

**ADVISORY COMMISSION ON CHILDHOOD VACCINES**  
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**March 8, 2018**

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***ADVISORY COMMISSION ON  
CHILDHOOD VACCINES***

***Agenda***

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

**5600 Fishers Lane, Rockville, MD 20857**

**Teleconference and Adobe Connect**

**Thursday, March 8, 2018**

(10:00 am Eastern Daylight Time)

Dial-in: 1-800-988-0218

Passcode: 9302948

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

<b>Time</b>	<b>Agenda Item</b>	<b>Presenter</b>
10:00 AM	Welcome and Chair Report	Ms. Beth Luthy, Interim Chair
10:10 AM	Public Comment on Agenda Items	Ms. Beth Luthy, Interim Chair
10:15 AM	Nomination and Vote for ACCV Chair & Vice Chair	Ms. Beth Luthy, Interim Chair
10:25 AM	Approval of December 2017 Minutes	Chair
10:30 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Director, DICP
11:00 AM	Report from the Department of Justice	Ms. Catharine Reeves, Deputy Director, Torts Branch, DOJ
11:30 AM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimbakuro CDC
11:45 PM	Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH
12:00 PM	Lunch Break	

<b>Time</b>	<b>Agenda Item</b>	<b>Presenter</b>
1:00 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	CDR Valerie Marshall CBER, FDA
1:15 PM	Update from the National Vaccine Program Office (NVPO)	Dr. Karin Bok 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	Chair
1:55 PM	Adjournment of the March 8, 2018 ACCV Meeting	Chair

DRAFT





# *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**

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

5600 Fishers Lane, 08N146B  
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**2018**  
***Meeting Dates***

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# **ADVISORY COMMISSION ON CHILDHOOD VACCINES**

## **2018 MEETING DATES**

March 8, 2018

June 14 & 15, 2018

September 6 & 7, 2018

December 6 & 7, 2018

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## **Advisory Commission on Childhood Vaccines**

**December 8, 2017**

**104<sup>th</sup> 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 that 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 *Santacrocce 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 influenzae 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, 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 reiterated her 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 her opinion that the presentations appear to be prepared only by HRSA, which could introduce bias. 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 ties 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. There was a comment 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) 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. Ms. Wrangham endorsed using data from the VICP awards for any petition as a resource to consider when making decisions about Table revisions.

2. There was a comment by a member of the Commission 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.

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 that many in the health care community have little faith in the reality of the PANDA. 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.



5. 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.

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.
1. Ms. Stewart, Mr. Howie, Mr. Sangiamo, Dr. Meissner and Ms. Luthy voted in favor of Option 2.
  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 December 31, 2017**

\$3,730,911,163

### **Figures for October 1, 2017 to December 31, 2017**

- Excise Tax Revenue: \$59,689,000
- Interest on Investments: \$15,997,486
- Total Income: \$75,695,486
- Interest as a Percentage of Total Income: 21%

*Source: U.S. Treasury, Bureau of Fiscal Service (January 25, 2018)*

**4**



## Data & Statistics

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

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

### **What does it mean to be awarded compensation?**

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

- 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, 5,362 petitions were adjudicated by the Court, and of those 3,626 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 19,178 petitions have been filed with the VICP. Over that 29-year time period, 17,079 petitions have been adjudicated, with 5,928 of those determined to be compensable, while 11,151 were dismissed. Total compensation paid over the life of the program is approximately \$3.8 billion.

### **The Latest Statistics**

[Read the current statistics report – updated as of March 1, 2018.](#)

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

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

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	110	250
DTaP-Hep B-IPV	63,245,627	5	9	27	41	46	87
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	27	41
DTP	0	1	1	3	5	2	7
DTP-HIB	0	0	0	3	3	1	4
Hep A-Hep B	14,706,195	0	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	5	35	47	28	75
Hepatitis B (Hep B)	172,993,779	6	11	59	76	65	141
HIB	111,200,358	2	1	7	10	10	20
HPV	101,405,935	15	13	96	124	156	280

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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	431	172	1,804	2,413	370	2,783
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	114	231
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	34	37
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	206,003,646	10	4	14	28	23	51
Rotavirus	98,664,187	12	6	17	35	10	45
Rubella	422,548	0	1	1	2	0	2
Td	61,869,752	9	7	58	74	24	98
Tdap	225,013,338	71	14	218	303	55	358
Tetanus	3,836,052	8	2	34	45	18	63
Unspecified	0	1	1	4	6	585	591
Varicella	110,095,393	6	8	27	41	18	59
<b>Grand Total</b>	<b>3,153,876,236</b>	<b>638</b>	<b>307</b>	<b>2,674</b>	<b>3,626</b>	<b>1,736</b>	<b>5,362</b>

**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



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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 3/01/2018

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	436	82	518	220	245
DTaP-Hep B-IPV	78	35	113	40	49
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	42	20	62	12	25
Td	200	3	203	120	74
Tdap	559	5	564	308	58
Tetanus	125	2	127	68	46
Hepatitis A (Hep A)	97	7	104	48	28
Hepatitis B (Hep B)	672	57	729	269	413
Hep A-Hep B	27	0	27	16	5
Hep B-HIB	8	0	8	5	3
HIB	42	3	45	16	20
HPV	367	15	382	122	150
Influenza	4,063	141	4,204	2,451	391
IPV	266	14	280	8	269
OPV	282	28	310	158	151
Measles	143	19	162	55	107
Meningococcal	64	2	66	41	7
MMR	955	61	1,016	398	575
MMR-Varicella	42	2	44	19	12
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	131	13	144	33	43
Rotavirus	87	4	91	54	21
Rubella	190	4	194	71	123
Varicella	95	9	104	61	30
Nonqualified1	97	9	106	3	99
Unspecified2	5,424	9	5,433	8	5,397
<b>Grand Total</b>	<b>17,917</b>	<b>1,261</b>	<b>19,178</b>	<b>5,928</b>	<b>11,151</b>

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<sup>1</sup> Nonqualified petitions are those filed for vaccines not covered under the VICP.

<sup>2</sup> 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	496
<b>Total</b>	<b>19,178</b>

## 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	186	86	272
<b>Total</b>	<b>5,928</b>	<b>11,151</b>	<b>17,079</b>

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**Awards Paid**

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

National Vaccine Injury Compensation Program  
 Monthly Statistics Report

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2017	706	\$252,245,932.78	\$22,045,785.00	131	\$4,441,724.32	52	\$3,363,464.24	\$282,096,906.34
FY 2018	249	\$81,559,563.57	\$7,714,205.62	47	\$2,246,725.16	29	\$2,571,070.20	\$94,091,564.55
<b>Total</b>	<b>5,916</b>	<b>\$3,570,055,142.30</b>	<b>\$178,189,627.88</b>	<b>5,285</b>	<b>\$77,184,626.26</b>	<b>395</b>	<b>\$30,234,515.14</b>	<b>\$3,855,663,911.58</b>

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

March 8, 2018

**CAPT Narayan Nair, MD**

**Director, Division of Injury Compensation Programs**

**Healthcare Systems Bureau (HSB)**

**Health Resources and Services Administration (HRSA)**





# DICP Update

## ACCV Meeting Highlights

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

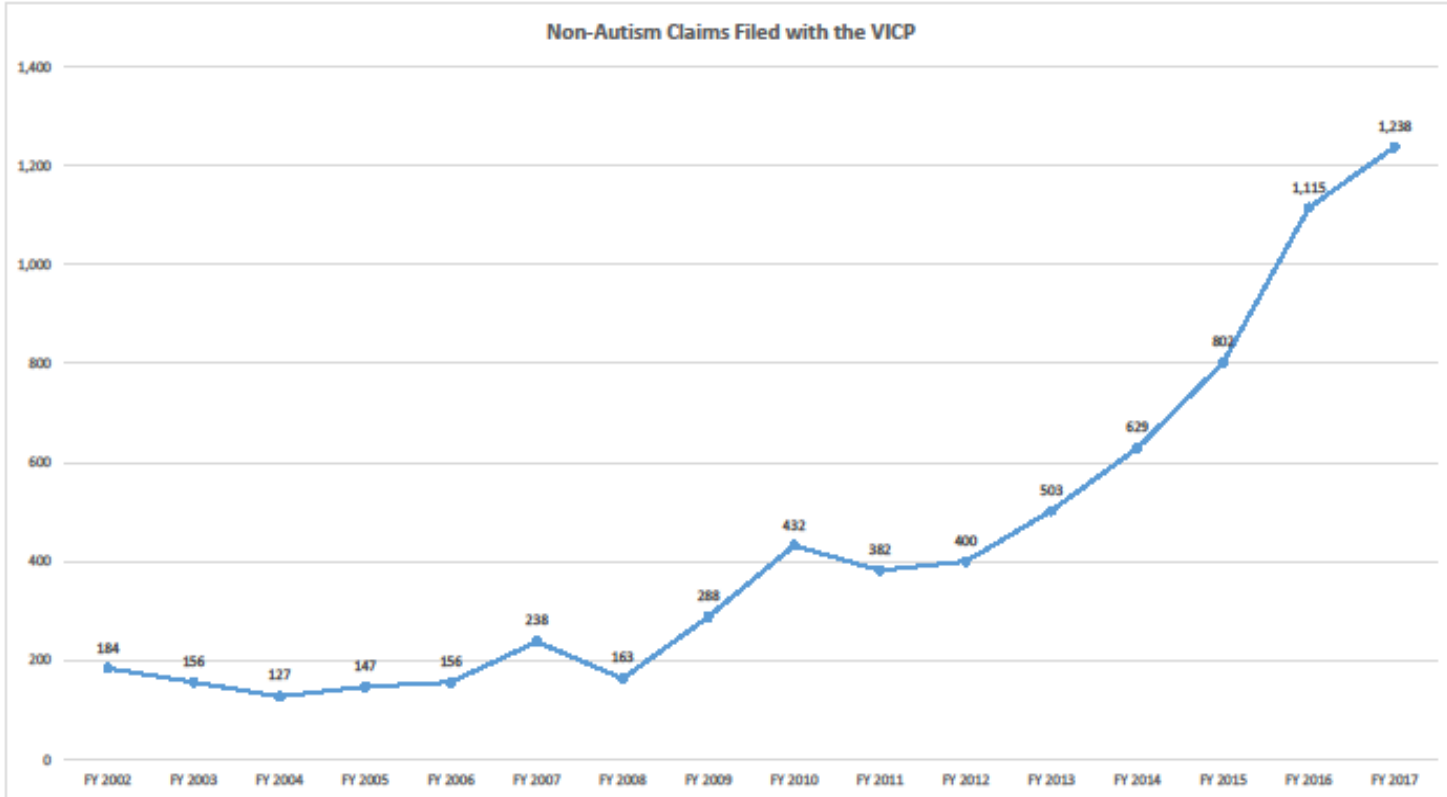


## Number of Petitions Filed as of March 1, 2018

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	496





# 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%



# Number of Claims Awaiting Review as of March 5, 2018

Fiscal Year	Claims Awaiting Review
2017	394
2018	145
Total	539



# Award Amounts Paid as of March 1, 2018

<u>Fiscal Year</u>	<u>Petitioners' Award</u>	<u>Attorneys' Fees &amp; Costs</u>
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	\$81,559,564	\$12,532,001



## Number of Adjudications as of March 1, 2018

Fiscal Year	Compensable	Dismissed	Total
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	186	86	272

# DICP Update

## Adjudication Categories for Non-Autism Claims FY 2015– FY 2018 as of March 1, 2018

Adjudication Category	FY 2016	FY 2017	FY 2018
<b>Compensable</b>	<b>697 (100%)</b>	<b>696 (100%)</b>	<b>186 (100%)</b>
❖ Concession	204 (29%)	183 (26%)	67 (36%)
❖ Court Decision (includes proffers)	44 (6%)	46 (7%)	22 (12%)
❖ Settlement	449 (65%)	467 (67%)	97 (52%)
<b>Not Compensable</b>	<b>168</b>	<b>173</b>	<b>62</b>
<b>Adjudication Total</b>	<b>865</b>	<b>869</b>	<b>248</b>





# DICP Update

## Vaccine Injury Compensation Trust Fund

- **Balance as of December 31, 2017**
  - \$3,730,911,163
- **Activity from October 1, 2017 to December 31, 2017**
  - Excise Tax Revenue: \$59,689,000
  - Interest on Investments: \$15,997,486
  - Total Income: \$75,695,486
  - Interest as a Percentage of Total Income: 21%

Source: U.S. Treasury, Bureau of the Fiscal Service (January 25, 2018)



# DICP Update

## Significant Activities

---

- **Implementation of Maternal Immunization Provisions**
  - The Notice of Proposed Rulemaking announcing proposed revisions to the Table is under review.
- **Highlights of Recent Outreach Activities**
  - Presentation to Biotechnology Information Organization
  - Presentation at Johns Hopkins Bloomberg School of Public Health



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

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

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# 5.2



# Report from the Department of Justice

**March 8, 2018**

**Catharine E. Reeves**  
*Deputy Director, Torts Branch*

# Statistics

Reporting Period: 11/16/17 – 2/15/18

- I. Total Petitions Filed in the United States Court of Federal Claims this reporting period: 272
  - A. Minors: 26
  - B. Adults: 246



# Statistics

Reporting Period: 11/16/17 – 2/15/18

## II. Total Petitions Adjudicated this reporting period: 181

A. Compensated: 142

i. Cases conceded by HHS: 56

1. Decision awarding damages: 0

2. Decision adopting Proffer: 56

3. Decision adopting Settlement: 0

ii. Cases not conceded by HHS: 86

1. Decision awarding damages: 0

2. Decision adopting Proffer: 0

3. Decision adopting Settlement: 86

B. Not Compensated/Dismissed: 39

i. Decision dismissing Non-OAP: 39

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): 4**

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

## Recently Decided Cases

*None decided at this time*

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

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

## Pending Cases

### Appeals by Petitioner:

- *D'Tiole v. HHS*: (Entitlement)
- *Anderson v. HHS*: (Entitlement)
- *Oliver v. HHS*: (Entitlement)
- *Depena v. HHS*: (Entitlement)
- *Olson v. HHS*: (Entitlement)

\*Yellow cases are new this reporting period

# Appeals: U.S. Court of Federal Claims

## Recently Decided Cases

### Appeals by Petitioner:

- *Pless v. HHS* (Attys' Fees and Costs): Affirmed
- *Rogero v. HHS* (Entitlement OAP): Affirmed
- *Santacroce v. HHS* (Attys' Fees and Costs): Remanded
- *Clubb v. HHS* (Entitlement): Affirmed
- *Olson v. HHS* (Entitlement): Affirmed
- *McCollum v. HHS* (Entitlement): Affirmed
- *Kukreja v. HHS* (Attys' Fees and Costs): Affirmed in Part, Reversed in Part
- *Hirmiz v. HHS* (Attys' Fees and Costs): Affirmed in Part, Reversed in Part
- *Caron v. HHS* (Entitlement): Affirmed
- *Krakov v. HHS* (Attys' Fees and Costs): Affirmed
- *Fairchild v. HHS* (Loss of Future Earnings): Remanded
- *Domke v. HHS* (Attys' Fees and Costs): Remanded

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:

- *Greene v. HHS* (Entitlement)
- *Diedrich v. HHS* (Entitlement)
- *Bender v. HHS* (Entitlement)
- *Caruso v. HHS* (Entitlement)
- *Crespo v. HHS* (Attys' Fees and Costs)
- *Harrington v. HHS* (Entitlement)

\*Yellow cases are new this reporting period

# Appeals: U.S. Court of Federal Claims

## Pending Cases (cont'd)

### Appeals by Respondent:

- *Spahn v. HHS* (Attys' Fees and Costs)
- *McCulloch v. HHS* (Attys' Fees and Costs)
- *Amankwaa v. HHS* (Attys' Fees and Costs)
- *Boatmon v. HHS* (Entitlement)
- *Cottingham v. HHS* (Attys' Fees and Costs)
- *Fairchild v. HHS* (Interim Damages)
- *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:

- *D'Tiole v. HHS* (March 6, 2018)
- *Anderson v. HHS* (April 5, 2018)

## U.S. Court of Federal Claims:

- *McCulloch v. HHS* (March 6, 2018)
- *McIntosh v. HHS* (March 22, 2018)



# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
1. HPV; Tdap; Meningococcal Vaccine	Hodgkin's Lymphoma	6 years 7 months
2. Flu	Focal Onset Seizure Activity	5 years
3. Tdap	Head Injury	4 years 5 months
4. MMR; Varicella	Seizure Disorder	3 years
5. Hib	Acute Cerebellar Ataxia	3 years
6. Flu	GBS	3 years
7. Flu	CIDP	2 years 7 months
8. Flu	GBS; ADEM	2 years 6 months
9. Flu	TM	2 years 5 months
10. Flu	GBS	2 years 3 months
11. Flu	Brachial Neuritis	2 years 3 months

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
13. Flu	Thrombocytopenia Polymyositis	2 years 2 months
14. Flu	Menier's Disease	2 years 1 month
15. Flu	GBS	2 years 1 month
16. PCV	GBS	2 years
17. Flu	SIRVA	2 years
18. Flu	SIRVA	2 years
19. Tdap; Varicella Vaccine; Flu	Benign Cyst	1 year 8 months
20. Tdap	GBS; Bell's Palsy	1 year 8 months
21. Flu	Parsonage Turner Syndrome	1 year 8 months
22. Td	Brachial Neuritis; Parsonage Turner Syndrome	1 year 7 months
23. Td	SIRVA	1 year 6 months

\*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
24. Flu	GBS	1 year 6 months
25. Flu	GBS	1 year 6 months
26. Flu	SIRVA	1 year 6 months
27. Flu	GBS	1 year 6 months
28. Flu	GBS; CIDP	1 year 5 months
29. Tdap	GBS	1 year 5 months
30. Flu	TM	1 year 5 months
31. Flu	GBS	1 year 5 months
32. Tdap; Flu	Axillary Nerve Injury; SIRVA	1 year 4 months
33. Flu	SIRVA	1 year 4 months
34. Flu	SIRVA	1 year 4 months

\*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
35. MMR	Encephalitis	1 year 4 months
36. Flu	SIRVA	1 year 3 months
37. Flu	GBS	1 year 3 months
38. DtaP; MMR; Polio; Varicella	Reactive Inflammatory Arthritis	1 year 3 months
39. Tdap	SIRVA	1 year 3 months
40. Flu	Optic Neuritis	1 year 3 months
41. Flu	Cyst; Abscess	1 year 3 months
42. Flu	SIRVA	1 year 3 months
43. Flu	Parsonage Turner Syndrome	1 year 3 months
44. Flu	GBS	1 year 2 months
45. Flu	SIRVA	1 year 2 months

\*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
46. Tdap	SIRVA	1 year 2 months
47. Flu	GBS	1 year 2 months
48. Flu	SIRVA	1 year 2 months
49. Flu	ADEM	1 year 2 months
50. TDaP; Flu	GBS	1 year 2 months
51. Flu	SIRVA	1 year 2 months
52. Flu	GBS; CIDP	1 year 2 months
53. Flu	SIRVA	1 year 2 months
54. Flu	SIRVA	1 year 2 months
55. Tdap	SIRVA	1 year 2 months
56. Flu	SIRVA	1 year 1 month

\*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
57. PCV	SIRVA	1 year 1 month
58. Flu	GBS	1 year 1 month
59. Flu	SIRVA	1 year 1 month
60. Tdap	SIRVA	1 year 1 month
61. Flu	SIRVA	1 year 1 month
62. Tdap	SIRVA	1 year 1 month
63. Flu	SIRVA	1 year 1 month
64. Tdap	SIRVA	1 year 1 month
65. Hep A; Hep B	Allergic Reaction	1 year
66. Flu	GBS	1 year
67. PCV	SIRVA	1 year

\*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
68. Flu	SIRVA	1 year
69. Flu	SIRVA	1 year
70. Flu	GBS	1 year
71. Flu	TM	1 year
72. Flu	GBS	1 year
73. Flu	GBS	1 year
74. Flu	SIRVA	1 year
75. Flu	SIRVA	1 year
76. Hep A; Hep B; Tetanus	SIRVA	1 year
77. Flu	SIRVA	9 months
78. Flu; Tdap	TM	9 months

\*Terms of compensated settlements memorialized by Stipulation

# Adjudicated Settlements\*

Reporting Period: 11/16/17 – 2/15/18

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
79. Flu	SIRVA	9 months
80. Flu	GBS	9 months
81. Flu	SIRVA	9 months
82. PCV	SIRVA	9 months
83. Flu	SIRVA	8 months
84. Flu	SIRVA	8 months
85. Flu	SIRVA	8 months
86. Flu	SIRVA	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.

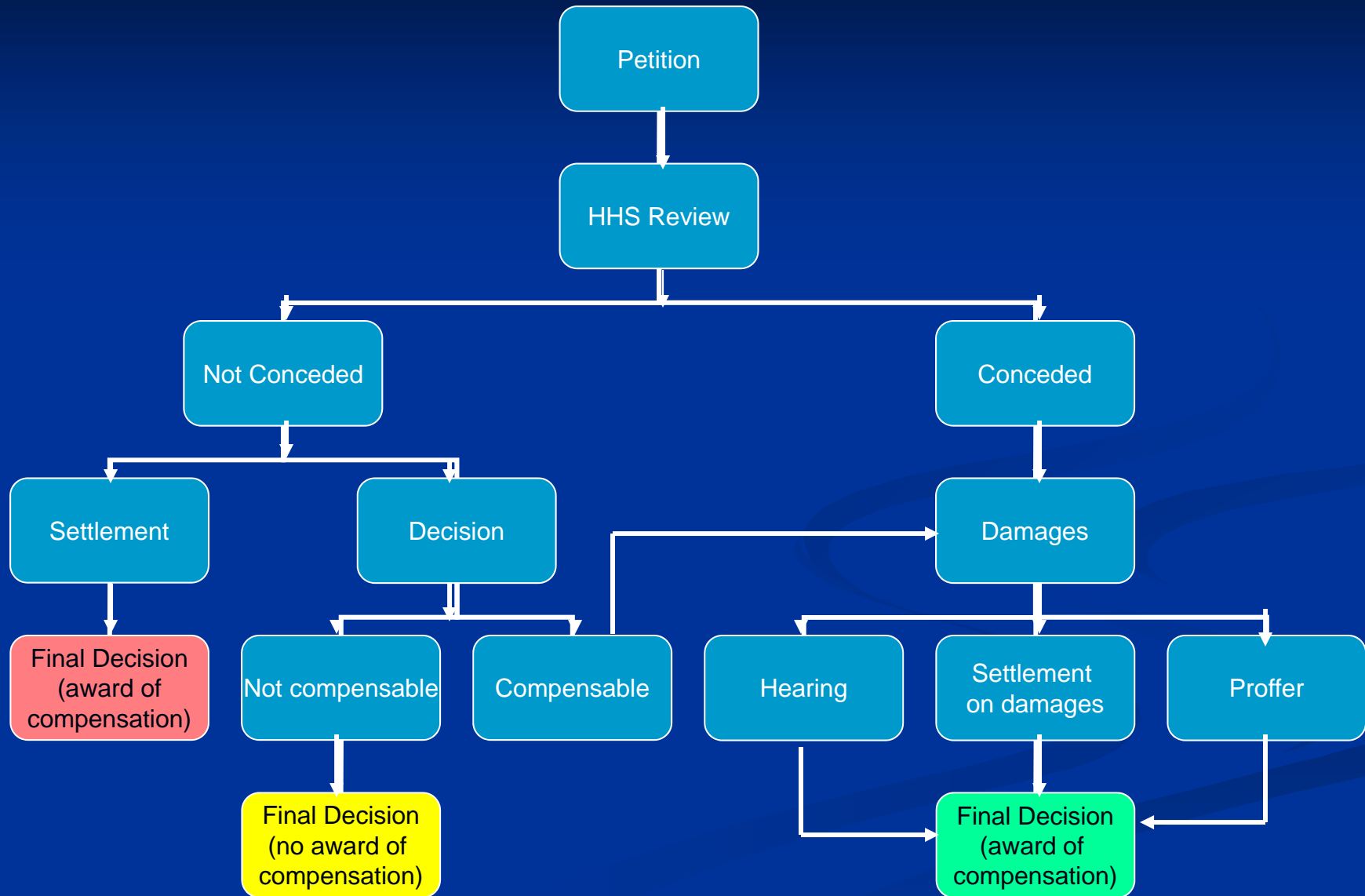
# Glossary of Terms

- **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.<sup>21</sup>

# 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

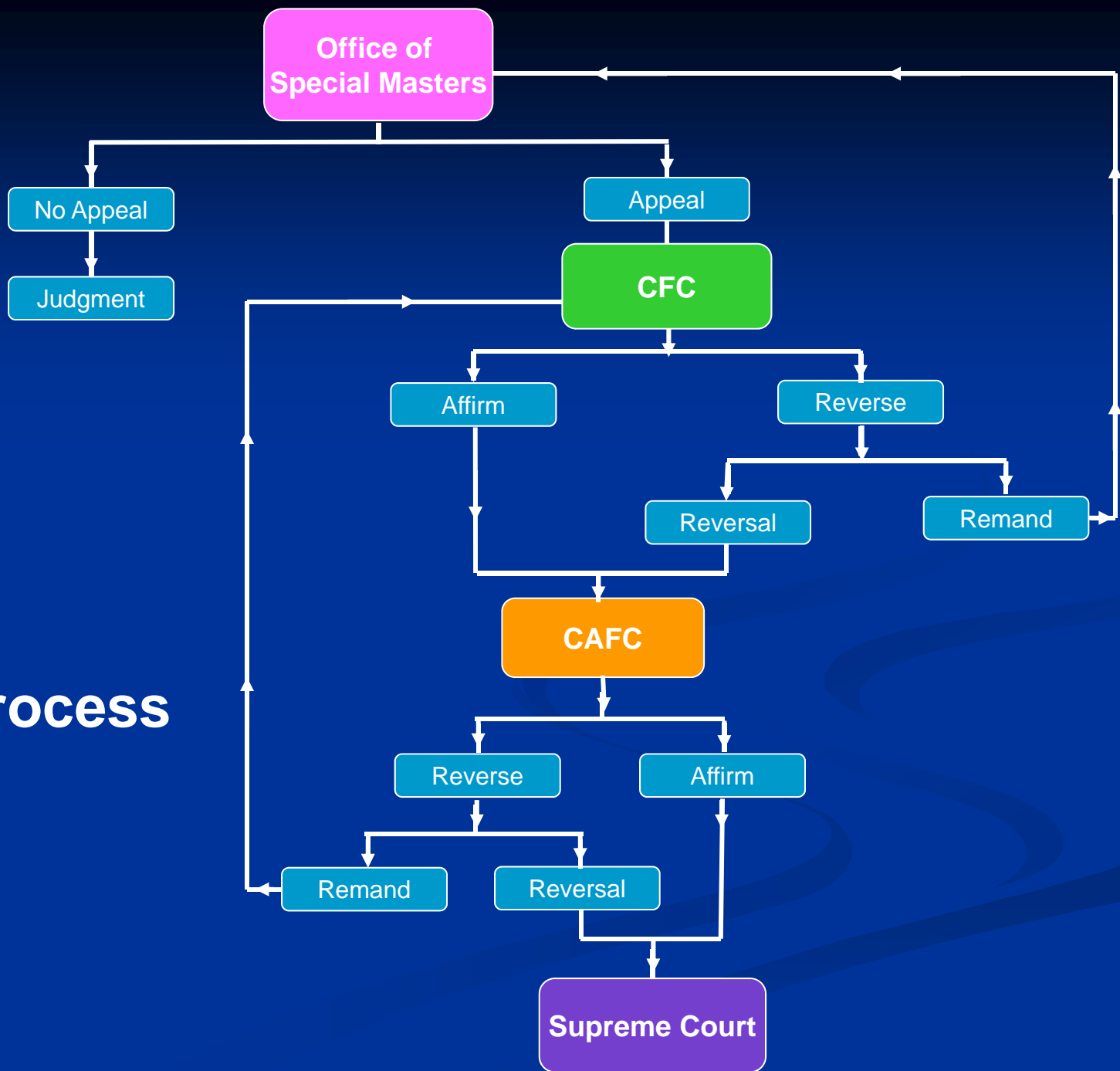
U.S. Supreme Court

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 Updates

**Tom Shimabukuro, MD, MPH, MBA**  
**Immunization Safety Office**  
**Centers for Disease Control and Prevention (CDC)**

Advisory Commission on Childhood Vaccines (ACCV)  
March 8, 2018

## Disclaimer

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

## Topics

- Updates from the February 2018 meeting of the Advisory Committee on Immunization Practices (ACIP)
- Selected publications

# Updates from the February 2018 meeting of the Advisory Committee on Immunization Practices (ACIP)

<https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2018-02-508.pdf>

## ACIP update – hepatitis vaccines

- HEPLISAV-B (Dynavax Technologies Corporation)
  - Recombinant, adjuvanted hepatitis B vaccine
  - Licensed in November 2017, approved for use in adults 18 years of age and older, 2 doses intramuscularly one month apart
- ACIP conducted Grading of Recommendations, Assessment, Development and Evaluation (GRADE) for HEPLISAV-B
- Vote (approved): HEPLISAV-B is a hepatitis B vaccine that may be used to vaccinate persons aged 18 years and older against infection caused by all known subtypes of hepatitis B virus

\*Language regarding votes is provisional until published in the MMWR

## ACIP update – hepatitis vaccines (cont.)

- Considerations for use of hepatitis A vaccines for post-exposure prophylaxis and international travel
- Votes (approved)
  - 1a: Hepatitis A vaccines should be administered for post-exposure prophylaxis for all persons  $\geq 12$  months
  - 1b: In addition to hepatitis A vaccine, immune globulin may be administered to persons  $>40$  years depending on the provider's risk assessment
  - 2: Hepatitis A vaccine should be administered to infants age 6-11 months traveling outside the United States when protection against hepatitis A is recommended

\*Language regarding votes is provisional until published in the MMWR

## ACIP update – influenza vaccines

- Presentations on:
  - Fluarix quadrivalent (GSK) efficacy in children 6-35 months of age
  - Influenza surveillance update for the 2017-2018 season
  - Interim estimates of 2017-2018 seasonal influenza vaccine effectiveness against medically attended influenza from the U.S. Flu VE Network
  - Results of a randomized trial of a new H1N1 live attenuated influenza vaccine (LAIV) strain in U.S. children
  - Review of effectiveness of LAIV

## ACIP update – influenza vaccines (cont.)

- Votes
  - For the 2018-2019 season, immunization providers may choose to administer any licensed, age appropriate, influenza vaccine (including LAIV, IIV, RIV). LAIV is an option for influenza vaccination for persons for whom it is otherwise appropriate.
    - Approved
  
  - Preferential recommendation for IIV over LAIV
    - Not approved

\*Language regarding votes is provisional until published in the MMWR



# ACIP update – human papillomavirus (HPV) vaccines

## ■ Safety presentations

- Vaccine Adverse Event Reporting System (VAERS) monitoring of 9vHPV vaccine from December 2014 through December 2017
  - No new safety signals or unexpected patterns observed
  - 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 (RCA) from October 2015 through October 2017
  - RCA signaled for several adverse events after 9vHPV
    - Syncope and injection site reactions were expected
    - Signals for allergic reaction, pancreatitis and appendicitis were not confirmed after further evaluation in the VSD

## ACIP update – human papillomavirus (HPV) vaccines (cont.)

- Harmonization of HPV vaccination age recommendations for females and males, background and considerations
- Trends in HPV-associated cancers – United States, 1999-2014
  - HPV-associated cancer rates are changing from 1999-2014
    - Increased:
      - Oropharyngeal cancer among men and women, anal cancer among men and women, vulvar cancer
    - Decreased:
      - Cervical cancer
    - Stable
      - Penile cancer, vaginal cancer

## ACIP update – human papillomavirus (HPV) vaccines (cont.)

- Trends in HPV-associated cancers – United States, 1999-2014
  - Oropharyngeal cancer is now the most common HPV-associated cancer and increasing, particularly among males
  - In the future, the HPV vaccine should decrease the burden of HPV-associated cancers, but it may take decades to see population-level impact due to the length of time between the initial HPV infection and the development of cancer

# ACIP update – Evidence-Based Recommendations Work Group Proposal

- Vote (approved)
  - The Evidence-Based Recommendations Work Group proposes that an Evidence to Recommendation framework be adopted and used by ACIP to support decision making

## ACIP update – other sessions

- Anthrax
- Pneumococcal
- Vaccines and other biologics for prevention and treatment of healthcare-associated infections
- Meningococcal disease
- Japanese encephalitis vaccine

## Selected publications

## Selected publications

- Moro et al. Assessing the safety of hepatitis B vaccination during pregnancy in the Vaccine Adverse Event Reporting System (VAERS), 1990-2016. *Vaccine*. 2018;36(1):50-54.
  - 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.

## Selected publications

- Loharikar, et al. Anxiety-related adverse events following immunization (AEFI): A systematic review of published clusters of illness. *Vaccine*. 2018;36(2):299-305.
  - Anxiety-related 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 is rapidly spread.



## Selected publications

- Tamez et al. Influenza B virus infection and Stevens-Johnson syndrome. *Pediatr Dermatol.* 2018;35(1):e45-e48.
  - A 2-year-old boy with influenza B infection and rapidly worsening targetoid skin lesions with mucosal involvement was diagnosed with Stevens-Johnson syndrome (SJS) and treated with oseltamivir and intravenous immunoglobulin, with resolution of illness. Subsequent quadrivalent inactivated influenza vaccine was well tolerated. This case highlights the rarity of SJS in the setting of influenza B infection and addresses the safety of administering subsequent influenza vaccines to such individuals.

## Selected publications

- Hibbs et al. Safety of vaccines that have been kept outside of recommended temperatures: Reports to the Vaccine Adverse Event Reporting System (VAERS), 2008-2012. *Vaccine*. 2018;36(4):553-558.
  - 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.

## Selected publications

- Haber et al. Safety of currently licensed hepatitis B surface antigen vaccines in the United States, Vaccine Adverse Event Reporting System (VAERS), 2005-2015. *Vaccine*. 2018;36(4):559-564.
  - This review of current U.S.-licensed hepatitis B vaccines administered alone or in combination with other vaccines did not reveal new or unexpected safety concerns. Vaccination errors were identified which indicate the need for training and education of providers on hepatitis B vaccine indications and recommendations. .

## Selected publications

- McNeil et al. Notes from the Field: Errors in Administration of an Excess Dosage of Yellow Fever Vaccine - United States, 2017. MMWR Morb Mortal Wkly Rep. 2018;67(3):109-110.
  - Most reports of errors in administration of an excess dosage of yellow fever vaccine did not involve an adverse event, but the error was costly in terms of follow-up medical evaluation and vaccine waste. Vaccine providers should follow the instructions provided with YF-VAX; preventive measures such as more distinctive packaging and in-service training in clinics that stock both the single and multidose vials might be helpful.
  - Available at: [https://www.cdc.gov/mmwr/volumes/67/wr/mm6703a6.htm?s\\_cid=mm6703a6\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6703a6.htm?s_cid=mm6703a6_w)

## Selected publications

- Wang et al. Methods for addressing "innocent bystanders" when evaluating safety of concomitant vaccines. *Pharmacoepidemiol Drug Saf.* 2018 Feb 13.
  - Analysis shows that when using a self-controlled design to investigate safety of concomitant vaccination, it can be critically important to adjust for time-invariant effect modifying risk factors, such as age at time of vaccination, which are structurally related to vaccination patterns due to recommended immunization schedules.

## Selected publications

- McNeil MM and DeStefano F. Vaccine-associated hypersensitivity. *J Allergy Clin Immunol*. 2018;141(2):463-472.
  - 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.

## Selected publications

- Kuntz et al. Myocarditis and pericarditis are rare following live viral vaccinations in adults. *Vaccine*. 2018 Feb 15. pii: S0264-410X(18)30204-4.
  - The occurrence of myopericarditis following live viral vaccination is rare with an estimated incidence of 0.24 per 100,000 vaccinated, which is not higher than the background rate and is much lower than the incidence rates reported following smallpox vaccination.

## Selected publications

- Li et al. Meningococcal conjugate vaccine safety surveillance in the Vaccine Safety Datalink using a tree-temporal scan data mining method. *Pharmacoepidemiol Drug Saf.* 2018 Feb 15.
  - In a pilot study, investigators demonstrated that the tree-temporal scan statistic data mining method can be successfully applied to screen broadly for a wide range of vaccine-AE associations within a large health care data network.



## Selected publications

- Arana et al. Post-licensure safety monitoring of quadrivalent human papillomavirus vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2009–2015. *Vaccine* (2018).
  - No new or unexpected safety concerns or reporting patterns of quadrivalent HPV vaccination (4vHPV) with clinically important AEs were detected. Safety profile of 4vHPV is consistent with data from pre-licensure trials and postmarketing safety data.

## Selected publications

- Sukumaran et al. Infant Hospitalizations and Mortality After Maternal Vaccination. *Pediatrics*. 2018;141(3):e20173310
  - 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.

# Thank you

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

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

**March 2018**



National Institute of  
Allergy and  
Infectious Diseases

**Seasonal  
Influenza  
Preparedness**

**Pandemic  
Influenza  
Preparedness**

# SCIENTIFIC AMERICAN

February 2018

## **We Need a Universal Flu Vaccine before the Next Pandemic Strikes**

*A century after the deadly  
pandemic of 1918, we're  
still not safe*



CI Paules, AS Fauci

AS Fauci/NIAID

Published online  
February 28, 2018



# The Journal of Infectious Diseases

## **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

AS Fauci/NIAID

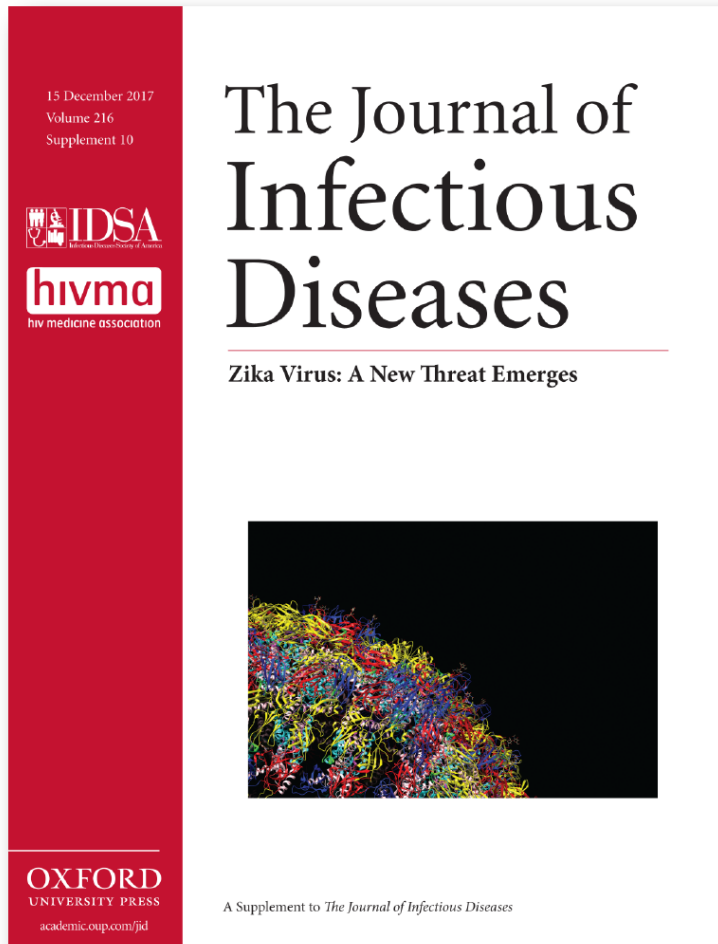


## **Emerging Viral Diseases from a Vaccinology Perspective: Preparing for the Next Pandemic**

BS Graham and NJ Sullivan

- Most pandemic threats are caused by viruses
  - From zoonotic or vector-borne sources
  
- Improving scientific preparedness for the next pandemic threat can be divided into four broad categories:
  - Pathogen surveillance and discovery
  - Basic biology and development of reagents and assays
  - Vaccine design and preclinical development
  - Manufacturing and clinical evaluation

# NIAID-Sponsored Zika Supplement Published



- 19 articles address various topics including history, epidemiology, virology, mosquito vectors, immunology, teratology, and vaccinology

# Phase 2/2b Clinical Trial of VRC Zika DNA Vaccine

## ■ Part A (non-placebo controlled)

- Launched 3/31/2017
- Fully enrolled – n=90

## ■ Part B (placebo-controlled)

- Launched 7/19/2017
- Target n=2,400 to 5,000



# Zika in Infants and Pregnancy (ZIP) Study

- Sponsors: NIH & Oswaldo Cruz Foundation (Fiocruz)/Brazil
- Current enrollment (opened Jan. 2016)
  - 5,993 mothers, 2,004 infants
- Follow women for Zika infection, infants for  $\geq 1$  yr
- Key endpoints: pregnancy outcomes, congenital anomalies, other developmental problems



AS Fauci/NIAID

# Zika in Infants and Pregnancy (ZIP) Study



**NICHD News & Info** @NICHD\_NIH · 6 Dec 2017

How do we understand the health risks of #Zika virus? With studies like ZIP.

In June 2016, NIH launched the **Zika in Infants and Pregnancy (ZIP) study**, a multi-country study to evaluate the health risks that Zika virus infection poses to pregnant women and their developing fetuses and infants.

191 views

0:09 / 2:25

Credit: NIAID, NIH

[pic.twitter.com/Af9qHgei2v](https://pic.twitter.com/Af9qHgei2v)

# NIH Research Initiative: Health Risk and Resilience After Hurricanes Irma and Maria

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- **Purpose:** To support 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 US Virgin Islands
- **Application due date:** April 16, 2018
- **Earliest start date:** July 2018
- **RFA-MD-18-006:**  
<https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-18-006.html>



**All of Us**  
RESEARCH PROGRAM

The  
Future of  
Health Begins  
With You

- *All of Us* Research Program seeks input on research priorities
  - Submissions for *All of Us* Research Priorities Workshop due Feb. 23
- *All of Us* Research Priorities Workshop to be held on March 21–23, 2018
  - <https://allofus.nih.gov/news-events-and-media/announcements/all-us-research-program-seeks-input-research-priorities>
- The program is launching in stages, beginning with a beta testing phase; National rollout is anticipated in Spring 2018

# 5.5



# Advisory Commission on Childhood Vaccines (ACCV)

## *Food and Drug Administration Update*

**March 8, 2018**



**CDR Valerie Marshall, MPH  
Immediate Office of the Director  
Office of Vaccines Research and Review (OVRR)  
Center for Biologics Evaluation and Research (CBER)  
Food and Drug Administration (FDA)**

## Fluarix – Expansion of Age Indication

- 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 indicated for persons 3 years of age and older.

# Southern Hemisphere Formulation

- 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.

# Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- The Vaccines and Related Biological Products Advisory Committee met on March 1, 2018 to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2018-2019 influenza season.



# Thank you!



# 5.6

THE NATIONAL VACCINE PROGRAM OFFICE

# NATIONAL VACCINE PROGRAM OFFICE UPDATE

ACCV, MARCH 8, 2018

Dr. Karin Bok  
Senior Vaccine Science Advisor

THE NATIONAL VACCINE PROGRAM OFFICE





# National Vaccine Advisory Committee

February 7-8, 2018



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

9:45am – 10:00am	Overview: HPV Report Recommendations Dr. Nathaniel Smith, NVAC Voting Member
10:00am – 10:15am	Surveillance Update and Overview of CDC Activities Dr. Nancy Messonnier, CDC
10:15am – 10:30am	NCI Cancer Control Research Dr. Sarah Kobrin, NCI
10:30am – 10:45am	NCI's Research Efforts on Reduced-dose HPV Vaccination Dr. Aimée Kreimer, NCI
10:45am – 11:00am	Achieving High Adolescent HPV Vaccination Coverage Dr. Anna-Lisa Farmer, Denver Health
11:00am – 11:15am	BREAK
11:15am – 11:30am	HPV Vaccination Initiatives at the American Cancer Society Dr. Debbie Saslow, ACS (presentation via phone)
11:30am – 12:00pm	Partner Updates and Implementation Activities Dr. Ann Edwards, AAP Dr. Pamela G Rockwell, AAFP Dr. Jennie Yoost, ACOG Dr. Cynthia Rand, APA Ms. Margaret Farrell, NCI, on behalf of CCCNP Ms. Gretchen Forsell, AHEC Dr. Amy Middleman, SAHM
12:00pm – 12:30pm	Discussion

# NVAC NEW HPV WORKING GROUP

## **Charge:**

The ASH has charged the NVAC to establish a working group that will produce a brief report by June 2018 on recommendations to “strengthen the effectiveness of national, state and local efforts to improve HPV vaccination coverage rates.”

HHS asks you to specifically consider:

- a) Many national organizations are currently supporting HPV efforts. Are there additional national organizations that might contribute to increasing HPV vaccination coverage?
- b) At the state level, many states have formed coalitions to support HPV vaccination efforts. Is there general guidance for states that do not yet have coalitions?
- c) Integrated healthcare delivery networks can successfully integrate comprehensive quality improvement approaches to increase vaccination coverage rates. How can state immunization programs and coalitions engage with health systems to work together on improving HPV vaccination coverage?
- d) Please specify recommendations on how to meet the needs of providers in rural areas?

1:30pm – 2:30pm

1:30pm – 1:45pm

21<sup>st</sup> Century Cures Act Report to Congress: Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century  
Dr. Angela Shen, NVPO

1:45pm – 1:55pm

Incentivizing the Development of Vaccines: Recommendations from the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria  
Dr. Timothy Cooke, NVAC Voting Member and PACCARB Vaccine Working Group Member

1:55pm – 2:10pm

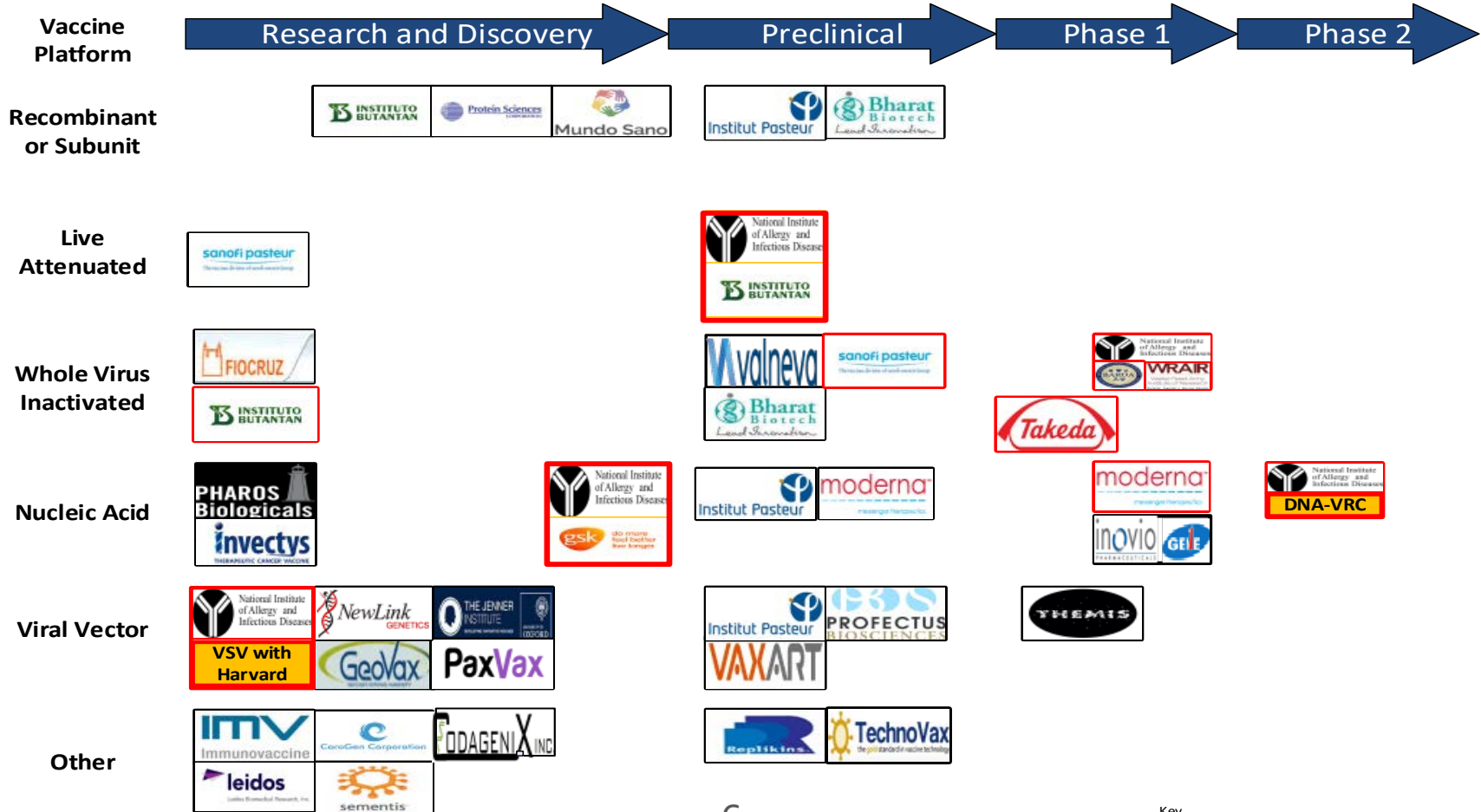
Zika Vaccine Development Update  
Dr. Robert Johnson, ASPR-BARDA

2:10pm – 2:30pm

Discussion

# ZIKA VACCINE LANDSCAPE

## JAN. 2018



2:30pm – 3:15pm VACCINE INNOVATION: NEXT GENERATION INFLUENZA VACCINE DEVELOPMENT		
	2:30pm – 2:40pm	Next Generational Influenza Vaccine Development Dr. Robert Johnson, ASPR-BARDA
	2:40pm – 2:50pm	NIAID Universal Influenza Vaccine Portfolio Dr. Teresa Hauguel, NIH
	2:50pm – 3:15pm	Discussion

# LANDSCAPE OF NEXT GENERATION INFLUENZA VACCINE CANDIDATES

## Pre Clinical

 Mini-HA	 H5 Immunity Management	
 SAM rna A CSL Company	 VLP	 Avatar Medical, LLC Headless HA
 Nanoparticles – HA stem, NP, TLR/CD40	 4xM2e HA LAIV	 Chimeric HAs
 DNA prime/subunit boost	 Centralized HA/NA inactivated vaccine	 H1N1 & H3N2 stem trimers
 M2e-HA stem	 Ad5-vectored HA, NP, M	 M2e CpG gold nanoparticles
 Surface antigen/adjuvant vaccine engineering (SAAVE)	 HA nanoparticles + free HA & NP	 M2e-TLR5 fusion protein
 Germline-targeted HA stem	 TLR5, TLR7/8 adjuvants	 Laser vaccine adjuvant
 Microneedle adjuvant GIFT4/IFN-lambda 2	 Nanoparticle adjuvant TNF, IL-12	 Nematode-secreted rASP-1 adjuvant

## Phase 1

 IN HA nanoemulsion	 HA Stabilized Stalk
 AM2 LAIV	 MVA prime and Ad5 Boost Vectors with M1 NP
 SynBio LAIV	 ANS1 LAIV
 Chimeric HA	 M2e - hepB core fusion
 mRNA	 DNA
 HA Nanoparticles	

## Phase 2

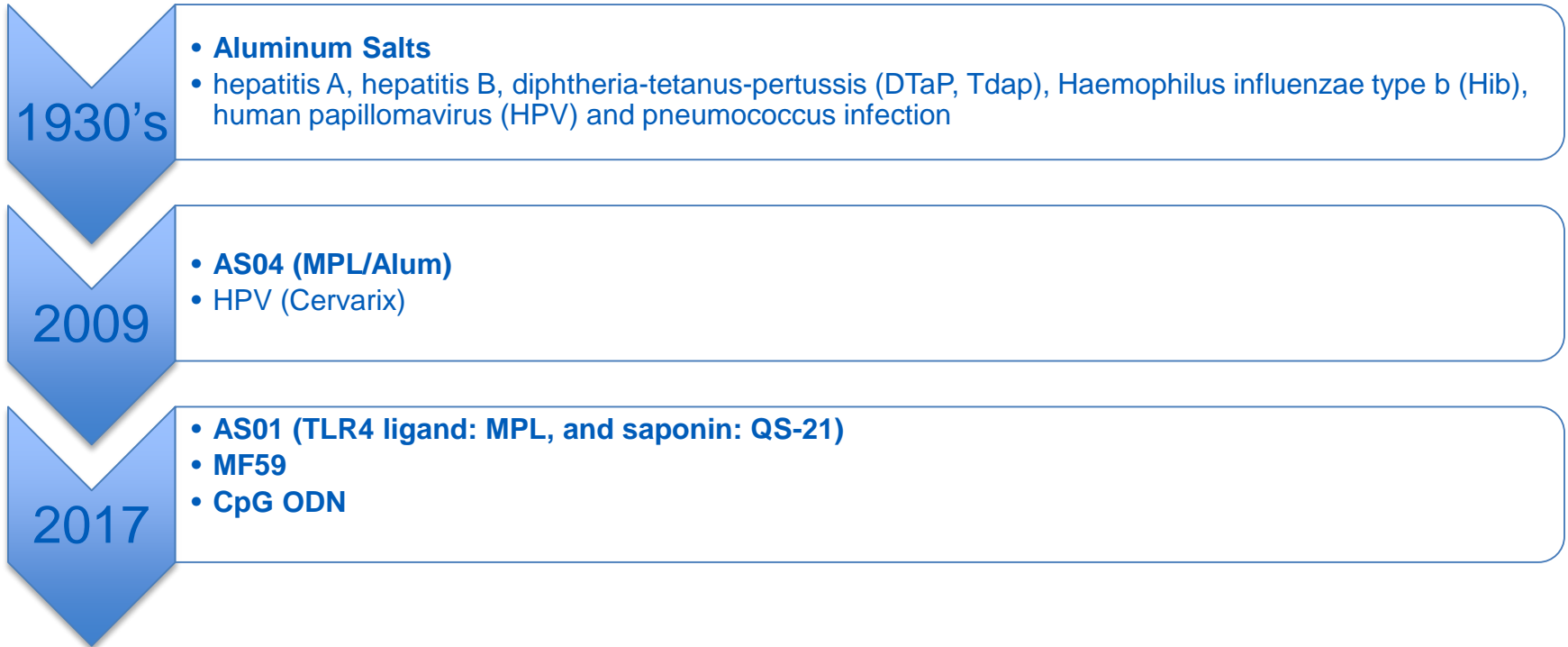
 Replication deficient hAd5 HA/TRL 3 agonist
 MVA Vector NP M1+TIV
 Conserved epitopes from HA + ND + M1
 Ad5 NasoVax
 NPA + NPB + M1 + M2 polypeptides
 VLP from tobacco plants

Version 1-18-2018

3:30pm – 5:15pm		VACCINE INNOVATION: VACCINE ADJUVANTS
	3:30pm – 3:45pm	Overview of Progress and Landscape in Adjuvants Dr. Karin Bok, NVPO
	3:45pm – 4:05pm	The NIAID Vaccine Adjuvant Program: A Pipeline Of Novel Compounds To Safely Enhance Vaccine Efficacy Dr. Wolfgang Leitner, NIH
	4:05pm – 4:25pm	Precision Vaccines: Using Adjuvants to Bring Precision Medicine to Vaccinology Dr. Ofer Levy, Boston Children’s Hospital
	4:25pm – 4:45pm	Vaccine Adjuvants Dr. Leonard Friedland, NVAC Member/BIO
	4:45pm – 5:15pm	Discussion



# TIMELINE OF ADJUVANTS AND ADJUVANT SYSTEMS USE IN THE U.S.



<b>11:00am – 12:30pm</b>		<b>DISPARITIES IN ADULT IMMUNIZATION</b>
11:00am – 11:15am	Disparities in Adult Immunization – 2016 NHIS Dr. Ram Koppaka, CDC	
11:15am – 11:30am	Understanding Dynamics Underlying Racial Disparities in Influenza Vaccination Dr. Sandra Crouse Quinn, University of Maryland	
11:30am – 11:45am	Examining Adult Immunization Knowledge, Perceptions, and Intentions with an Emphasis on Race and Ethnicity: Insights from a 2017 National Survey Ms. Judith Mendel, NVPO	
11:45am – 12:00pm	CMS Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs) Improving Medicare Beneficiary Immunizations Among Disparate Populations Dr. Shiree Southerland, CMS	
12:00pm – 12:30pm	Discussion	

# HHS ANNOUNCEMENTS

- HHS New Secretary of Health and Human Services  
**Alex Azar**



- HHS, OASH, New Assistant Secretary for Health  
**Dr. Brett P. Giroir**



# THANK YOU

Karin Bok

[Karin.Bok@hhs.gov](mailto:Karin.Bok@hhs.gov)

202-690-1191

<http://www.hhs.gov/nvpo/>

<http://www.vaccines.gov/>

# 6.1

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<https://www.wsj.com/articles/flu-vaccine-less-effective-than-earlier-estimates-1518718596>

U.S.

# Flu Vaccine Less Effective Than Earlier Estimates

Getting a shot this season will reduce a person's risk of getting the flu by 36%, according to the CDC; in a good year, it is 60% effective



A woman receives a flu shot in San Francisco last month. This year's vaccine is less effective than previously estimated. PHOTO: JUSTIN SULLIVAN/GETTY IMAGES

By Sarah Toy

Updated Feb. 15, 2018 5:29 p.m. ET

This year's flu vaccine is slightly less effective overall than earlier estimates but still reduces a person's chance of contracting the flu by a little over a third, according to the latest numbers from the Centers for Disease Control and Prevention.

Getting a flu shot this season will reduce a person's risk of getting the flu and needing to see the doctor by 36%. Earlier this year, the CDC estimated it would be about 40%.

That doesn't seem high, especially when compared to vaccines for other infectious diseases, William Schaffner, an infectious disease specialist and professor of preventive medicine at Vanderbilt University School of Medicine in Nashville, Tenn., said of the vaccine.

"But you will have some protection, which is better than nothing. And even if you do get sick, you'll be less likely to have complications and get hospitalized," he said.

During a briefing on Thursday, officials from the Department of Health and Human Services urged Americans to get flu shots, saying flu activity would likely remain intense for several more weeks. The main illness-causing strain of flu this season is the influenza A strain H3N2, known for its severity, according to the CDC, but both the A and B strains have proven serious and even deadly in past weeks.

In a good year, a flu vaccine's effectiveness is about 60% overall. It was 40% last season and 48% in 2015-16. In 2014-15, which was also dominated by H3N2, it was just 19%.

When it comes to H3N2 specifically, the vaccine this season is only 25% effective, according to the new CDC estimates. Earlier this year, the CDC estimated it would be around 30% against

H3N2.

Last season's vaccine didn't do much better, reducing the risk of contracting H3N2 and needing to see the doctor by 32%.

"Traditionally, we have had trouble developing an effective H3N2 vaccine," said Dr. Schaffner.

The CDC's findings show better vaccine effectiveness against H3N2 than was previously reported by Canadian and Australian researchers. In October, Australian researchers reported a 10% vaccine effectiveness against the strain. Canadian scientists reported 17% earlier this month.

One theory for the flu vaccine's low effectiveness against H3N2 has to do with how it is made. Most vaccines are made from viruses grown in chicken eggs. The viruses must adapt to grow in the egg, introducing changes that may contribute to mismatches between the vaccine and circulating virus strains.

This season's vaccine provides slightly better protection against other strains of the influenza virus, according to the CDC data, which was drawn from five surveillance sites across the country. It is 67% effective against H1N1, the other influenza A virus in circulation, and 42% effective against the influenza B viruses. Influenza B cases tend to rise during the second half on in the flu season.

In a way, that could be a good thing, said Paul Sax, an infectious disease specialist and clinical director of the Division of Infectious Diseases at Brigham and Women's Hospital in Boston. "With flu B on the rise, the vaccine is potentially more effective for the remainder of the season," he said.

Children seem to draw the most benefit from the flu vaccine—kids between 6 months and 8 years old who got the flu shot were 59% less likely to get the flu and see the doctor than those who didn't, according to the CDC's estimates. The agency said on Thursday that of the 63 children who have died from the flu or related complications this season, three out of four weren't vaccinated.

This flu season has been an especially harsh, with high rates of hospitalizations and doctors' visits. Schools have had to close due to widespread absenteeism among students and staff and hospitals have struggled to deal with the onslaught of patients.

**Write to Sarah Toy at [sarah.toy@wsj.com](mailto:sarah.toy@wsj.com)**

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# 6.2



<https://www.usnews.com/>

Mouse Study Another Step Toward 'Heroin Vaccine'

Feb. 21, 2018, at 7:00 a.m.

Mouse Study Another Step Toward 'Heroin Vaccine'



**By Amy Norton**

*HealthDay Reporter*



(HEALTHDAY)

---

TUESDAY, Feb. 20, 2018 (HealthDay News) -- Researchers say they are one step closer to testing a heroin vaccine in humans -- in what they hope will become an additional weapon in fighting America's opioid epidemic.

Scientists at The Scripps Research Institute, in California, have developed an experimental vaccine that appears safe and effective in animals. It also has a long enough shelf-life to be practical.

Those are all key hurdles, the researchers said, and the vaccine is almost ready for testing in people.

No one will know what the effects or toxicities could be until those human trials are done, said Sandra Comer, a researcher who was not involved in the study.

"But based on this pre-clinical testing [in animals], it looks promising," Comer said. She's a professor at Columbia University and scientist with the New York State Psychiatric Institute, in New York City.

The findings, published Feb. 8 in the journal *Molecular Pharmaceutics*, come amid a stream of bad news on the U.S. opioid epidemic.

Opioids include certain prescription painkillers -- such as OxyContin and Vicodin -- as well as illegal drugs like heroin and illicitly made versions of the painkiller fentanyl.

Recent research has found that Americans' prescription opioid abuse seems to be leveling off. But overdose deaths are climbing.

Last year, a government study highlighted the toll that heroin, alone, is taking. From 2002 to 2016, annual deaths from heroin soared by 533 percent nationwide -- from just under 2,100 deaths to more than 13,200.

Right now, several drugs -- methadone, buprenorphine and naltrexone -- can be used to treat opioid addiction. Methadone and buprenorphine act on the same brain targets as opioids, and suppress withdrawal symptoms and cravings. Naltrexone blocks the effects of opioids in the brain.

The idea behind the experimental vaccine is to train the immune system to recognize and bind to heroin molecules, according to the Scripps researchers, led by Candy Hwang.

That, in turn, blocks the drug from reaching the brain to create a "high."

Comer, who is also studying an experimental opioid vaccine, said the approach has a few possible advantages.

Buprenorphine and methadone have the potential for abuse, but that would not be an issue with a vaccine, Comer said. Nor would people have to go through detox before getting a vaccine, she explained -- which is necessary with naltrexone.

Plus, Comer said, a vaccine could potentially be given to people who are on existing medications. Then, if they stopped treatment -- as often happens -- the vaccine could continue to prevent them from getting high, and offer a chance to get them back into treatment.

The Scripps researchers have been working on a heroin vaccine for several years. They tested an earlier formulation in 2013 and found it was safe and effective in rodents and non-human primates. However, experts point out that research in animals frequently doesn't produce similar results in humans.

In this latest study, Hwang's team tested 20 formulations.

According to the researchers, heroin molecules do not trigger an immune system response, so any vaccine needs an effective "carrier protein" to do that job. The vaccine also needs an "adjuvant" -- an ingredient that enhances the immune system's response to the carrier protein.

Hwang's team was able to zero in on a formulation that protected lab mice from fatal heroin overdoses - - and stayed stable at room temperature for at least 30 days.

That vaccine contained an adjuvant, called alum, that already is approved by the U.S. Food and Drug Administration, the researchers explained.

Current medications help many people with opioid dependence, but there is clearly a need for more options, said Charles Neighbors, director of health services research for the National Center on Addiction and Substance Abuse, in New York City.

"The disease course of opioid use disorders is long, with most people cycling through periods of treatment, then return to use, then back to treatment," Neighbors said. "Recovery is hard, so we need more tools to help those in need."

But while researchers work on new treatments, many people lack access to the current therapies, he said.

Neighbors pointed to some obstacles, including community opposition to methadone clinics, and the need for doctors to be certified to prescribe buprenorphine.

Plus, some providers who treat substance abuse believe that the medications for opioid dependence "reinforce" addiction, he added.

"And yet," Neighbors said, "the scientific evidence is clear that, without medications, most individuals with significant dependence on opioids will not be able to enter sustained recovery."

**More information**

The National Center on Addiction and Substance Abuse has information on [treatment resources](#).

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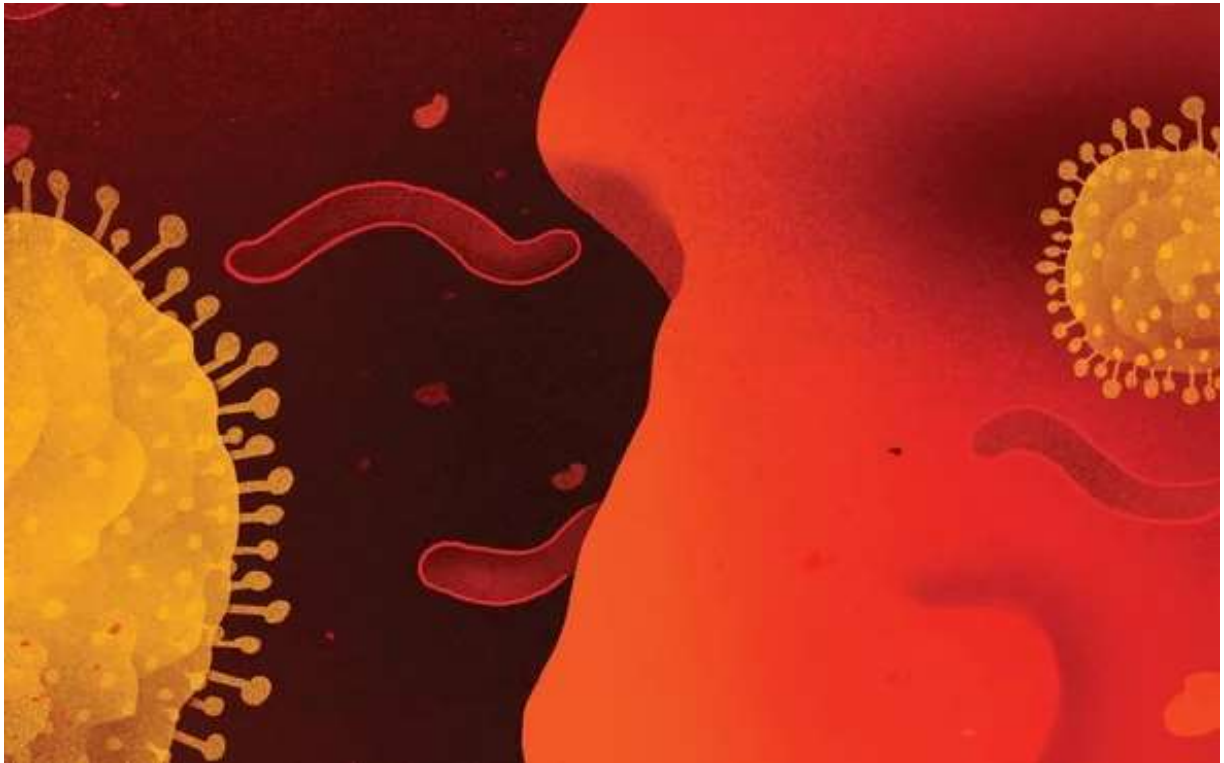
# 6.3

## PUBLIC HEALTH

# We Need a Universal Flu Vaccine before the Next Pandemic Strikes

A century after the deadly pandemic of 1918, we're still not safe

By Catharine I. Paules, Anthony S. Fauci on February 1, 2018



*Credit: Christina Ung*

This year the world will mark the 100th anniversary of one of the most devastating infectious disease events in recorded history: the 1918 influenza pandemic, which caused an estimated 50 million to 100 million deaths worldwide.

There were several reasons for the awful toll. First, most people likely had no preexisting immune protection to the brand-new strain that had emerged. Second, this particular virus may have been unusually lethal. Third, crowding and poor sanitation allowed for rampant disease transmission, especially in regions where access to health care was limited. And finally, antiviral drugs and flu vaccines were still decades in the future.

Over the past century we have made substantial advances in all these areas. But we are still unprepared for the inevitable appearance of a virus like the one that struck a century ago. Even an ordinary seasonal flu epidemic will still kill some 12,000 to 56,000 people every year in the U.S. alone. That is because seasonal viruses continually evolve, and although we update our vaccines frequently, they may be only 40 to 60 percent effective. Moreover, seasonal vaccines may provide little or no protection against pandemic flu. Pandemic viruses typically arise from a process referred to as an antigenic shift, in which the new virus acquires, usually from animal influenza viruses, one or more genes that are entirely novel (as seems to have happened in 1918, when all eight pandemic virus genes were novel).



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In the years since 1918, three influenza pandemics associated with antigenic shifts occurred: in 1957, 1968 and 2009. In each of these instances, however, the new viruses emerged via the mixing of animal influenza virus genes with those of the 1918-descended viruses already circulating in the human population, which meant that many people were at least partially immune. That, plus lower viral pathogenicity and improvements in public health infrastructure and medical treatment, is what probably led to less catastrophic pandemics.

We must also tackle the issue of “prepandemic” influenza viruses—those that could potentially cause pandemics but that have not (yet) done so. Human infections with avian influenza viruses have occurred with increasing frequency over the past two decades. Prepandemic vaccines against various strains of H5N1 and H7N9 viruses have been developed and in some cases stockpiled; similar to seasonal influenza viruses, however, these avian strains are subject to antigenic drift within their avian hosts. Many of the H7N9 avian viruses that have jumped species from poultry to cause human infections in China in 2016 and 2017 have changed significantly from 2013 avian strains. As a result, the human immune responses elicited by a vaccine developed against the 2013 H7N9 virus may not be effective against 2017 strains.

The remarkable capacity of influenza viruses to undergo antigenic drift or shift to overcome and escape human population immunity leaves us vulnerable to a public health disaster potentially as serious as the 1918 pandemic. To meet this global health challenge, scientists are working to develop “universal influenza vaccines”—new types of inoculations that can provide protection not only against changing seasonal influenza viruses but also against the inevitable pandemic viruses that will emerge in the future.

Recently the National Institute of Allergy and Infectious Diseases convened a workshop with leading experts in the influenza field to address the need for better influenza vaccines. Among many obstacles to developing a universal vaccine, the most formidable is our incomplete understanding of the immune responses that protect people against influenza, including the role of immunity at mucosal surfaces.

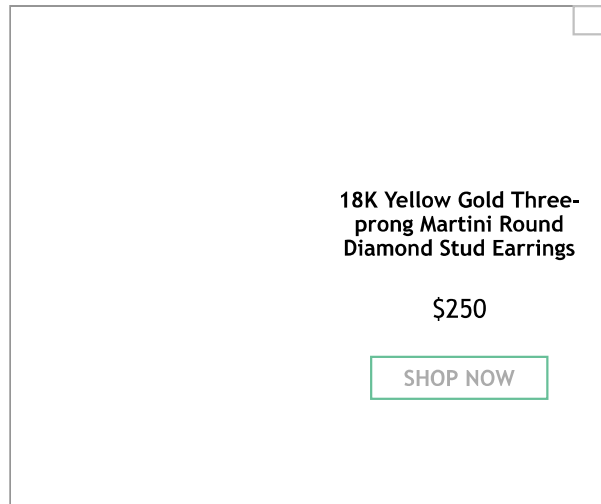
One approach is to design a vaccine to generate antibody responses to parts of the virus that are common to all influenza strains and do not readily change by mutation. It is also crucial to clarify how other parts of the immune system work together with antibodies to protect against influenza. The hurdles in the development of such vaccines are daunting. But we are optimistic that we can apply existing tools and experimental strategies to meet the challenge. As we note the centennial of the 1918 flu pandemic, let us remind ourselves of the importance of this line of research in preventing a repeat of one of the most disastrous events in the history of global health.

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