	176,194,118	8	7	40	55	31	86
Hepatitis B (Hep B)	185,428,393	9	11	61	81	74	155
HIB	119,947,400	3	1	8	12	10	22
HPV	111,677,552	15	16	103	134	174	308
Influenza	1,518,400,000	615	204	2,014	2,833	466	3,299
IPV	72,962,512	0	0	4	4	3	7
Measles	135,660	0	0	1	1	0	1
Meningococcal	94,113,218	1	5	37	43	10	53

National Vaccine Injury Compensation Program
 Monthly Statistics Report

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2017 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
MMR	101,501,714	23	15	82	120	123	243
MMR-Varicella	24,798,297	9	1	10	20	15	35
Mumps	110,749	0	0	0	0	0	0
Nonqualified	0	0	0	3	3	36	39
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	228,588,846	17	6	25	48	32	80
Rotavirus	107,678,219	16	6	18	40	12	52
Rubella	422,548	0	1	1	2	0	2
Td	65,170,306	10	8	60	78	25	103
Tdap	248,258,803	88	22	241	351	69	420
Tetanus	3,836,052	11	1	40	52	20	72
Unspecified	0	1	1	4	6	588	594
Varicella	116,063,014	8	9	28	45	18	63
Grand Total	3,454,269,356	868	358	2,946	4,172	1,922	6,094

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2017 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were for multiple vaccines later identified in the Special Masters' decisions

National Vaccine Injury Compensation Program
Monthly Statistics Report

Definitions

Compensable – The injured person who filed a petition was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the petition by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession:** HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision:** A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).

For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:

1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
 2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement:** The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
 - **Non-compensable/Dismissed:** The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
 1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
 2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
 3. The injured person voluntarily withdrew his or her petition.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 2/04/2019

Vaccines	Filed Injury	Filed Death	Filed Grand Total	Compensated	Dismissed
DTaP-IPV	10	0	10	2	3
DT	69	9	78	26	52
DTP	3,286	696	3,982	1,273	2,709
DTP-HIB	20	8	28	7	21
DTaP	452	82	534	224	251
DTaP-Hep B-IPV	83	36	119	42	50
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	43	21	64	14	27
Td	206	3	209	121	75
Tdap	666	6	672	344	68
Tetanus	135	2	137	73	47
Hepatitis A (Hep A)	101	7	108	54	31
Hepatitis B (Hep B)	691	60	751	272	418
Hep A-Hep B	31	0	31	16	5
Hep B-HIB	8	0	8	5	3
HIB	43	3	46	17	20
HPV	383	15	398	128	163
Influenza	4,897	166	5,063	2,789	446
IPV	268	14	282	8	269
OPV	282	28	310	158	151
Measles	143	19	162	55	107
Meningococcal	71	2	73	42	8
MMR	973	61	1,034	402	582
MMR-Varicella	47	2	49	20	13
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	178	15	193	48	47
Rotavirus	94	5	99	56	23
Rubella	190	4	194	71	123
Varicella	101	9	110	63	30
Nonqualified ¹	100	9	109	3	101
Unspecified ²	5,426	9	5,435	9	5,399
Grand Total	19,037	1,295	20,332	6,358	11,269

¹ Nonqualified petitions are those filed for vaccines not covered under the VICP.

² Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	412
Total	20,332

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	329	509
FY 2011	266	1,740	2,006
FY 2012	265	2,533	2,798
FY 2013	369	649	1,018
FY 2014	372	191	563
FY 2015	517	137	654
FY 2016	697	179	876
FY 2017	696	183	879
FY 2018	537	188	725
FY 2019	78	17	95
Total	6,358	11,269	17,627

National Vaccine Injury Compensation Program
 Monthly Statistics Report

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	\$1,317,654.78	\$54,107.14	0	\$0.00	0	\$0.00	\$1,371,761.92
FY 1990	88	\$53,252,510.46	\$1,379,005.79	4	\$57,699.48	0	\$0.00	\$54,689,215.73
FY 1991	114	\$95,980,493.16	\$2,364,758.91	30	\$496,809.21	0	\$0.00	\$98,842,061.28
FY 1992	130	\$94,538,071.30	\$3,001,927.97	118	\$1,212,677.14	0	\$0.00	\$98,752,676.41
FY 1993	162	\$119,693,267.87	\$3,262,453.06	272	\$2,447,273.05	0	\$0.00	\$125,402,993.98
FY 1994	158	\$98,151,900.08	\$3,571,179.67	335	\$3,166,527.38	0	\$0.00	\$104,889,607.13
FY 1995	169	\$104,085,265.72	\$3,652,770.57	221	\$2,276,136.32	0	\$0.00	\$110,014,172.61
FY 1996	163	\$100,425,325.22	\$3,096,231.96	216	\$2,364,122.71	0	\$0.00	\$105,885,679.89
FY 1997	179	\$113,620,171.68	\$3,898,284.77	142	\$1,879,418.14	0	\$0.00	\$119,397,874.59
FY 1998	165	\$127,546,009.19	\$4,002,278.55	121	\$1,936,065.50	0	\$0.00	\$133,484,353.24
FY 1999	96	\$95,917,680.51	\$2,799,910.85	117	\$2,306,957.40	0	\$0.00	\$101,024,548.76
FY 2000	136	\$125,945,195.64	\$4,112,369.02	80	\$1,724,451.08	0	\$0.00	\$131,782,015.74
FY 2001	97	\$105,878,632.57	\$3,373,865.88	57	\$2,066,224.67	0	\$0.00	\$111,318,723.12
FY 2002	80	\$59,799,604.39	\$2,653,598.89	50	\$656,244.79	0	\$0.00	\$63,109,448.07
FY 2003	65	\$82,816,240.07	\$3,147,755.12	69	\$1,545,654.87	0	\$0.00	\$87,509,650.06
FY 2004	57	\$61,933,764.20	\$3,079,328.55	69	\$1,198,615.96	0	\$0.00	\$66,211,708.71
FY 2005	64	\$55,065,797.01	\$2,694,664.03	71	\$1,790,587.29	0	\$0.00	\$59,551,048.33
FY 2006	68	\$48,746,162.74	\$2,441,199.02	54	\$1,353,632.61	0	\$0.00	\$52,540,994.37
FY 2007	82	\$91,449,433.89	\$4,034,154.37	61	\$1,692,020.25	0	\$0.00	\$97,175,608.51
FY 2008	141	\$75,716,552.06	\$5,191,770.83	74	\$2,531,394.20	2	\$117,265.31	\$83,556,982.40
FY 2009	131	\$74,142,490.58	\$5,404,711.98	36	\$1,557,139.53	28	\$4,241,362.55	\$85,345,704.64
FY 2010	173	\$179,387,341.30	\$5,961,744.40	59	\$1,933,550.09	22	\$1,978,803.88	\$189,261,439.67
FY 2011	251	\$216,319,428.47	\$9,572,042.87	403	\$5,589,417.19	28	\$2,001,770.91	\$233,482,659.44
FY 2012	249	\$163,491,998.82	\$9,241,427.33	1,020	\$8,649,676.56	37	\$5,420,257.99	\$186,803,360.70
FY 2013	375	\$254,666,326.70	\$13,543,099.70	704	\$7,012,615.42	50	\$1,454,851.74	\$276,676,893.56
FY 2014	365	\$202,084,196.12	\$12,161,422.64	508	\$6,824,566.68	38	\$2,493,460.73	\$223,563,646.17
FY 2015	508	\$204,137,880.22	\$14,507,692.27	117	\$3,484,869.16	50	\$3,089,497.68	\$225,219,939.33
FY 2016	689	\$230,140,251.20	\$16,225,881.12	99	\$2,741,830.10	59	\$3,502,709.91	\$252,610,672.33

National Vaccine Injury Compensation Program
 Monthly Statistics Report

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2017	706	\$252,245,932.78	\$22,045,785.00	131	\$4,441,724.32	52	\$3,363,464.24	\$282,096,906.34
FY 2018	522	\$199,658,492.49	\$16,658,440.14	111	\$5,091,269.45	58	\$5,220,096.78	\$226,628,298.86
FY 2019	167	\$65,974,844.02	\$4,874,333.22	20	\$1,253,210.26	15	\$1,019,523.69	\$73,121,911.19
Total	6,356	\$3,754,128,915.24	\$192,008,195.62	5,369	\$81,282,380.81	439	\$33,903,065.41	\$4,061,322,557.08

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals,

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.

5.1

The National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs Update (DICP)

Advisory Commission on Childhood Vaccines (ACCV)

March 8, 2018

CAPT Narayan Nair, MD

Director, Division of Injury Compensation Programs

Healthcare Systems Bureau (HSB)

Health Resources and Services Administration (HRSA)



DICP Update

ACCV Meeting Highlights

- Update on HRSA VICP Activities
- Update from the Department of Justice Vaccine Litigation Office
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH, NVPO
- Update from the ACCV Work Group



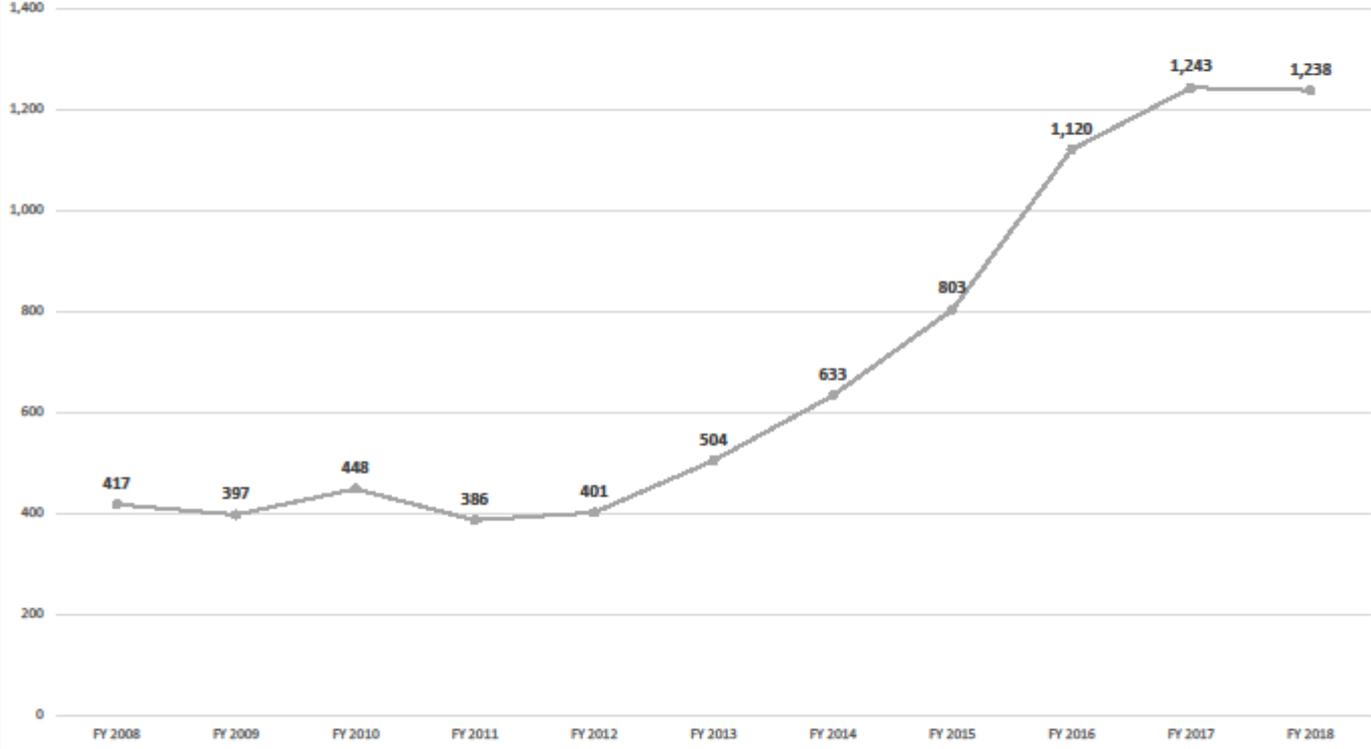
Number of Petitions Filed as of February 1, 2019

Average annual number of petitions filed during FY 2009-2013 = 427

Fiscal Year	Total
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	412



VICP Claims Filed Fiscal Years 2008 - 2018



Five-Year Trend in Number of Claims Filed versus Administrative Funding

Fiscal Year (FY)	No. of Claims Filed	No. of Claims Percentage Change	Administrative Funding (\$ in millions)	Administrative Funding Percentage Change
2014	633	---	\$6.46	----
2015	803	27%	\$7.50	16%
2016	1,120	39%	\$7.50	0%
2017	1,243	11%	\$7.75	3%
2018	1,238	-0.4%	\$9.2	19%
2019	446 (As of 2/6/19)	---	\$9.2	0%



Number of Claims Awaiting Review As of February 11, 2019

Fiscal Year	Claims Awaiting Review
2017	0
2018	371
2019	366
Total	737



Award Amounts Paid as of February 1, 2019

<u>Fiscal Year</u>	<u>Petitioners' Award</u>	<u>Attorneys' Fees & Costs</u>
FY 2012	\$163,491,999	\$23,311,362
FY 2013	\$254,666,327	\$22,010,567
FY 2014	\$202,084,196	\$21,479,450
FY 2015	\$204,137,880	\$21,082,059
FY 2016	\$230,140,251	\$22,470,421
FY 2017	\$252,245,933	\$29,850,973
FY 2018	\$199,658,492	\$26,969,806
FY 2019	\$65,974,844	\$7,147,067



Number of Adjudications as of February 1, 2019

Fiscal Year	Compensable	Dismissed	Total
FY 2013	369	649	1,018
FY 2014	372	191	563
FY 2015	517	137	654
FY 2016	697	179	876
FY 2017	696	183	879
FY 2018	537	188	725
FY 2019	78	17	95



DICP Update

Adjudication Categories for Claims

FY 2017 – FY 2019 as of February 6, 2019

Adjudication Category	FY 2017	FY 2018	FY 2019
Compensable	696 (100%)	538 (100%)	115 (100%)
❖ Concession	187 (27%)	189 (35%)	40 (35%)
❖ Court Decision (includes proffers)	47 (7%)	63 (12%)	7 (6%)
❖ Settlement	462 (66%)	286 (53%)	68 (59%)
Not Compensable	183	188	32
Adjudication Total	879	726	147



DICP Update

Vaccine Injury Compensation Trust Fund

- **Balance as of December 31, 2018**
 - \$3,849,055,005
- **Activity from October 1, 2018 to December 31, 2018**
 - Excise Tax Revenue: \$56,010,000
 - Interest on Investments: \$20,168,764
 - Total Income: \$76,178,764
 - Interest as a Percentage of Total Income: 26%

Source: U.S. Treasury, Bureau of the Fiscal Service (February 6, 2019)



DICP Update

Significant Activities

- **Implementation of Maternal Immunization Provisions**
 - 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*.
 - Comment period ended on October 1, 2018, and 49 comments were received and are being reviewed.
 - Responses to comments will be included in the Final Rule.



- Information on ACCV meetings, presentations and minutes can be found at:

<http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html>



DICP Update

Contact Information

Public Comment/Participation in Commission Meetings

Annie Herzog, ACCV Principal Staff Liaison

5600 Fishers Lane, Room 08N146A

Rockville, Maryland 20857

Phone: 301-443-6634

Email: aherzog@hrsa.gov

Web: hrsa.gov/about/organization/bureaus/hsb/

Twitter: twitter.com/HRSAgov

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National Institutes of Health Update

Claire Schuster, MPH
National Institute of Allergy and Infectious Diseases
National Institutes of Health

March 2019



National Institute of
Allergy and
Infectious Diseases

H7N9 Influenza Research



Credit: NIAID

- NIAID is supporting five Phase 2 clinical trials testing experimental H7N9 influenza vaccines



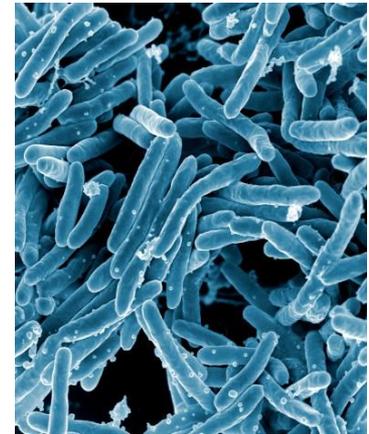
U.S. Department of Health and Human Services

NIH News
National Institutes of Health

National Institute of Allergy and
Infectious Diseases (NIAID)

<http://www.niaid.nih.gov>
January 23, 2019

Temperature-Stable Experimental Tuberculosis Vaccine Enters Clinical Testing



Credit: NIAID

- Phase 1 clinical trial testing freeze-dried, temperature-stable formulation of TB vaccine candidate (ID93)
- Conducted at Saint Louis University School of Medicine Center for Vaccine Development

NIH Notice on Acute Flaccid Myelitis

- **Title:** Notice of Interest in Advancing Research in Acute Flaccid Myelitis and Guillain-Barre Syndrome (NOT-NS-19-029)
 - Issued by NINDS, NIAID and NICHD on Dec. 20, 2018
- **Purpose:** To encourage new applications and requests for supplements to support research on the causes, diagnosis, prevention or treatment of AFM, GBS and other acute neurological conditions of muscle weakness/paralysis triggered by infectious agents or related immune responses

Studying Effects of Maternal Opioid Use on Newborns

- **Title:** HEAL Initiative: Antenatal Opioid Exposure Longitudinal Study Consortium
 - Issued by NICHD on Dec. 10, 2018
- **Purpose:** To invite applications from consortia composed of a Data Coordinating Center and 2 or more Clinical Sites to conduct a multi-center prospective cohort study of infants exposed to opioids in utero compared to unexposed infants. During a 2-year follow-up period, infants will be assessed with serial measures including neuroimaging, medical, neurodevelopmental, behavioral, and home, social, and family life assessments.

NIH Seeking Input on Tickborne Disease Research Priorities

- NIH is developing a strategic plan to advance tickborne disease research and development.
- NIH invites public input on the tickborne disease research priorities NIH should continue or adopt over the coming years.



Credit: NIAID

5.5

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

March 8, 2018



CDR Valerie Marshall, MPH, PMP

Immediate Office of the Director

Office of Vaccines Research and Review (OVRR)

Center for Biologics Evaluation and Research (CBER)

Food and Drug Administration (FDA)

New Vaccine Approval - VAXELIS

- In December 2018, the FDA approved Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine (VAXELIS)
 - VAXELIS is indicated for active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to Haemophilus influenzae (H. influenzae) type b.
 - VAXELIS is approved for use as a 3 dose series in children 6 weeks through 4 years of age (prior to the 5th birthday).

Ixario (Japanese Encephalitis Vaccine, Inactivated, Adsorbed)

- In October 2018, the FDA approved a supplement to the biologics license application for Ixario to:
 - i) include an alternate primary immunization series of two 0.5 mL doses of IXIARO administered at 7 days apart for individuals 18 through 65 years of age, and
 - ii) update the IXIARO package insert to include data to support the concomitant use of IXIARO primary immunization series, two 0.5 mL doses administered 28 days apart, with U.S.-licensed rabies vaccine (RabAvert®) administered for pre-exposure prophylaxis.

Fluzone Quadrivalent

- In February 2019, FDA approved a supplement to the biologics application for Fluzone Quadrivalent to include the 2019 Southern Hemisphere formulation and associated labeling revisions.

Vaccines and Related Biological Products Advisory Committee

- On March 6, 2019, the Center for Biologics Evaluation and Research's (CBER) VRBPAC met in an open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2019 to 2020 influenza season.
- On March 7, 2019, the committee met in open session to discuss and make recommendations on the safety and effectiveness of Dengue Tetravalent Vaccine (Live, Attenuated) (DENGIVAXIA) manufactured by Sanofi Pasteur.



Thank you!



5.6