**ADVISORY COMMISSION ON CHILDHOOD VACCINES**
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**June 15, 2018**


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# *ADVISORY COMMISSION ON CHILDHOOD VACCINES*

## ***Agenda***

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)**

# Teleconference and Adobe Connect

## Friday, June 15, 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 December 2017 & March 2018 Minutes | Ms. Beth Luthy, Chair |
| 10:25 AM | Work group update | Work group Chair |
| 10:55 AM | Report from the Division of Injury Compensation Programs | Dr. Narayan Nair<br>Director, DICP |
| 11:15 AM | Report from the Department of Justice | Ms. Catharine Reeves,<br>Deputy Director, Torts Branch, DOJ |
| 11:35 AM | Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities | Dr. Maria Cano<br>CDC |
| 11:50 PM | Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities | Dr. Barbara Mulach<br>NIAID, NIH |
| 12:00 PM | Lunch Break | |

| Time | Agenda Item | Presenter |
|---|---|---|
| 1:00 PM | Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities | CDR Valerie Marshall<br>CBER, FDA |
| 1:15 PM | Update from the National Vaccine Program Office (NVPO) | Dr. Karin Bok<br>NVPO |
| 1:30 PM | Public Comment (follows the preceding topic and may commence earlier or later than 1:30 pm) | |
| 1:45 PM | Future Agenda Items/New Business | Ms. Beth Luthy, Chair |
| 1:55 PM | Adjournment of the June 15, 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
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**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 & 7, 2018
December 6 & 7, 2018

# 2.1

**Advisory Commission on Childhood Vaccines**

**March 8, 2018**

**105th Meeting**

**Members Present**

Karlen E. (Beth) Luthy, D.N.P., Chair ('18)
H. Cody Meissner, MD, Vice Chair ('19)
Kathleen F. Gaffney, PhD, RN ('19)
John Howie, J.D., ('19)
Dino S. Sangiamo, J.D. ('19)
Tina Tan, MD, ('19)
Alexandra Stewart, J.D. ('18)
Martha Toomey ('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 Chair Report from Beth Luthy, Chair**

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 that all commission members were present, except for Alexandra Stewart, who was expected to join the meeting at a later time. Further introductions confirmed that Narayan Nair and Andrea Herzog (DICP staff), Andrea Davey (OGC), Catharine Reeves (DOJ), and ex officio members Valerie Marshall (FDA), and Tom Shimabukuro (ISO/CDC) were also present.

**Public comments related to the agenda**

Theresa Wrangham, representing the National Vaccine Information Center (NVIC), asked that some of her comments at the December 8, 2017 meeting of the ACCV be clarified. Specifically, with regard to the Institute of Medicine (IOM) study mentioned during the meeting, including comments from HRSA representatives, she said the record should include an explanation of how the IOM graded studies that were relied on to develop the report recommendations. The record should include a clarification of the causality and the quality of the science relied on. Ms. Wrangham stated that for most vaccine adverse events there is a lack of quality research or an absence of research. She suggested that there should be confirmation that the information presented by HRSA in this area was evaluated by the IOM, if it was reviewed.

Ms. Wrangham stated that during the December 2017 ACCV meeting she recommended that any individual from the public who presented the request for revision be allowed to present, on the record, a rationale for requesting the revision. Ms. Wrangham commented that this

recommendation was not accurately reflected in the minutes of the December meeting. However, she did commend the commission for inviting such public comment.

There were no other public comments about the agenda.

**Nomination and vote for ACCV chair and vice chair**

Ms. Luthy invited nominations for vice chair and for chair. She offered the first nomination for vice chair, Cody Meissner. There were no objections to the nomination and no other nominations were forthcoming. Ms. Luthy invited nominations for chair, and Ms. Toomey nominated Ms. Luthy. There were no objections and no other nominations were forthcoming. Ms. Toomey made a motion to accept Ms. Luthy's nomination. Each commissioner present was polled, and the vote was unanimous. Ms. Luthy called for a vote on the nomination of Dr. Meissner. Each commissioner present was polled, and the vote was unanimous.

**Approval of the December 8, 2017 minutes**

Ms. Luthy asked if staff was able to provide any guidance about the exceptions voiced by Ms. Wrangham, and Ms. Herzog suggested that it would require review of the minutes. She suggested deferring approval of the minutes until the next ACCV meeting so that the transcript and the audio recording of the meeting discussion could be reviewed.

Ms. Toomey stated that she had an issue related to the minutes. During the meeting she asked several times for information about the origin of the reports on which the commission based its recommendations, and the identity of the individual or agency funding the reports. She said she did not receive a response to the question during the meeting, and the minutes did not reflect her concern. Ms. Toomey commented that a specific question concerned the addition of tics to the Vaccine Injury Table (Table) and asked at the meeting about the report that concerned tics. She added that she felt there was insufficient research about tics and about PANDAS.

Ms. Luthy restated the concerns that should be reflected in the minutes. Ms. Toomey added that there was insufficient information about those two injuries and that the commission's understanding of the issue was incomplete. She felt the commission's treatment of the recommendation appeared to be dismissive. Ms. Luthy agreed that Ms. Toomey's point of view should be included in the minutes.

Dr. Meissner commented that Dr. Nair did a credible job in presenting the known facts about PANDAS, considering there is very little data in the literature about the condition. He felt the commission carefully followed the ACCV Guiding Principles. He added that the issue is not the existence of PANDAS, but that there is no evidence of an association between immunization and PANDAS.

Ms. Luthy stated that the December minutes should accurately reflect the comments of both Ms. Wrangham and Ms. Toomey. Therefore, the approval of the minutes should be deferred until proper review of the meeting proceedings is completed. There was consensus that approving the December 2017 ACCV meeting minutes should be tabled.

**Report from the DICP, Dr. Narayan Nair, Director**

Dr. Nair congratulated Ms. Luthy and Dr. Meissner on their selection to lead the ACCV as chair and vice chair. He briefly reviewed the highlights of his presentation and provided a brief discussion of the statistics related to claims filed since 2008. From 2008 to 2012, the average number of claims filed annually was 410. Since then the number has been steadily increasing; in Fiscal Year 2017, the number of claims filed with the DICP was 1,243. Through March 1, 2018 of the current fiscal year, 496 claims have been filed. Dr. Nair showed a chart of the comparison of the number of claims files versus the administrative funding for HRSA only. There was a steady year to year increase claims filed, but not corresponding increases in funding for HRSA.

| Fiscal Year | Claims Filed | % increase | HRSA funding | % increase |
|---|---|---|---|---|
| 2014 | 633 | 26% | $6.46 million | -.03 |
| 2015 | 803 | 27% | $7.50 million | 16% |
| 2016 | 1,120 | 39% | $7.50 million | no increase |
| 2017 | 1,243 | 11% | $7.75 million | 3% |

Currently, there is a backlog of 539 claims that have medical records awaiting for review by DICP Medical Officers. 394 claims filed in 2017, and 145 claims filed to date in FY 2018. Total petitioners' awards have increased each year since 2014 and were about $252.3 million in 2017 and about $81.5 million to date in FY 2018. Total attorneys' fees and costs were $29.9 million in FY 2017 and $12.5 million to date in FY 2018.

In FY 2017, there were 877 claims adjudicated; 696 were deemed compensable and 181 were dismissed. To date in FY 2018, those numbers are 186 compensable and 86 dismissed. Of the compensable cases in FY 2017, 183 were concessions, 46 were the result of court decisions or proffers, and 467 were resolved by settlement between the parties involved. To date, in FY 2018, 248 cases have been adjudicated: 67 were resolved by concession, 22 by court decision, 97 by settlement and 62 were not compensable.

Finally, the balance in the Vaccine Injury Compensation Trust Fund was $3.7 billion on December 31, 2017. There was revenue of $59 million from excise taxes and $16 million from interest on the fund, for a total revenue of $75.6 million.

Significant activities of the DICP include a Notice of Proposed Rulemaking to implement maternal immunization provisions in the 21st Century Cures Act of 2016, specifically adding vaccines recommended for routine use in pregnant women as a category of covered on the Table, is currently under review. In the area of outreach, presentations have been made to the Biotechnology Innovation Organization and to the Johns Hopkins Bloomberg School of Public Health.

Dr. Nair concluded his presentation by providing contact information and Internet references to commission staff, the ACCV, DICP and HRSA.

During discussion, Dr. Nair clarified that the backlog of 539 claims from FY 2017 and FY 2018 was caused due to significant increases in claims filed and the inability to hire staff and contractors to conduct medical reviews of claims before they are adjudicated. There are two medical teams that review incoming claims, one for adults and one for children, and DICP also utilizes the services of outside contract reviewers to manage the case load. The backlog began in

2017, when claims outpaced the ability of staff to review them. Asked about the time to process a claim to final adjudication, Dr. Nair indicated that the average time is about two years.

There was a request to clarify the term "non-autism" case since the term suggests that there are also autism cases. Dr. Nair explained that about 15 years ago, a large number of claims were filed alleging autism was caused by vaccines. The U.S. Court of Federal Claims (Court) chose a fraction of those cases for review, which resulted in a determination that vaccines were not a factor and did not cause autism. Dr. Nair stated that the program has never compensated an individual based on a claim that autism was the primary injury. There have been individuals compensated who had diagnoses of autism in addition to other conditions.

Mr. Howie commented that the timeline from filing a claim to resolution for a civil case is much shorter than that of a vaccine injury compensation claim. In the latter instance, the attorneys are required to be able to present their case when the claim is filed, which is a major part of the legal argument. Mr. Howie asserted that the pre-litigation effort required to file a petition with the VICP is much greater than in a civil suit, which can be filed almost the same day as the alleged civil injury, after which the legal case is developed. If the backlog continues, or gets longer, the time to resolution will be lengthier.

Mr. Howie asked if a determination has been made as to how many reviewers will be needed to reverse or eliminate the backlog, whether new reviewers are being recruited, and whether the commission's previous recommendation to add staffing can be accomplished. Dr. Nair stated that the President's budget proposal includes additional funds for the program operations. Requests for additional funding in the program budget has been communicated to Congress, but if there is no increase or if the increase is inadequate the backlog will continue. Dr. Nair stated that his task is not to direct the commission with regard to any action, but to provide information that will help the commission in its deliberative process. He added that an increase in staffing in proportion to the increase in the caseload would alleviate the backlog.

There was a question about why there were 649 adjudicated claims dismissed in 2013 (63%), compared to 369 compensable claims, when typically compensable claims exceed dismissed claims. The following four years, dismissed cases fell to 20% of total claims, the more usual ratio. Dr. Nair responded that it was partially the result of increases in claims for SIRVA and influenza, but more because of dismissals resulting from the Court's ruling in the Omnibus Autism Proceeding. There was a discussion about the length of time that passes between filing a claim and final resolution and distribution of the first compensation payment, which could take more than 10 years. Ms. Toomey noted that in her son's case, the first compensation payment was made 14 years after filing the claim. She added that the government's attorney was very adversarial in eliciting her testimony. Ms. Reeves stated she was sorry that Mrs. Toomey had an unpleasant experience, but that DOJ attorneys always treat petitioners with respect.

It was observed that some of the delay might be because the medical records were not completely submitted at the time of the claim, requiring additional time to assemble and submit additional records. It could also be that the approach of the statute of limitations might push the plaintiff's attorney to file a claim with incomplete records. Another reason for the lengthened timeframe for adjudication of cases is the fact that attorneys must assemble the entire case before filing. In some compensation cases, the Court may direct that expert testimony be deferred until there is a determination of its relevance. In civil cases, some of that process can be accomplished while the case is proceeding.

Ms. Luthy closed the discussion and invited Ms. Reeves to make the Department of Justice presentation. Ms. Luthy noted that Ms. Stewart had joined the meeting.

**Report from the Department of Justice (DOJ), Catharine Reeves, Deputy Director, Torts Branch**

Ms. Reeves explained that the DOJ reporting period was different from the DICP reporting period, and begins on November 15 and ends on February 15. During the DOJ reporting period, 272 petitions were filed. The majority of cases were for adults, which is consistent with the same period last year. The number of petitions filed to date indicates that the number of petitions projected to be filed during FY 2018 will also be similar to last fiscal year. There were 181 cases adjudicated, 142 compensated and 39 not compensated/dismissed. Of those compensated, 56 were conceded by HHS and resolved by proffer, and 86 were resolved by settlement. Thirty-nine, all non-OAP, cases were not compensated/dismissed. Four petitions were voluntarily withdrawn.

No cases were decided at the U.S. Court of Appeals for the Federal Circuit (CAFC), but five were pending.

At the Court of Federal Claims (CFC), 12 cases were decided during the reporting period, evenly split between attorneys' fees and costs decisions and entitlement decisions, plus one case involving loss of future earnings, which is an element of damages. At the CFC, six motions for review filed by petitioners are pending: five involving entitlement and one involving attorneys' fees and costs. The other seven cases pending at the CFC involve motions for review filed by HHS (six for attorneys' fees and costs, one for entitlement, and one seeking interim damages).

Regarding oral arguments, two were heard on March 6, D'Tiole v. HHS (CAFC) and McCulloch v. HHS (CFC), and two are scheduled in 2018: Anderson v. HHS on April 5 (CAFC), and McIntosh v. HHS on March 22 (CFC).

Ms. Reeves showed the adjudicated settlements beginning with the case that took the longest to resolve (a Hodgkin's lymphoma case that took six years and seven months to resolve) and ending with the case that was most expeditiously resolved (a flu vaccine claim of SIRVA that took only seven months to resolve).

During discussion, Ms. Toomey commented that the proceedings seemed to be very adversarial, which caused some discomfort among the petitioners because they saw claims filed under the Program as citizens versus their own government. Ms. Reeves commented that even though the Program is designed to be less adversarial than customary civil procedure, the government is the defendant and not the drug manufacturers, as had been the practice before the Program's enactment. As such, the government is required to assess whether the claim is or is not valid, which may sometimes lead to an adversarial experience. But the Program is less adversarial and time-consuming than traditional civil litigation. There is no discovery, which can be a time-consuming process in civil litigation (that work is done before filing for Program claims), and the rules of evidence are less restrictive. The rules make it easier and faster to navigate the compensation claim process in the Program versus the traditional civil litigation process.

When asked how and whom to contact to promote congressional support without violating federal laws, Dr. Nair commented that federal employees cannot lobby Congress. The Program does inform congressional staff about Program affairs, if requested. There was also a question about whether the details of a settlement decision are publicly available. Ms. Reeves

stated that decisions adopting settlements are published, but the details of the process by which the settlement was reached are not. This is to protect the privacy of individuals, especially the injured parties. Ms. Reeves also noted that cases are settled for many different reasons. Dr. Nair added that decisions awarding compensation are not necessarily based on the scientific arguments. There are a number of reasons that compensation may be granted despite a lack of an airtight scientific rationale. There is also language in each case compensated through negotiated settlement that the Secretary does not concede that the vaccine in question caused the injury. Ms. Luthy ended the discussion and invited Dr. Shimabukuro to make his presentation.

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

Dr. Shimabukuro stated that he would provide an update of the February 2018 meeting of the Advisory Committee on Immunization Practices (ACIP), and review selected recent publications. He informed the group that the information related to the meeting would be published on the ACIP web site.

At one session of the ACIP meeting there was a presentation on HEPLISAV-B (Dynavax Technologies Corporation), a recombinant, adjuvanted hepatitis B vaccine licensed in November 2017, and approved for use in adults 18 years of age and older, with 2 doses given intramuscularly one month apart. ACIP conducted a Grading of Recommendations, Assessment, Development and Evaluation (GRADE) for the vaccine. By vote at the meeting, HEPLISAV-B was recommended as a hepatitis B vaccine that can be administered in the age group for which it is indicated.

There was also a discussion about the use of hepatitis A vaccines for post-exposure prophylaxis and international travel. From that discussion, the following recommendations were approved by vote:

- Hepatitis A vaccines should be administered for post-exposure prophylaxis for all persons 12 months of age and older
- In addition to hepatitis A vaccine, immune globulin may be administered to persons over 40 years of age depending on the provider's risk assessment
- Hepatitis A vaccine should be administered to infants age 6-11 months traveling outside the United States when protection against hepatitis A is recommended

There was a presentation on Fluarix quadrivalent (GSK) efficacy in children 6-35 months of age, essentially an extension of the existing age recommendation for the vaccine. An influenza surveillance update was provided for the 2017-2018 season. That season has been mainly an H3N2 season, although there has been a small increase in influenza B at the time of the ACIP presentation. Influenza-like illness has been the highest since 2009. Interim estimates of 2017-2018 seasonal influenza vaccine effectiveness against medically attended influenza from the U.S. Flu Vaccine Effectiveness Network was 36% at the time of the presentation. There will be a presentation at the June ACIP meeting that will update the final vaccine effectiveness number.

There was a presentation of the results of a randomized trial of a new H1N1 live attenuated influenza vaccine (LAIV) strain in U.S. children. The immunogenicity of that vaccine was similar to that observed prior to seasons when there were vaccine effectiveness problems with LAIV. Based on the data presented for LAIV, there was a vote that resulted in

recommending LAIV as an influenza vaccine for the 2018-2019 season; immunization providers may choose to administer any licensed, age-appropriate, influenza vaccine (including LAIV, IIV, and RIV). LAIV is an option for influenza vaccination for persons for whom it is otherwise appropriate. A vote on whether to recommend a preference for inactivated influenza vaccine (IIV) over LAIV failed to achieve a majority. The recommendation was rejected.

There were two presentations on human papillomavirus (HPV) vaccines. Vaccine Adverse Event Reporting System (VAERS) monitoring of 9vHPV vaccine from December 2014 through December 2017. No new safety signals or unexpected patterns were observed. The safety profile of 9vHPV is consistent with data from pre-licensure trials and post-licensure data on 4vHPV. Vaccine Safety Datalink (VSD) Rapid Cycle Analysis data from October 2015 through October 2017 revealed signals that met the predefined statistical threshold for several adverse events after 9vHPV, including syncope and injection site reactions (which were anticipated); however signals for allergic reactions, pancreatitis, and appendicitis were not confirmed after further evaluation. The session also included a discussion of harmonization of HPV age recommendations for males and females, and trends in HPV-associated cancer. There were changes in cancer rates from 1999 through 2014: increased oropharyngeal and anal cancer among men and women, and increased vulvar cancer in women, and decreased cervical cancer. Penile and vaginal cancer did not change. Oropharyngeal cancer is the most common HPV-related cancer now, and it is increasing, particularly among males. The HPV vaccine should decrease the HPV-associated cancer burden, but because of the long time between HPV infection and the appearance of cancer, it may take decades to see the impact.

Finally, the Evidence-Based Recommendations Work Group proposed that an Evidence to Recommendation framework be adopted and used by ACIP to support decision-making. Other sessions at the ACIP meeting included presentations on anthrax, pneumococcal vaccines and other biologics for prevention and treatment of healthcare-associated infections, meningococcal disease, and Japanese encephalitis vaccine. Asked whether the HPV vaccine contributed to the decline in cervical cancer, Dr. Shimabukuro stated that there were certainly confounding factors, making it difficult to settle on a definitive connection to the vaccine.

Turning to recent publications, Dr. Shimabukuro mentioned the following:

- Moro et al, in Vaccine, 2018, 36(1) 50-54, assessed the safety of hepatitis B vaccination during pregnancy has not been well studied. This analysis of VAERS reports involving hepatitis B vaccination during pregnancy did not identify any new or unexpected safety concerns. The vaccine is not specifically recommended for pregnant women, so there is limited data on the safety of the vaccination. This paper did not identify any new risks. The hepatitis B vaccine is inactivated so there is no reason to believe it would be different from other inactivated vaccines.
- Loharikar, et al, in Vaccine. 2018;36(2): 299-305, found that anxiety-related adverse events following immunization (AEFI) clusters can be disruptive to vaccination programs, reducing public trust in immunizations and impacting vaccination coverage; response efforts to restore public confidence can be resource intensive. Health care providers should have training on recognition and clinical management of anxiety-related AEFI; public health authorities should have plans to prevent and effectively manage anxiety-related AEFI clusters. Prompt management of these occurrences can be even more important in an era of social media, in which information rapidly spreads.

- Hibbs et al, in Vaccine. 2018; 36(4): 553-558, looked at the safety of vaccines that have been stored in conditions outside the recommended temperatures (basically a study of medical errors) which can affect potency. There do not appear to be any serious risks involved. This review does not indicate any substantial direct health risk from administration of vaccines kept outside of recommended temperatures. However, there are potential costs and risks, including vaccine wastage, possible decreased protection, and patient and parent inconvenience related to revaccination. Maintaining high vigilance, proper staff training, regular equipment maintenance, and having adequate auxiliary power are important components of comprehensive vaccine cold chain management.
- McNeil MM and DeStefano F., in the Journal of Allergy Clinical Immunology, 2018;141(2):463-472, found that vaccine-associated hypersensitivity reactions are not infrequent; however, serious acute-onset, presumably IgE-mediated or IgG and complement- mediated anaphylactic or serious delayed-onset T cell-mediated systemic reactions are considered extremely rare. Hypersensitivity can occur because of either the active vaccine component (antigen) or one of the other components.
- Arana et al. looked at data from the Vaccine Adverse Event Reporting System (VAERS), 2009–2015, reported on post-licensure safety monitoring of quadrivalent human papillomavirus vaccine for unexpected safety concerns or reporting patterns of quadrivalent HPV vaccination (4vHPV) with clinically important adverse events. The safety profile of 4vHPV is consistent with data from pre-licensure trials and post-marketing safety data. The first VAERS review of this 4vHPV vaccine, Gardasil, looked at the first 2.5 years from licensure to 2009. This review looked at data through 2015 when the U.S. began transitioning to the 9-valent HPV vaccine. There were no new or unexpected safety concerns for the quadrivalent HPV vaccine. The paper was published in Vaccine in 2018.
- The last paper by Sukumaran et al on Infant Hospitalizations and Mortality after Maternal Vaccination was published in Pediatrics 2018. It focused on the first six months of life and mothers vaccinated with Tdap. There are limited studies of the long-term safety in infants for vaccines administered during pregnancy. In this VSD study, the authors found no association between vaccination during pregnancy and risk of infant hospitalization or death in the first 6 months of life. These findings support the safety of current recommendations for influenza and Tdap vaccination during pregnancy.

Dr. Shimabukuro ended his presentation.

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

CDR Marshall announced that in January 2018, the FDA approved a supplement to the Biologics License Application (BLA) for Influenza Vaccine (Fluarix® Quadrivalent) to extend the age range to include children 6 to 35 months of age. The vaccine was previously approved for persons three years of age and older. In January 2018, the FDA approved a supplement to the

Biologics License Application (BLA) for Influenza Vaccine (Fluzone) to include the 2018 Southern Hemisphere formulation.

On March 1, 2018, the FDA Vaccines and Related Products Advisory Committee selected the influenza vaccine strains for the 2018-2019 flu seasons for the Northern Hemisphere, which begins in the fall of 2018. The recommendations are based on worldwide surveillance data. The committee voted unanimously to include an A/Michigan/45/2015 (H1N1) 09-like virus. The panel voted unanimously to include an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus, which is a change from the 2017-2018 vaccine. The group voted by majority, to include a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage), which is a change from this season's vaccine. The committee also voted unanimously to include a B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage) as the second influenza B strain in the quadrivalent vaccine.

CDR Marshall concluded her report. There were no questions or comments from commission members.

**Update from the National Vaccine Program Office (NVPO), Dr. Karin Bok, NVPO**

Dr. Bok commented that the National Vaccine Advisory Committee (NVAC) included an update on implementation of HPV recommendations. In that presentation there was a discussion of the Assistant Secretary for Health mandate to establish a working group, which will produce a brief report by June 18, on recommendations to "strengthen the effectiveness of national, state and local efforts to improve HPV vaccination coverage rates." The second presentation was about the state of research on new vaccines and included a discussion on incentivizing vaccine development. An overview of Zika vaccine development by BARDA/ASPR revealed that there are many candidate vaccines in the research pipeline, from basic research to Phase II trials. During the NVAC meeting there was also a review of the next generation of influenza vaccines, which includes a significant number of new vaccines in Phase I and Phase II trials, part of which is the objective of developing a universal vaccine that will allow a single annual inoculation. The final NVAC session was an update on vaccine adjuvants that provided details on three new adjuvants licensed in 2017 -- AS01 (TLR4 ligand: MPL, and saponin: QS-21); MF59; and CpG ODN. That was followed by a discussion of disparities in adult immunization.

Finally, HHS announced the appointments of the new Secretary of Health and Human Services, Dr. Alex Azar, and the new Assistant Secretary for Health, ADM Brett Giroir.

**Future agenda items**

Ms. Luthy stated that since Dr. Mulach had not yet returned to the conference call, the next agenda item to be addressed would be future agenda items and new business. Ms. Luthy stated that three items had been mentioned during earlier discussions: final review and approval of the December meeting minutes; the current backlog and need to increase HRSA reviewers; and an update on the Commission vacancy, which would be filled by the parent or legal representative of a vaccine-injured child.

Dr. Nair commented on the vacancy, noting that his office had reached out to the Department of Justice for suggestions, and to John Howie for possible suggestions from the petitioner's bar. When asked about whether the vacancy could be filled by an individual with a vaccine injury, Dr. Nair commented that the charter requires two parents. Therefore, neither of

those slots could be filled by a vaccine-injured person. It is possible that a person with a qualifying vaccine injury (requires a court decision in favor of the claimant) could occupy the slot designated for a member of the public. There is information on the program web site (search web for ACCV) that explains how to apply for a position on the Commission, and the petitioner's bar might have information that could help. There was a suggestion that the process could be more proactive, in the sense of a recruitment effort. Mr. Howie stated that he had made the announcement to attorneys who are involved with the Vaccine Injured Petitioners Bar Association and to the American Association for Justice. Dr. Nair added that no parent had independently applied for membership on the commission.

Ms. Luthy invited other suggestions for future agenda items. Ms. Stewart suggested a clarification by Ms. Reeves of the resolution of claims related to HPV, Tdap and Hodgkin's lymphoma that was discussed during her presentation. She added that a discussion of future research on conditions such as PANDAS, could be enlightening and suggested the discussions could be added to the ex-officio presentations.

John Howie suggested that, when presentations are made regarding revisions to the Table, if the revision was proposed by a member of the public or other person, that the person making the proposal be invited to explain his or her rationale. He added that it might be helpful to establish a work group to review the items discussed thus far and finalize the parameters of the discussions for each.

There was a brief discussion about the best way to establish a work group that could review the several recommendations already submitted to the Secretary, with an eye to reformatting them and resubmitting, since there are newly appointed individuals in the Department to address those recommendations. Dr. Nair suggested that all the recommendations may not be appropriate to send to the Secretary and that each should be reviewed to determine the most appropriate recipient for any communication that is chosen.

Ms. Luthy summarized the discussion; the commission was in favor of establishing a work group to focus on process. There was consensus to schedule a conference call for those commission members interested in pursuing the establishment of the work group.

Ms. Luthy invited Dr. Mulach to make the NIH/NIAID presentation.

**Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)**

Dr. Mulach commented that, although there are vaccines for flu, there is always the possibility that a mutation could produce a strain that would threaten a pandemic. This year marks the 100th anniversary of the 1918 pandemic that caused many deaths worldwide. Dr. Mulach briefly discussed the NIAID strategic plan for the development of a universal influenza vaccine. CDC, BARDA, NIH and FDA and are making presentations on seasonal influenza and vaccine effectiveness to the House Energy and Commerce Subcommittee on Oversight and Investigations while ACCV is meeting.

Barney Graham and Nancy Sullivan published a paper, "Emerging Viral Diseases from a Vaccinology Perspective: Preparing for the Next Pandemic" in the journal Nature Immunology that discussed better preparation and more effective platforms for vaccines that will improve response time. In retrospect, the Zika epidemic just suddenly appeared two years ago, followed by a huge effort to understand the disease and develop vaccines. Nineteen papers appeared in the Journal of Infectious Diseases to explain the history, epidemiology, virology, immunology

and the unique characteristics and disease cycle of the mosquito that transmits the disease. Understanding the cycle provides an opportunity to develop ways to interrupt, slow or stop the spread of the disease.

There is a Zika DNA vaccine (VRC 705) going through clinical trials. A Part A non-placebo-controlled trial of 90 subjects began in March 2017, and a Part B placebo-controlled trial of up to 5,000 subjects launched in July 2017. In 2016, NIH launched a very large study to evaluate the entire range of health risks related to Zika virus infection in pregnant women and their babies. This study is co- sponsored by Fundacao Oswaldo Cruz-Fiocruz (Fiocruz), a national scientific research organization linked to the Brazilian Ministry of Health in Brazil. Currentlyalmost 6,000 mothers and 2,000 infants have been enrolled. The study is looking at the course of Zika infection, focusing on pregnancy outcomes, congenital anomalies, and other developmental problems.

Dr. Mulach described an NIH research initiative on health risks and resilience after hurricanes Irma and Maria. It supports time-sensitive research on risk and resilience factors related to short-and long-term health outcomes following Hurricanes Irma and Maria in Puerto Rico and the U.S. Virgin Islands. The research is expected to start in July 2018.

Finally, Dr. Mulach commented on the "All of Us Research Program" which was described at the December ACCV meeting. The program is an effort to gather data from a million or more individuals living in the United States to accelerate research and improve human health. The study will look at various lifestyles, environment and biology, to try to develop precision medicine and more personalized medicine. Ideas for research were solicited from participants and due by February 23, 2018. There will be a workshop at NIH in March 2018 to review the ideas submitted.

During discussion, Dr. Mulach was asked about research on reducing the threat of Zika infection by altering the genetics of the mosquito to prevent reproduction of mosquitoes that can carry the Zika virus. Dr. Mulach commented that the intent of this approach is to affect the disease risk but not the environment.

Ms. Luthy closed the ex-officio presentations part of the agenda.
Dr. Shimabukuro announced that he would be leaving the commission as an ex officio member and Mike McNeil would be taking over the responsibilities of reporting for the Immunization Safety Office. He expressed his appreciation for the diligent work of the HRSA staff who made the commission work so well during the past few years.

**Public comment**

**1. Dr. Hooker – Parent/Private Citizen**

Dr. Hooker stated that he was the parent of a vaccine-injured male. He said his son's claim was in the VICP claims process for 13 years, and when the claim was finally heard in 2016, it was dismissed based on the statute of limitations. He commented on the tics discussion from the previous ACCV meeting. He noted that thimerosal is still in multi-dose formulations of flu vaccine administered to infants, toddlers and pregnant women. The CDC response to the petition at the last meeting was scientifically inaccurate. A Thompson et al study in the New England Journal of Medicine (2007) and a 2012 study in the Journal of Pediatric Psychology, both showed a definitive and statistically significant relationship between thimerosal exposure and tics in boys. Dr. Hooker cited four other studies in peer-reviewed literature attesting to the relationship between thimerosal and tics, and the finding by the 2001 IOM Immunization Review

Committee, that a relationship between thimerosal and neurodevelopmental disorders is biologically plausible.

Dr. Hooker stated that he believed the petition should have been voted on or tabled for further review. Dr. Hooker suggested there should be a mechanism to facilitate more research by independent scientists to look at the link between thimerosal exposure and tics. Dr. Hooker expressed his concern about the negative adversarial process that parents face when pursuing a claim for an injury such as the one under discussion.

There was a question from a commission member about pursuing a discussion of Dr. Hooker's statement, and it was determined that such a discussion would have to occur at a time other than that provided on the agenda for public comment.

**2. Theresa Wrangham – Executive Director, NVIC**

Ms. Theresa Wrangham from NVIC, explained that the NVIC has followed the commission's work since its creation. The NVIC was co-founded by parents of children injured by the DPT vaccine 36 years ago. As the only federal commission concerned with vaccine-injured individuals, the ACCV is extremely important. There should be a discussion about how to reach out to Congress to provide the funding needed to close the research gaps that the IOM has repeatedly, over the last 20 years, identified. The lack of quality science to support causality results in obstacles to adding injuries to the Table. That, in turn, increases the level of adversarial proceedings that require parents to prove that the injuries to their children were caused by vaccine.

Ms. Wrangham observed that most of the recommendations to the Secretary of HHS go unanswered. It is also clear that, unlike many federal commissions, the ACCV does not publish reports. The NVAC issues very prompt reports which have resulted in parents not being able to opt out of vaccinations for their children. However, vaccine approval is fast-tracked. The IOM has stated that potential vaccine injuries cannot be determined until the vaccines are in use. The vaccine research mandate in the 1986 Act is not being addressed and it is creating the caseload discussed earlier in the meeting. Because injuries are slow to be placed on the Table, litigation on vaccine injuries increases. However, Guillain–Barré Syndrome (GBS) was added as an injury related to flu vaccine partly because of commission action.

NVIC has a standing request for more transparency in publishing information about injury awards. There is a way to do that without violating individual confidentiality. Ms. Wrangham stated that she would be pleased to serve on a work group looking into that issue.

Concerning membership on the commission, there is nothing in the law that requires that a parent be a successful petitioner in the VICP. Ms. Wrangham, who is also the parent of a vaccine-injured child, stated that a parent submitted her name for commission membership 18 months ago. She explained that she did not pursue membership because she was not aware of the process to be approved and she was never advised of her status.

The NVIC made a request that the commission revisit the recommendations made by the Altarum group and the Banyan group that observed there is no follow-up after an award to assess the opinions of those involved to see if the award recipients felt that the awards were adequate. Those groups stated that many are not aware of the process and many will not make it through the process, in part because of the statute of limitations.

Ms. Wrangham renewed the NVIC request that, like the NVAC, the ACCV issue informative reports that could be submitted to Congressional staff, rather than make repeated

recommendations to the Secretary, that are usually of no avail. She also felt that the commission should make room on its agenda for input from individuals, like those who file petitions for additions to the Table.

Ms. Luthy confirmed that there were no other callers who were interested in making a public comment. She stated that the e-mail about the new work group would be forthcoming. Dr. Nair stated he would investigate the question about qualifications for parental membership on the commission.

**Adjournment**

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

# 2.2

**Advisory Commission on Childhood Vaccines**

**December 8, 2017**
**104th Meeting**

**Members Present**

Karlen E. Luthy, D.N.P., Interim Chair, ('18)
John Howie, J.D. ('19)
H. Cody Meissner, MD, ('19)
Dino Sangiamo, J.D. ('19)
Alexandra Stewart, J.D. ('18)
Martha Toomey ('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 from Beth Luthy, Interim Chair**

Ms. Luthy called the meeting to order. After the introduction of Commission members present, Ms. Luthy invited public comment on the meeting agenda. Public comment on agenda items:

1. A member of the public, Janet Cakir, requested time to comment on several issues that would be discussed during the meeting, including: comments on methyl mercury and tics, the petition related to adding Pediatric Autoimmune Neuropsychiatric Syndrome (PANS), Pediatric Infection-Triggered Autoimmune Neuropsychiatric Disorders (PITANDS), and Pediatric Autoimmune Neuropsychiatric Disorders (PANDAS) to the Vaccine Injury Table, and the petition related to adding acute demyelinating encephalomyelitis (ADEM) to the Vaccine Injury Table (Table). Ms. Luthy reminded her that this opportunity to comment related only to the relevance of the agenda items as topics for discussion, and not for substantive discussion of those topics. Ms. Luthy offered assurance that members of the public would have the opportunity to comment after the discussion of each agenda item. In addition, she explained that each petition would be presented separately, followed by public comment limited to the substance of the petition, followed by Commissioners' discussion, followed by a vote of the Commission on the petition.
2. Ms. Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC), noted a minor error in the September minutes. The title of NVIC was inaccurately described as the National Vaccine Injury Center. Ms. Wrangham expressed concern that representatives of HRSA usually make presentations on

agenda items and discussion of issues is usually limited to ACCV members and staff, and the public has little opportunity to participate in a give-and-take conversation. She added that the National Academy of Medicine (NAM) (formerly Institute of Medicine (IOM)) relies on a format of providing a "report card" that includes considerations of the quality of evidence from scientific literature, epidemiological data, causality rationale and so on. Ms. Wrangham felt it would be helpful to follow the NAM model in making presentations such as those concerning Table revisions.

**Approval of September 8, 2017 ACCV Meeting Minutes**

Ms. Luthy invited approval of the minutes of the September 2017 meeting, noting that the NVIC name would be corrected to read National Vaccine Information Center, not Injury Center. A motion to approve the minutes was made and it was seconded. However, a vote by Commission to approve the minutes did not occur until later in the meeting. At that time, there was a motion to approve the minutes and it was seconded. Then, the Commission voted to approve the minutes.

**Report from the DICP, Dr. Narayan Nair, Director**

Dr. Nair welcomed the Commission members, staff and members of the public. He especially welcomed the new members who were participating in their first ACCV meeting. Dr. Nair reviewed the agenda for the meeting, which included presentations of petitions to add injuries to the Table. Beginning with statistical information, Dr. Nair announced that 401 petitions were filed in 2012 and the number of petitions filed annually has increased significantly every year since 2012. The number of petitions filed in FY 2017 was 1,243. To date, there have been 215 petitions filed in FY 2018, indicating there will be more petitions filed in FY 2018 than there were in FY 2017. The petitioners' awards in FY 2017 totaled $252 million (nearly $30 million to attorneys' fees/costs), and for the first two months of FY 2018 the awards were $31 million ($5.7 million for attorneys' fees/costs). Finally, the total cases adjudicated in FY 2017, which may have been filed in a prior fiscal year, were 836 (683 compensable, 153 dismissed), and thus far in FY 2018, 90 cases were adjudicated (53 compensable, 37 dismissed). Of the 686 non-autism cases adjudicated in FY 2017, HHS conceded 26%, the court decided 7%, and the majority, 67%, were settled by agreement between the parties involved.

Dr. Nair reported that the Vaccine Injury Compensation Trust Fund had a balance of $3.7 billion at the end of FY 2017, and had received total income of $331 million from excise taxes ($270 million), interest income (nearly $57 million), and a refund from prior year of $5 million.

A significant activity since the last report to the Commission was the vote on revised language to the Table. A Notice of Proposed Rulemaking published in the Federal Register regarding that change is being developed. DICP presented information about SIRVA (shoulder injuries related to vaccine administration) at the Advisory Committee on Immunization Practices (ACIP) in October 2017. Dr. Nair noted that the Commission would discuss several pending petitions.

During the discussion, there was clarification that the Court's web site publishes specific case decisions for those interested.

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

Ms. Reeves welcomed the commissioners. Ms. Reeves noted that the reporting period for the Department of Justice (DOJ) is different from that of the Division of Injury Compensation Programs. Ms. Reeves referenced the DOJ Power Point materials as part of her presentation for the three-month period from August 16, 2017 to November 15, 2017. During this reporting period, 396 petitions were filed, compared to 355 petitions filed during the same period last year. Of those 396, 33 were filed on behalf of children (8%) and 363 were filed by adults (92%). (DOJ PP at 2). Ms. Reeves noted that majority of these petitions involve claims for shoulder injury related to vaccine administration (SIRVA).

With regard to total cases adjudicated, Ms. Reeves noted that most cases—approximately 80%—continue to resolve by settlement. Ms. Reeves noted that 196 claims were adjudicated this quarter, compared to 222 for the same period last year. (DOJ PP at 3). There were 141 cases compensated. Of those 141 cases, 56 were conceded by HHS. Of those 56 conceded cases, 54 were resolved by a decision adopting a proffer and 2 were resolved by a decision awarding damages. There were 85 cases compensated but not conceded by HHS. Of those, all 85 cases were resolved by a decision adopting a settlement stipulation. (DOJ PP at 3). There were 55 cases dismissed. Of those, 36 non-OAP cases were resolved by decisions dismissing the petition, and 19 were dismissed from the OAP. (DOJ PP at 3). There were 5 petitions voluntarily withdrawn. (DOJ PP at 4).

Turning to appeals, two appeals filed by petitioners at the U.S. Court of Appeals for the Federal Circuit (CAFC) were affirmed. (DOJ PP at 5). H.L. v. HHS involved entitlement. In Simmons v. HHS, the CAFC discussed when it is appropriate for a special master to award attorneys' fees and costs when a petitioner is not compensated, and provided more guidance on what constitutes reasonable basis. Four appeals regarding entitlement remain pending in D'Tiole v. HHS, Anderson v. HHS, Oliver v. HHS, and Depena v. HHS. (DOJ PP at 6).

Ms. Reeves discussed appeals at the CFC, and noted that four appeals filed by petitioners were decided by the CFC. (DOJ PP at 7). Two of the four appeals concerned attorneys' fees and costs and two concerned entitlement. The court affirmed the special master's decisions in the cases concerning entitlement and in one of the cases regarding attorneys' fees and costs. In Cottingham v. HHS, the CFC remanded and the case remains pending before the special master for further proceedings. Fourteen cases remain pending at the CFC. (DOJ PP 8-9).

No oral arguments are scheduled at the CAFC. An oral argument in Santacroce v. HHS before the CFC was scheduled for December 12, 2017. (DOJ PP at 10).

Ms. Reeves noted the history of adjudicated settlements, which are listed in order of the time they took to resolve. (DOJ PP at 11-18). Most of the cases involved injuries related to Guillain-Barré Syndrome and SIRVA, and most cases resolved within two years of filing, which is notable considering the increasing case load.

Dr. Meissner remarked that it was interesting that 10% or fewer petitions were filed on behalf of minors with the remainder being adults, and that among adults the flu vaccine was the most alleged vaccine. He noted that we should be educating people about administering vaccines to prevent SIRVA injuries. Dr. Nair responded that SIRVA is the only theoretically preventable vaccine injury, that HHS had recently presented at ACIP with the CDC's Immunization Safety Office about SIRVA, and that he believed that CDC was conducting outreach activities regarding vaccine administration.

Mr. Sangiamo asked for further clarification about Simmons v. HHS. Ms. Reeves responded that Simmons held that reasonable basis cannot be based on the actions of the attorney filing on the eve of the statute of limitations. She noted that previously special masters and the CFC have looked at the totality of the circumstances, including a looming statute of limitations, to determine whether reasonable basis exists, and that the CAFC held in Simmons that a looming statute of limitations by itself is insufficient. Ms. Reeves is hopeful that attorneys will be more careful about filing petitions, especially considering the limited resources at the Court, DOJ, and HHS, but it remains to be seen how Simmons will impact the filing of cases.

Mr. Howie asked what measures have been implemented to move cases faster and more efficiently. Ms. Reeves noted that DOJ attorneys have more than 100 cases on their dockets, and while DOJ was allowed to hire six more attorneys who are in the hiring pipeline, there is a learning curve once they start. Ms. Reeves also noted that HHS does not have funding to increase resources and the Court cannot increase the number of special masters without an act of Congress. Ms. Toomey noted that the ACCV had submitted a recommendation to the Secretary requesting increased funding, but that recommendation had not been acted upon.

**Petition to Add Injuries to the Vaccine Injury Table - Introduction, Dr. Nair, Director, DICP**

Dr. Nair briefly described the purpose of the Table, which, in accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub.L. 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa–14(c)), authorizes the Secretary of HHS to create and modify/update/revise the Table. The Table lists vaccines covered by the VICP and the injuries, disabilities, illnesses, conditions, (including death), resulting from the administration of the listed vaccines. The Table also includes the timeline in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, or death is to occur after vaccine administration for purposes of receiving compensation under the Program. The Table also is a legal mechanism for defining complex medical conditions and permits "presumption of causation" if no other cause is found. Dr. Nair noted that, although any claim that fits all criteria is eligible for compensation, a claim for an injury not on the Table may be filed by anyone, and will be heard based on the merits of each case and the preponderance of evidence submitted.

Several years ago, the Commission developed "Guiding Principles for Recommending Changes in the Vaccine Injury Table." The Commission believed that the Table must be scientifically and medically credible, and the final decision about accepting or rejecting a recommendation must be made for the benefit of the petitioner. The Guiding Principles recognize that some data is more valuable in assessing causality than other data and the Commission established a hierarchy to assign weight to various data (briefly listed in descending order of weight):

- Clinical laboratory data
- Challenge/re-challenge/de-challenge data involving non-re lapsing symptoms or diseases controlled clinical trials
- Controlled clinical trials (including, but not limited to, double-blind, placebo controlled

clinical trials)

- Controlled observational cohort and case-control studies and studies based on Vaccine Safety Datalink (VSD) database.
- Uncontrolled observational studies such as ecological studies
- Case series
- Data from passive surveillance systems (e.g., Vaccine Adverse Event Reporting System (VAERS)
- Case reports
- Editorial articles on scientific presentations
- Non-peer reviewed publications

Dr. Nair reiterated that several petitions to add injuries to the Table would be discussed during the meeting, including:

- Asthma, Food Allergies and Autism (Food Allergies/Autism will be addressed separately) (vaccines not specified)
- Pediatric Infection Triggered Autoimmune Neuropsychiatric Disorders (PITANDS); and/or Pediatric Autoimmune and Neuropsychiatric Syndrome (PANS); and Pediatric Autoimmune Neuropsychiatric Disorder Associated with group A Streptococcus (PANDAS) for pertussis, pneumococcal conjugate and Haemophilus influenza type b (Hib) vaccines
- Experimental Autoimmune Encephalomyelitis for pertussis vaccines
- Tics (vaccines not specified)

Dr. Nair explained that the process for preparing the petitions for Commission consideration included a review of the Institute of Medicine report, described above, and an independent literature search with support from the NIH National Library of Medicine, focusing on English-language peer reviewed publications.

Dr. Nair began a discussion of the petition to add food allergies to the Table, reminding the Commission that a private citizen has submitted a request to add food allergies to the Table. A request to add food allergies to the Table was previously received from the same individual in 2016, that petition was reviewed at the December 2016 ACCV meeting, and the ACCV voted to not add food allergies to the Table. The individual resubmitted an expanded request in April 2017 to include food allergies, asthma and autism to the Table. After additional research, no new information was found concerning food allergies.

Responding to the autism claim in the request, Dr. Nair recalled that the CFC ordered Omnibus Autism Proceedings in July 2002 due to about 5,600 claims alleging autism. These claims were addressed in a two-phase discovery process that lasted until 2006. During the 2002, Omnibus Autism Proceedings petitioners submitted over 200,000 pages of documents and the issue was processed in entitlement hearings in 2007 and 2008. Decisions were handed down in 2009 and 2010, affirmed on appeal, that there was no evidence that the measles-mumps-rubella (MMR) vaccine, with or without thimerosal, causes autism. Current scientific evidence continues to support those decisions.

In addition, Dr. Nair explained that, in 2011, the National Academy of Medicine reviewed evidence and found no causal relationship between MMR vaccine and autism. The ACCV heard that report in September 2011 and March 2012. The DICP reviewed medical

literature from peer reviewed English language clinical publications and determined that there was no publications that concluded that other vaccines cause autism. Additionally, a number of national and international medical associations, academies and institutions have conducted independent studies that arrived at the same conclusion. HHS affirmed the position that autism is not caused by any vaccines in the Final Rule amending the Table (82 FR 6294, 6298).

At the end of his comments, Dr. Nair reviewed the provisions of the Guiding Principles. He concluded that the Commission would consider two options with regard to the autism Table revision – either add autism as an injury to the Vaccine Injury Table, or not add autism as an injury to the Table. Ms. Luthy stated that the Commission could ask questions regarding the presentation, followed by an opportunity for public comment, and a final vote on the options.

During the discussion, Martha Toomey, a Commissioner, asked who paid for the various studies. Dr. Nair responded that the studies were financed through various sources. There was an observation that, contrary to a statement made about reports from other national and international health entities; there are studies in the literature that indicate that autism can be caused by vaccines. Ms. Luthy invited public comment.

1. A member of the public commented that the DTaP (Diphtheria-Tetanus-Acellular Pertussis) vaccine package insert contains a statement that autism can be a complication from vaccination. She made a technical comment about the Stephano case (cited in a presentation) concerning the density of lipopolysaccharides in whole cell and acellular pertussis, which could affect the number of antigens present, which in turn can influence the effect of vaccine as causative of autism. The private citizen also mentioned an allegation that African- American children from Georgia develop autism at a higher rate than the general population; she felt this is a research question that should be addressed.
2. Theresa Wrangham, Executive Director of the NVIC reiterated the opinion that the DICP data lacks the weighting or ranking of the NAM data, mentioned previously. She added that the NAM only expressed a position on MMR vaccine, asserting that there was inadequate data to make valid conclusions about other vaccines. Ms. Wrangham reiterated that the presentations appear to be prepared only by HRSA, which could introduce bias. Ms. Wrangham reiterated NVIC's position that petitioners should be invited to present their petitions to the ACCV. Ms. Toomey, citing the court decision that her son's autism was a vaccine injury eligible for compensation, stated that this action belies any claim that a vaccine cannot cause autism.

Prior to the final vote, Ms. Luthy invited questions or comments from the Commission members. Asked about the package insert comment, Dr. Shimabukuro indicated that that question should be directed to the Food and Drug Administration, the agency responsible for package inserts. LCDR Marshall stated that mention of adverse events in a package insert does not necessarily support a direct association. Ms. Luthy invited each member of the quorum to submit an oral vote:

Option 1 – Add autism to the Table.
Option 2 – Do not add autism to the Table.

The result of the vote was five in favor of Option 2 and one in favor of Option 1. Ms. Stewart, Mr. Howie, Mr. Sangiamo, Dr. Meissner and Ms. Luthy voted for Option 2. Ms.

Toomey voted for Option 1.

Ms. Luthy invited Dr. Rubin to discuss the petition requesting that tics be added as an injury to the Table.

**Petition to Add Tics as an Injury to the Vaccine Injury Table, Dr. Mary Rubin, Medical Officer, DICP**

Dr. Rubin stated that a private citizen submitted a formal request to HHS and the ACCV to add tics as an injury to the Table as a disorder resulting from vaccination based on a claim made by two CDC employees. Dr. Rubin explained that tics are sudden, rapid, non-rhythmic recurrent movements or vocalizations (brief sounds or more complex utterances and with Tourette's syndrome, may include involuntary obscenities). Tics typically diminish during sleep, and can be controlled, at least temporarily, in some cases. Tics usually develop in 5-10% of early school age children (4-6), with peak severity between 10-12 years of age, and decline during adolescence. Tics are believed to be caused by abnormal chemical reaction in the brain. Tics may be exacerbated by stress, excitement and exhaustion. Males are affected more frequently than females; otherwise, the disorder is similar in both.

Diagnosis is symptom-specific, and four categories are typically identified: Tourette's disorder (not attributed to the physiologic effects of a substance or other medical disorder); persistent motor or vocal tic disorder (criteria never met for Tourette's); and provisional tic disorder (criteria not met for either Tourette's or persistent disorder); and other specified or non-specified tic disorder. Diagnosis of tic disorder is complex and only specialists can make reliable diagnosis. Treatment is variable, and includes education and managing disabling tics; there are also cognitive-behavioral therapies and medication in severe cases.

Dr. Rubin reviewed the ACCV Guiding Principles discussed previously. There was no supporting citation provided in the private citizen's request, but a literature search revealed a paper published in the Journal of Pediatric Psychology, entitled "Thimerosal exposure in early life and neuropsychological outcomes 7-10 years later." (J.P. Barile et al). The article described research related to thimerosal exposure in early life. Researchers measured seven neuropsychological outcomes, one of which was tics. The researchers found no statistically significant responses in six of the seven outcomes. However, there was a statistically significant response in the outcome measuring tics in boys, although additional confirmation is needed to develop a more reliable and valid measure of tics. There were significant limitations to the results – training of the clinical observers was brief (about 30 minutes focused on diagnosis of Tourette's); although tics run in families, the lack of response in girls needs further explanation; and the response/participation rate was low (only 30% of eligible subjects chose to participate, which could introduce bias).

The private citizen's petition did not identify the vaccine types or whether the vaccines contained thimerosal. Thimerosal is a mercury-based preservative. Dr. Rubin discussed two types of mercury, methyl mercury and ethyl mercury. Methyl mercury is formed in the environment and is typically found in food. Ethyl mercury is found when the body breaks down thimerosal, and is cleared from the blood more quickly than methyl mercury. There is no evidence of harm from thimerosal in vaccines; however, the compound was removed from vaccines in 2001. MMR, varicella, pneumococcal vaccines, and inactivated polio vaccines, never contained thimerosal. Influenza vaccines are manufactured with and without thimerosal, and no vaccines recommended for children contain thimerosal.

Dr. Rubin reviewed a study by S. Iqbal et al, looking at the number of antigens in early childhood vaccines and neuropsychological outcomes at age 7 to 10 years; and as described previously, there were seven outcomes, one of which was tic disorder. The children showed no adverse response for antigens in vaccines during the first two years of life, and neurological outcomes in later life. The analysis assumed that levels of immune response were similar for all antigens, which was an oversimplification. In addition, enrollment was less than 30%, which could introduce selection bias. There were also recall issues related to self-reporting. Finally, antigen exposure in that early (1990s) trial were considerably greater than antigen exposure in the current vaccination schedule.

In a search for additional data on tic disorders, very few papers were found. The few that were found included substantial data on thimerosal, a compound that is no longer included in vaccines for children. A study by Leslie, D. L., R. A. Kobre, et al. (2017), entitled "Temporal Association of Certain Neuropsychiatric Disorders Following Vaccination of Children and Adolescents: A Pilot Case-Control Study," (Front Psychiatry) concluded that the onset of some neuropsychiatric disorders (obsessive compulsive disorder, anorexia nervosa, anxiety disorder, chronic tic disorder, attention deficit hyperactivity disorder, major depressive disorder and bipolar disorder) may be temporally related to prior vaccinations. There were a number of limitations related to the Leslie study. There is limited literature on tics and tic disorders, and vaccinations. The tic symptoms are usually part of a complex diagnosis. Further research on tics alone is required.

Dr. Rubin reviewed the Guiding Principles for revising the Table, and noted that the options that the Commission must consider are:

Option 1 - Add tics/tic disorders to the Table.
Option 2 - Do not add tics/tic disorders to the Table.

Dr. Rubin invited comments or questions from Commission members. There was a question regarding the funding source for the studies mentioned and Dr. Shimabukuro reiterated that the studies were funded under the Centers for Disease Control and Prevention (CDC) Vaccine Safety Datalink (VSD) program. There was a request that Dr. Thompson, whose papers the petition discussed, be invited to discuss the issues with the Commission. There was a comment that the articles were not peer reviewed and must therefore be considered in that light. Martha Toomey, a commissioner, commented that because of a lack of peer reviewed literature and research, the Commission may not have sufficiently reliable information to make a decision about adding or not adding tics to the Table. There was a brief discussion about whether there was sufficient reliable information about tics and causation to choose an option. There was no consensus concerning the ability to vote, but the Commission agreed to invite public comment. Public comments:

1. A public participant (Katherine) confirmed that Dr. Thompson was still at CDC and should be able to participate. She played a recording, allegedly of Dr. Thompson stating, that the Barile paper replicated the fact that vaccines cause tics and that there were efforts by CDC to hide association between vaccines and tics.
2. A public participant (Janet Cakir) commented that the Thompson, Iqbal and Barile studies relied on the same database. She observed that the information/data was manipulated to facilitate analysis. For example, data concerning encephalitis, a brain

inflammation, was removed prior to analysis. Similarly, all data regarding low birth weight babies was removed, which diluted the impact of thimerosal since the effect is dose dependent (the smaller the baby, the greater the drug effect). Finally, all adverse outcomes were not necessarily reported. She cited a number of papers that compared the effects of methyl and ethyl mercury, which appear to be similar.

3. There was a comment from Theresa Wrangham, acting as a private citizen, who said that thimerosal was suggested for the National Toxicology Program, although the resolution or outcome of that recommendation is not clear. She also noted that a manufacturer of multi-dose thimerosal, which contains mercury, could convert that product to mercury-free thimerosal if there was a demand for the mercury-free product, which there apparently is not.

Ms. Luthy invited Commission comment about the motions on the floor to decide on options. There was a question about whether the commissioners could rely on knowledge accumulated from any sources or from personal experience, or only on information presented at the meeting. Dr. Nair stated that the purpose is to obtain input broadly from the members, and from all valid information sources. He felt the Commission could make a determination about the options based on their personal knowledge and on the information heard during the meeting. By a voice vote, the members agreed to vote on the options:

Option 1 - Add tics as a vaccine injury to the Table.
Option 2 - Do not to add tics as an injury to the Table.

Ms. Luthy invited each member of the Commission to vote. The result of the vote was five in favor of Option 2 and one in favor of Option 1. Ms. Stewart, Mr. Howie, Mr. Sangiamo, Dr. Meissner and Ms. Luthy voted for Option 2. Ms. Toomey voted for Option 1.

After a recess for lunch, the Commission reconvened and Ms. Luthy invited Dr. Stryer to discuss the petition requesting that asthma be added as an injury to the Table.

**Petition to Add Asthma as an Injury to the Vaccine Injury Table, Dr. Stacy Stryer, Medical Officer, DICP**

Dr. Stryer stated that on April 3, 2017, a private citizen petitioned HHS and the ACCV to add asthma to the Table because the injection of food allergen-contaminated vaccines causes sensitization and subsequently asthma. Asthma is a respiratory disorder that results in difficulty breathing and other physiological problems. There is a wide variety of causative factors including genetic predisposition, underdeveloped lungs, exposure to environmental contaminants, viral infections, obesity, allergies, and others, including atopy (the production of immunoglobulin E (IgE) antibodies). When an individual is exposed to a specific allergen, these antibodies bind to the allergen, causing an allergic reaction. This results in breathing difficulties, for example, and may effect permanent changes in the bronchial airway.

Dr. Stryer reviewed the Guiding Principles for recommending changes to the Table, discussed previously. The private citizen who submitted the petition supported his claim by referencing a non-peer reviewed article that he wrote and self-published online and citing 15 references. The article was entitled, “Medical Muddles that Maim our Children with Allergies, Asthma and Autism”. He asserts that individuals may develop IgE-mediated sensitization by

injection of food proteins in vaccines. Then when they inhale the sensitized food particles, they can suffer asthma symptoms. Individuals can also become sensitized to "pathogen associated vaccine antigens" via IgE. Upon inhalation of these particles, such as influenza viral particles, pertussis bacteria particles, etc., they will develop asthma symptoms. Dr. Stryer described all of the articles submitted by the petitioner that related to vaccine-induced IgE, and the implication that it leads to asthma. However, there is no evidence in publications submitted that vaccination leads to IgE antibody or the most common causes of wheezing in childhood, namely respiratory syncytial virus and human rhinovirus. There is no evidence that individuals develop IgE sensitization by injection of food proteins in vaccines and that subsequent inhalation of these particles causes symptoms of asthma. In addition, there is no evidence that inhalation of vaccine antigens triggers asthma symptoms via an IgE mechanism.

Dr. Stryer explained that after reviewing the petitioner's submission, she looked at the scientific literature, starting with the 2012 IOM Report, "Adverse Effects of Vaccines: Evidence and Causality". The report reviewed studies of asthma exacerbation or reactive airway disease episodes in children and adults after both live attenuated influenza vaccine (LAIV) and inactivated influenza vaccine in children younger than 5 years of age and in persons 5 years of age or older. The IOM deemed the evidence inadequate to either accept or reject a causal relationship between either vaccine and asthma exacerbation or reactive airway episodes in individuals of any age. Dr. Stryer stated that the IOM does not support adding asthma to the Table with regard to influenza vaccine and did not evaluate evidence related to other vaccines. .

A search of other literature focused on an important 2007 "Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma", sponsored by the National Heart, Lung, and Blood Institute (NHLBI). Neither this report, nor four additional reports identified in the search, mentioned vaccines as a potential cause or risk factor in the development or exacerbation of asthma. Further literature searches did not result in the identification of peer reviewed articles that mentioned food allergen-contaminated vaccines or pathogen-associated vaccine antigens in the development or exacerbation of asthma. The search identified numerous studies that evaluated the development of asthma after vaccination. The overwhelming majority found no causality between vaccination and the development of asthma.

Dr. Stryer briefly mentioned 15 studies that evaluated vaccines and asthma which showed no association between vaccines and asthma. Many of the studies were from the International Study of Allergies and Asthma in Children (ISAAC), established in 1991. ISAAC proposed a standardized methodology and approach to the research. Some of the studies came from the CDC VSD, which looked at high-risk infants. Sample sizes varied from a few hundred, to several hundred thousand, to one that evaluated all online studies which included millions of children.

Finally, Dr. Stryer discussed four studies that showed mixed (mainly negative) results between vaccines and asthma. One study (McDonald, 2008) showed a delay in onset of asthma in subjects who received four or more doses of DPT when the vaccination was delayed by six months. Dr. Stryer reviewed the Guiding Principles again.

There was a brief discussion among Commission members, with regard to the homogeneous Manitoba population and in the case of more delay, less risk of DTP vaccine/asthma, the indication of a dose-dependent relationship is clear, and the effect of an urban versus non-urban setting is probably irrelevant. Ms. Luthy invited public comment before voting on the options. Public comments:

1. Janet Cakir, commented on the Manitoba study. In response to the presentation of the study and limitations of the study, Ms. Cakir commented that the participants of the study would have the same environmental exposure if they were all from Manitoba, Canada and a comparative (urban vs. suburban) sample isn't necessary.
2. Ms. Wrangham, Executive Director of the NVIC, endorsed using data from the VICP awards for any petition as a resource to consider when making decisions about Table revisions. Ms. Wrangham cited the addition of Guillain-Barré as an example.

Martha Toomey, a commissioner, commented that there are enough challenges to adding an injury to the Table such that the Commission should encourage simplifying the process rather than making it more adversarial.

Ms. Luthy invited each member of the Commission to submit an oral vote.

Option 1 – Add Asthma to the Vaccine Injury Table.
Option 2 – Do not add Asthma to the Vaccine Injury Table.

The result of the vote was unanimous, six in favor of Option 2 and none in favor of Option 1. Ms. Stewart, Ms. Toomey, Mr. Howie, Mr. Sangiamo, Dr. Meissner and Ms. Luthy voted for Option 2.

**Petition to Add Pediatric Autoimmune Neuropsychiatric Syndrome (PANS), Pediatric Infection-Triggered Autoimmune Neuropsychiatric Disorder (PITAND), and Pediatric Autoimmune Neuropsychiatric Disorders Associated with with Group A Streptococcus (PANDAS) as Injuries to the Vaccine Injury Table, Dr. Mark Ditmar, Medical Officer, DICP**

Ms. Luthy commented that there were several e-mails concerning the next petition, indicating a higher than usual interest in PANS, PITAND and PANDAS. Dr. Ditmar stated that a private citizen submitted petitions on February 20, 2017 and March 20, 2017, to add PANS, PITAND and/or PANDAS to the Table. The petitions assert that components of pertussis present in vaccines cause the development of PANS and/or PITAND and that components of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) present in vaccines cause or enable the development of PANS and/or PANDAS.

Dr. Ditmar explained that PANS, PITAND and PANDAS might develop from an autoimmune response. These disorders may produce a physical movement abnormality and a behavioral or psychiatric disorder. The immune response may cause antibodies to affect various parts of the body including the heart (carditis), joints (arthritis), skin (rashes) and potentially the brain that results in involuntary movements.

In 1995, a disorder was identified in four individuals that would become known as PITAND, which was successfully treated with plasmapheresis, intravenous immunoglobulin (IVIG) or prednisone. Then a larger cohort was diagnosed with a complex disorder that would become PANDAS, with five similar symptoms--1) presence of obsessive compulsive disorder (OCD) or tic disorder; 2) prepubertal symptom onset, 3) acute symptom onset and episodic (relapsing-remitting course); 4) temporal association between group A strep infection and symptom onset/exacerbation; and 5) neurologic abnormalities (particularly hyperactivity and

choreiform movements). Shortly thereafter, the same researchers refined the nomenclature to add PANS.

In the first petition, to support the claim that pertussis-containing vaccines cause PANS and/or PITAND, the petition outlines a mechanism of molecular mimicry and autoantibody-mediated neuronal cell signaling. In the second petition, which involved pneumococcal and Hib vaccines, not pertussis, the petitioner described a slightly different mechanism that resulted in the same disorders. The 2012 IOM study did not address PANS, PITANDS or PANDAS; nor did it recognize any possible association between pneumococcal conjugate vaccines and *Haemophilus influenzae* type b (Hib) vaccines or any other vaccine and PANS and/or PANDAS.

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Dr. Ditmar commented that the petitions raised questions. Specifically,

- Is PANS and/or PITAND and/or PANDAS mechanistically established as an autoimmune process via molecular mimicry and autoantibody mediated neuronal cell signaling, and is PANS and/or PANDAS mechanistically established as a result of blood brain barrier disruption that results in the same effect?
- Do pertussis-containing vaccines or pertussis infections generate antibodies that could result in acute neuropsychiatric symptoms?
- Do pneumococcal vaccines or pneumococcal infections and Hib vaccines or Hib infections cause or enable the development of acute neuropsychiatric symptoms?
- Do natural pertussis infections or pertussis-containing vaccines trigger PANS and/or PITAND?
- Do natural pneumococcal infection or Hib infection, or conjugate pneumococcal vaccines and Hib vaccines trigger PANS and/or PANDAS?
- Are PANS and/or PITAND and/or PANDAS generally accepted as independent disease entities?

Dr. Ditmar stated that an extensive review of the literature was conducted and he discussed the results of the review. He said:

- No published study that examines anti-neuronal antibodies including anti-dopamine receptor 1 (DR1), anti-dopamine receptor 2 (DR2), anti-tubulin, anti-lysoganglioside – GM1 or antibody-mediated activation of calcium calmodulin dependent protein kinase II (CaMKII) in children suspected of PANS and/or PITAND following pertussis infection or following pertussis immunization was found.
- No published case report of conjugate pneumococcal vaccines or pneumococcal infections and Hib vaccines or Hib infections causing or enabling the development of acute neuropsychiatric symptoms via a mechanism of blood-brain barrier disruption with GAS antibody-mediated CNS cross-reaction in a susceptible child were found.
- No published case report of PANS, PITAND and/or PANDAS following pertussis vaccination or during or following pertussis infection were found.
- No published case report of PANS, PITAND and/or PANDAS following either pneumococcal conjugate or *Haemophilus influenzae* type b (Hib) vaccination or pneumococcal or Haemophilus influenzae type b infection were found.
- The diagnoses of PANS, PITAND and/or PANDAS are controversial and are not validated as an officially-recognized independent disease entity. Dr. Ditmar added that

he categorized PANS, PITAND and PANDAS as investigational diagnoses and not as established or universally accepted diagnoses.

Dr. Ditmar reiterated the options for the Commission to consider.

With regard to Petition 1:

Option 1 - Add PANS and/or PITAND as injuries associated with the pertussis vaccine to the Vaccine Injury Table.

Option 2: Do not add PANS and/or PITAND as injuries associated with the pertussis vaccine to the Vaccine Injury Table.

With regard to Petition 2:

Option 1: Add PANS and/or PANDAS as injuries associated with pneumococcal conjugate vaccine and *Haemophilus influenzae* type b (Hib) vaccine to the Vaccine Injury Table.

Option 2: Do not add PANS and/or PANDAS as injuries associated with pneumococcal conjugate vaccine and *Haemophilus influenzae* type b (Hib) vaccine to the Vaccine Injury Table.

Ms. Luthy invited discussion from Commission members. There was a discussion of the food issues mentioned in the presentation, particularly in light of the lack of certitude of the defined diagnostic criteria for each condition. There was a comment from Commissioner Martha Toomey, that many in the health care community have little faith in the reality of PANDA and that calling PANDA controversial is adversarial and shouldn't be used in the discussion. There was also a comment that the medical community's response to a PANDA diagnosis can be, frankly, dangerous treatments, like plasmapheresis. Ms. Luthy invited comments from the public. Public comments:

1. A participant from the public, a parent (Daniel Humphreys) expressed concern over the number of references to the VSD, which is only accessible to individuals who are mainly pro-vaccine. He was also concerned that autism is not on the Table, which is a significant issue among those with vaccine-injured children. He noted that a positive vaccine response is for the immune system to attack itself, which is not discussed. Mr. Humphreys discussed the lack of public knowledge about the Table and expressed concern that the VICP's three-year time limit to file a claim is insufficient. He also commented that, contrary to Food and Drug Administration (FDA) recommendations, there is a tendency for doctors to administer multiple pathogens, up to dozens.
2. Another public participant, a parent (Janet Cakir), referring to diagnostic criteria and whether or not PANDAS exist, noted that on the NIH web pages there is a clear list of symptoms – the presence of clinical obsessions, compulsion, or tics. She mentioned that her children exhibited one or more of these symptoms and, on advice of medical experts,

treatment with immunoglobulins essentially cured the conditions, but it was very expensive. These children need to be able to rely on the Table.

3. An audio recording allegedly of Dr. Thompson, CDC, expressing his belief that vaccines can cause tics was played.
4. A participant from the public, a parent (Joel Troyer) told his personal story of his child's diagnosis of autism and PANS, which he believes is a result of childhood vaccinations. Mr. Troyer discussed current proposed state level legislation requiring insurance companies to cover PANS/PANDAS treatments. He also expressed his opinion that PANS/PANDAS should be added to the Table.

   A participant from the public, a parent (Karen McMillan), related her personal experience with her child's injury, which she believes was vaccine-related. Ms. McMillan, suggested that physicians be required to share information about vaccine injury programs with parents when a child has an illness following a vaccination. She also recommends that physicians be required to comply/assist with a parent's decision to file a vaccine injury claim.
5. Theresa Wrangham, Executive Director of the NVIC, commented that the IOM reported for 25 years on the lack of evidence of vaccine related injuries and that there needs to be more research.

Ms. Luthy invited each member of the quorum to submit an oral vote. On Petition 1, the result of the vote was five in favor of Option 2, one in favor of Option 1. Ms. Toomey voted in favor of Option 1.

On Petition 2, the result of the vote was five in favor of Option 2, one in favor of Option 1. Ms. Stewart, Mr. Howie, Mr. Sangiamo, Dr. Meissner and Ms. Luthy voted in favor of Option 2. Ms. Toomey voted in favor of Option 1.

**Petition to Add Experimental Autoimmune Encephalomyelitis (EAE) and/or Acute Demyelinating Encephalomyelitis (ADEM) as Injuries to the Vaccine Injury Table, Dr. Terry Dalle-Tezze, Medical Officer, Pediatric Team Lead, DICP**

Dr. Dalle-Tezze set a framework for the discussion, noting that encephalopathy is already on the Table for the pertussis vaccine. Acute Demyelinating Encephalopathy (ADEM) is a type of encephalopathy, but it was neither specifically included nor excluded in the Table until 2017, when ADEM was excluded as an encephalopathy diagnosis. The decision for the Commission is whether to include or exclude ADEM for the pertussis vaccination. Dr. Dalle-Tezze stated that the following wording was included in the petition:

- "I…petition for the addition of Experimental Autoimmune Encephalomyelitis EAE)…and provide a scientific review in support of my petition."
- "Experimental Autoimmune Encephalopathy (EAE), sometimes called acute disseminated encephalomyelitis…can be triggered by pertussis-containing vaccines. On January 19, 2017, the Secretary at the time clarified this disorder and excluded it from the Injury Table because it involves demyelination."
- "With this petition, I am requesting that the Secretary list Experimental Autoimmune Encephalomyelitis as an adverse event following pertussis vaccination"

Dr. Dalle-Tezze further quoted the petitioner:

- "Combination of pertussis vaccine and amyloid beta open the blood brain barrier allowing entry of anti-MOG antibodies resulting in monophasic inflammatory disease with sparse perivenous demyelination"
- "EAE following pertussis vaccination is a recognized disorder routinely initiated in laboratories using pertussis vaccinations"
    - "Documented to have occurred in a case-control study"
        - Specific study not mentioned (cited) in petition.
    - "VAERS database revealed 7 reports within the last decade"
        - Source/citations for this information not mentioned in petition.

Providing some background for EAE, Dr. Dalle-Tezze explained that EAE is not a disease, illness or injury in humans. EAE is an inflammatory demyelinating condition of the central nervous system (CNS) induced in the laboratory by the generation of an immune response against myelin epitopes. EAE is an experimental model used for studying autoimmunity. Animals are injected with antigens that have similar epitopes to CNS neural tissue. Antibodies are formed which attack the CNS and cause demyelination. CNS neural tissues (from rabbit brains) were used in the production of vaccine. CNS neural tissue antigens were unknowingly injected along with the vaccine. Vaccines with lower concentrations were less effective, and when concentrations of vaccine were increased, meningoencephalomyelitis occurred. With regard to pertussis, Dr. Dalle-Tezze explained that pertussis antigen (particles from pertussis bacteria) have been used in EAE studies because of its immunogenicity. Acellular pertussis vaccinations do not contain pertussis antigen. Finally, EAE has been critical to understanding CNS demyelinating conditions including ADEM and multiple sclerosis (MS).

Dr. Dalle-Tezze stated that the petitioner submitted 12 articles in support of his petition. Summarizing, he stated that the articles present a strong argument for the validity of the importance of EAE research. EAE is an instrumental tool in the study of demyelinating CNS conditions, including MS and ADEM. The experimental EAE studies have no relevance to pertussis vaccinations and/or ADEM. They do not provide any evidence or support to the allegations that pertussis vaccinations cause ADEM. These studies on EAE do not provide any support that ADEM should be added to the Table.

Dr. Dalle-Tezze continued with a discussion of encephalopathy. Dr. Dalle-Tezze stated that the Table covers acellular pertussis vaccination and encephalopathy/encephalitis when onset is within 72 hours, and there is evidence of acute encephalopathy as well as evidence of chronic encephalopathy, and no evidence of an alternate cause and/or other conditions as set forth in the Qualifications and Aids to Interpretation (QAI). In 2017, the QAI was revised regarding ADEM to reflect the following language:

> *"Exclusionary criteria for encephalitis.* Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:
>
> acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on

MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen, but is a minor component)."

Dr. Dalle-Tezze summarized the issues related to pertussis vaccinations and encephalopathy:

- Critical review of literature does not support vaccine causation between whole cell pertussis vaccinations and encephalopathy/encephalitis
- Critical review of literature does not support vaccine causation between acellular pertussis vaccinations and encephalopathy/encephalitis

Dr. Dalle-Tezze explained that the Secretary's and ACCV's decisions in 2015 on acellular pertussis and encephalopathy/encephalitis was published in the Federal Register on July 29, 2015. Despite the lack of literature to support vaccine causation with acellular pertussis and encephalopathy/encephalitis, the Secretary made the decision to keep encephalopathy/encephalitis on the Table for acellular pertussis. This decision was supported by the ACCV.

Dr. Dalle-Tezze continued his presentation addressing ADEM . Pathologically ADEM is an autoimmune condition of the central nervous system with hallmark symptoms of encephalopathy and demyelination in the CNS. ADEM etiology is unclear, but infectious etiology is suspected. In general terms, ADEM is a disease of the brain that alters brain structure and function. ADEM is a type of encephalopathy. Because of its autoimmune etiology, the timeframe for the Table is 7-10 days (versus 72 hours for acellular pertussis). The IOM failed to find a causal relationship between the pertussis vaccine and ADEM. Dr. Dalle-Tezze summarized his conclusions related to pertussis and ADEM:

- Most current literature does not support a relationship between whole cell pertussis and encephalopathy/encephalitis.
- Most current literature does not support a relationship between acellular pertussis vaccination and encephalopathy/encephalitis.
- ADEM is a very distinct condition from other forms of encephalopathy/encephalitis.
- The distinction was large enough that the IOM 2011 Report considered ADEM separately from encephalopathy/encephalitis.
- ADEM has a distinct autoimmune etiology.
    - Onset of 72 hours is not supported by the medical literature (hence the 7-10-day criterion).
    - ADEM is strongly associated with prodromal symptoms.
    - ADEM exhibits characteristic CNS demyelination.
- The 2012 IOM report does not support vaccine causation.
- Literature provided by the petitioner does not support vaccine causation.
- Current medical literature does not support vaccine causation.

Dr. Dalle-Tezze concluded his remarks and reminded the Commission of the options:

Option 1 - Add EAE/ADEM as an injury associated with acellular pertussis vaccines to the Vaccine Injury Table.

Option 2 - Do not add EAE/ADEM as an injury associated with acellular pertussis vaccines to Vaccine Injury Table.

If an injury is not on the Table or if the alleged injury and/or condition does not satisfy the Table's requirements, the petitioner must show that the vaccine caused the injury and/or condition. In addition, no other cause for the injury can be found. Many non-Table injuries are compensated by the program each year, typically through negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine caused the alleged injury.

Ms. Luthy invited comments from the Commissioners. There was a question of whether or not it would be acceptable to omit consideration of EAE, and vote only on the ADEM options. Dr. Dalle-Tezze agreed that that would make sense. Ms. Luthy invited comment from the public. Public comments:

1. A member of the public, Janet Cakir, expressed concern that ignoring or minimizing the importance of EAE research would be a mistake. She also expressed concern that pertussis toxin is in the acellular pertussis vaccine, which suggests that more research on the composition of the vaccine would be in order.
2. There was a comment from a member of the public, Jerry, who took exception to the predominance of physicians on the panel. The commenter expressed the opinion that doctors, albeit with medical degrees, may not have the depth of experience necessary to make recommendations on this narrow issue and related the opinion that many medical professionals and parents are not adequately educated on vaccines. The commenter expressed his belief that the Commission should vote for Option 1.

Following the public comment session, some Commission members noted that there had been significantly more participation from the public in this meeting than in previous meetings.

Ms. Luthy invited each member of the Commission to submit an oral vote. The result of the vote was four in favor of Option 2 and one in favor of Option 1. Ms. Stewart, Mr. Sangiamo, Dr. Meissner, and Ms. Luthy voted in favor of Option 2. Ms. Toomey voted in favor of Option 1.

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

Dr. Shimabukuro provided a summary of the proceedings of the October 2017 meeting of the Advisory Committee on Immunization Practice, which addressed the herpes zoster vaccine, the hepatitis B vaccine (Dynavax), live attenuated influenza vaccine (LAIV), a mumps outbreak, and a report of shoulder dysfunction following immunization. He also briefly discussed selected publications since the last ACCV meeting.

The FDA recently licensed the herpes zoster adjuvant subunit (HZ/su) vaccine. There is strong evidence that the vaccine is efficacious and durable, with minimal waning of efficacy in

the first four years after receiving the vaccine. In clinical trials, it had an acceptable safety profile, although it was locally reactogenic. About 20% of all herpes episodes occur in the age group 50 to 59, and the cost effectiveness of the vaccine is similar or better than most adult vaccines. HZ/su (inactivated) is one of two herpes vaccines available; the other is ZOSTAVAX, a live vaccine, ZVL.

The two vaccines have not been studied in a head-to-head trial, but HZ/su efficacy is considerably higher than ZVL, over 90% in adults over the age of 60. The effectiveness of ZVL is 64% for adults in their sixties, dropping to only 18% for those who reach 90. There is also significant waning of effectiveness after the first year. Neither vaccine was associated with serious adverse events in immunocompetent individuals, although HZ/su is more reactogenic. HZ/su leads to more disease prevention and decreased overall costs.

Three votes were taken at the ACIP meeting: ACIP recommended HZ/su for immunocompetent adults age 50 and older (unanimous); ACIP recommended HZ/su for individuals previously vaccinated with ZVL after a minimum interval of at least 8 weeks (12 in favor, 3 opposed); and ACIP recommended HZ/su be preferred over ZVL (8 in favor, 7 opposed). Dr. Shimabukuro stated that there is limited safety data on HZ/su so safety monitoring will be important during the uptake period, with enhanced VAERS surveillance and rapid cycle analysis in CDC's Vaccine Safety Datalink (VSD).

Dr. Shimabukuro commented that a new hepatitis B vaccine is available, HEPLISAV-B, licensed after the ACIP September meeting. It is a two-dose series completed in one month (versus the previous 3-dose, 6-month series). It has shown higher protection in adults than other available hepatitis B vaccines.

Dr. Shimabukuro discussed influenza. LAIV has not been recommended for immunization during the past two flu seasons, but additional data on LAIV effectiveness will be available in December 2017. Dr. Shimabukuro also described the final results of a recently published VSD study looking at inactivated influenza vaccine (IIV) and spontaneous abortion or miscarriage. This case-control study showed that miscarriage was significantly associated with IIV receipt in the 28 day exposure window. A similar VSD study before 2009 pandemic and other studies have not found an association between IIV and miscarriage. In the current study, the association between IIV and miscarriage was significant in the 2010-11 influenza season, but not in the 2011-12 season. In both seasons, the association was elevated only in the 28-day window and only in women who received influenza A H1N1pdm09-containing vaccine in the prior season. A follow-up study is underway, and no policy change has been proposed.

Dr. Shimabukuro pointed out there have been several mumps outbreaks since 2015, mainly in university settings. An ACIP workgroup had reviewed and discussed evidence on MMR vaccination in outbreak settings that a 3rd dose of MMR would improve protection for those at increased risk due to an outbreak.. ACIP voted unanimously that persons previously vaccinated with 2 doses of MMR and who are at increased risk of mumps due to outbreak should receive a 3rd dose.

Dr. Shimabukuro discussed an ACIP session on shoulder dysfunction following influenza immunization based on VAERS reports submitted between 2010 and 2016. The familiar term SIRVA was not used because the term implies a causal relationship and VAERS is a passive reporting system and not designed to determine causality. The number of reports ranged from 128 to 223 per year, with a higher percentage of reports among females. Of the reports, 70% were about individuals 19 to 59 years, and only a few were in younger individuals (0 to 18

years). The most commonly reported possible contributing factor was vaccine given too high on the arm. Most commonly reported places of vaccination were pharmacies and doctors' offices and hospitals. There does not appear to be an increase in shoulder dysfunction reports following IIV and recent influenza seasons. The shoulder dysfunction reports amounted to about 2% of all IIV VAERS reports during the analytic period.

Finally, Dr. Shimabukuro told the commission there were ACIP sessions on human papillomavirus vaccine, an adult and child/adolescent immunization schedule vote, Japanese encephalitis vaccine, and pneumococcal vaccines.

Finally, Dr. Shimabukuro commented on selected published papers, reporting on two of the thirteen papers provided in PDF format to Commission members.

A VSD study by McCarthy and colleagues addressed recommendations for a study topic from the IOM 2013 report on the childhood immunization schedule. Specifically, is there a risk of death following childhood vaccination?

McCarthy et al. Patterns of childhood immunization and all-cause mortality. Vaccine. 2017. pii: S0264-410X(17)31442-1.

- Although there were few deaths, the results do not indicate a difference in risk of all-cause mortality among fully vaccinated versus under vaccinated children.
- Findings support the safety of the currently recommended immunization schedule with regard to all-cause mortality.

Another study by Woo and colleagues looked at the safety of trivalent recombinant influenza vaccine in VAERS The recombinant vaccine is not an egg-based vaccine. It is made using an insect vector and does not contain residual egg protein, which has been suspected to be implicated in anaphylactic reactions.

Woo et al. Post-marketing safety surveillance of trivalent recombinant influenza vaccine: Reports to the Vaccine Adverse Event Reporting System. Vaccine. 2017; 35(42): 5618-5621.

- Allergic reactions following recombinant influenza vaccine were reported.
- Occurrence of anaphylaxis and other allergic reactions in some individuals may reflect an underlying predisposition to atopy that may manifest itself after an exposure to any drug or vaccine, and it does not necessarily suggest a causal relationship with the constituents specific to the vaccine product administered.

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

Responding to an earlier question, Ms. Schuster announced that NIH is supporting trials for several Zika vaccine candidates. Two papers were published in Lancet for two Phase 1 trials of different candidate vaccines.

Ms. Schuster began her presentation talking about influenza and the fact that NIH is focusing research efforts on seasonal and pandemic influenza preparedness. She discussed a specific strain, H7N9, which first appeared in China in 2013. Most cases of H7N9 influenza occur through contact with infected poultry or contaminated environments, including live poultry

markets. There have been five waves of the virus, involving over 1,600 total human cases resulting in more than 600 deaths.

The most recent wave accounted for over half of the total cases. In response to the first wave, NIAID launched two Phase 2 trials in 2013 to assess an investigational H7N9 vaccine made from inactivated virus; results were published in JAMA in 2014 and 2015. The research showed efficacy and the need for two doses of vaccine and the H7N9 vaccine was added to the U.S. emergency stockpile of vaccines. In 2017, the H7N9 vaccine was tested and found to be inadequate in providing protection against the most recent H7N9 strain. A new vaccine is needed. Researchers are working on a universal influenza vaccine that would protect against most flu strains. In June 2017, NIAID organized a workshop, The Pathway to a Universal Influenza Vaccine. Scientists are working on a vaccine that would target parts of the influenza virus that remain relatively unchanged from year to year. The workshop report was published in Immunity on October 17, 2017.

Ms. Schuster continued her presentation discussing Ebola. Results from a large randomized clinical trial in Liberia show that two experimental vaccines pose no major safety concerns, and can elicit an immune response within a month of immunization that lasts for a year or more. This NIAID-sponsored research was published on October 12, 2017 in the New England Journal of Medicine.

Ms. Schuster discussed a new seven-year initiative on Environmental Influences on Child Health Outcomes (ECHO). It will look at multiple studies of cohorts of women and children who have previously participated in other studies. The focus is on upper/lower airway, obesity, pre-, peri- and post-natal outcomes, and neurodevelopment. In October 2017, NIH announced a new study, named ACT NOW, looking for treatment options for newborns with opioid withdrawal syndrome, a disorder caused by exposure to opioids during pregnancy.

Ms. Schuster announced a new NIAID Now blog, that includes a post on an NIAID-funded study that focuses on biological mechanisms underlying immune responses to the flu vaccine and how these change with age. Describing immune profiles measured prior to vaccination may predict a person's antibody response to the seasonal flu vaccine.

Finally, Ms. Schuster announced that experts from NIAID and the World Health Organization Collaborating Centre for Reference and Research on Influenza (Australia) discussed how preparing vaccines in eggs may contribute to limited effectiveness. Mutations occurring in these vaccines may have contributed to decreased vaccine effectiveness during the 2016-2017 influenza season in the U.S. and 2017 flu season in Australia. The researchers emphasized the importance of targeted vaccine research and development of a universal flu vaccine.

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

CDR Marshall stated that the FDA approved two vaccines, both of which Dr. Shimabukuro mentioned by in his presentation. The FDA approved zoster vaccine recombinant, adjuvanted (Shingrix), in October 2017. Glaxo Smith Kline (GSK) manufactures the vaccine, and it is intended for prevention of herpes zoster (shingles) in adults aged 50 years and older. The trial excluded individuals with a history of herpes zoster. After the age of 50, a person's risk for shingles increases. Shingles typically present as a painful, itchy rash that develops on one

side of the body and can last for two to four weeks. Even if the rash disappears, a person can experience post herpetic neuralgia (PHN), pain lasting from at least three months up to several years. Shingrix is a non-live, recombinant adjuvant subunit vaccine given intramuscularly in two doses.

In November 2017, the FDA approved Hepatitis B Vaccine, Recombinant, Adjuvant (Heplisav), manufactured by Dynavax Technologies Corporation, for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Hepatitis B is a serious liver infection caused by the hepatitis B virus (HBV). Heplisav contains hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist adjuvant to enhance the immune response and is administered intramuscularly in two doses.

CDR Marshall commented that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on November 7, 2017 to discuss the clinical development plan of Pfizer's investigational Staphylococcus aureus vaccine (SA4Ag), intended for pre-surgical prophylaxis in elective orthopedic surgical populations. Invasive *Staphylococcus aureus* infections (SSIs) are a serious complication after elective surgeries and cause significant morbidity and mortality. It is the most common infection related to surgical settings. To address this unmet medical need, Pfizer has proposed a clinical development plan to support traditional approval of their investigational SA4Ag vaccine for use in adults undergoing elective orthopedic surgery. Pfizer initiated a large double-blind, placebo controlled clinical trial to evaluate the safety and efficacy of a single dose of the vaccine to prevent postoperative Staph aureus infection in adults 18 to 85 years of age scheduled to undergo spinal fusion surgery.

The purpose of this VRBPAC meeting was to seek input regarding the clinical data needed to support an indication for use in adults undergoing elective orthopedic surgery, with a focus on the extent to which safety and efficacy data accrued in a spinal surgery population can be generalized to other elective orthopedic surgical populations. The consensus of the committee members was that, if the trial succeeds, it may be valid to generalize the safety and efficacy to other orthopedic surgical procedures. Experts expressed varied opinions about whether the results could be broadly generalized, or whether the results should apply only to similar surgical procedures, such as knee and hip replacements.

**Update from the National Vaccine Program Office (NVPO), Dr. Karin Bok, NVPO**

Dr. Bok described a meeting in August 2017, on vaccine confidence sponsored by the NVPO and Emory University. Preliminary discussions settled on several focus areas: measuring and tracking vaccine confidence; communication and community strategies to increase vaccine confidence; health care provider strategies to increase vaccine confidence; developing policy strategies to increase vaccine confidence; and continued support and monitoring of the state of vaccine confidence. The meeting convened researchers, government agencies, and healthcare organizations to learn more about the work being done to address: vaccine confidence, hesitancy, and acceptance; to share new research and identify gaps; to strengthen the community of professionals working to increase vaccine confidence; and to discuss issues with leaders in related fields. Several studies were described:

- The NVPO conducted a poll of parents in 2016, which revealed that most parents surveyed consented to vaccines for their children as recommended, and most parents trusted their child's doctor as a reliable source of vaccine information, although there was concern about the number of vaccines, ingredients, and potential side effects.
- There was a mother's longitudinal study that showed that vaccine decisions were typically made before a child is born and seldom changed. Vaccine confidence typically increased over time and with experience, and with discussion with the family doctor often at the two-month office visit.
- Another study included interviews with vaccine-hesitant parents, who typically sought more details on side effects of vaccines and the potential consequences of not vaccinating. Finally, confidence levels of parents varied more than in the highly confident parents who were polled in 2016, described above.

Dr. Bok described a study from the Hennepin County Public Health Department that looked at communications planning and implementation during an outbreak. The study population was mainly Somali-Minnesotan. There were 70 measles cases, mainly in unvaccinated Somali children. A major outreach program of more than 150 visits by trusted health community leaders resulted in 25,000 vaccinations in a short period of time, which included an eightfold increase in vaccination of Somali-Minnesotan children. Dr. Bok briefly described another study using digital and social media in support of vaccine communication, and other efforts to improve confidence in HPV and zoster vaccination programs, and to improve healthcare providers' communication skills about HPV vaccines. Finally, there was a discussion about vaccine laws as they apply to school vaccination programs, including discussion of the various exemption options available to parents.

**Public Comment**

Ms. Luthy invited public comment.

1. A public commenter, Janet Cakir, a parent submitted a power point presentation and discussed the progress of the Commission's work on the statute of limitations, which began in December 2013 with an ACCV recommendation to extend the statute of limitations from three years to eight years after the first symptom of injury or death. Ms. Cakir's presentation discussed the timeline of the ACCV's recommendation. Written recommendations were submitted to Secretary Sebelius in 2013. The Secretary replied in 2014, pledging to consider extending the statute of limitations; however, in April 2014, Secretary Sebelius resigned. Secretary Burwell followed, but there was no action on the recommendation by 2015. Ms. Cakir observed no apparent contact between HHS and the responsible congressional committee that would have addressed the recommendation. Ms. Cakir observed that there has been a breakdown in the functioning of the VICP in that petitioners apparently are not being heard. She expressed the opinion that the examples of the petitions previously discussed and voted on are witness to the fact that the program designed to compensate them for injuries is accommodating too few petitioners. Petitioners face a long process of proving their injury; by a more effective process to list injuries in the Table could

reduce the length of the process in many situations. Ms. Cakir also expressed concern over the objectivity of the Commission and the people who decide to add injuries to the Table.

Ms. Luthy discussed the time limitations and invited individuals to submit written comments via e-mail, which would be published in the minutes of the meeting. Alternatively, a telephone comment would be acceptable if limited to no more than two minutes.

2. There was a comment from a member of the public, Andrea Woodruff, asking about the rate of the excise tax, suggesting that it should be reviewed since it has not changed in many years.

Ms. Luthy noted that there were no other requests for public comment.

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

Ms. Luthy and others mentioned several future agenda items suggested during the course of the meeting, including:

- Revisit the ACCV subcommittees (there were previous subcommittees, one of which was the Process Working Group, which discussed the statute of limitations),
- Discuss including as a member of the committee, an individual who has had a vaccine injury, preferably an adult,
- Discuss allowing a substitution for the general public commission member or a parent of a vaccine-injured child,
- Election of a permanent (not interim) chair and vice chair,
- Consider inviting advocates like Bobby Kennedy to make a presentation, and
- Discussion of the resource issues that negatively affect the work of the DOJ and the Court.

**Adjournment**

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

# 3

Vaccine Injury Compensation Trust Fund

## Balance as of March 31, 2018

$3,745,870

## Figures for October 1, 2017 to March 31, 2018

- Excise Tax Revenue: $136,534,047
- Interest on Investments: $32,162,138
- Total Income: $168,696,185
- Interest as a Percentage of Total Income: 19%

*Source: U.S. Treasury, Bureau of Fiscal Service (May 5, 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 80 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, 5,426 petitions were adjudicated by the Court, and of those 3,676 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 19,361 petitions have been filed with the VICP. Over that 29-year time period, 17,168 petitions have been adjudicated, with 5,999 of those determined to be compensable, while 11,169 were dismissed. Total compensation paid over the life of the program is approximately $3.8 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 | | | Compensable Total | Dismissed/Non-Compensable Total | Grand Total |
|---|---|---|---|---|---|---|---|
| | | Concession | Court Decision | Settlement | | | |
| DT | 794,777 | 1 | 0 | 5 | 6 | 4 | 10 |
| DTaP | 95,532,634 | 17 | 24 | 99 | 140 | 111 | 251 |
| DTaP-Hep B-IPV | 63,245,627 | 5 | 11 | 26 | 42 | 46 | 88 |
| DTaP-HIB | 1,135,474 | 0 | 1 | 2 | 3 | 2 | 5 |
| DTaP-IPV | 21,143,570 | 0 | 0 | 2 | 2 | 1 | 3 |
| DTap-IPV-HIB | 56,635,096 | 3 | 4 | 7 | 14 | 28 | 42 |
| DTP | 0 | 1 | 1 | 3 | 5 | 2 | 7 |
| DTP-HIB | 0 | 0 | 0 | 3 | 3 | 1 | 4 |
| Hep A-Hep B | 14,706,195 | 1 | 0 | 15 | 16 | 4 | 20 |
| Hep B-HIB | 4,787,457 | 1 | 1 | 2 | 4 | 1 | 5 |
| Hepatitis A (Hep A) | 163,305,725 | 7 | 6 | 36 | 49 | 29 | 78 |
| Hepatitis B (Hep B) | 172,993,779 | 6 | 11 | 59 | 76 | 65 | 141 |
| HIB | 111,200,358 | 2 | 1 | 8 | 11 | 10 | 21 |
| HPV | 101,405,935 | 15 | 15 | 96 | 126 | 157 | 283 |

| 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 | | | Compensable Total | Dismissed/Non-Compensable Total | Grand Total |
|---|---|---|---|---|---|---|---|
| | | Concession | Court Decision | Settlement | | | |
| Influenza | 1,372,400,000 | 435 | 188 | 1,828 | 2,451 | 377 | 2,828 |
| 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 | 7 | 49 |
| MMR | 94,815,650 | 21 | 16 | 80 | 117 | 115 | 232 |
| Mumps | 110,749 | 0 | 0 | 0 | 0 | 0 | 0 |
| MMR-Varicella | 21,349,409 | 8 | 1 | 11 | 20 | 13 | 33 |
| Nonqualified | 0 | 0 | 0 | 3 | 3 | 35 | 38 |
| OPV | 0 | 1 | 0 | 0 | 1 | 5 | 6 |
| Pneumococcal Conjugate | 206,003,646 | 10 | 4 | 15 | 29 | 23 | 52 |
| Rotavirus | 98,664,187 | 12 | 6 | 17 | 35 | 10 | 45 |
| Rubella | 422,548 | 0 | 1 | 1 | 2 | 0 | 2 |
| Td | 61,869,752 | 9 | 8 | 58 | 75 | 23 | 98 |
| Tdap | 225,013,338 | 72 | 17 | 218 | 307 | 56 | 363 |
| Tetanus | 3,836,052 | 8 | 2 | 35 | 45 | 19 | 64 |
| Unspecified | 0 | 1 | 1 | 4 | 6 | 585 | 591 |
| Varicella | 110,095,393 | 6 | 8 | 27 | 41 | 18 | 59 |
| **Grand Total** | **3,153,876,236** | **643** | **332** | **2,701** | **3,676** | **1,750** | **5,426** |

**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 5/01/2018

| Vaccines | Filed | | | Compensated | Dismissed |
|---|---|---|---|---|---|
| | Injury | Death | Grand Total | | |
| DTaP-IPV | 10 | 0 | 10 | 2 | 1 |
| DT | 69 | 9 | 78 | 26 | 52 |
| DTP | 3,286 | 696 | 3,982 | 1,273 | 2,709 |
| DTP-HIB | 20 | 8 | 28 | 7 | 21 |
| DTaP | 441 | 82 | 523 | 220 | 245 |
| DTaP-Hep B-IPV | 79 | 36 | 115 | 41 | 49 |
| DTaP-HIB | 11 | 1 | 12 | 7 | 4 |
| DTaP-IPV-HIB | 43 | 20 | 63 | 12 | 26 |
| Td | 205 | 3 | 208 | 120 | 74 |
| Tdap | 576 | 6 | 582 | 312 | 58 |
| Tetanus | 128 | 2 | 130 | 69 | 46 |
| Hepatitis A (Hep A) | 98 | 7 | 105 | 48 | 28 |
| Hepatitis B (Hep B) | 676 | 57 | 733 | 269 | 414 |
| Hep A-Hep B | 29 | 0 | 29 | 16 | 5 |
| Hep B-HIB | 8 | 0 | 8 | 5 | 3 |
| HIB | 42 | 3 | 45 | 16 | 20 |
| HPV | 368 | 14 | 382 | 122 | 154 |
| Influenza | 4,184 | 144 | 4,328 | 2,514 | 400 |
| IPV | 267 | 14 | 281 | 8 | 269 |
| OPV | 282 | 28 | 310 | 158 | 151 |
| Measles | 143 | 19 | 162 | 55 | 107 |
| Meningococcal | 64 | 2 | 66 | 41 | 7 |
| MMR | 959 | 61 | 1,020 | 398 | 576 |
| MMR-Varicella | 43 | 2 | 45 | 19 | 12 |
| MR | 15 | 0 | 15 | 6 | 9 |
| Mumps | 10 | 0 | 10 | 1 | 9 |
| Pertussis | 4 | 3 | 7 | 2 | 5 |
| Pneumococcal Conjugate | 138 | 14 | 152 | 35 | 43 |
| Rotavirus | 89 | 4 | 93 | 54 | 21 |
| Rubella | 190 | 4 | 194 | 71 | 123 |
| Varicella | 97 | 9 | 106 | 61 | 30 |
| Nonqualified1 | 97 | 9 | 106 | 3 | 100 |
| Unspecified2 | 5,424 | 9 | 5,433 | 8 | 5,398 |
| **Grand Total** | **18,095** | **1,266** | **19,361** | **5,999** | **11,169** |

[1] Nonqualified petitions are those filed for vaccines not covered under the VICP.
[2] Unspecified petitions are those submitted with insufficient information to make a determination.

## Petitions Filed

| Fiscal Year | Total |
|---|---|
| FY 1988 | 24 |
| FY 1989 | 148 |
| FY 1990 | 1,492 |
| FY 1991 | 2,718 |
| FY 1992 | 189 |
| FY 1993 | 140 |
| FY 1994 | 107 |
| FY 1995 | 180 |
| FY 1996 | 84 |
| FY 1997 | 104 |
| FY 1998 | 120 |
| FY 1999 | 411 |
| FY 2000 | 164 |
| FY 2001 | 215 |
| FY 2002 | 958 |
| FY 2003 | 2,592 |
| FY 2004 | 1,214 |
| FY 2005 | 735 |
| FY 2006 | 325 |
| FY 2007 | 410 |
| FY 2008 | 417 |
| FY 2009 | 397 |
| FY 2010 | 448 |
| FY 2011 | 386 |
| FY 2012 | 401 |
| FY 2013 | 504 |
| FY 2014 | 633 |
| FY 2015 | 803 |
| FY 2016 | 1,120 |
| FY 2017 | 1,243 |
| FY 2018 | 679 |
| **Total** | **19,361** |

# 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 | 193 | 564 |
| FY 2015 | 517 | 138 | 655 |
| FY 2016 | 697 | 179 | 876 |
| FY 2017 | 696 | 181 | 877 |
| FY 2018 | 257 | 104 | 361 |
| **Total** | **5,999** | **11,169** | **17,168** |

# 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 | 324 | $115,493,471.10 | $10,459,731.99 | 64 | $3,194,990.45 | 36 | $3,137,308.44 | $132,285,501.98 |
| **Total** | **5,991** | **$3,603,989,049.83** | **$180,935,154.25** | **5,302** | **$78,132,891.55** | **402** | **$30,800,753.38** | **$3,893,857,849.01** |

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

# Advisory Commission on Childhood Vaccines

# June 15, 2018

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

# DICP Update
# ACCV Meeting Highlights

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

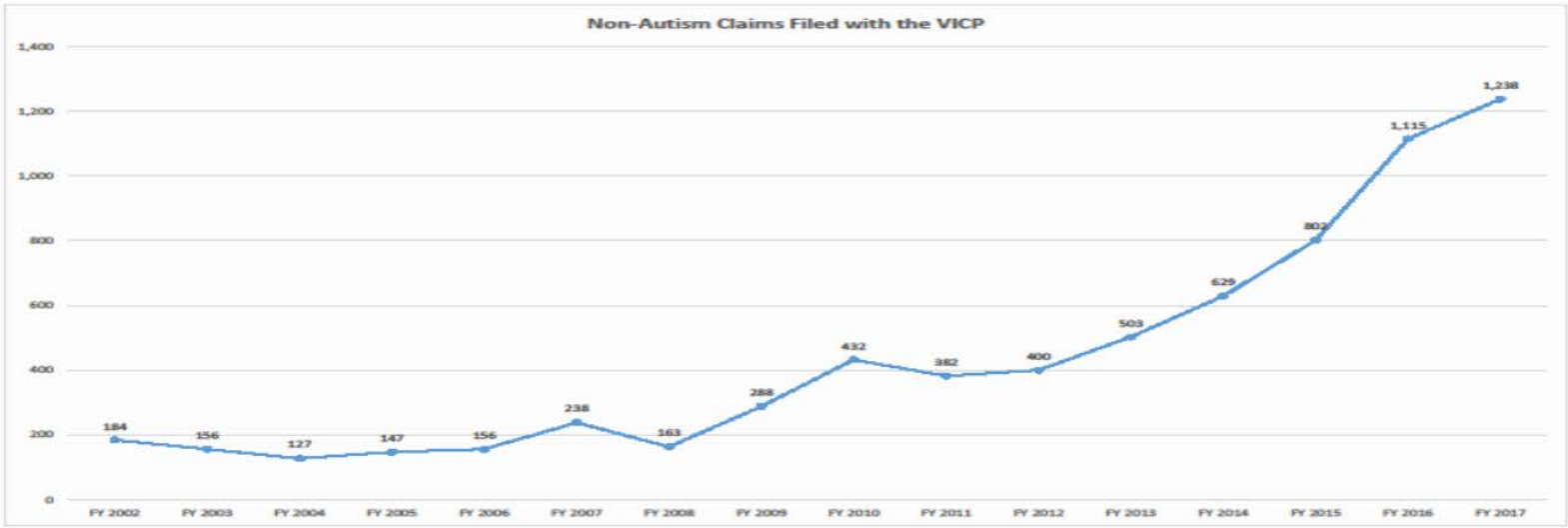
# DICP Update

# Number of Petitions Filed as of May 1, 2018

## Average annual number of petitions filed during FY 2008-2012 = 410

| Fiscal Year | Total |
|---|---|
| FY 2013 | 504 |
| FY 2014 | 633 |
| FY 2015 | 803 |
| FY 2016 | 1,120 |
| FY 2017 | 1,243 |
| FY 2018 | 679 |

# Non-Autism Claims Filed with VICP



# 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 |
|---|---|---|---|---|
| **2013** | 504 | ---- | $6.48 | ---- |
| **2014** | 633 | 26% | $6.46 | -0.3% |
| **2015** | 803 | 27% | $7.50 | 16% |
| **2016** | 1,120 | 39% | $7.50 | 0% |
| **2017** | 1,243 | 11% | $7.75 | 3% |
| **2018** | 679 (As of 5/1/18) | ----- | $9.2 | 19% |

HRSA Healthcare Systems

# Number of Claims Awaiting Review

| Fiscal Year | Claims Awaiting Review |
|---|---|
| 2017 | 0 |
| 2018 | 559 |
| Total | 559 |

# Award Amounts Paid as of May 1, 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 | $115,493,471 | $16,792,031 |

# DICP Update
# Number of Adjudications as of May 1, 2018

| Fiscal Year | Compensable | Dismissed | Total |
|---|---|---|---|
| FY 2012 | 265 | 2,533 | 2,798 |
| FY 2013 | 369 | 649 | 1,018 |
| FY 2014 | 371 | 193 | 564 |
| FY 2015 | 517 | 138 | 655 |
| FY 2016 | 697 | 179 | 876 |
| FY 2017 | 696 | 181 | 877 |
| FY 2018 | 257 | 104 | 361 |

HRSA Healthcare Systems

# DICP Update

## Adjudication Categories for Non-Autism Claims FY 2015– FY 2018 as of May 4, 2018

| Adjudication Category | FY 2016 | FY 2017 | FY 2018 |
|---|---|---|---|
| **Compensable**<br>❖Concession<br>❖Court Decision (includes proffers)<br>❖Settlement | **697 (100%)**<br>204 (29%)<br>43 (6%)<br>450 (65%) | **696 (100%)**<br>183 (26%)<br>46 (7%)<br>467 (67%) | **128 (100%)**<br>49 (38%)<br>7 (6%)<br>72 (56%) |
| **Not Compensable** | **168** | **173** | **42** |
| **Adjudication Total** | **865** | **869** | **170** |

# DICP Update
# Vaccine Injury Compensation Trust Fund

- **Balance as of March 31, 2018**
  - $3,745,870,228
- **Activity from October 1, 2017 to March 31, 2018**
  - Excise Tax Revenue: $136,534,047
  - Interest on Investments: $32,162,138
  - Total Income: $168,696,185
  - Interest as a Percentage of Total Income: 19%

Source: U.S. Treasury, Bureau of the Fiscal Service (May 5, 2018)

# DICP Update
# Significant Activities

- **Implementation of Maternal Immunization Provisions**
  - On April 4, 2018, the Notice of Proposed Rulemaking (NPRM) proposing to add the category of vaccines recommended for pregnant women to the Vaccine Injury Table was published in the *Federal Register*.
  - A public hearing is scheduled for September 17, 2018, 10:00-11:30 am (EST) which will provide the public an opportunity to comment on this NPRM.

- **Highlights of Recent Outreach Activities**
  - On April 24, provided an overview of the program to managers of HRSA Regional Offices so they inform grantees about the program.

# 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
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# 5.2


# Report from the Department of Justice

## June 15, 2018

Catharine E. Reeves
*Deputy Director, Torts Branch*

# Statistics

## Reporting Period: 2/16/18 – 5/15/18

I. **Total Petitions Filed in the United States Court of Federal Claims this reporting period: 263**

   A. Minors: 23

   B. Adults: 240

# Statistics

## Reporting Period: 2/16/18 – 5/15/18

**II. Total Petitions Adjudicated this reporting period: 147**

A. Compensated: 113

i. Cases conceded by HHS: 43

1. Decision awarding damages: 0
2. Decision adopting Proffer: 43
3. Decision adopting Settlement: 0

ii. Cases not conceded by HHS: 70

1. Decision awarding damages: 2
2. Decision adopting Proffer: 0
3. Decision adopting Settlement: 68

B. Not Compensated/Dismissed: 34

i. Decision dismissing Non-OAP: 34

ii. Decision dismissing OAP: 0

# Statistics

## Reporting Period: 11/16/17 – 2/15/18

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 2

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

## Decided Cases

**Appeals by Petitioner:**

- *D'Tiole v. HHS:* (Entitlement)
- *Anderson v. HHS:* (Entitlement)
- *Galindo v. HHS:* (Writ of Mandamus)

*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:**

- *Oliver v. HHS:* (Entitlement)
- *Depena v. HHS:* (Entitlement)
- *Olson v. HHS*: (Entitlement)
- *McCollum v. HHS:* (Entitlement)
- *Krakow v. HHS:* (Atty's Fees and Costs)
- *Rogero v. HHS:* (Entitlement)

*Yellow cases are new this reporting period

# Appeals: U.S. Court of Federal Claims

## Decided Cases

**Appeals by Petitioner:**

- *Caruso v. HHS:* (Entitlement)
- *Bender v. HHS:* (Entitlement)
- *Diedrich v. HHS:* (Entitlement)
- *Greene v. HHS:* (Entitlement)

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

# Appeals: U.S. Court of Federal Claims

## Decided Cases

**Appeals by Respondent:**

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

*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:**

- *Crespo v. HHS:* (Attys' Fees and Costs)
- *Harrington v. HHS:* (Entitlement)
- *L.P. p/o/g Petty v. HHS:* (Attorneys' Fees & Costs)
- *Gramza v. HHS:* (Entitlement)
- *Moczek v. HHS:* (Entitlement)
- *Soghomanian v. HHS:* (Entitlement)
- *Highland v. HHS:* (Attys' Fees and Costs)

*Yellow cases are new this reporting period

# Appeals: U.S. Court of Federal Claims

## Pending Cases

**Appeals by Respondent:**

- *Spahn v. HHS:* (Attys' Fees and Costs)
- *Amankwaa v. HHS:* (Attys' Fees and Costs)
- *Boatmon v. HHS:* (Entitlement)
- *Cottingham v. HHS:* (Attys' Fees and Costs)
- *McIntosh v. HHS:* (Attys' Fees and Costs)

*Yellow cases are new this reporting period

# Scheduled Oral Arguments

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

- *Oliver v. HHS:* (June 6, 2018)
- *Depena v. HHS:* (July 9, 2018)

U.S. Court of Federal Claims:

- *Boatmon v. HHS:* (June 5, 2018)

# Adjudicated Settlements*

## Reporting Period: 2/16/18 – 5/15/18

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 1. DTaP; IPV/OPV; PCV-13; Hep B; Rotavirus vaccinations | TM | 4 Years 3 Months |
| 2. MMR; PCV; Hep A | ADEM | 4 Years |
| 3. HPV | RA | 4 Years |
| 4. Flu | Acute Hemorrhagic Leukoencephalitis: Annuity | 4 Years |
| 5. Flu | Neurologic Injuries | 3 Years 5 Months |
| 6. Flu | Lupus | 3 Years 5 Monhs |
| 7. Hep A; Flu | Immune Trombocytopenic Purpura | 3 Years |
| 8. Tdap | CRPS | 3 Years |
| 9. Flu | NMBDA Receptor Encephalitis | 2 Years 6 Months |
| 10. Flu | GBS | 2 Years 5 Months |
| 11. Flu | Sensorineural hearing loss | 2 Years 5 Months |
| 12. Hep A | Autoimmune Aplastic Anemia | 2 Years 5 Months |

*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements*

**Reporting Period: 2/16/18 – 5/15/18**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 13. Flu | PMR | 2 Years 3 Months |
| 14. Flu | GBS | 2 Years 2 Months |
| 15. Flu | CIDP | 2 Years 2 Months |
| 16. Flu | TM | 2 Years |
| 17. Flu | GBS; Cerebellitis; Neuropathy | 2 Years |
| 18. Flu | Paresthesia; Cervical/Cranial Dystonia | 1 Year 8 Months |
| 19. Flu | TM | 1 Year 7 Months |
| 20. Flu | ADEM | 1 Year 7 Months |
| 21. Flu | SIRVA | 1 Year 6 Months |
| 22. Flu | GBS | 1 Year 6 Months |
| 23. TDaP | SIRVA | 1 Year 6 Months |

*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements*

**Reporting Period: 2/16/18 – 5/15/18**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 24. Flu | TM | 1 Year 5 Months |
| 25. Flu | CIDP | 1 Year 5 Months |
| 26. Flu | Encephalopathy; Death | 1 Year 5 Months |
| 27. Flu | SIRVA | 1 Year 4 Months |
| 28. Flu | GBS | 1 Year 4 Months |
| 29. Tdap; MCV | GBS | 1 Year 4 Months |
| 30. Flu | SIRVA | 1 Year 4 Months |
| 31. TDaP | GBS | 1 Year 4 Months |
| 32. PCV | SIRVA | 1 Year 4 Months |
| 33. Flu | PMR | 1 Year 3 Months |
| 34. Flu | SIRVA | 1 Year 3 Months |

*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements*

**Reporting Period: 2/16/18 – 5/15/18**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 35. Flu | SIRVA | 1 Year 3 Months |
| 36. TDaP | GBS | 1 Year 3 Months |
| 37. Flu | Brachial Plexitis | 1 Year 3 Months |
| 38. Flu | SIRVA | 1 Year 2 Months |
| 39. Flu | SIRVA | 1 Year 2 Months |
| 40. Flu | TM | 1 Year 2 Months |
| 41. Flu | SIRVA | 1 Year 2 Months |
| 42. Flu | SIRVA | 1 Year 2 Months |
| 43. Flu | SIRVA | 1 Year 2 Months |
| 44. Flu | GBS | 1 Year 2 Months |
| 45. Flu | GBS | 1 Year 2 Months |

# Adjudicated Settlements*

**Reporting Period: 2/16/18 – 5/15/18**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 46. Flu | SIRVA | 1 Year 1 Month |
| 47. Flu | SIRVA | 1 Year 1 Month |
| 48. Flu | SIRVA; Parsonage Turner Syndrome | 1 Year 1 Month |
| 49. Flu | SIRVA | 1 Year 1 Month |
| 50. Flu | SIRVA | 1 Year 1 Month |
| 51. Flu | ADEM | 1 Year 1 Month |
| 52. PCV | SIRVA | 1 Year 1 Month |
| 53. Flu | SIRVA | 1 Year 1 Month |
| 54. Varicella Vaccine | Varicella | 1 Year |
| 55. Flu | SIRVA | 1 Year |
| 56. Flu | PCV; SIRVA | 1 Year |

*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements*

## Reporting Period: 2/16/18 – 5/15/18

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 57. Flu | SIRVA | 1 Year |
| 58. Flu | SIRVA | 1 Year |
| 59. Flu | TM | 1 Year |
| 60. PCV | SIRVA | 1 Year |
| 61. Flu | GBS | 1 Year |
| 62. Flu | SIRVA | 1 Year |
| 63. TDaP | SIRVA | 9 Months |
| 64. Flu | SIRVA | 9 Months |
| 65. TD | GBS | 9 Months |
| 66. Flu | SIRVA | 9 Months |
| 67. Flu | SIRVA | 9 Months |

*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements*

**Reporting Period: 2/16/18 – 5/15/18**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| 68. Flu | GBS | 7 Months |

Terms of compensated settlements memorialized by Stipulation

# 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.

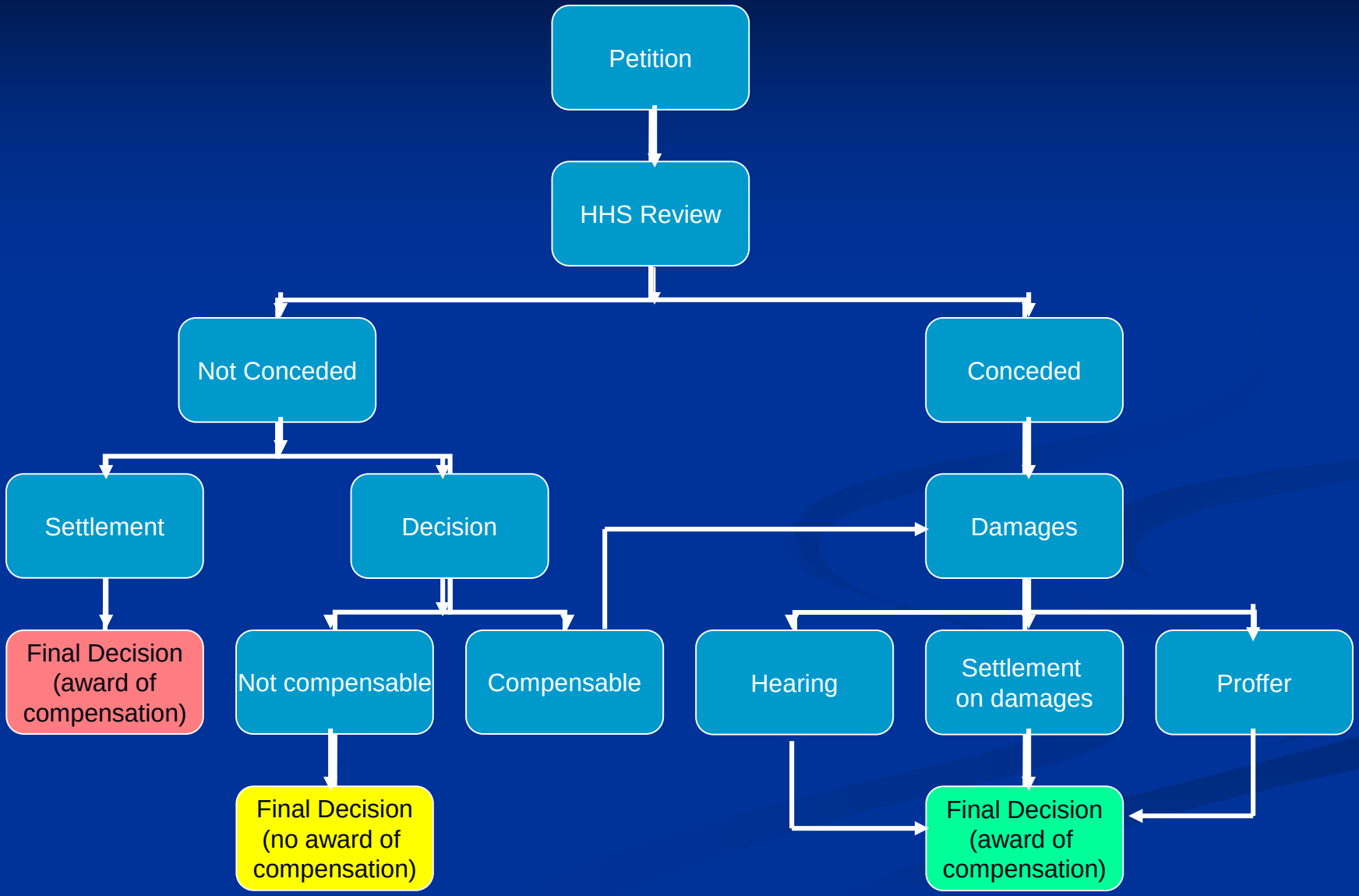
# Glossary of Terms

- **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

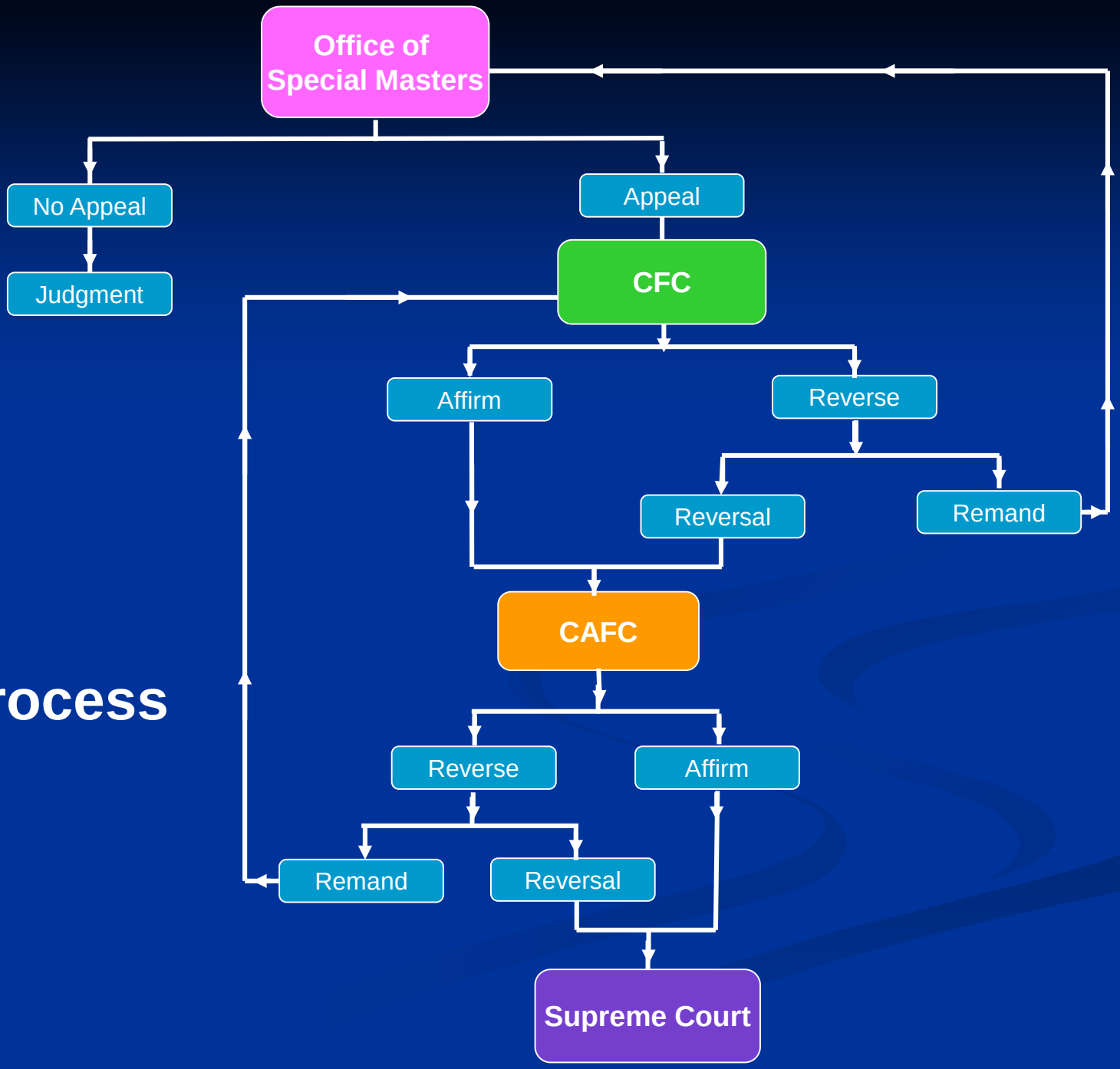
U.S. Supreme Court

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

**Jonathan Duffy, MD, MPH**
**Immunization Safety Office**
**Centers for Disease Control and Prevention (CDC)**

Advisory Commission on Childhood Vaccines (ACCV)
June 15, 2018

# Disclaimer

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

# Topics

- Recent presentations at meetings & presentations for upcoming June ACIP meeting
- Selected publications

# 48th National Immunization Conference, May 15-17, Atlanta, GA

- Oral presentations
  - Vaccine administration errors - Beth Hibbs et al.
  - Human papillomavirus (HPV) and HPV vaccination in the United States - Julianne Gee et al.
  - Updates from the CDC's Immunization Safety Office - Maria Cano, Theresa Harrington, Tiffany Suragh
  - Maternal vaccine safety monitoring at the CDC - Pedro Moro, Karen Broder, Lakshmi Sukumaran, Oidda Museru
- Posters
  - The healthcare provider's role in vaccine safety - Elaine Miller et al.
  - Safety of currently licensed hepatitis B vaccines in the United States, Vaccine Adverse Event Reporting System (VAERS), 2005-2015 - Penina Haber et al.
  - Safety of Menactra® vaccine: a review of reports to the Vaccine Adverse Event Reporting System (VAERS), 2005-2016 - Myers TR, McNeil MM, Ng C, Cano M.

# Preventive Medicine Conference, May 23-26, Chicago

- Tiffany Suragh et al. Unintentional administration of insulin instead of influenza vaccine (poster presentation)
  - Available at http://www.acpm.org/m/event_details.asp?id=940903

# Upcoming ACIP Meeting

- Advisory Committee on Immunization Practices (ACIP)
  - June 20-21, Atlanta, Ga
  - https://www.cdc.gov/vaccines/acip/meetings/upcoming-dates.html

- Influenza session will include following ISO presentations:
  - 2017-2018 influenza season vaccine safety update
  - Narcolepsy following adjuvanted monovalent pandemic H1N1 influenza vaccines: results of the SOMNIA study

# Upcoming ACIP Meeting (cont.)

- Pneumococcal Session – Safety of 13-valent pneumococcal conjugate vaccine (PCV13) in adults aged ≥65 years old

- Herpes Zoster Session – Herpes Zoster Vaccination: Evaluation Update

# Selected publications

# Award: Health Care Systems Research Network Paper of the Year

- Kharbanda EO, Vazquez-Benitez G, Romitti PA, Naleway AL, Cheetham TC, Lipkind HS, Klein NP, Lee G, Jackson ML, Hambidge SJ, McCarthy N, DeStefano F, Nordin JD; Vaccine Safety Datalink. First trimester influenza vaccination and risks for major structural birth defects in offspring. J Pediatr. 2017 Aug;187:234-239.
  - Award was presented at the HCSRN meeting in Minneapolis in April 2018
  - Conclusion: First trimester maternal IIV exposure was not associated with an increased risk for selected major structural birth defects in a large cohort of singleton live births.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/28550954

# Recent Publication

- Markowitz LE, Gee J, Chesson H, Stokely S. Ten years of human papillomavirus vaccination in the United States. Academic Pediatrics, March 2018, 18(2S):S3-S10.
  - Since human papillomavirus (HPV) vaccine was first introduced for females in the United States in 2006. The United States adopted a gender neutral routine HPV immunization policy in 2011. The safety profile has been well established from 10 years of postlicensure monitoring. Vaccination coverage is increasing, although it remains lower than for other vaccines recommended for adolescents. Despite low coverage, the early effects of the HPV vaccination program have exceeded expectations.
  - Available at http://europepmc.org/abstract/med/29502635

# Recent Publication (cont.)

- Irving SA, Groom HC, Stokley S, McNeil MM, Gee J, Smith N, Naleway AL. Human papillomavirus vaccine coverage and prevalence of missed opportunities for vaccination in an integrated healthcare system. Acad Pediatr. 2018 Mar;18(2S):S85-S92.
  - No significant differences in HPV vaccine coverage were identified at intervention clinics. However, coverage rates were increasing before the start of the intervention and might have been influenced by ongoing health system best practices. HPV vaccine coverage rates varied significantly according to department.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/29502643

# Recent Publication (cont.)

- Glanz JM, Newcomer SR, Daley MF, DeStefano F, Groom HC, Jackson ML, n BJ, McCarthy NL, McClure DL, Narwaney KJ, Nordin JD, Zerbo O. Association between estimated cumulative vaccine antigen exposure through the first 23 months of life and non-vaccine targeted infections from 24 through 47 months of age. JAMA. 2018 Mar 6;319(9):906-913.
  - Among children aged 24–47 months with emergency department and inpatient visits for infectious diseases not targeted by vaccines compared with children without such visits, there was no significant difference in estimated cumulative vaccine antigen exposure through the first 23 months of life.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/29509866

# Recent Publication (cont.)

- Daley MF, Shoup JA, Newcomer SR, Jackson ML, Groom HC, Jacobsen SJ, McLean HQ, Klein NP, Weintraub ES, McNeil MM, Glanz JM. Assessing potential confounding and misclassification bias when studying the safety of the childhood immunization schedule. Acad Pediatr. 2018 Mar 28.
  - For receiving no vaccines, the observed agreement between parent report and EHR data was 94.0% (kappa 0.79); for receiving all vaccines with no delays, the observed agreement was 87.3% (kappa 0.73). Although most asthma risk factors (allergic rhinitis; eczema; food allergies; family asthma history) reported by parents did not differ significantly between children in the vaccination groups studied, several factors (aeroallergen sensitivity; breastfeeding) differed significantly between groups.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/29604461

# Recent Publication (cont.)

- Liang JL, Tiwari T, Moro P, Messonnier NE, Reingold A, Sawyer M, Clark TA. Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR April 27, 2018 / 67(2);1–44.
  - Available at https://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm?s_cid=rr6702a1_x

# Recent Publication

- Miller ER, Lewis P, Shimabukuro TT, Su J, Moro P, Woo EJ, Jankosky C, Cano M. Post-licensure safety surveillance of zoster vaccine live (Zostavax®) in the United States, Vaccine Adverse Event Reporting System (VAERS), 2006-2015. Hum Vaccin Immunother. 2018 Mar 26:1-23.
  - Conclusions: Findings from our safety review of ZVL are consistent with those from pre-licensure clinical trials and other post-licensure assessments. Transient injection-site reactions, HZ, and rashes were most frequently reported to VAERS following ZVL. Overall, our results are reassuring regarding the safety of ZVL.
  - Available at https://www.ncbi.nlm.nih.gov/pubmed/29580194

# Recent Publication (cont.)

- Donahue, JG, Kieke BA, King JP, Mascola MA, Belongia EA. Response to three Letters to the Editor regarding: Donahue JG, et al. Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010-11 and 2011-12. Vaccine 35 (2017) 5314-5322. Vaccine 36 (2018) 2231-2232.
  - Available at https://www.sciencedirect.com/science/article/pii/S0264410X17317978

# 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**

**June 2018**

NIH National Institute of Allergy and Infectious Diseases

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NIH National Institutes of Health
*Turning Discovery Into Health*

FOR IMMEDIATE RELEASE
Thursday, March 15, 2018

News Release

## H7N9 Influenza Vaccine Clinical Trials Begin

- Inactivated 2017 H7N9 influenza vaccine manufactured by Sanofi Pasteur with or without AS03 adjuvant
- Phase 2 trials will enroll up to 420 volunteers ages 19 to 64 years and up to 300 volunteers >65 years of age

1 AS Fauci/NIAID

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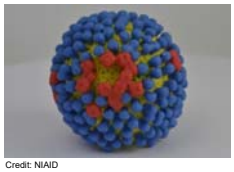
## Influenza Vaccine Research

NIH News

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
April 6, 2018

**Research Offers Clues for Improved Influenza Vaccine Design**



*Influenza vaccines that better target the influenza surface protein called neuraminidase could offer broad protection against various influenza strains and lessen severity of illness*

Credit: NIAID

2

Y Chen *et al*. Influenza infection in humans induces broadly cross-reactive and protective neuraminidase-reactive antibodies. Cell (2018 Apr 5)

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Published online February 28, 2018
The Journal of Infectious Diseases
IDSA
hivma

**A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases**

EJ Erbelding, D Post, E Stemmy, PC Roberts, A Deckhut Augustine, S Ferguson, CI Paules, BS Graham, AS Fauci

- Three key research areas:
  - Improve understanding of transmission, natural history, and pathogenesis of influenza infection
  - Precise characterization of influenza immunity and correlates of immune protection
  - Support rational design of universal influenza vaccines

3 AS Fauci/NIAID

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## Universal Influenza Vaccine

NIH News

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
May 4, 2018

**NIAID-Sponsored Trial of a Universal Influenza Vaccine Begins**

- Phase 2 clinical trial of experimental vaccine (M-001) intended to protect against multiple influenza strains
  - To test safety and ability to produce potentially broad protective immune responses
  - Vaccine alone and when followed by a standard, licensed seasonal influenza vaccine
- Conducted by NIAID-funded Vaccine and Treatment Evaluation Units

4

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## Webinar: Clinical Trial Networks


www.youtube.com/user/niaid

NIH National Institute of Allergy and Infectious Diseases

5


- May 6, 2018: NIH opened national enrollment for the *All of Us* Research Program to advance precision medicine

https://allofus.nih.gov/

6 The *All of Us* Anthem: https://www.youtube.com/watch?v=BSq08AduVGA

# 5.5

# Advisory Commission on Childhood Vaccines (ACCV)

## *Food and Drug Administration Update*

## June 15, 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)**

# Zoster Vaccine – Updated Labeling

- In April 2018, the FDA approved a supplement to the Biologics License Application (BLA) for Zoster Vaccine Live, (Zostavax, Merck) to revise the package insert to:
  - Include data from an interim analysis of an observational study that support longer-term effectiveness of Zostavax in individuals 50 years of age and older.
- To fulfill requirements of a postmarketing commitment, Merck conducted this study to assess the duration of protection against Herpes Zoster.

# Japanese Encephalitis Vaccine – Updated Labeling

- In April 2018, the FDA approved a supplement to the BLA for Japanese Encephalitis Vaccine, Inactivated, Adsorbed (Ixario, Valneva) to:
  - Update the package insert with immunogenicity and safety data from long-term pediatric clinical studies.
  - And include a recommendation for a booster dose at least 11 months after completion of the primary vaccination series for individuals less than 17 years of age who are at risk of continued exposure or re-exposure to Japanese encephalitis virus.

# Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate): Updated Labeling

- In April 2018, the FDA approved a supplement to the BLA for Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (Hiberix, GSK) to:
  - Update the package insert to include safety and effectiveness data from the booster phase of Study Hib- 097 that verify and describe the clinical benefit of Hiberix administered as a booster dose for active immunization.

# Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- VRBPAC met on May 17, 2018 to discuss approaches for demonstrating effectiveness of group B streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant.

# Ebola Outbreak in the Democratic Republic of the Congo (DRC)

- FDA is engaged with our interagency partners and medical product developers to advance the development of vaccines for Ebola.
- FDA has been in close contact with our interagency partners, medical product developers, the World Health Organization, and our international regulatory counterparts to help advance response efforts in the DRC.
- FDA is supporting vaccination efforts in DRC by primarily providing scientific and regulatory advice to WHO and supporting access to vaccine.

# Thank you!


FDA
U.S. FOOD & DRUG
ADMINISTRATION

# 5.6

# 6.1

# Vaccines Alone Won't Beat Ebola

A deep understanding of the Congo's culture and time-honored public-health tactics are the keys to controlling the outbreak.


Kenny-Katombe Butunka / Reuters

ED YONG | MAY 24, 2018 | HEALTH

*Updated on May 25 at 3:12 p.m. ET*

Three people who had been infected with Ebola recently left an isolation ward at Wangata Hospital against medical advice, according to the Democratic Republic of the Congo's Ministry of Health. The hospital lies in Mbandaka, a city of 1.2 million, where health workers are trying to contain the Congo's ninth Ebola outbreak. One patient was on the mend, but decided to leave on Sunday and didn't come back. Two more left with their families on Monday and went to church. One died at home, before his body was returned to the hospital for safe burial. The other returned voluntarily, before passing away at the hospital.

Choices like these make it harder to control this outbreak, which had already spread to 58 possible cases, as of Wednesday evening. But they are also understandable.

On a recent trip to the Congo, I met several survivors of past Ebola outbreaks, several of whom had left hospitals and gone home. Partly, that's because an isolation ward can be a horrendous place, with walls and floors sometimes covered with vomit, feces, and urine. But partly, it's also because the very concept of an isolation ward is an anathema to many Congolese people.

In the Cor ulder the burden of ak), a family hac ndry was drying on a washing line. "In an outbreak, you want to separate sick and healthy people, but here, if people are sick, everyone's there," one survivor told me. "Here, for we who live in communities, it is solitude that kills us."

That mindset continues after death. Families will clean and dress the bodies of their loved ones. They'll caress, kiss, and embrace them. Spouses might even spend a night next to their deceased partners. Through these bonds of affection, Ebola, which spreads through bodily fluids, can easily jump from one host into an entire family. The worst thing about the virus is not its deeply exaggerated bloodiness, but its ability to corrupt the bonds of community. It is a pathogen well suited to a world where sickness and death are met with touch and affection.

To bill these choices and practices, and others like them, as superstitions is misguided. These are the result of deeply held religious and cultural beliefs. "If you're asking someone to not do the typical thing they do to grieve and mourn, you need to provide an appropriate alternative that achieves the same cultural end," says Maimuna Majumder, an epidemiologist at MIT. "That's usually the piece that goes missing. You can't do that if you're othering these kinds of practices."

Fortunately, the Ministry of Health understands that."We can't forcibly prevent family members from touching a [patient]," says the spokesperson Jessica Ilunga. "So we've been really stepping up our community-engagement activities, by involving traditional and religious leaders. They have a huge influence on the community."

That is how outbreaks are contained—without community buy-in, resources and fancy new technology won't be enough. Unlike most of the Congo's previous outbreaks, mobile laboratories are now operating, allowing researchers to confirm possible cases faster. As I reported on Monday, accurate digital maps are being made. Tablets with freely available software allow field workers to enter and compare data in real time without having to rely on printed paper. And most excitingly, health workers are starting to deploy an experimental vaccine called rVSV-ZEBOV.

The vaccine has been lauded as a "game changer"—and rightly so. In over 40 years of Ebola outbreaks, never has such a tool been available from the start. But it is still understudied in the field, and its existence doesn't guarantee

whose case numbers are still growing as "contained," also billed the vaccine's use as "the first time Ebola was met with more than just the crude tools of quarantine and hospice care."

"Of course you want vaccines, but yellow fever and cholera are perfect examples of disease where we have vaccines and still get raging outbreaks," says Nahid Bhadelia, a physician at Boston University who helped to tackle Ebola in Sierra Leone. "We still need the public-health pillars."

By that she means: finding infected people and tracking their contacts; ensuring hygienic practices that keep infections from spreading; and engaging with communities. These are old-school measures. Public Health 101. But they're also the bedrock of any outbreak response. They're vital for diseases that have no available vaccines or treatments, like Lassa fever, which is currently breaking out in Liberia, or Nipah, which has risen again in India. And they're *still* vital when vaccines *are* available.

Around 7,500 doses of vaccine have so far been sent to the Congo, and 73 have been used as of Thursday afternoon, according to Guillaume Ngoie Mwamba. He is leading the DRC's vaccination program and, to show people that the vaccine is safe, was the first to get the shot.

The plan is to start by immunizing health workers, people who have come into contact with confirmed patients, and contacts of those contacts. This "ring vaccination" strategy entirely depends on basic public health. Without a full list of contacts, the rings will be broken and the Ebola will slip out. "If you don't know the chain, who do you vaccinate?" says Seth Berkley of Gavi, a nonprofit that has supported the vaccination campaign. That's why the vaccine has thus far only been used in Mbandaka. It has taken longer to flesh out the contact lists in rural Bikoro and Iboko, where most cases have occurred, although Mwamba expects vaccination to begin there on Saturday.

Even with complete lists, there's a lot of work to do. The Ministry of Health noted yesterday that some people from

director from the Ministry of Health, held a meeting with a Bikoro citizens' association to draw up plans for better communicating with the community.

For a start, there's a language barrier. The Congo has upward of 200 languages. In Bikoro, around 90 percent of people speak Lingala, the main local dialect; to reach the people who don't, the ministry is also translating its messages into N'Tomba, which is spoken by 40 percent of the region.

This kind of outreach must precede the deployment of the rVSV-ZEBOV vaccine, which brings with it several complications. Berkley says that people in the affected province are used to vaccination campaigns where entire communities get shots for diseases like measles or tetanus. But there aren't enough doses of the Ebola vaccine for that. The ring-vaccination strategy, where only certain people get immunized, is a trickier concept to convey.

Since the vaccine hasn't yet been licensed, it is being rolled out as part of a clinical trial.* In a similar small trial in Guinea, rVSV-ZEBOV proved to be 100 percent effective at preventing Ebola infections, but only during the tail end of an outbreak. It's unlikely to offer perfect protection in a more realistic setting, so it's vital that vaccinated people don't let their guard down. The vaccine also takes 10 days to provide full protection; it has only been 16 days since the new Congo outbreak was first declared.

"If you say to people that it's 100 percent effective, and all contacts get vaccinated, some subset of them will develop Ebola because they've already been incubating the virus," says Berkley. "We have to be careful to not lose confidence in the vaccine."

These challenges are not insurmountable. Mwamba tells me that there was originally some resistance to the vaccine among people in Mbandaka but after speaking to the communications team, everyone who was approached agreed to get the shot.

Reassuringly, a team of experts from Guinea, who were all involved in the rVSV-ZEBOV vaccination trial from 2015, arrived in Mbandaka on Sunday. They are intimately familiar with Ebola, ring vaccination, and this particular vaccine. "They've very important," says Mwanba. "They're training the Congolese, and I think by the end of this outbreak, we'll have enough capacity to fight new epidemics on our own when they come again." So far, the vaccination team includes six of the Guineans, along with 18 Congolese health workers. More people from Mbandaka and Bikoro are also being recruited to enhance local knowledge.

This vaccine may well help beat Ebola. But even if it does, its success will have been predicated on "crude tools"—on tracing contacts, on speaking a shared language, on cultural understanding, on trust. "It's not surprising that people often don't see how important these measures are," says Majumder. "In public health, when you do your job right, no one knows that you do it."

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* An earlier version of this story incorrectly suggested that the use of the vaccine as part of a clinical trial affected the nature of informed consent. We regret the error.

**ABOUT THE AUTHOR**

**ED YONG** is a staff writer at *The Atlantic*, where he covers science.

Twitter Email

# 6.2

CIVIC

# Idaho Has High Rate of Vaccination-Exempted Students

In the 2016-17 school year, more than 1,000 of Idaho's kindergartners were vaccine-exempt.

By **Associated Press**, Wire Service Content


Parents or guardians of school-age children can request medical, religious and philosophical exemptions for vaccinations. (JOE AMON/THE DENVER POST VIA GETTY IMAGES)

**BY JUSTYNA TOMTAS, LEWIS**ton Tribune

LEWISTON, Idaho (AP) — As students excitedly eye summer break, some parents are in the process of preparing younger family members for kindergarten.

That likely means attending a local kindergarten registration event, where they'll learn it's time to think about immunizations.

School officials generally require parents or guardians to bring an up-to-date record of their kids' vaccines to kindergarten registration in the spring or provide one prior to the start of the school year.

**RELATED CONTENT**

Is Wealth the Only Road to Community Health?

In recent years, Idaho has been a leader in vaccination exemption rates, but not in a good way, according to health professionals. The exemption rate, referring to students whose parents have asked the state for a vaccine waiver, has been one of the highest – if not the highest – in the nation for the past several years.

For the 2016-17 school year, the childhood vaccination exemption rate in Idaho was 6.5 percent, according to the Centers for Disease Control and Prevention. Only Alaska and Oregon beat out the Gem State with exemption rates of 6.8 and 6.7 percent, respectively.

The number of families choosing not to vaccinate concerns local health officials, who say immunizations are the most efficient defense currently available against a variety of serious diseases.

"It provides the best protection we have from childhood illnesses, and that's for the individual child," said Mike Larson, public health nurse at the Idaho North Central Health District. "There are no 100 percent guarantees, but it's the best benefit we have or know of to protect children."

When a child is vaccinated, Larson said, he or she is able to protect others who do not or cannot get their shots.

"It's not only protecting (the child), but also it's protecting the other children who may be medically fragile and cannot be vaccinated or a child that's immunocompromised (has a weakened immune system) that won't respond to a vaccine well," he said. "The more children you have immunized and not susceptible to whatever illness it is, it increases the herd immunity and protects other children who can't be vaccinated, don't respond to the vaccines, or frankly, it protects those that parents don't want to vaccinate."



The number of vaccinated kindergarten students varies greatly throughout the region.

According to the 2016-17 Idaho School Immunization Report, compiled by the state Department of Health and Welfare, McSorley Elementary School in Lewiston had one of the highest rates of students fully up-to-date on vaccinations.

The numbers show 95.5 percent of kids had all the shots they needed, while the remaining 4.5 percent of students had exemptions on file with the school.

But for other schools, particularly in rural areas, the numbers were sometimes dramatically lower.

At Prairie Elementary School in Cottonwood, only 48.1 percent of kindergartners in the 2016-17 school year were adequately immunized. The school had exemptions on file for 22.2 percent of them. The remaining about 30 percent of kindergartners did not show up in the report.

Prairie Elementary School Secretary Lynn Rehder, who is in charge of the school's kindergarten roundup event and who submits immunization records to the state, declined to comment on the topic.

Other schools in north central Idaho ran the gamut.

Webster Elementary had the lowest percentage of kindergarten students immunized among Lewiston public schools during the 2016-17 school year with 82.9 percent. There were exemptions on file for 17.1 percent of the students.

In Lapwai, 76.5 percent of kindergartners were adequately immunized. The school did not have any exemptions on file, according to the report.

[ **READ:** Health Progress Stalls for African-Americans ]

Juliaetta Elementary kindergartners had an adequately immunized rate of 61.5 percent, with 7.7 exemptions on file.

In Kamiah, 79.5 percent of students had their required shots, with exemptions for 15.4 percent on file. During Kamiah's kindergarten roundup event, the school made sure a nurse was on hand to discuss any concerns parents had.

At least five area school districts contacted by the Tribune declined to comment, stated immunization information was unavailable or did not return multiple requests for comment.

There are three types of vaccine exemptions parents or guardians of school-age children can request: medical, religious or for philosophical reasons.

For Idaho's kindergarten population of 22,589 for the 2016-17 school year, there were 85 medical exemptions, 127 religious exemptions and 1,265 philosophical exemptions, accounting for 1,478 students in all.

Two percent of the students enrolled in kindergarten were conditionally admitted, which means their vaccinations were not up-to-date, but they had an appointment to do so. According to data in the annual report, it's not uncommon for schools to have a gap between the number of students who are up-to-date on vaccinations and the number of exemptions on file.

The majority of schools, in fact, do have a gap, and some of the students who fall into that gap are kids who are not up-to-date on shots, said Idaho Department of Health and Welfare spokeswoman Niki Forbing-Orr.



Larson cautions that immunization numbers reported to the state represent only a glance at the current situation.

"It gets tricky when you look at the national numbers of what percentage of kids have immunizations," he said. "You have to be careful what you are looking at, because it's a snapshot of a very specific time."

Larson explained some kids may not have the vaccinations required by a certain age, but might come into compliance several days later. Then they're up-to-date, but that's not reflected in the state numbers.

The Centers for Disease Control and Prevention cautions vaccination coverage or exemption estimates may be "under- or overestimated because of improper or absent documentation." The agency also said it's difficult to make state-by-state comparisons, because state requirements differ.

Idaho school districts are required to report their vaccination numbers to the state at the beginning of November. The numbers for the 2017-18 year should be available at the end of May or in early June, Forbing-Orr said.

For the past five years, the exemption rate for kindergarten students has hovered right around the 6 percent mark. The overall percentage statewide of kindergartners who are adequately immunized is 86.1 percent. The Department of Health and Welfare hopes to increase that number to 95 percent.

Opposition to vaccinations is nothing new. According to the National Center for Biotechnology Information – a branch of the National Institutes of Health – opposition has existed as long as immunizations have.

The topic was reignited when President Donald Trump ran for office. He linked vaccines to autism – a claim that has been debunked.

**RELATED CONTENT**

Rebuilding With Resilience After Disasters

Larson said the autism link is a myth that still lingers.

"That is the challenge that we have today," he said. "It's difficult for people to realize and recognize what the true facts are. Right now, anyone can say anything on the internet and claim they are the expert on it and not have facts to back it up."

Health and Welfare Department officials understand parents may have concerns when it comes to immunizations.

"It's natural to have questions, but consider the source when you are seeking information on immunizations," Forbing-Orr said. "You can trust your pediatrician and your doctor to give you the information you need to make an informed choice."

The department works closely with schools and medical providers to give parents the tools they need to make educated choices about vaccinating their kids, she said.

In January, an Idaho Senate panel introduced legislation that would have made it easier for parents to opt out of vaccinations for their children. The bill would have allowed parents to submit a letter rather than utilize the state exemption form. It never received a public hearing.

The bill was supported by Health Freedom Idaho, which promotes "vaccine choice."

In Washington, the statewide vaccine exemption rate for the 2016-17 year was 4.8 percent. It increased from 4.5 percent the prior year. Out of the 87,142 kindergarten students reported during that time frame, 4,161 were without vaccinations.

In 2015, the Clarkston School District had about 200 students who did not meet the state's requirements. The district organized voluntary vaccination clinics to bring the children up-to-date. About 3 percent of students had vaccine exemptions at that time.

The district was unable to provide updated immunization statistics before the Tribune's deadline.



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Information from: Lewiston Tribune, http://www.lmtribune.com

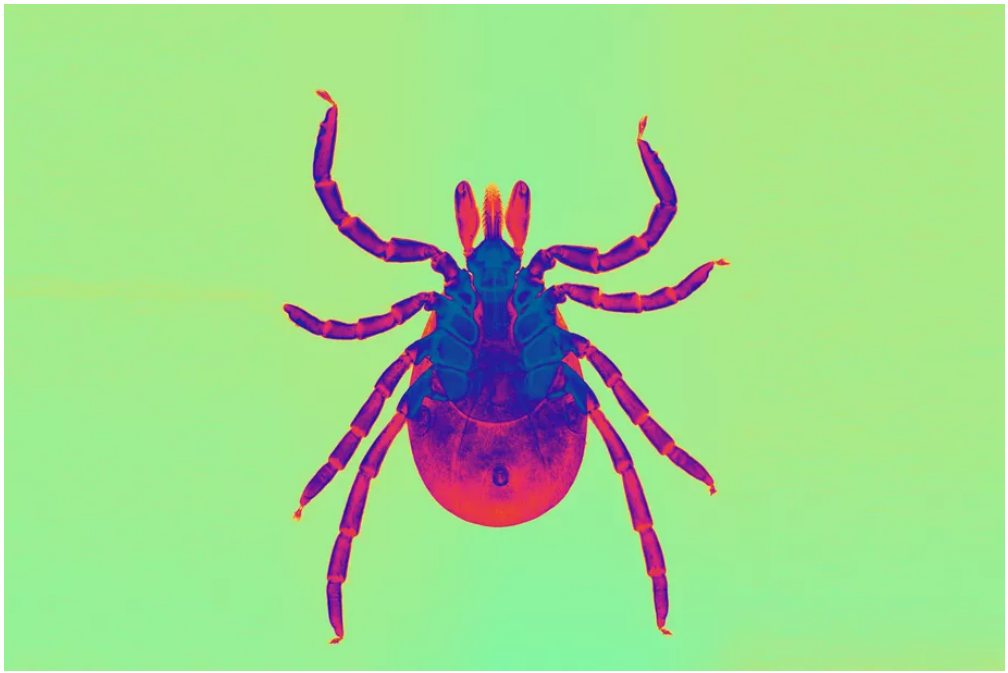
# 6.3

Vox

# The incredibly frustrating reason there's no Lyme disease vaccine

Your dog can get vaccinated for Lyme. You cannot.

By Brian Resnick | @B_resnick | brian@vox.com | May 7, 2018, 12:20pm EDT



The deer tick spreads the bacteria that causes Lyme. | Adapted from Ed Reschke/Getty Creative Images

Lyme has quickly become one of the most common infectious diseases in America, with many as 300,000 people infected every year. And public health officials fear the bacterial infection, which jumps from ticks to humans, will only spread farther and faster as climate change makes more parts of the US habitable for ticks.

Lyme can be treated with antibiotics. And there are many ways to prevent tick bites. But there's no vaccine available if you want extra protection against the disease (unless you're a **dog**).

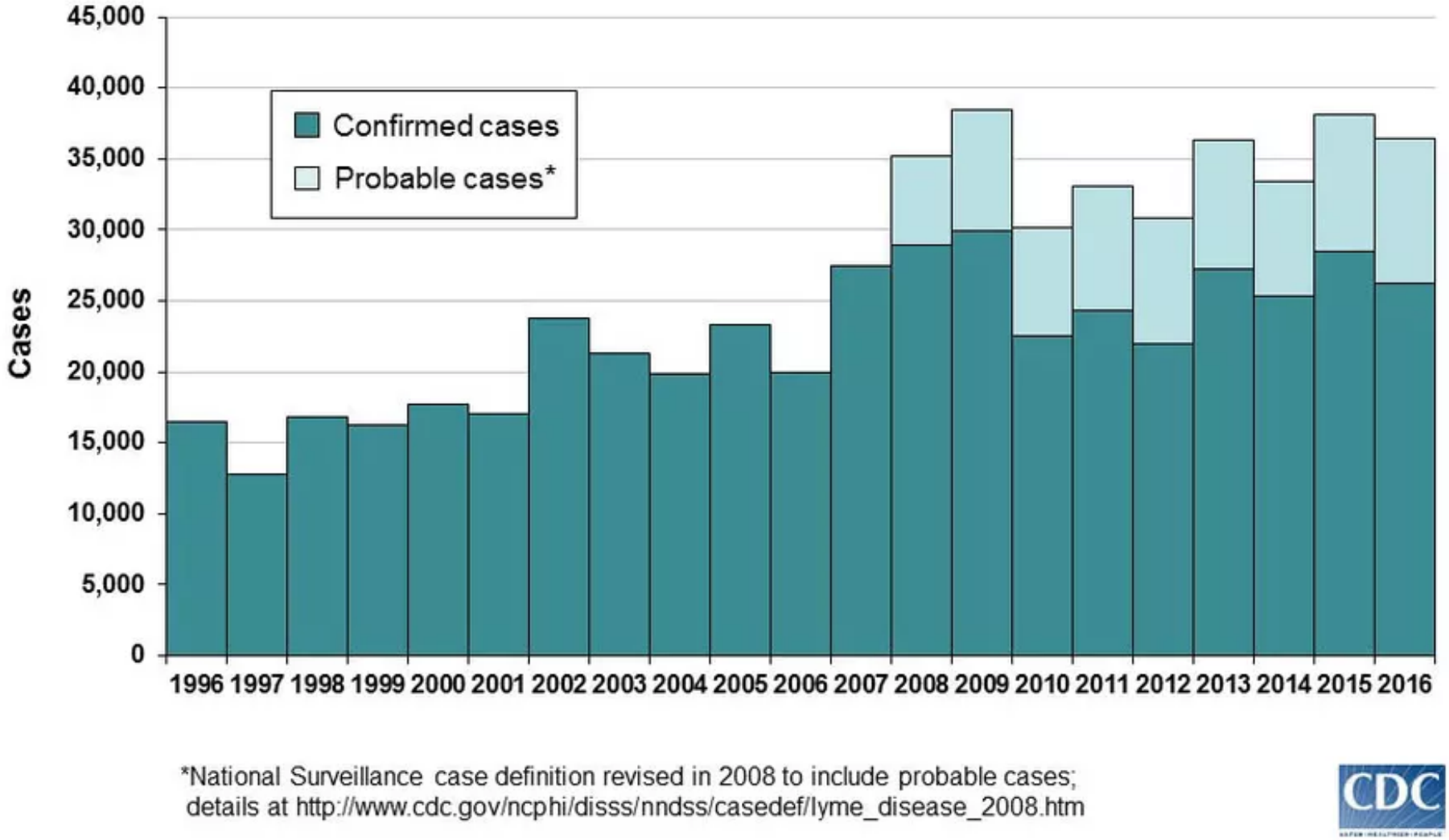
Yet in the late 1990s and early 2000s, a vaccine called LYMErix was sold to prevent between **76 and 92 percent of infections**. Hundreds of thousands of people got it — until vaccine fear knocked it off the market.

The LYMErix story is worth retelling today. It's a stark reminder of how anti-vaccine mania of the past few decades is leaving us all more susceptible to disease.

## The Lyme vaccine was effective

Lyme first appeared in the US seemingly out of nowhere, spreading between ticks and people in Connecticut.

By the 1990s, it was possible to be infected with Lyme from a tick bite in much of the northeastern US — and there were around 15,000 **confirmed** cases a year. (Today, there are more than 35,000 confirmed or probable cases of Lyme each year and many more cases that go completely unreported.)




The number of Lyme cases continues to climb. These are just the probable and confirmed cases. There could be as many as 300,000 cases that go unreported each year. | CDC

Recognizing the increasing public health hazard, the drug manufacturer SmithKline Beecham (now called GlaxoSmithKline) developed a vaccine that targeted the outer protein of the bacteria that causes Lyme. The Food and Drug Administration approved it in 1998.

The vaccine **worked** by targeting the bacteria while it was still inside the tick's body, the website History of Vaccines **explains**. The bacteria would be neutralized before the tick ever had the chance to transfer the bacteria into the human body.

LYMErix wasn't a perfect vaccine, as Gregory Poland, a Mayo Clinic vaccine researcher, explained **in a 2011 retrospective** in the journal *Clinical Infectious Diseases.* It required three doses over the course of the year, and was not approved for people under age 15. It was optional, and doctors had a hard time assessing whom to recommend it to (there were few maps of Lyme-carrying ticks' range at the time). And the vaccine only protected against the North American strain of Lyme. Finally, it was somewhat expensive at $50 a dose, and it was **not universally** covered by health insurance.

But it was effective, preventing Lyme in **up to 90 percen**t of the people who were vaccinated will all three doses, with few side effects. And at first, the vaccine was pretty popular; about 1.5 million doses **were** injected before 2000.

## LYMErix debuted near the beginning of anti-vaccine mania

Getty Images/Collection Mix: Subjects RM

LYMErix had the misfortune of being approved the same year some people were becoming suspicious of vaccines in the United States. In 1998, the journal *Lancet* published a **now-retracted study that (falsely)** claimed the measles, mumps, and rubella vaccine (MMR) was linked to autism, and the modern anti-vax movement was born.

At the same time, a few members of the FDA panel that approved LYMErix had voiced a theoretical concern that the drug could cause an autoimmune reaction leading to arthritis. The idea was that as the immune system learned to attack the protein that covered the Lyme bacteria, it could overreact and start to attack healthy tissue in the body. This side effect didn't occur in the clinical trial. It was just a hypothetical possibility.

The FDA panel eventually unanimously approved the drug, but the fear of an autoimmune reaction trickled down to the public.

What happened next was a perfect storm to drive the product from the market. A 2000 study **found** the vaccine contributed to autoimmune arthritis in hamsters. Other research posited (but didn't prove) that it was possible some people were more genetically predisposed to develop this type of autoimmune response in reaction to the vaccine.

Sure enough, some LYMErix recipients soon began to complain publicly that the drug was causing them to develop joint pain. National news media were reporting on the concerns, casting them in a harrowing light. In the 2000, ABC **news** told the story of a man who fell ill with a "fever and an intense, hellish pain" after taking the vaccine.

The FDA looked into the claims but never found a connection between the vaccine and arthritis. By 2001, 1.4 million does of the vaccine had been distributed, but the FDA's Vaccine Adverse Events Reporting System only picked up on 59 reports of arthritis.

"The arthritis incidence in the patients receiving Lyme vaccine occurred at the same rate as the background in unvaccinated individuals," a 2007 paper in *Epidemiology and Infection* **explains**.

Overall FDA's VAERS only picked up on 905 reports of any adverse side effects at all — a tiny amount compared to the number of people who had gotten the shots.

## The vaccine was pulled from the market, despite evidence finding it was safe

But it was too late. Already, there was "significant media coverage, sensationalism, the development of anti-Lyme vaccine groups ... who urged withdrawal of the vaccine from the market," Poland explained in his 2011 article. A class-action lawsuit **targeted** SmithKline Beecham, claiming the company did not do enough to warn people of potential autoimmune side effects.

The FDA continued to follow up with an additional drug safety trial to try to settle the matter for the public. The trial was supposed to last four years. But sales of LYMErix had plummeted "from about 1.5 million doses in 1999 to a projected 10,000 doses in 2002," the National Institute of Allergy and Infectious Diseases explains on its website.

So the manufacturer pulled it from the market, despite the fact that early data from the additional safety trial found "no differences in any significant adverse reactions noted between control subjects and vaccinated persons," Poland writes.

Concerning side effects sometimes **do emerge after a drug comes on the market**. But you need hard data to establish them. And the FDA's investigations into LYMErix never found any evidence of autoimmune side effects.

"Although studies never adequately substantiated the safety concerns associated with LYMErix," the *Epidemiology and Infection* article states, "the decline in public tolerance for risk and uncertainty combined with the relatively low morbidity of Lyme disease contributed to the inability of the vaccine to find a market niche."

In 2000s, Lyme still didn't infect that many people, and the public was more concerned about the Lyme vaccine than the disease itself. But now infections rates are rising and we're left without a crucial tool to stop its spread.

## Where are we now?

As Julia Belluz reported at **Vox**, Lyme cases **tripled** between 2004 and 2016, spread by an increased number of infected ticks. It's now the most common vector-borne (i.e., transmitted by an insect or animal) disease in the United States. And climate change seems to be partly to blame: As temperatures warm, a greater proportion of the US becomes hospitable to the ticks. Overall, vector-spread diseases like chikungunya, Zika, and West Nile are spreading faster than ever.

And still, if you wanted to protect yourself with a **Lyme disease vaccine**, you couldn't get one. As Belluz explained, prevention efforts currently focus on avoiding tick bites. That means covering up exposed skin when spending time in wooded areas, using insect repellent, and checking your body for ticks (and removing them) after you've spent time outdoors in tick-laden areas.

WBUR in Boston reports there have been some small **efforts to revive** LYMErix (its patent has now expired), but the pharmaceutical industry has lost interest in it, and grassroots efforts have gone unfunded. The Lyme vaccine for dogs works in a similar manner to LYMErix. But while it does help control the spread of the disease, it doesn't make up for the lack of a vaccine in humans.

"Low demand for the vaccine and its subsequent withdrawal from the market represent a loss of a powerful tool for Lyme disease prevention," the authors of the *Epidemiology and Infection* article state. For many, symptoms last months, leading to painful arthritis, heart problems, and nerve pain. Though Lyme is treatable, it needs to be diagnosed early for people to avoid its worst symptoms. A vaccine would provide a greater margin of error if a tick bite goes unnoticed.

Unscientific anti-vaccine movements leave us all more unsafe down the line. We see examples of this in the news all the time. Diseases long controlled by vaccines, like **measles**, are now starting to pop back up in concerning numbers. In Japan, vaccination rates for HPV vaccine plummeted in recent years **due to fearmongering**.

Vaccines can be a hard sell because people need to take them when they're healthy, and no vaccine has zero risk of side effects. But when we take a vaccine, we're not just protecting ourselves — we're protecting those around us, and ensuring a less infected future. The LYMErix vaccine was optional, and anti-vaccine fears have left millions without the option to take it at all.

A French **company** is developing a new Lyme vaccine, New Scientist **reports**. It would protect against the different strains of Lyme that circulate worldwide, but it's just getting out of **Phase I safety trials**, which means it would be many years before it arrives on the market, if proven safe.

We can't count on having a vaccine anytime soon. But we can count on more ticks coming our way.

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**From:** Herzog, Andrea (HRSA)

**Subject:** FW: Fw:PUBLIC comment ON FEDERAL REGISTER
**Date:** Tuesday, May 29, 2018 7:30:13 AM

Annie Herzog
Principal Staff Liaison, ACCV
Division of Injury Compensation Programs
Healthcare Systems Bureau
Health Resources and Services Administration
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**From:** Jean Public <jeanpublic1@yahoo.com>
**Sent:** Friday, May 25, 2018 3:51 PM
**To:** Herzog, Andrea (HRSA) <AHerzog@hrsa.gov>; INFO@TAXPAYER.NET; MEDIA@CAGW.ORG
**Subject:** Fw:PUBLIC comment ON FEDERAL REGISTER

THE PEOPLE OF THIS UNITED STATES IN RECOGNITION OF 1 OUT OF 25 BABIES BORN AND TAKING VACCINES BEING FOUND TO BE AUTISTIC, WITH THEIR PARENTS CERTIFICYING THAT THIS HAPPENED SHORTLY AFTER APPLICATION OF VACCINES, IT IS INCUMBENT ON THIS COMMITTTEE TO START OPENING UP EXACTLY WHAT IS HAPPENING WITH THE RIGID SNEAKY UNDERHANDED APPLICATION OF VACCINES AND THE CLAIM TJHAT THE VACCINES DONT HURT CHIDLREN, WHEN WE FACTUALLY SHOW THAT 1 OUT OF 25 CHILDRENS BODIES CANNOT TAKE THESE VACCINES AND REMAIN HEALTH. ENDLESS DOCUMENTED CASES HAVE BEEN SHOWN OF HEALTHY KIDS WHO GOT THE VACCINE AND THEN TURNED INTO NOT NORMAL CHILDREN. THERE ARE SEVERAL PROBLEM AREAS: THE FAR TOO MASSIVE APPLICATION OF SO MANY VACCINES TO SMALL BODIES IN FAR TOO CLOSE TIMES. THE FACT THAT THE VACCINES MAY NOT BE STORED OR APPLOIED CORRECTLY. THE FAILURE TO MONITOR CLOSELY ENOUGH THE PURCHASE OF EGGS, WITH A DOCUMENTED RECALL HISTORY OF 200 MILLION EGGS AT A TIME FOR CARRYIN ECOLI THAT CAN KILL A P ERSON. FAITH IN BIG PHARMA IS MISPLACED WHEN THE PUBLIC CAN GET NO ANSWERS AT ALL TO THESE ISSUES, WHICH THEY BRING UP. THE FAILURE TO MATCH THE VACCINE WITH ANY OFFENDING VIRUSUS ALSO SHOWS A PROGRAM COMPLETELY OFF BASE. IT IS TIME THAT THIS AGENCY ALSO APPLY ITSELF TO THIS ISSUE. THIS COUNTRY CANNOT CONTINUE TO STAND HAVING 1 OUT OF 25 BOYS TURN IN TO CHILDREN WHO CANNOT CARE FOR THEMSELVES IN ANY WAY SHAPE OR FORM THAT WILL BRING DOWN A COUNTRY VERY FAST INTO 4TH WORLD STATUS, BELOW THIRD WORLD STATUS. WHAT IS BEING DONE. THE FACTS ARE OUT THERE. THE PARENTS AND CHILDREN ARE OUT THERE. WHY INSTEAD OF DEFENDING ITSELF IS THIS AGENCY NOT INVESTIGATING, ASKING

QUESTIONMS. THIS IS NOT SCIENCE GOING ON AT THIS COMMISSION. THIS IS SNEAKINESS. THIS COMMENT IS FOR THE PUBLIC RECORD. PLEASE RECEIPT. JEANPUBLIEE JEANPUBLIC@GMAIL.COM

[Federal Register Volume 83, Number 102 (Friday, May 25, 2018)]
[Notices]
[Pages 24317-24318]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2018-11298]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

# Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Advisory Committee meeting.

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SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold a public meeting. This meeting will be open to the public.

DATES: Friday, June 15, 2018, from 10:00 a.m. to 2:00 p.m. ET.

ADDRESSES: The meeting is a teleconference and webinar. The conference call-in number is 1-800-988-0218; passcode: 9302948. The webinar link is https://hrsa.connectsolutions.com/accv/. Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview.

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Principal Staff Liaison, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; phone: (301) 443-6593; or email: aherzog@hrsa.gov.

SUPPLEMENTARY INFORMATION:

Background: The ACCV advises the Secretary on the implementation of the Vaccine Injury Compensation Program (VICP). Other activities of the ACCV include: Recommending changes to the Vaccine Injury table, at its own initiative or as the result of the filing of a petition; advising the Secretary on implementing section 2127 of the Public Health Service Act (PHS Act) regarding

[[Page 24318]]

the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125 (b) of the PHS Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted

to carry out the VICP.

Agenda: During the June 15, 2018, meeting, agenda items may include updates from DICP, Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). Information about the ACCV, a roster of members, the meeting agenda, as well as past meeting summaries, is located on the ACCV website: http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html. Agenda items are subject to change as priorities dictate.

Public Participation: Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACCV should be sent to Annie Herzog by June 5, 2018. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Annie Herzog, using the address and phone number above at least 10 days prior to the meeting.

Amy P. McNulty,
Acting Director, Division of the Executive Secretariat.
[FR Doc. 2018-11298 Filed 5-24-18; 8:45 am]
BILLING CODE 4165-15-P

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hearings prior to adoption and submittal of this rule, in accordance with the requirements of CAA sections 110(a)(2) and 110(l).

We are also approving Rules 130, 220, and 230 because we have determined these rules satisfy all of the statutory and regulatory requirements for an NSR permit program (including the PSD program) as set forth in the applicable provisions of part C of title I of the Act and in 40 CFR 51.165 and 40 CFR 51.307. The revisions to these rules also resolve the limited disapproval issues from the October 2016 action.

Our TSD, which can be found in the docket for this rule, contains a more detailed discussion of the approval criteria.

*C. Public Comment and Proposed Action*

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules because they fulfill all relevant requirements. We will accept comments from the public on this proposal until May 4, 2018. If we take final action to approve the submitted rules, our final action will incorporate these rules into the federally enforceable SIP.

**III. Incorporation by Reference**

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the NSCAPCD rules described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

**IV. Statutory and Executive Order Reviews**

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 4, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, New Source Review, Particulate matter, Reporting and recordkeeping requirements.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: March 26, 2018.

**Deborah Jordan,**

*Acting Regional Administrator, Region IX.*

[FR Doc. 2018–06878 Filed 4–3–18; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 100

**RIN 0906–AB14**

## National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** As required by a recent amendment to the VICP's authorizing statute, the Secretary of the Department of Health and Human Services (Secretary) proposes to amend the National Vaccine Injury Compensation Program (VICP) Vaccine Injury Table (Table) to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant

women. Thus, the Secretary is only seeking public comment on how the addition of this new category is proposed to be formatted on the Table.

**DATES:** Written comments must be submitted on or before October 1, 2018.

**ADDRESSES:** You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB14 in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only *one* of these ways to minimize the receipt of duplicate submissions.

1. Federal eRulemaking Portal. You may submit comments electronically to *http://www.regulations.gov.* Click on the link ''Submit electronic comments'' on HRSA regulations with an open comment period. You may submit attachments to your comments in any file format accepted by *Regulations.gov.*

2. Regular, express, or overnight mail. You may mail written comments to the following address only: Health Resources and Services Administration, Department of Health and Human Services, Attention: HRSA Regulations Officer, 5600 Fishers Lane, Room 13N82, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. Delivery by hand (in person or by courier). If you prefer, you may deliver your written comments before the close of the comment period to the same address, 5600 Fishers Lane, Room 13N82, Rockville, MD 20857. Please call one of our HRSA Regulations Office staff members at telephone number (301) 443–1785 in advance to schedule your arrival. This is not a toll-free number.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, the program cannot accept comments by facsimile (FAX) transmission. When commenting, by any of the above methods, please refer to file code (#HRSA–0906–AB14). Comments received on a timely basis will be available for public inspection online at *www.regulations.gov* or in person at the Health Resources and Services Administration's offices, 5600 Fishers Lane, Room 13N82, Rockville, MD, Monday through Friday of each week from 8:30 a.m. to 5:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Please visit the National Vaccine Injury Compensation Program's website, *http://www.hrsa.gov/vaccine-compensation/,* or contact Dr. Narayan Nair, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857. Phone calls can be directed to (855) 266–2427. This is a toll-free number.

**SUPPLEMENTARY INFORMATION:** The Department of Health and Human Services (HHS) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any supporting data. We must consider all relevant written comments received during the comment period before issuing a final rule. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please see the ''For Further Information'' box above for the names and contact information to obtain this information in an accessible format. Please visit *http://www.HHS.gov/regulations* for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

## Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa-10 *et seq.*), established the VICP as a no-fault alternative to the traditional legal system for resolving vaccine injury petitions and to provide compensation for individuals thought to be injured by certain vaccines. Congress has amended the statute governing the VICP several times since 1986. Petitions for compensation under this Program are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes findings as to eligibility for, and the amount of, compensation.

To be entitled to an award under the VICP, a petitioner must establish a vaccine-related injury or death, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a Table injury. That is, a petitioner may show that the vaccine recipient received a covered vaccine and suffered an injury of the type listed for that vaccine in the regulations at 42 CFR 100.3—the Table—and that the onset of such injury took place within the time period specified in the Table. If these criteria are met, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination (see 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a)). Currently, cases are often resolved by negotiated settlements between the parties and approved by the Court. In negotiated settlements, HHS and the Court have not concluded, based upon review of the evidence, that the vaccine caused the alleged injury.

Revisions to the Table are authorized under subsections 2114(c) and (e) of the Public Health Service (PHS) Act (42 U.S.C. 300aa–14(c) and (e)). Prior to the 21st Century Cures Act (Pub. L. 114–255), the only vaccines covered under the VICP were those recommended for routine administration to children by the CDC (for example, vaccines that protect against seasonal influenza), subject to an excise tax by Federal law, and added to the Program by the Secretary. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illness, disability, injury, or condition covered; and the requisite time period when the first symptom or manifestation of onset or of significant aggravation after the vaccine administration must begin to receive the Table's legal presumption of causation. One category of the Table, ''Item XVII,'' includes ''Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.'' Two injuries—Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope—are listed as associated injuries for this category. Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are covered under the VICP prior to being added to the Table as a separate vaccine category through Federal rulemaking.

The 21st Century Cures Act amended section 2114(e) of the PHS Act (42 U.S.C. 300aa–14(e)) to expand the types of vaccines covered under the VICP. *See* section 3093(c)(1) of the 21st Century Cures Act. The revised statute requires that the Secretary 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). *See* section 2114(e)(3) of the PHS Act (42 U.S.C. 300aa–14(e)(3)). Currently, the CDC recommends only two vaccines for routine administration in pregnant women: (1) The tetanus, diphtheria, and

acellular pertussis vaccine,[1] and (2) the seasonal influenza vaccine.[2] These categories of vaccines are already covered under the VICP, as the CDC recommends them for routine administration to children and they are subject to an excise tax.

**Discussion of Proposed Table Changes**

Congress enacted a mechanism for modification of the statutory Table, through the promulgation of regulatory changes by the Secretary, after consultation with the Advisory Commission on Childhood Vaccines (ACCV). As required by statute, the Secretary is proposing to revise the Table to include new vaccines recommended by the CDC for routine administration in pregnant women, and seeks comment on the means of effectuating this revision. The Secretary also proposes retaining the two injuries currently associated with Item XVII of the Table, SIRVA and vasovagal syncope, as Table injuries for vaccines recommended by the CDC for routine administration in pregnant women. In its 2012 Report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the Institute of Medicine considered SIRVA and vasovagal syncope as mechanistic injuries resulting from the injection of a vaccine and not from the contents of a particular formulation of a vaccine. Thus, these conditions are listed as Table injuries for any new vaccine recommended by the CDC for routine administration to children (after the imposition of an excise tax and publication by the Secretary of a notice of coverage) to account for any newly developed injected vaccines that potentially may lead to SIRVA or syncope. Therefore, the Secretary proposes including these injuries on the Table for new vaccines recommended by the CDC for routine administration in pregnant women.

On September 8, 2017, the Program consulted the ACCV regarding options for adding this new category of vaccines to the Table. The ACCV voted unanimously to amend the existing language in Item XVII of the Table to include ''and/or pregnant women'' after ''children'' permitting coverage under the VICP of any new vaccine recommended by CDC for routine administration in pregnant women and subject to an excise tax after publication by the Secretary of a notice of coverage. They viewed this option as a simple approach to revising the Table, rather than adding a new general Item XVII to the Table for vaccines recommended for routine administration in pregnant women. Therefore, the Secretary is proposing to amend the existing language in Item XVII of the Table to include ''and/or pregnant women'' after ''children'' in accordance with the ACCV's recommendation which would add to that general category of the Table, any new vaccine recommended by the CDC for routine administration in pregnant women, after imposition of an excise tax and publication of a notice of coverage.

HHS seeks comments regarding the proposed method of revising the Table, that is, to amend the existing language in Item XVII to include ''and/or pregnant women'' after ''children'' which would add to that general category of the Table any new vaccine recommended by the CDC for routine administration in pregnant women after imposition of an excise tax and publication of a notice of coverage. HHS notes that an important consideration in proposing changes to the Table is the clarity of such changes.

Petitions must be filed within the applicable statute of limitations. With the proposed change, the general statute of limitations applicable to petitions filed with the VICP, set forth in 42 U.S.C. 300aa–16(a) continue to apply. Specifically, in the case of an injury, the claim must be filed within 36 months after the first symptoms appeared. In the case of a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

In addition, 42 U.S.C. 300aa–16(b) allows petitioners an alternative statute of limitations of 2 years from the date of the Table change for injuries or deaths that occurred up to 8 years before the Table change if the revision makes a petitioner eligible to seek compensation or significantly increases the likelihood of a petitioner obtaining compensation. However, the alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) is not applicable at this time for this proposed Table change. At present, there are no vaccines to add to the Table under the revised general category because the only vaccines the CDC recommends for routine administration in pregnant women are already covered on the Table—(1) the diphtheria, tetanus, and pertussis vaccine and (2) the seasonal influenza vaccine—because they are also recommended by the CDC for routine administration to children, are subject to an excise tax. However, in the future, when any new vaccine not already covered under the VICP is recommended by the CDC for routine administration in pregnant women, subject to an excise tax, and added to the Table (and/or any additional associated injury), the alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) would apply, if the effect of the revision would be to make an individual, who was not eligible before the revision, eligible to seek compensation under the Program or to significantly increase the individual's likelihood of obtaining compensation.

Based on the requirements of the Administrative Procedure Act, HHS publishes an NPRM in the **Federal Register** before a regulation is promulgated. The public is invited to submit comments on this proposed rule. HHS specifically requests the public's views on the proposed option for adding new vaccines recommended by the CDC for routine administration in pregnant women to the Table. In addition, a public hearing will be held for this proposed rule. After the 180-day public comment period has ended, the comments received and HHS's responses to the comments will be addressed in the preamble of the final rule. HHS will publish the final rule in the **Federal Register**.

**Additional VICP Provisions in the 21st Century Cures Act**

While not seeking comment on these changes in response to this NPRM, the Secretary notes that the 21st Century Cures Act included additional amendments to the Vaccine Act. The 21st Century Cures Act also amended section 2111 of the PHS Act (42 U.S.C. 300aa–11) to permit 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. *See* section 3093(c)(2) of the 21st Century Cures Act, adding 42 U.S.C. 300aa–11(f). The amendments to this section also provide 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 such woman was administered the vaccine. *See* section 3093(c)(3) of the 21st Century Cures Act, amending 42 U.S.C. 300aa–11(b)(2). These provisions do not require regulatory actions to implement.

[1] Centers for Disease Control and Prevention. MMWR Morbid Mortal Wkly Rep. 2011 Oct 21:60(41); 1424–26. Available from: *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a4.htm.*

[2] Centers for Disease Control and Prevention. Pregnancy and vaccination: Guidelines for vaccinating pregnant women. Last updated Aug 2016. Website: *https://www.cdc.gov/vaccines/pregnancy/hcp/guidelines.html#flu1.*

**Economic and Regulatory Impact**

HHS has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act, and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

**Executive Orders 12866, 13563, and 13771**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As discussed below, HHS estimates that this proposed rulemaking is not ''economically significant'' as measured by the $100 million threshold, and hence not a major rule under the Congressional Review Act.

The Secretary has determined that no substantial additional administrative and compensation resources are required to implement the requirements in this proposed rule. Compensation will be made in the same manner. As in all other VICP cases, to be found entitled to compensation, petitioners will need to prove by a preponderance of the evidence either that they meet the requirements of the Table or that their injury was actually caused by the vaccine, unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table Notice of Proposed Rulemaking is ''not significant'' because no substantial resources are required to implement the requirements in this rule. This rule adds ''and/or pregnant women'' to the new vaccines category (Item XVII) on the Table. Currently, the only vaccines recommended for routine administration in pregnant women are: (1) The tetanus, diphtheria, and acellular pertussis vaccine; and (2) the seasonal influenza vaccine. These vaccines are already on the Table because they are recommended for routine administration to children and have an excise tax imposed on them. Therefore, this rule does not have a significant impact on a substantial number of small entities. Additionally, this rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the final rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on State, local, and Tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The provisions of this proposed rule do not, on the basis of family well-being, affect the following family elements: Family safety; family stability; marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

This proposed rule is not being treated as a ''significant regulatory action'' as defined under section 3(f) of Executive Order 12866. As stated above, this proposed rule will modify the Table based on legal authority.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. It has been determined that this proposed rule is a not significant and thus is exempt from regulatory or deregulatory action for the purposes of Executive Order 13771.

**Impact of the New Rule**

This proposed rule will allow any new vaccines that in the future are recommended by the CDC for routine administration in pregnant women and subject to a Federal excise tax to be covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking. In addition, this proposed rule will have the effect of making it easier for future petitioners alleging injuries that meet the criteria in the Vaccine Injury Table to receive the Table's presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated their injury).

**Paperwork Reduction Act of 1995**

This proposed rule has no information collection requirements.

Dated: March 16, 2018.

**George Sigounas,**

*Administrator, Health Resources and Services Administration.*

Approved: March 28, 2018.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

Accordingly, 42 CFR part 100 is proposed to be amended as set forth below:

## PART 100—VACCINE INJURY COMPENSATION

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

**Authority:** Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. In § 100.3 amend the Table in paragraph (a) by adding ''and/or pregnant women'' after ''children'' to the existing language in Item XVII of the Table as follows:

**§ 100.3 Vaccine injury table.**

(a) * * *

| Vaccine | Illness, disability, injury or condition covered | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration |
|---|---|---|
| XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage. | A. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | B. Vasovagal syncope ..... | ≤1 hour. |

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 1

**[GN Docket No. 18–22; FCC 18–18]**

## Encouraging the Provision of New Technologies and Services to the Public

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, the Commission is committed to improving the process for enabling the introduction of new technologies and services that serve the public interest and made available to the public on a timely basis. Therefore, the Commission proposes guidelines and procedures to implement.

**DATES:** Comments are due May 4, 2018. Reply comments are due May 21, 2018.

**FOR FURTHER INFORMATION CONTACT:** Paul Murray, Office of Engineering and Technology, 202–418–0688, *Paul.Murray@fcc.gov.*

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Notice of Proposed Rulemaking, GN Docket No. 18–22, FCC 18–18, adopted February 22, 2018, and released February 23, 2018. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW, Washington, DC 20554. The full text may also be downloaded at: *https://transition.fcc.gov/Daily_Releases/Daily_Business/2018/db0223/FCC-18-18A1.pdf.* People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

### Synopsis

1. *Background.* Section 7, entitled ''New Technologies and Services,'' reads in its entirety as follows:

(a) It shall be the policy of the United States to encourage the provision of new technologies and services to the public. Any person or party (other than the Commission) who opposes a new technology or service proposed to be permitted under this Act shall have the burden to demonstrate that such proposal is inconsistent with the public interest.

(b) The Commission shall determine whether any new technology or service proposed in a petition or application is in the public interest within one year after such petition or application is filed. If the Commission initiates its own proceeding for a new technology or service, such proceeding shall be completed within 12 months after it is initiated.

2. *Discussion.* In this NPRM, the Commission proposes to adopt rules describing guidelines and procedures to implement the stated policy goal of section 7 ''to encourage the provision of new technologies and services to the public.'' Although the forces of competition and technological growth work together to enable the development and deployment of many new technologies and services to the public, the Commission has at times been slow to identify and take action to ensure that important new technologies or services are made available as quickly as possible. The Commission has sought to overcome these impediments by streamlining many of its processes, but all too often regulatory delays can adversely impact newly proposed technologies or services.

3. Section 7 reflects clear Congressional intent to encourage and expedite provision of technological innovation that would serve the public interest. To better align purpose and practice, the Commission propose a set of rules that will allow the Commission to effectively breathe life into section 7. As noted above, this law applies to new technologies or services proposed to be permitted in a petition or application, as well as to Commission-initiated proceedings for new technologies and services.

4. By its terms, § 7 could apply to any petition or application that includes a proposal involving the use of new technologies and services. Accordingly, the Commission proposes to interpret § 7 to include petitions for rulemaking or waiver of the Commission's rules as well as applications for authorization of any type of technology or service within the Commission's statutory purview, whether radio-based, wired, or otherwise. The Commission also proposes to interpret § 7 to apply to any petitions or applications that properly could be resolved either by the Commission or by any Bureau or Office pursuant to delegated authority. Whether the Commission itself, or a particular Bureau or Office acting on delegated authority, would address the § 7-related issue would depend on the particular filing, the nature of the request, and the kind of decision(s) and course(s) of action regarding the proposed new technology or service that may be deemed appropriate under the circumstances.

5. The Commission proposes adopting a new subpart in part 1 that sets forth specific procedures and timetables for action with respect to requests in petitions or applications for § 7 consideration. These procedures and timetables are designed to ensure that the Commission or Bureau/Office identifies and moves swiftly to promote new technologies and services that are in the public interest. These new rules would not replace or substitute for the Commission's existing rules for processing petitions and applications (*e.g.,* the part 1 rules for rulemaking proceedings and for applications involving common carriers or wireless radio services, the part 25 rules for satellite service applications, the part 73 and 74 rules for broadcast service applications, among many other rule parts dealing with applications). Instead, they would specify additional steps to ensure that timely decisions are made on § 7 requests suited to serve the public interest.

6. Section 7 establishes a timeline by which the Commission must determine