ADVISORY COMMISSION ON CHILDHOOD VACCINES
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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

Teleconference and Adobe Connect

Thursday, December 6, 2018

(10:00 am Eastern Daylight Time)

Dial-in: 1-800-988-0218
Passcode: 9302948

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

Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Ms. Beth Luthy, Chair
10:10 AM	Public Comment on Agenda Items	Ms. Beth Luthy, Chair
10:15 AM	Approval of September 2018 Minutes	Ms. Beth Luthy, Chair
10:20 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Director, DICP
10:50 PM	Report from the Department of Justice	Ms. Catharine Reeves, Deputy Director, Torts Branch, DOJ
11:20 AM	ACCV Work Group Update	Ms. Martha Toomey, Work Group Chair
12:00 PM	Lunch	
1:00 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Michael McNeil CDC
1:15 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
1:30 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	CDR Valerie Marshall CBER, FDA
1:45 PM	Update from the National Vaccine Program Office (NVPO)	Ms. Ann Aikin NVPO
2:00 PM	Public Comment (follows the preceding topic and may commence earlier or later than 2:00 pm)	
2:15 PM	Future Agenda Items/New Business	Ms. Beth Luthy, Chair
2:30 PM	Adjournment of the December 6, 2018 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

April 12, 2018

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 2018)
Chair
Associate Professor
College of Nursing, Brigham Young University
Health Professional

Alexandra Stewart, J.D., (Term Expires 2018)
The George Washington University,
School of Public Health and Health Services
Attorney

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

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

Vacant Position
Parent of a Vaccine Injured Child

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

Martha Toomey, (Term Expires 2018)
Parent of a Vaccine Injured Child

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

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

EX-OFFICIO MEMBERS

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

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

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

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

2018
Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2018 MEETING DATES

March 8, 2018
June 15, 2018
September 6, 2018
December 6 & 7, 2018

2019 MEETING DATES

March 7 & 8, 2019
June 6 & 7, 2019
September 5 & 6, 2019
December 5 & 6, 2019

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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 role 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. T here 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 Fluad 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 Zostafax. 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 Wranghamr.

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. 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.

3

Vaccine Injury Compensation Trust Fund

Balance as of September 30, 2018

$3,857,743,855

Figures for October 1, 2017 to September 30, 2018

- Excise Tax Revenue: $304,341,863
- Interest on Investments: $69,318,571
- Prior Year Refunds: $4,738,788
- Total Income: $378,399,222
- Interest as a Percentage of Total Income: 18.32%

Source: U.S. Treasury, Bureau of Fiscal Service (November 6, 2018)

4

HRSA
Health Resources & Services Administration

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:

- Almost 75 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 2016 over 3.1 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 5,564 petitions were adjudicated by the Court, and of those 3,773 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 20,018 petitions have been filed with the VICP. Over that 30-year time period, 17,536 petitions have been adjudicated, with 6,276 of those determined to be compensable, while 11,260 were dismissed. Total compensation paid over the life of the program is approximately $4.0 billion.

VICP Adjudication Categories, by Alleged Vaccine
For Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 through 12/31/2016

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 12/31/2016 (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	95,532,634	17	25	101	143	112	255
DTaP-Hep B-IPV	63,245,627	5	11	26	42	47	89
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	21,143,570	0	0	2	2	2	4
DTap-IPV-HIB	56,635,096	3	5	7	15	29	44
DTP	0	1	1	3	5	2	7
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	14,706,195	2	0	15	17	4	21
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	163,305,725	7	7	38	52	30	82
Hepatitis B (Hep B)	172,993,779	6	11	59	76	68	144
HIB	111,200,358	2	1	8	11	10	21
HPV	101,405,935	15	16	100	131	163	294
Influenza	1,372,400,000	444	190	1,883	2,517	400	2,917
IPV	69,510,722	0	0	4	4	3	7
Measles	135,660	0	0	1	1	0	1
Meningococcal	82,762,503	1	5	36	42	8	50

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 12/31/2016 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
MMR	94,815,650	22	15	82	119	114	233
Mumps	110,749	0	0	0	0	0	0
MMR-Varicella	21,349,409	9	1	10	20	14	34
Nonqualified	0	0	0	3	3	35	38
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	206,003,646	10	4	17	31	24	55
Rotavirus	98,664,187	12	6	18	36	10	46
Rubella	422,548	0	1	1	2	0	2
Td	61,869,752	10	8	57	75	24	99
Tdap	225,013,338	74	19	224	317	57	374
Tetanus	3,836,052	8	1	38	47	19	66
Unspecified	0	1	1	4	6	585	591
Varicella	110,095,393	6	8	28	42	18	60
Grand Total	3,153,876,236	659	338	2,776	3,773	1,791	5,564

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2016 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

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 11/01/2018

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	448	82	530	222	249
DTaP-Hep B-IPV	82	36	118	42	50
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	43	21	64	14	27
Td	205	3	208	121	75
Tdap	634	6	640	338	67
Tetanus	134	2	136	73	47
Hepatitis A (Hep A)	101	7	108	50	30
Hepatitis B (Hep B)	689	60	749	271	418
Hep A-Hep B	30	0	30	16	5
Hep B-HIB	8	0	8	5	3
HIB	42	3	45	16	20
HPV	378	15	393	124	163
Influenza	4,660	156	4,816	2,728	443
IPV	268	14	282	8	269
OPV	282	28	310	158	151
Measles	143	19	162	55	107
Meningococcal	68	2	70	42	8
MMR	970	61	1,031	401	581
MMR-Varicella	45	2	47	20	13
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	170	15	185	47	47
Rotavirus	93	4	98	56	23
Rubella	190	4	194	71	123
Varicella	99	9	108	63	30
Nonqualified1	100	9	109	3	101
Unspecified2	5,425	9	5,434	8	5,398
Grand Total	**18,733**	**1,285**	**20,018**	**6,276**	**11,260**

[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

	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	98
Total	**20,018**

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	371	192	563
FY 2015	517	137	654
FY 2016	697	179	876
FY 2017	696	183	879
FY 2018	516	190	706
FY 2019	18	5	23
Total	**6,276**	**11,260**	**17,536**

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

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	78	$8,966,295.90	$1,693,320.34	9	$695,857.57	10	$547,157.64	$11,902,631.45
Total	**6,267**	**$3,697,120,367.12**	**$188,827,182.74**	**5,358**	**$80,725,028.12**	**434**	**$33,430,699.36**	**$4,000,103,277.34**

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 (SCCV)

December 6, 2018

CAPT Narayan Nair, MD
Director, Division of Injury Compensation Programs
Healthcare Systems Bureau (HSB)
Health Resources and Services Administration (HRSA)

HRSA Healthcare Systems

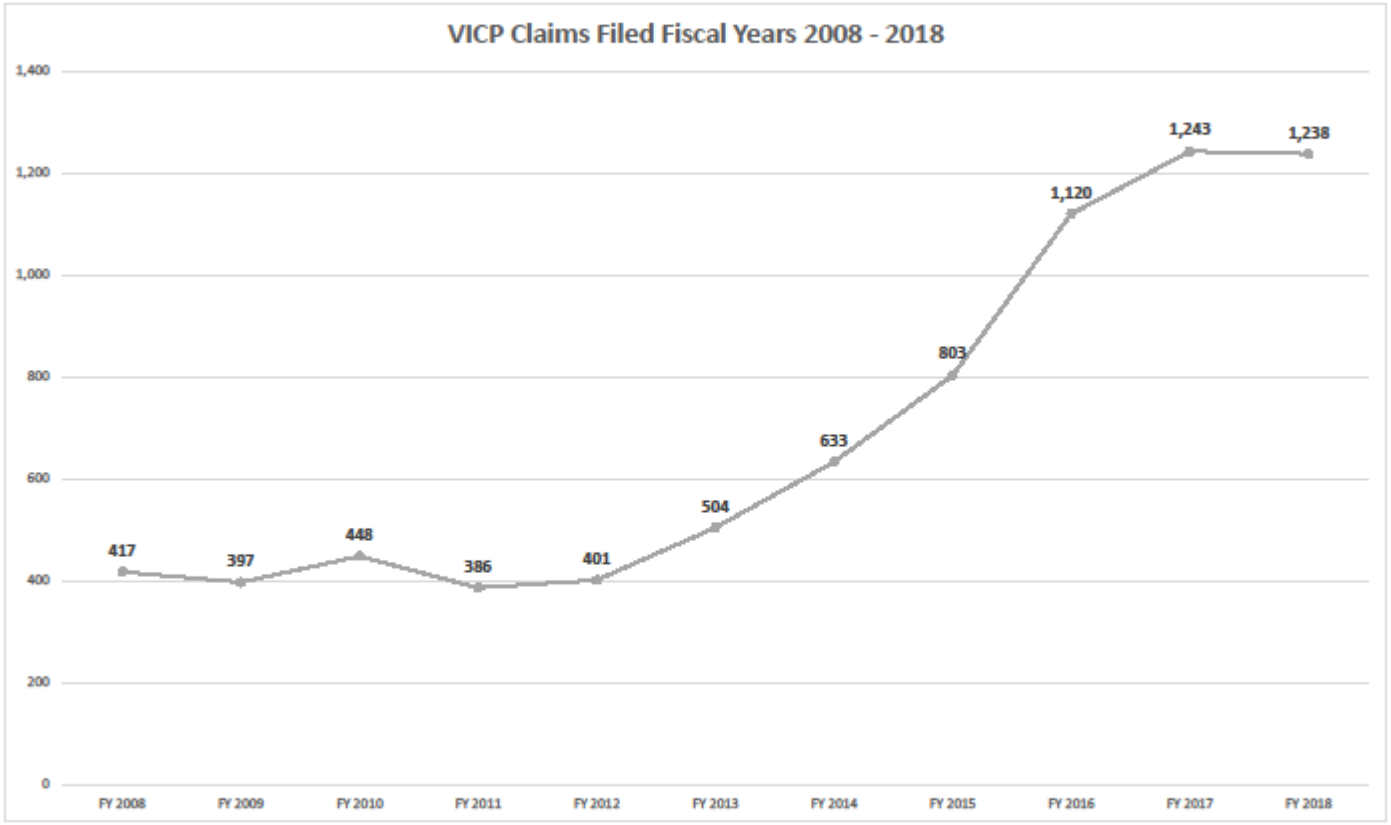
DICP Update
ACCV Meeting Highlights

- 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

DICP Update
Number of Petitions Filed as of November 30, 2018

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	203


VICP Claims Filed Fiscal Years 2008 - 2018
1,400
1,200
1,000
800
600
400
200
0
417
397
448
386
401
504
633
803
1,120
1,243
1,238
FY 2008
FY 2009
FY 2010
FY 2011
FY 2012
FY 2013
FY 2014
FY 2015
FY 2016
FY 2017
FY 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	203 (As of 12/3/18)	---	$9.2	0%

HRSA Healthcare Systems

Number of Claims Awaiting Review As of December 3, 2018

Fiscal Year	Claims Awaiting Review
2017	0
2018	547
2019	147
Total	694

Award Amounts Paid as of November 30, 2018

Fiscal Year	Petitioners' Award	Attorneys' Fees & Costs
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	$26,969,807
FY 2019	$41,278,232	$4,868,572

DICP Update

Number of Adjudications as of November 30, 2018

Fiscal Year	Compensable	Dismissed	Total
FY 2013	369	649	1,018
FY 2014	371	192	563
FY 2015	517	137	654
FY 2016	697	179	876
FY 2017	696	183	879
FY 2018	530	189	719
FY 2019	41	9	50

DICP Update

Adjudication Categories for Claims
FY 2017 – FY 2019 as of December 3, 2018

Adjudication Category	FY 2017	FY 2018	FY 2019
Compensable ❖Concession ❖Court Decision (includes proffers) ❖Settlement	**696 (100%)** 187 (27%) 47(7%) 462 (66%)	**531 (100%)** 183 (34%) 63 (12%) 285 (54%)	**42 (100%)** 17 (40%) 0 (0%) 25 (60%)
Not Compensable	**183**	**189**	**14**
Adjudication Total	**879**	**720**	**56**

HRSA Healthcare Systems

DICP Update
Vaccine Injury Compensation Trust Fund

- **Balance as of September 30, 2018**
  - $3,857,743,855
- **Activity from October 1, 2017 to September 30, 2018**
  - Excise Tax Revenue: $304,341,863
  - Prior Year Refunds: $4,738,788
  - Interest on Investments: $69,318,571
  - Total Income: $378,399,222
  - Interest as a Percentage of Total Income: 18.32%

Source: U.S. Treasury, Bureau of the Fiscal Service (November 6, 2018)

HRSA Healthcare Systems

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.

DICP Update
ACCV Meeting Information

- 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
Facebook: facebook.com/HHS.HRSA

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5.2

Report from the Department of Justice

December 6, 2018

Catharine E. Reeves
Deputy Director, Torts Branch

Statistics

Reporting Period: 8/16/18 – 11/15/18

I. **Total Petitions Filed in the United States Court of Federal Claims this reporting period: 375**

   A. Minors: 23

   B. Adults: 352

Statistics

Reporting Period: 8/16/18 – 11/15/18

II. Total Petitions Adjudicated this reporting period: 181

A. Compensated: 144

i. Cases conceded by HHS: 52

1. Decision awarding damages: 0
2. Decision adopting Proffer: 52
3. Decision adopting Settlement: 0

ii. Cases not conceded by HHS: 92

1. Decision awarding damages: 3
2. Decision adopting Proffer: 0
3. Decision adopting Settlement: 89

B. Not Compensated/Dismissed: 37

i. Decision dismissing Non-OAP: 36

ii. Decision dismissing OAP: 1

Statistics

Reporting Period: 8/16/18 – 11/15/18

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 6

Appeals: U.S. Court of Appeals for the Federal Circuit

Decided Cases

Appeals by Petitioner:

- *Gaiter v. HHS* (Entitlement): Affirmed
- *Rogero v. HHS* (Entitlement): Affirmed

Appeals by Respondent:

- None at this time

All decisions are available on the CAFC's website: http://www.cafc.uscourts.gov

Appeals: U.S. Court of Appeals for the Federal Circuit

Pending Cases

Appeals by Petitioner:

- *McCollum v. HHS* (Entitlement)
- *Oliver v. HHS* (Entitlement)
- *Olson v. HHS* (Entitlement)
- *R.K. v. HHS* (Attys' Fees and Costs)
- *Rogero v. HHS* (Entitlement)
- *Boatmon v. HHS* (Entitlement)
- *Moczek v. HHS* (Entitlement)

Appeals by Respondent:

- *McCulloch v. HHS* (Attys' Fees)
- *Fairchild v. HHS* (Interim Damages)

*Yellow cases are new this reporting period

Appeals: U.S. Court of Federal Claims

Decided Cases

Appeals by Petitioner:

- *A.M. v. HHS* (Entitlement): Affirmed
- *Austin v. HHS (*Entitlement): Affirmed
- *Bekiaris v. HHS* (Attys' Fees): Affirmed
- *Kreizenbeck v. HHS* (Entitlement): Affirmed

Appeals by Respondent:

- None at this time

All decisions are available on the CFC's website: http://www.uscfc.uscourts.gov

Appeals: U.S. Court of Federal Claims

Pending Cases

Appeals by Petitioner:

- *Bender v. HHS* (Entitlement)
- *Cottingham v. HHS* (Attys' Fees and Costs)
- *De Souza v. HHS* (Attys' Fees & Costs)
- *Dougherty v. HHS* (Entitlement)
- *L.P. p/o/g Petty v. HHS* (Attys' Fees & Costs)
- *Miles v. HHS* (Entitlement)
- *Skinner-Smith v. HHS* (Entitlement)
- *Gipple v. HHS* (Entitlement)
- *Heddens v. HHS* (Entitlement)
- *Maciel v. HHS* (Entitlement)

*Yellow cases are new this reporting period

Appeals: U.S. Court of Federal Claims

Pending Cases

Appeals by Petitioner:

- *Prepejchal v. HHS* (Entitlement)
- *Sanchez v. HHS* (Entitlement)
- *Webb v. HHS* (Entitlement)

Appeals by Respondent:

- None at this time

*Yellow cases are new this reporting period

Scheduled Oral Arguments

U.S. Court of Appeals for the Federal Circuit:

- None scheduled at this time

U.S. Court of Federal Claims:

- None scheduled at this time

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
1. Flu	Focal Onset Seizure Activity	6 Years
2. Flu	GBS; ADEM	5 Years 10 Months
3. Flu; Hep A; HPV	MS	5 Years 9 Months
4. Flu	SIRVA	5 Years 5 Months
5. Flu	GBS	5 Years 5 Months
6. DTaP	Seizures; Development Delays	5 Years 5 Months
7. Flu	Optic Neuritis	3 Years 10 Months
8. Flu	Necrotizing Muscle Myopathy; Death	3 Years 7 Months
9. Flu	Acute Cerebellitis; Cerebellar Ataxia	3 Years 5 Months
10. Flu	Dermatomyositis	3 Years 4 Months
11. Flu	GBS	2 Years 9 Months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
12. HPV	TM	2 Years 9 Months
13. Flu	Bell's Palsy	2 Years 7 Months
14. Flu	GBS	2 Years 2 Months
15. TDaP	MMF	2 Years 3 Months
16. Flu	TM	2 Years 2 Months
17. Hep A; MMR; Varicella	Oculomotor Nerve Palsy	2 Years 2 Months
18. MMR; TDaP; Hep A	ITP	2 Years 1 Month
19. Flu	Neurological Demyelinating Injury	2 Years 1 Month
20. Flu	Urticaria	2 Years 1 Month
21. Prevnar	SIRVA; Serum Sickness; Chronic Serum Sickness; Inflammatory Polyarthritis; Chronic Kidney Disease; Liver Complications; Acute Renal Failure; Chronic Renal Failure; Metabolic Acedosis; Microscopic Hematuria; Proteinuria; Renal Glycosuria; Colitis	2 Years 1 Month
22. Flu	GBS	2 Years 1 Month

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
23. Flu	SIRVA	2 Years
24. Flu	GBS/MFV	2 Years
25. Flu	GBS	1 Year 11 Months
26. Flu	CIDP	1 Year 10 Months
27. Flu	GBS	1 Year 10 Months
28. Flu	GBS	1 Year 9 Months
29. Flu	SIRVA	1 Year 9 Months
30. Flu	SIRVA	1 Year 9 Months
31. Flu	CIDP	1 Year 9 Months
32. Flu	GBS; CIDP	1 Year 9 Months
33. Flu	GBS	1 Year 9 Months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
34. Flu	GBS	1 Year 8 Months
35. Flu	GBS	1 Year 9 Months
36. Flu	GBS/MFV	1 Year 8 Months
37. Flu	TM	1 Year 7 Months
38. Flu	SIRVA	1 Year 7 Months
39. Flu	SIRVA	1 Year 7 Months
40. Flu	Chronic Myopericarditis	1 Year 7 Months
41. Flu	SIRVA	1 Year 7 Months
42. Flu	GBS; TM	1 Year 7 Months
43. Flu	SIRVA	1 Year 7 Months
44. Flu; Pneumococcal Conjugate	SIRVA; Bilateral Shoulder Injuries	1 Year 6 Months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
45. Flu	SIRVA	1 Year 6 Months
46. Flu	SIRVA	1 Year 6 Months
47. Flu	SIRVA	1 Year 5 Months
48. Flu	SIRVA	1 Year 5 Months
49. Flu	CIDP	1 Year 5 Months
50. Flu	TM	1 Year 5 Months
51. Flu	SIRVA	1 Year 5 Months
52. Flu	SIRVA	1 Year 5 Months
53. Flu	Brachial Neuritis; Parsonage Turner Syndrome	1 Year 3 Months
54. Flu	SIRVA	1 Year 5 Months
55. Flu	SIRVA	1 Year 4 Months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
56. Flu	SIRVA	1 Year 4 Months
57. Flu	GBS; Death	1 Year 4 Months
58. Flu	GBS	1 Year 4 Months
59. TD	SIRVA; Bursitis; Tendinopathy	1 Year 3 Months
60. Flu	GBS	1 Year 4 Months
61. TDaP	SIRVA	1 Year 4 Months
62. Flu; Pneumococcal Vaccine	Bilateral Shoulder Pain; Rash	1 Year 3 Months
63. Flu	SIRVA	1 Year 4 Months
64. Flu	SIRVA	1 Year 3 Months
65. Flu	SIRVA	1 Year 4 Months
66. Flu	TM	1 Year 3 Months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
67. TDaP	SIRVA	1 Year 2 Months
68. Flu; TDaP	SIRVA	1 Year 3 Months
69. TDaP	SIRVA	1 Year 2 Months
70. TDaP; Flu	SIRVA	1 Year 3 Months
71. Flu	SIRVA	1 Year 2 Months
72. Flu	GBS	1 Year 2 Months
73. Flu	SIRVA	1 Year 2 Months
74. Flu	SIRVA	1 Year 1 Month
75. Flu	SIRVA	1 Year 2 Months
76. Flu	Visual Disturbance; Dizziness; Fatigue; Pain; Cognitive Difficulties	1 Year 2 Months
77. TDaP	SIRVA	1 Year 1 Month

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
78. Flu	SIRVA	1 Year
79. Flu	SIRVA	1 Year 1 Month
80. Flu	GBS; Polymyositis	1 Year 1 Month
81. Flu	SIRVA	1 Year 1 Month
82. Flu	SIRVA	1 Year 1 Month
83. Flu	SIRVA	1 Year 1 Month
84. Flu	SIRVA	1 Year 1 Month
85. Flu	SIRVA	1 Year
86. Flu	SIRVA	1 Year
87. Flu	SIRVA	11 Months
88. Meningococcal Vaccine; Prevnar	Pyoderma Gangrenosum; Dermatis	11 Months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 8/16/18 – 11/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
89. TDaP	SIRVA	10 Months

Appendix

Glossary of Terms

- **Petitions Adjudicated:** Final judgment has entered on the petition in the United States Court of Federal Claims.
- **Final Judgment:** Clerk of Court, United States Court of Federal Claims, enters judgment awarding or denying compensation.
- **Compensable:** Petitioner received an award of compensation, which can be achieved through a concession by HHS, settlement, or decision on the merits by the special master, United States Court of Federal Claims.
- **Conceded by HHS:** HHS concluded that a petition should be compensated based on review and analysis of the medical records.

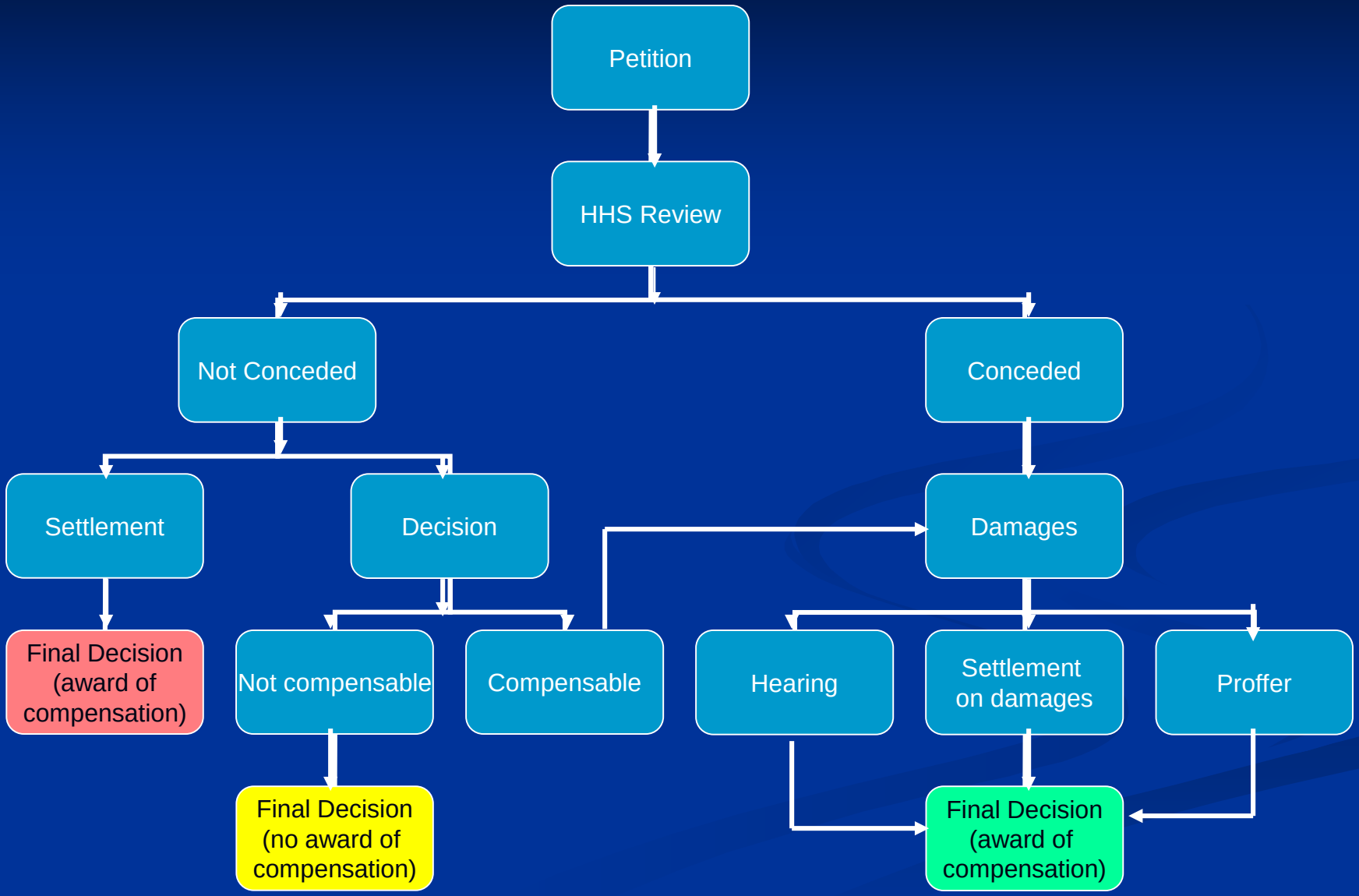
Glossary of Terms

- **Settlement:** Petition is resolved via a negotiated settlement between the parties, and results in the filing of a stipulation that memorializes the terms of the settlement.
- **Decision:** Special Master issues decision on the merits of the petition.
- **Non-compensable/Dismissed:** Petition dismissed.
- **Proffer:** After discussions between the parties regarding a reasonable amount of damages, respondent will file a suggested award of compensation, known within the Program as a "Proffer," which is also agreed to by petitioners and their counsel. The Proffer is reviewed by the presiding special master to determine that it represents a reasonable measure of the amount of the award and describes compensation pursuant to 42 U.S.C. § 300aa-15(a). The special master issues a final decision consistent with the terms of the Proffer.

Glossary of Terms

- **Affirmed:** Case has been reviewed on appeal, and the court on appeal agreed with the decision of the lower court.
- **Reversed:** Case has been reviewed on appeal, and the court on appeal disagreed with the decision of the lower court. The court on appeal typically provides reasons for reversing, and that decision becomes the law of the case, absent further appeal.
- **Remanded:** Case has been reviewed on appeal, and the reviewing court has a problem with the decision, and sends it back to the lower court. Typically, a case is remanded with a specific question or issue for the lower court to address.
- **Vacated:** Case has been reviewed on appeal, and the reviewing court has voided the lower court's decision.

Petition Processing in the Office of Special Masters



Levels of Appeal in Vaccine Act Cases

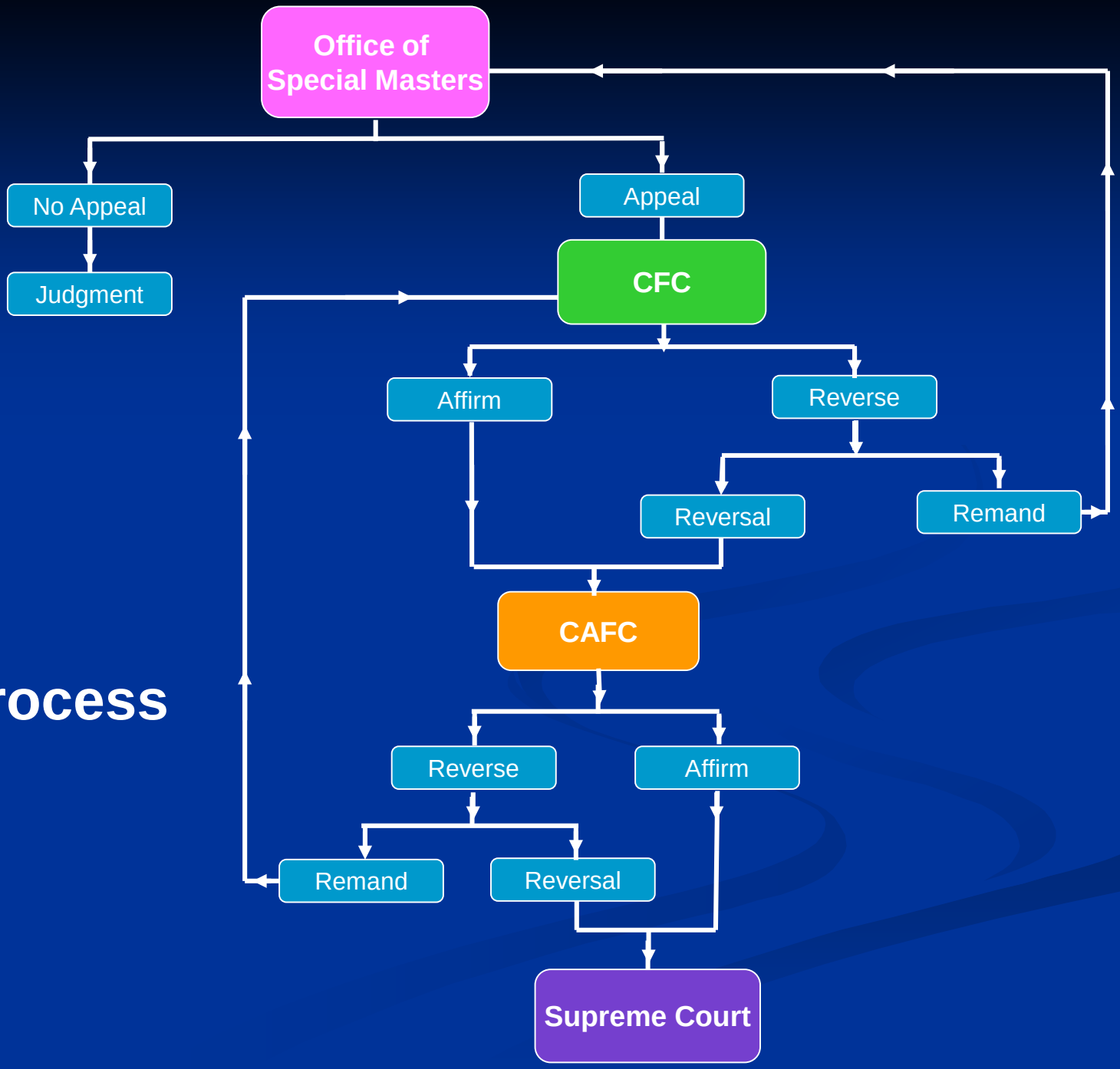
U.S. Supreme Court

U.S. Court of Appeals for the Federal Circuit

U.S. Court of Federal Claims

Office of Special Masters

Appeals Process



5.3

Centers for Disease Control and Prevention Immunization Safety Office Update

Michael M. McNeil, MD, MPH
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)

Advisory Commission on Childhood Vaccines (ACCV)
December 6, 2018

Disclaimer

- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the CDC

Topics

- Presentations at October 2018 ACIP meeting*
- Selected publications

*https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2018-10-508.pdf

ACIP Update – Use of hepatitis A vaccines for routine vaccination of the homeless- Vote

- Routine 2-dose hepatitis A vaccination of the homeless would reduce both the hepatitis A infection risk of this vulnerable population and risk of large-scale outbreaks
- All persons aged 1 year or older experiencing homelessness should be routinely immunized against hepatitis A

  - **Yes - Unanimous vote (13)**

ACIP Update – Human Papillomavirus Vaccine: Study of primary ovarian insufficiency (POI) and adolescent vaccination

- 199,078 females aged 11-34 years enrolled at the Kaiser Northwest VSD site from August 2006-December 2014
- 58,871 received quadrivalent HPV vaccine (4vHPV); 119,078 tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap), 46,231 meningococcal conjugate vaccine (MenACWY), 84,783 inactivated influenza vaccine (IIV)
- Age-adjusted POI hazard ratios for
  - 4vHPV: 0.3 (0.07-1.36)
  - Tdap: 0.88 (0.37-2.10)
  - MenACWY: 0.94 (0.27-3.23)
  - IIV: 1.42 (0.59-3.41)
- No evidence of increased risk of POI after HPV or other adolescent vaccinations

Naleway AL, et al. Primary Ovarian Insufficiency and Adolescent Vaccination. Pediatrics Sept.2018: 142(3)

ACIP Update – Human Papillomavirus Vaccine: Expanded age range for 9-valent HPV vaccine (9vHPV)

- Data submitted to FDA in support of expanded age range through 45 years including from a randomized clinical trial of quadrivalent HPV (4vHPV) vaccine which found high efficacy in women naïve to vaccine type
- U.S. data to inform policy considerations for mid-adult vaccination
  - HPV incidence decreases with ageing, but new infections can occur in adults
  - Many adults are already exposed to a 9vHPV type but not to all 9vHPV types
  - 4vHPV post licensure data from 11 studies in 6 countries shows lower vaccine effectiveness with increasing age at vaccination
  - Preliminary data from three US health economic models of nona-valent HPV (9vHPV) vaccine is mixed in terms of benefits and review by ACIP is ongoing

*

ACIP Update – Influenza Vaccine Effectiveness in Preventing Hospitalizations during Pregnancy

- PREVENT Network
  - Collected information on acute respiratory or febrile illness (ARFI) hospitalizations in pregnant women 18-50 years, identified by ICD-9/ICD-10 discharge diagnosis codes and contemporaneous clinician ordered real time reverse transcription polymerase chain reaction (rRT-PCR) test for influenza
  - Influenza vaccine effectiveness calculated using test negative design
- Findings
  - Across sites and seasons (2010-2016) influenza vaccines had the potential to prevent 40% of influenza-associated hospitalizations during pregnancy

ACIP Update – Half vs Full Dose Influenza Vaccine in Children

- Study evaluated the safety and immunogenicity of 0.5 ml dose of Fluzone Quadrivalent (Sanofi Pasteur) vs. approved 0.25 ml dose in children aged 6-35 months
- Phase IV, randomized, observer-blinded, 2-arm, multicenter study in the US [cohort of 2,190 healthy children 6-35 months]
- Findings
  - Safety profile of a 0.5 ml (full-dose) is similar to 0.25 ml (half-dose) and may be more immunogenic
  - Clinical trial results are consistent with findings from other studies
- Biologic license application (BLA) submitted to FDA to permit use of a 0.5 ml dose of Fluzone Quadrivalent in children as young as 6 months of age

ACIP Update – Pertussis Vaccines

- Workgroup has convened to reconsider repeat Tdap vaccination
  - Application for FDA label change to remove “single use” language
    - Manufacturer of one product filed a biologic license application and review expected to be completed by January 2019
    - Many providers not stocking both Td and Tdap vaccines; thus allowing Tdap for the decennial Td booster would be easier for providers
  - Findings of revaccination studies of Adacel by Sanofi Pasteur (Td537) and Boostrix by GSK (009 and 012) suggest these vaccines are safe and effective when administered 8-12 years following prior Adacel vaccination or 9-10 years after prior Boostrix administration

Selected publications

Recent Publication

- 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
  - Social media and online search engines are useful resources for identifying reports of cluster anxiety-related AEFIs and the geographic location of the researcher is an important factor to consider when conducting these studies. Solely relying upon traditional peer-reviewed journals may seriously underestimate the occurrence of such cluster events.
  - Available at https://doi.org/10.1016/j.vaccine.2018.08.064

Recent Publication

- 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 Recomm Rep 2018 Aug 24; 67(3):1-20**
  - This report focuses on the recommendations for use of vaccines for the prevention and control of influenza during the 2018–19 season in the United States. A background document containing further information and a brief summary of these recommendations are available at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html.
  - Available at https://www.cdc.gov/mmwr/volumes/67/rr/rr6703a1.htm?s_cid=rr6703a1_w

Recent Publication

- 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) Epub 2018 Aug 21
  - Investigators did not find a statistically significant elevated risk of POI after HPV, Tdap, IIV, or MenACWY vaccination in this population-based retrospective cohort study. These findings should lessen concern about POI risk after adolescent vaccination.
  - Available at http://pediatrics.aappublications.org/content/early/2018/08/17/peds.2018-0943.figures-only

Recent Publication

- 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.
  - These data continue to support the generally favorable safety profile of JE-VC. Reporting rates of adverse events were similar to those of the previous analysis. Although reporting rates of adverse events in children could not be calculated, there were low numbers of reported events in this age group. Post-licensure adverse event surveillance for this relatively new vaccine continues to be important to monitor adverse event reporting rates and identify possible rare serious events.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/29891351

Recent Publication

- 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.
  - Most women who received maternal HepB did not have high-risk indications for vaccination which suggests providers are comfortable with maternal vaccination and may prefer to take opportunities to vaccinate even in the absence of a high-risk indication for vaccination. No increased risk for the adverse events that were examined were observed among women who received maternal HepB or their offspring.
  - Available at https://doi.org/10.1016/j.vaccine.2018.08.074

Recent Publication

- 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
  - Available at https://www.researchgate.net/publication/328537603_Adverse_events_following_purified_chick_embryo_cell_rabies_vaccine_in_the_Vaccine_Adverse_Event_Reporting_System_VAERS_in_the_United_States_2006-2016

Recent Publication

- 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.
  - Tdap was well-tolerated in pregnant and nonpregnant women. Pregnant women were more likely to report moderate/severe pain at the Tdap injection-site compared with nonpregnant women, but did not necessitate medical visits. Prior Tdap receipt did not increase occurrence of moderate/severe local or systemic reactions in pregnant women. Serologic responses to all vaccine antigens were robust.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/30219367

Recent Publication

- 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)
  - Investigators did not identify any new or unexpected safety concerns in this review of 2vHPV reports to VAERS.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/30229993

Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

5.4

National Institutes of Health Update

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

December 2018

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

September 5, 2018

Clinical Trial Testing Topical Cream Plus Influenza Vaccine in Progress

Cream Regimen Could Boost Immunity

- Phase 1 clinical trial examining whether imiquimod cream can boost body's immune response to H5N1 influenza vaccine
- Enrolling 50 healthy adults ages 18-50 years
- Conducted by NIAID-funded Vaccine and Treatment Evaluation Unit (VTEU) site at Baylor College of Medicine

U.S. Department of Health and Human Services

NIH News

National Institutes of Health

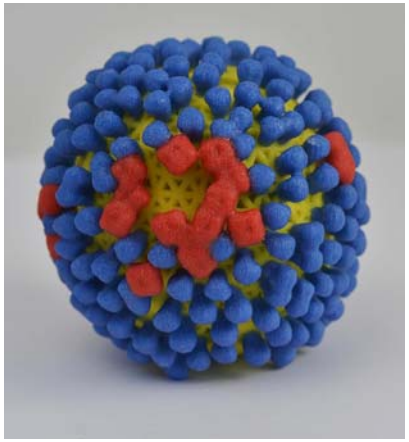
National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov

September 17, 2018

Experimental nasal influenza vaccine tested in kids, teens

NIH-supported Phase 1 trial of potential broadly protective vaccine



Credit: NIAID

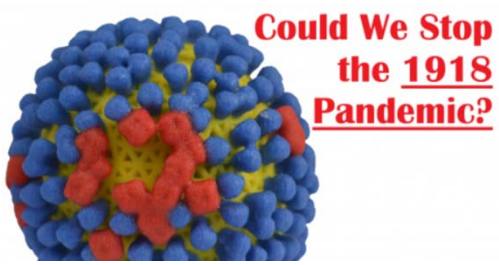
- Phase 1 trial testing the safety and immune-stimulating ability of an experimental nasal influenza vaccine
- Conducted by NIAID-funded VTEU site at Saint Louis University

1918 Influenza Pandemic

Video: Could the 1918 Influenza Pandemic Happen Again?

November 1, 2018

Could an influenza virus like the one which caused the 1918 pandemic emerge today? If it did, could we stop it? In a short video, NIAID experts discuss how seasonal and pandemic influenzas change over time, and how researchers are working to improve influenza vaccines.

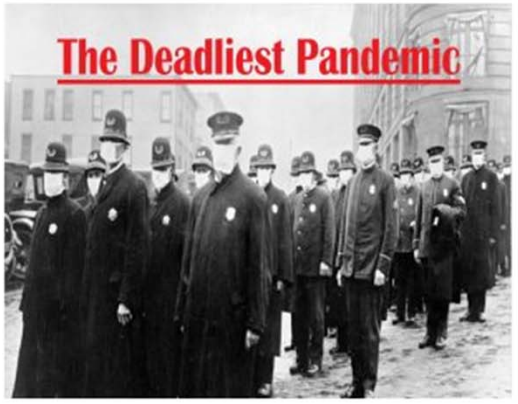


Credit: NIAID

Video: What Was the 1918 Influenza Pandemic?

October 30, 2018

In this short video, NIAID experts describe why the 1918 influenza was the most deadly pandemic in all recorded history, and how scientists are still studying it today.



Original image from the National Archives

https://www.niaid.nih.gov/news-events/blog

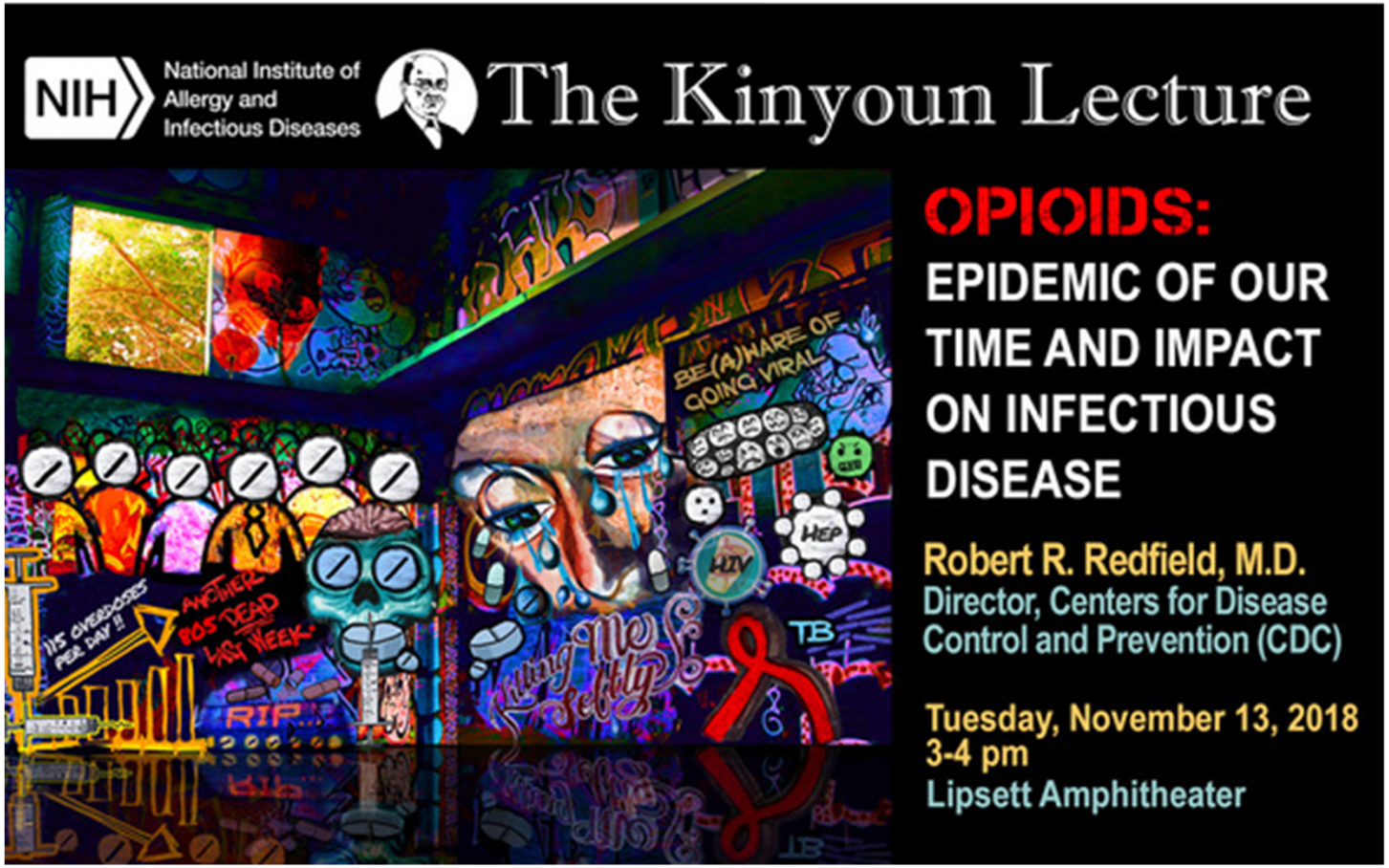
Pediatric Clinical Research Partnership

- Research partnership between NIAID and Children's National Health System launched in 2017
  - To develop and conduct collaborative clinical research studies focused on young children with allergic, immunologic, infectious and autoinflammatory diseases
- Inaugural symposium held on Sept. 17, 2018

Informational Webinar:
New NIAID Infectious Diseases Clinical Trial Funding Opportunities

FAQs and presentations are posted on the NIAID website:
https://www.niaid.nih.gov/research/future-infectious-disease-research

2018 Kinyoun Lecture – Opioids: Epidemic of Our Time and Impact on Infectious Disease



https://videocast.nih.gov/ Search: Kinyoun Lecture

5.5

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

December 6, 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)

Afluria Quadrivalent

- In October 2018, the FDA approved a supplement to the Biologics License Application (BLA) for Afluria and Afluria Quadrivalent Influenza Vaccine to extend the pediatric age range to person 6 months of age – 59 months of age.
  - The vaccine was previously indicated for persons 6 years of age and older.

Gardasil

- In October 2018, the FDA approved a supplement to the BLA for Human Papillomavirus 9-valent Vaccine, Recombinant (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
  - Boys and men 16-26 years of age

Thank you!


FDA
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ADMINISTRATION

5.6

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Update from the National Vaccine Program Office (NVPO)

Advisory Commission on Childhood Vaccines December 6, 2018 Meeting

Ann Aikin
Communication's Director
Acting NVAC Designated Federal Officer
National Vaccine Program Office

December 2018

National Vaccine Advisory Committee (NVAC)– September Meeting

- The meeting focused broadly on vaccine innovation and included
  - panel presentations on public-private partnerships related to vaccine development, valuing vaccines, and advances in vaccination technologies
  - spotlight sessions on Cytemegalovirus (CMV) vaccines in the pipeline, the new Shingrix vaccine, and funding unmet needs projects
- Each meeting day concluded with a series of presentations highlighting opportunities to prevent HPV-related cancers, as well as agency and liaison updates and public comment.
- The meeting recording, slides, and written summary are available online at https://www.hhs.gov/nvpo/nvac/meetings/2018/09-12/index.html.

Future NVAC Meetings

- The next public meeting will be a virtual meeting on February 5, 2019.

- The agenda will be made available online closer to the meeting date at https://www.hhs.gov/nvpo/nvac/meetings/index.html.

#WhyIFightFlu

To encourage flu vaccination this season, we worked with the Assistant Secretary for Health, Admiral Brett Giroir, to use social media to tell people why they should get their flu vaccine.

- HHS Blog Post
- Social Media Outreach
- Supporting materials

Sparking Regional Action to Implement the NAIP

- Adult immunization rates are low and—recognizing this need—NVPO worked with partners to develop the National Adult Immunization Plan in 2016.
- To spark action on the plan, in 2018 we worked with HHS Regional Offices to hold six meetings across the country on adult immunization topics like financing, quality improvement, and communication strategies. (Regions 3, 5, 6,7,8, 9)
- In these meetings, we engaged federal and non-federal stakeholders to take action on adult immunization through a one-day stakeholder meeting focused on developing regional approaches to improving adult immunization rates.
- The meetings were very successful—engaging nearly 300 diverse partners across the nation. And, they continue to have impact with many states and regions continuing to meet to make progress on these issues. A final meeting summary from 2018 is available on our website at: www.hhs.gov/nvpo/national-adult-immunization-plan/show-support-for-naip
- NVPO will continue the meeting series in 2019 with four HHS Regional Offices.

Lessons Learned
(First Year of Initiative)

- Despite operating within resource-constrained environments, stakeholders across the country are eager to improve adult immunization rates through collaboration and coordination.
- Inter-regional knowledge sharing
- Value of remote participation
- Increased visibility of NVPO and the NAIP
- Engaged new and existing partners
- Maximized and leverage opportunities and work already being conducted by stakeholders
- Regional offices are a powerful tool for OASH and should be an integral part of our work

NVAC NATIONAL VACCINE ADVISORY COMMITTEE

Ann Aikin, MA
National Vaccine Program Office

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@HHSvaccines

6

DRAFT

Recommendation for Increased Funding to Support Additional Special Masters, Staffing and/or Funding Resources for the National Vaccine Injury Compensation Program (VICP)

Background

From FY 2013 to FY 2017, the number of VICP claims filed has more than doubled from 504 to 1,243, as shown in Table 1. This dramatic upsurge is primarily due to the increase in the number of claims filed resulting from receipt of the seasonal influenza vaccine which accounts for approximately 60 percent of claims filed annually. Because of the large number of influenza vaccines administered each year, when the influenza vaccine was added to the Vaccine Injury Table (Table), many more people became eligible to file a claim with the VICP.

Table 1. Five-Year Trend in Number of Claims Filed versus Health Resources and Services Administration (HRSA) Administrative Costs

Fiscal Year (FY)	No. of Claims Filed	HRSA Administrative Funding *($ in millions)*
2013	504	$6.48
2014	633	$6.46
2015	803	$7.50
2016	1,120	$7.50
2017	1,243	$7.75

We strongly agree with inclusion of the influenza vaccine in the VICP, but wish to note the resulting increase in workload as a consequence of the addition of this vaccine. Due to the significant increase in VICP claims filed annually, the workload for components of HRSA, Department of Justice (DOJ), and the Office of the Special Masters (OSM) of the U.S. Court of Federal Claims (Court) involved in the VICP has more than doubled since 2013. HRSA, DOJ and the Court struggle to adjudicate/resolve claims efficiently, fairly and quickly. But the backlog of unresolved claims is lead to delays in compensation. The Court is concerned that the gap between the number of claims filed each month as compared to the number of claims closed each month will continue to widen.

The present level of funding limits the ability of HRSA and DOJ from hiring medical officers and attorneys who are necessary to resolve the backlog of claims. Another issue that would need to be addressed is that the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) contains a provision limiting the number of special masters who can be appointed, which further contributes to the backlog.

The personnel shortage requires a permanent solution because HRSA, DOJ and the Court expect that VICP claims will continue to increase. The majority of VICP claims filed are for adults claiming seasonal flu vaccine-related injuries. The Centers for Disease Control and Prevention (CDC) reports that the number of adults and children administered seasonal flu vaccine increases every year; this suggests that the increase in the volume of claims filed with the VICP is not a temporary trend and will continue to grow. For example, HRSA anticipates 1,720 claims filed in FY 2019, a 25% increase over the projected FY 2018 level of 1,380 claims filed. The Final Rule modifying the Table was published on March 21, 2017, and, under the Vaccine Act, petitioners

have two years from the effective date of Table changes to file claims for injuries or deaths that occurred up to eight years preceding the Table modification date. The FY anticipated number of FY 2019 claims accounts for this statutory deadline for filing claims related to specific changes to the Table.

In addition, the number of claims filed is expected to continue to increase because the 21st Century Cures Act (Cures Act) which was enacted in December 2016 requires the Secretary to revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). It also permits both a woman who received a covered vaccine while pregnant and any live-born child who was in utero at the time such woman received the vaccine to be considered persons to whom the covered vaccine was administered. The Cures Act also mandates that a covered vaccine administered to a pregnant woman constitutes more than one vaccine administration—one to the mother and one to each live-born child who was in utero at the time the woman received the vaccine.

While the number of claims filed has more than doubled over the last five years, HRSA's administrative funding has increased by only 19 percent from FY 2013 to FY 2017, as shown in Table 2. The size of DOJ's staff has increased by only 35% since FY 2012, even though there has been a 300% increase in the number of cases filed since FY 2012, when compared to the number of cases filed between FY 2006 and FY 2012. Beginning in FY 2017, the VICP experienced a backlog of claims because the increased number of claims filed exceeded the level of funding available to conduct medical reviews. In FY 2018, HRSA's administrative resources increased by 19 percent as compared to FY 2017 funding. While the HRSA FY 2018 budget increase allows the VICP to review more claims than in FY 2017, the unprecedented growth in claims filed continues to outpace funding levels. The backlog will continue to increase, resulting in delays in compensating petitioners since claims are on a waiting list for more than six months pending review.

Even though VICP claims have increased, resources for HRSA, DOJ, and the Court have not had commensurate increases. Without such increases in funding, specifically to hire additional staff, the rise in the number of claims filed will result in continued and growing delays in compensation to petitioners.

The Vaccine Injury Compensation Trust Fund (Trust Fund) provides funding to compensate vaccine-related injury or death claims. It also provides funding to pay the administrative expenses for HRSA, DOJ and the Court. However, Congress is required to appropriate separate funding from the Trust Fund for each of these Federal entities as demonstrated in Table 2 on the next page.

Table 2. Congressional Appropriations for HRSA, DOJ and the Court's Administrative Expenses

Fiscal Year	HRSA	DOJ	Court	Total
2014	6,464,000	7,833,000	5,327,000	19,624,000
2015	7,500,000	7,833,000	5,423,000	20,756,000
2016	7,500,000	9,358,000	6,050,000	22,908,000
2017	7,750,000	10,000,000	6,510,000	24,260,000
2018	9,200,000	10,000,000	8,230,000	27,430,000

The ACCV recommends that the Secretary support efforts to increase funding to provide more resources, particularly to hire more staff for HRSA, DOJ and the Court, specifically the 1) Division of Injury Compensation Programs, HRSA, 2) Vaccine Litigation Section, Torts Branch, Civil Division, DOJ and 3) OSM of the Court.

Recommendation 1

The ACCV recommends that the Secretary propose an amendment to the Vaccine Act to authorize appointing eight or more special masters. The current provision states:

> *"There is established within the United States Claims Court an office of special masters which shall consist of not more than 8 special masters."* (Sec. 2112(c)(1) of the Public Health Service Act [42 U.S.C. § 300aa-12(c)(1)])

The proposed provision would state:

> *"There is established within the United States Claims Court an office of special masters which shall consist of at least 8 special masters."*

Recommendation 2

The ACCV recommends that the Secretary support efforts to increase the annual appropriations of the HRSA, DOJ and the OSM of the Court to provide the necessary resources to implement the VICP.