ADVISORY COMMISSION ON CHILDHOOD VACCINES
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September 20, 2016

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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

July 25, 2016

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

5600 Fishers Lane, Room 09N17

Rockville, MD 20857

Teleconference and Adobe Connect

September 20, 2016

(10:00 am – 3:15 pm Eastern Daylight Time)

Dial in: 1-800-779-3561

Passcode: 8164763

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

Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Dr. Kristen Feemster, Chair
10:10 AM	Public Comment on Agenda Items	Dr. Kristen Feemster, Chair
10:15 AM	Approval of June 2016 Minutes	Dr. Kristen Feemster, Chair
10:20 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Acting Director, DICP
10:50 AM	Report from the Department of Justice	Ms. Catharine Reeves, Acting Deputy Director, Torts Branch, DOJ
11:20 AM	Update from ACCV Process Work Group	Ms. Martha Toomey ACCV
12:00 PM	Lunch	
12:30 PM	Review of Vaccine Information Statements	Skip Wolfe CDC
2:00 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Michael McNeil CDC
2:15 PM	Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH

Time	Agenda Item	Presenter
2:30 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	LCDR Valerie Marshall CBER, FDA
2:45 PM	Public Comment (follows the preceding topic and may commence earlier or later than 3:00 pm)	Dr. Kristen Feemster, Chair
3:00 PM	Future Agenda Items/New Business	Dr. Kristen Feemster, Chair
3:15 PM	Adjournment of the September ACCV Meeting	Dr. Kristen Feemster, Chair

Charter

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

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

Objectives and Scope of Activities

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

Description of Duties

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

Agency or Official to Whom the Commission Reports

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

Support

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

Estimated Annual Operating Costs and Staff Years

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

Designated Federal Official

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

Estimated Number and Frequency of Meetings

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

Duration

Continuing.

Termination

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

Membership and Designation

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

The Commission shall be composed of the following:

(1) Nine members appointed by the Secretary as follows:

(A) three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians;

(B) three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and

(C) three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials), each of whom shall be a non-voting ex officio member.

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

Subcommittees

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

Recordkeeping

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

4 – ACCV Charter

Filing Date

July 21, 2016

Approved:

JUL 20 2016
Date

Jason E. Bennett
Director, Division of Executive Secretariat

Roster

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV) ROSTER
DIVISION OF INJURY COMPENSATION PROGRAMS (DICP)
5600 Fishers Lane, 08N146B
Rockville, MD 20857

ACCV MEMBERS

Kristen A. Feemster, M.D., M.P.H., M.S.H.P.,
Chair ('16)
Assistant Professor- UPenn School of Medicine,
Division of Infectious Diseases
The Children's Hospital of Philadelphia
CHOP North- 3535 Market St, Rm 1511
Philadelphia, PA 19104
email: feemster@email.chop.edu

Jason Smith, J.D.,
Vice-Chair ('16)
Assistant General Counsel
Pfizer Inc.
500 Arcola Road
Dock E – Office D 4214
Collegeville, PA 19426
e-mail: jason.smith@pfizer.com

Charlene Douglas, Ph.D., M.P.H., R.N. ('16)
Associate Professor, George Mason University
4400 University Drive, Mail Stop 3C4
Fairfax, VA 22030-4444
e-mail: cdouglas@gmu.edu

Vacant Position - Pediatrician

Luisita dela Rosa, Ph.D. ('16)
22640 Lamplight Place
Santa Clarita, CA 91350
e-mail: louiedrosa@gmail.com

Edward Kraus, J.D., ('16)
Associate Professor of Clinical Practice
Chicago-Kent College of Law
565 West Adams, Suite 600
Chicago, IL 60661
e-mail: ekraus@kentlaw.edu

Martha Toomey, ('18)
PO Box 236
Orlean, VA 20128
e-mail: mjtoomey1995@yahoo.com

Alexandra Stewart, J.D., ('18)
The George Washington University,
School of Public Health and Health
Services
950 New Hampshire Ave, N.W.
2nd Floor
Washington, DC 20052
e-mail: stewarta@gwu.edu.com

Karlen E. (Beth) Luthy, D.N.P., A.R.P.N. ('18)
Associate Professor
College of Nursing, Brigham Young University
457 SWKT
Provo, UT 84602
e-mail: beth_luthy@byu.edu

EX-OFFICIO MEMBERS

Bruce Gellin, M.D.
Director, National Vaccine Program Office
200 Independence Ave, S.W. Room 736E
Washington, D.C. 20201-0004
(202)690-5566 (Direct)
(202)690-7560 (Fax)
e-mail: bgellin@osophs.dhhs.gov

Marion Gruber, Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics, Evaluation and Research
Food and Drug Administration
1451 Rockville Pike, Rm 3312
Rockville, MD 20852
(301)796-2630
(301)402-1290 (Fax)
e-mail: marion.gruber@hda.hhs.gov

Barbara Mulach, PHD
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane, Rm 7G61,
Rockville, MD 20852
(240)627-3332 (Direct)
e-mail: Barbara.Mulach@nih.hhs.gov

Tom Shimabukuro, M.D., M.P.H., M.B.A
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road
Clifton Building, Mail Stop D-26
Atlanta, GA 30333
(404)639-4848 (Direct)
(404)639-8834 (Fax)
e-mail: tshimabukuro@cdc.gov

DICP STAFF

Narayan Nair, M.D.
Acting Director, DICP
Executive Secretary, ACCV
(301)443-9350 (Direct)
(301)443-0704 (Fax)
e-mail: nnair@hrsa.gov

Andrea Herzog
Principal Staff Liaison, ACCV
(301)443-6634 (Direct)
(301)443-8196 (Fax)
e-mail: aherzog@hrsa.gov

OFFICE OF THE GENERAL COUNSEL

Andrea Davey, J.D.
Attorney
(301)443-4500 (Direct)
(301)443-2639 (Fax)
e-mail: Andrea.Davey@hhs.gov

2016 -2017
Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2016 MEETING DATES

March 3, 2016
June 3, 2016
September 20, 2016
December 1 & 2, 2016

2017 MEETING DATES

March 2 & 3, 2017
June 1 & 2, 2017
September 7 & 8, 2017
December 7 & 8, 2017

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Advisory Commission on Childhood Vaccines

June 3, 2016

100th Meeting

Members Present

Kristen A. Feemster, M.D., Chair (’16)
Charlene Douglas, Ph.D. (’16)
Edward Kraus, J.D. (’16)
Karlen E. Luthy, (’18)
Luisita dela Rosa, Ph.D. (’16)
Jason Smith, J.D. (’16)
Martha Toomey (’18)
Alexandra Stewart, (‘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., Acting Director, DICP
Andrea Herzog, Staff Liaison

Welcome, Report of the Chair and Approval of Minutes
Kristen Feemster, ACCV Chair

Dr. Feemster called the meeting to order and completed a roll call, reflected above, for the record and briefly reviewed the agenda..

Public Comment on Agenda Items

Dr. Feemster invited public comment on the agenda. Ms. Theresa Wrangham, Executive Director, National Vaccine Information Center commented regarding the petition to add injuries for seasonal influenza vaccine to the Vaccine Injury Table (Table), and the presentation available online from the DICP stating there is insufficient medical research to support adding many of the items in the petition to the Table.

The National Childhood Vaccine Injury Act of 1986 that established the Advisory Commission on Childhood Vaccines (ACCV or Commission) spelled out a broad range of responsibilities for the Secretary of HHS to continually monitor and improve vaccines for children, which should include support for research. The Commission has recommended that Congress provide sufficient funds to underwrite that charge. There have been four successful petitions with regard to vaccine-induced multiple sclerosis related to influenza vaccine, which must have generated sufficient medical evidence to support the petitions, despite the indication that there is likely insufficient research-based evidence in the scientific literature. Ms. Wrangham suggested that the data provided by the petitioners in those four cases could be

helpful in the deliberations that will occur under the agenda item, although she doubted that it would be included in the DICP presentation.

Dr. Feemster noted that there were no other comments concerning the agenda.

Approval of March 3, 2016 minutes

Dr. Feemster invited approval of the March 3, 2016 meeting minutes. On motion duly made and seconded, the minutes were unanimously approved.

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

Dr. Nair welcomed all present and on the teleconference line, and expressed appreciation for their participation. Reviewing the agenda, he noted that the Department of Justice (DOJ) would provide an update, and that DICP would provide information about the petition to add injuries from seasonal influenza vaccines to the Vaccine Injury Table (VIT), and the Commission would hear updates from the ex-officio members (Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and National Vaccine Program Office (NVPO).)

Dr. Nair noted that, with four months remaining in the fiscal year, 707 petitions have been filed, continuing the consistent trend since 2011 of annual increases in petitions filed. As of June 1, 2016, there have been 346 compensable claims and two dismissed claims. Adjudications for non-autism claims totaled 346, made up of 96 (28%) compensable; 32 (9%) court decisions; and 218 (63%) by settlement. There were two claims dismissed. Asked about why the latter number was significantly lower than in previous years, Dr. Nair stated that no analysis of the dismissals had been made to explain the decrease.

Monetary awards for petitioners as of June 1, 2016, were over $140 million, and attorneys' fees were about $13 million. The Trust Fund stands at $3.6 billion as of March 31, 2016, with excise tax revenue of $130 million, interest income of $27 million, for a net income of $157 million.

Dr. Nair commented that the Notice of Proposed Rulemaking for the revisions to the Table was published in July 2015, the required public hearing was held on January 14, 2016 and the public comment period closed ten days later, on January 25, 2016. The Department is reviewing those comments in order to develop the final rule.

Recalling that a private citizen exercised the right to request the addition of injuries related to adding food allergies to the VIT, Dr. Nair commented that the Commission had reviewed that request and agreed not to make a recommendation regarding the petition. That citizen subsequently submitted additional information about the request, but after further consideration a decision was made to abide by the Commission's original determination.

Finally, Dr. Nair mentioned the DICP outreach activities. The revised VICP web site was launched on February 19, 2016. DICP also participated in two major meetings in April --

the National Hispanic Medical Association Annual Meeting (in collaboration with FDA's Office of Women's Health), and a presentation to pharmacy students and pharmacists at Howard University.

In closing, Dr. Nair mentioned that the Senate had introduced a bill that would provide VICP coverage for pregnant women and in utero injuries related to maternal immunizations.

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

Ms. Reeves welcomed the commissioners and reported that Vince Matanoski has retired and that she is serving as the Acting Deputy Director. Ms. Reeves referenced the Department of Justice Power Point materials as part of her presentation for the three-month period from February 16, 2016 to May 15, 2016. As noted after the meeting, the DOJ statistics inadvertently included cases for which judgment had not entered, so these notes reference the amended presentation circulated on June 15, 2016 (Amended DOJ PP). During this reporting period, 206 petitions were filed. Of those, 38 were filed on behalf of children (18%) and 168 were filed by adults (82%). (Amended DOJ PP at 2). The number of new filings is slightly lower than in the previous reporting period.

With regard to total cases adjudicated, Ms. Reeves noted that 216 claims were adjudicated this quarter. (Amended DOJ PP at 3). There were 167 cases compensated. Of those 167 cases, 61 were conceded cases by HHS. Of those 61 conceded cases, 1 was resolved by a decision awarding damages, 59 were resolved by a decision adopting a proffer, and 1 was resolved by a decision adopting a settlement stipulation. Ms. Reeves noted that the number of cases adjudicated this period was similar to the number last period. There were 106 cases compensated but not conceded by HHS. Of those, all 106 cases were resolved by a decision adopting a settlement stipulation. (Amended DOJ PP at 3). There were 49 cases dismissed. Of those, 46 non-OAP cases were resolved by decisions dismissing the petition, and 3 were dismissed from the OAP. (Amended DOJ PP at 3). Ms. Reeves noted that it was not clear why there was a discrepancy between the 49 cases DOJ reported as having been dismissed and the 2 cases that DICP reported. There were 9 petitions voluntarily withdrawn, which Ms. Reeves remarked was an increase compared to last period. (Amended DOJ PP at 4).

Turning to appeals, six cases filed by petitioners were decided by the U.S. Court of Appeals for the Federal Circuit (CAFC). (Amended DOJ PP at 5). In *Padmanabhan v. HHS*, which was discussed at the last meeting, the CAFC affirmed the dismissal of the case per curiam, and petitioner filed a combined petition for panel rehearing and en banc rehearing. In *Moriarty v. HHS*, the CAFC vacated the decision by the U.S. Court of Federal Claims (CFC) and remanded the case. The CAFC affirmed in *D'Angiolini v. HHS* and *Milik v. HHS*, and affirmed per curiam in *Greenberg v. HHS* and *Nuttall v. HHS.* An affirmative appeal in *Guerrero v. HHS* was voluntarily dismissed by respondent. In addition to four appeals filed by petitioners that are pending, two new appeals were filed by petitioners in *R.K. v. HHS* and *Canuto v. HHS*, with the latter having been filed between the reporting period and this meeting. (Amended DOJ PP at 6).

Ms. Reeves discussed appeals at the CFC, and noted that six appeals filed by petitioners were decided by the CFC. Of those six, four were affirmed, one motion for review was denied with the prior decision dismissing the case for failure to prosecute being affirmed, and one motion for review was denied with the prior remand decision being affirmed. (Amended DOJ PP at 7). In addition, in

one appeal filed by respondent regarding attorney's fees and costs, the special master's decision was affirmed. Ms. Reeves noted that petitioners filed seven new appeals to the CFC, three of which were filed since submitting the initial DOJ PP. Those three are *Valle v. HHS*, *Murphy v. HHS*, and *Lasnetski v. HHS.* (Amended DOJ PP at 8). Respondent filed appeals in two cases regarding attorney's fees and costs, in *Simmons v. HHS* and *Garrison v. HHS*, with the latter having been filed between the reporting period and this meeting. Four cases remain pending at the CFC. (Amended DOJ PP 8).

No cases are scheduled for oral argument at the CAFC or CFC. (Amended DOJ PP at 9).

Ms. Reeves noted the history of adjudicated settlements, which are listed in order of the time they took to resolve. (Amended DOJ PP at 10-20).

Ms. Toomey asked whether it is quicker for a petitioner to proceed to hearing or settle. Ms. Reeves responded that settlements tend to proceed through the system quickly, but there are many reasons why cases can take longer to resolve. Ms. Reeves noted that one of the settlements that took years to resolve involved delays in obtaining medical records, significant pre-hearing procedural history, and an entitlement hearing, and the case settled after the hearing while the parties were waiting for a decision. Ms. Reeves commented that the VICP process still remains far quicker than the normal tort system.

Mr. Kraus commented on the discrepancy in the reported cases dismissed by DOJ and DICP, and requested that there be follow-up regarding the numbers. Ms. Overby commented that there may be a lag between when HHS receives the judgment from the court or DOJ. Ms. Reeves noted that the numbers will be confirmed and reported to the ACCV.

Petition to Add Injuries for Seasonal Influenza Vaccine to the Table, Terry Dalle-Tezze, Pediatric Team Lead, DICP

Dr. Dalle-Tezze explained that the National Childhood Vaccine Injury Act of 1986 (the Act), authorized the Secretary of HHS to maintain the Table, and provided a way for the Secretary to modify the Table through the federal rulemaking process. The Act also allows any person to petition the Secretary to modify the Table and, unless frivolous, the petition is referred to the Commission for review and comment or recommendations. Once a comment has been submitted, the Commission has 180 days to submit a recommendation to the Secretary, who then either initiates the rulemaking process by publishing notice of proposed rulemaking in the Federal Register proposing changes to the Table, or publishes a statement in the Federal Register explaining the rationale for not conducting the rulemaking process.

Although most claims do not fit the parameters of the Table, a petitioner may seek compensation for an alleged injury by providing proof of causation, and/or proof of significant aggravation of an existing condition. The standard of proof is preponderance of evidence. The petitioner must show that the injury lasted more than six months, or resulted in an inpatient hospitalization and surgical intervention, or death. The ACCV has established and published guidance, "Guiding Principles for Recommending Changes to the Vaccine Injury Table." The Guiding Principles include two tenets: the Table revisions should be scientifically and medically credible; and any change should, whenever possible, be made to the benefit of the petitioner.

Dr. Dalle-Tezze provided an overview of his presentation which discussed a review of the medical and scientific literature regarding of neurological injuries and influenza vaccines; a discussion of the purpose of the DOJ quarterly report (which is reviewed at each Commission meeting), the role of the Vaccine Adverse Event Reporting System (VAERS), and a review of the medical literature related to multiple sclerosis and transverse myelitis as they relate to influenza vaccines. The discussion also considered two questions posed in the petition:

1. "There appears to be sufficient evidence to amend the VIT [Table] to include a "catch all" phrase with respect to adverse health conditions/injuries associated with the flu vaccine. The "catch all" phrase may read as follows: "any adverse neurological disorder or condition." This would preclude having to list each neurological condition separately. The timeline could be set at an appropriately agreed upon time post flu vaccination (e.g., 90 days)." This would cover all neurologic injuries and conditions that might pertain to influenza vaccine

2. "Should a "catch all" phrase not be used, at a minimum, the Table should list anaphylaxis, shoulder injury related to vaccine administration (SIRVA), vasovagal syncope, multiple sclerosis (MS), Guillain-Barrè Syndrome (GBS), transverse myelitis (TM), and myelitis as being associated with the flu vaccine." It was noted that anaphylaxis is already covered by the Table for most vaccines.

Dr. Dalle-Tezze summarized the questions in the petition.

- First, should any or all neurologic disorders be added to the Table as an injury for influenza vaccine?
- Second, should multiple sclerosis and myelitis/transverse myelitis be added to the Table as injuries for the influenza vaccine?

The petition also cited the DOJ Quarterly Reports and the VAERS Reports as "sufficient evidence to amend the VIT," because both specifically identify those injuries as being related to influenza vaccine. Dr. Dalle-Tezze suggested that the Commission is familiar with the DOJ Quarterly Reports since they are discussed at each ACCV meeting. The reports primarily provide statistical information about claims files, adjudications and final settlements. However, he stated that the settlement of a claim does not imply vaccine causation. There are many reasons to settle a case and the settlement does not provide a reliable rationale for any vaccine injury. That caveat is explained in detail on the VICP web site.

The value of the VAERS reports lies in the fact that over 30,000 reports are collected annually and although about 85% are mild reactions, the remaining reports include serious adverse events. VAERS is a voluntary passive reporting system that may include descriptive errors, incomplete information, underreporting, and VAERS provides no proof that the vaccine was a causative factor (only that the event occurred following vaccination). Nonetheless, it is a helpful tool in detecting new or rare events, monitoring any increases in adverse events,

identifying risk factors, and assessing the safety of new vaccines. Neither the DOJ Quarterly Reports nor the VAERS reports ascribe injury causality to any vaccine.

Dr. Dalle-Tezze discussed the response to question #1 in the petition stating that the medical and scientific literature does not support that any neurological disorder or condition is caused by influenza vaccines. The 2012 Institute of Medicine report, "Adverse Effects of Vaccines: Evidence and Causality", which looked at a number of specific possible neurological conditions, concluded that there was inadequate evidence to accept or reject a causal relationship. With regard to the proposal to add any neurological disorder or condition to the Table, the proposal was too broad in scope to justify including any neurological injury, and the ACCV guideline that "the Table should be scientifically and medically credible" would not be met.

Concerning question #2, the list of specific conditions, one on the list, anaphylaxis, is currently on the Table for most vaccines, and is proposed as an addition for varicella, influenza, meningococcal and HPV vaccines. GBS, SIRVA and vasovagal syncope are also proposed as injuries for influenza vaccine. Question #2 also requested addition of MS, myelitis and TM, and the Department added acute disseminated encephalomyelitis (ADEM), although the latter was not in the petition request. There was a conclusion in the 2012 IOM report that the epidemiological data was insufficient to suggest a causal relationship between influenza vaccine and MS, and the report concluded that the evidence is inadequate to accept or reject a causal relationship. Other studies cited and found in the scientific literature do not support the theorys that influenza vaccine causes MS, and that adding the injury to the Table would not comply with the guideline that the Table should be scientifically and medically credible. The 2012 IOM report also looked at myelitis and flu vaccine and came to a similar conclusion. Finally, although not in the petition, the IOM report also found that evidence in the medical and scientific literature does not support a causal link between ADEM and influenza vaccine.

Dr. Dalle-Tezze explained that the Commission has four options to consider for the addition of injuries for the influenza vaccine:

1. add all neurologic injuries to the Table;
2. add multiple sclerosis to the Table;
3. add myelitis/transverse myelitis to the Table; and/or
4. add none of the above to the Table.

Dr. Feemster invited questions and comments. Mr. Smith asked for comments from the physicians on the Commission and Dr. Feemster observed that, from Dr. Dalle-Tezze's presentation, it appears clear that there is no reliable causal relationship between the flu vaccine and the injuries discussed. Dr. Nair added that, even without the additions to the Table, claimants can still pursue compensation. There was a concern that the term "all neurologic injuries" was too broad. It would include autism spectrum disorder, which may not be appropriate. There was also a comment that the Commission had not heard conclusive evidence that MS and myelitis have a clear flu vaccine-related causal related relationship. Finally, opting for the fourth proposal (add nothing discussed to the Table) does not preclude revisiting the issues in the future.

On motion duly made and seconded, the Commission unanimously approved the fourth option, "Do not add any of the above to the Table" for influenza vaccines.

Dr. Feemster invited reports from the ex officio members.

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

Dr. Cano provided an update of the February 2016 Advisory Committee on Immunization Practices (AICP), addressing selected sessions beginning with the session on human papillomavirus (HPV) vaccines. The U.S. administers a three-dose schedule for 4-valent, 9-valent and 2-valent HPV injections. Merck is conducting a clinical trial of a two-dose 9-valent vaccine that appears to compare favorably with the present 3-dose regimen. The FDA is reviewing that clinical trial. Merck is also looking at a 2-dose schedule for a 4-valent vaccine, but does not intend to submit the data to FDA. The transition to the 9-valent vaccine should be completed by the end of 2016.

With regard to meningococcal disease, there have been outbreaks of the disease in men who have sex with men (MSM), and HIV infection increases the risk of infection. During the outbreaks, MenACWY vaccine was recommended for MSM and there is a consideration for recommending the vaccine for HIV-infected individuals as well as MSM. Further studies are needed to better understand the epidemiology. Next steps include continued vaccination with MenACWY and enhanced surveillance of the populations at risk, cost effectiveness and GRADE analyses are in progress.

Dr. Cano explained that Ixiaro (Valneva) is the only vaccine available in the U.S. for Japanese encephalitis. It was licensed in 2009 for adults. In 2012 ACIP recommended a booster dose, and in 2013 the age range recommendation was extended to children 2 months old or older. ACIP will probably update its original 2010 recommendation; FDA is reviewing safety and efficacy data that might justify a booster dose for children.

Dr. Cano discussed influenza vaccine effectiveness, noting that for the 2015-2016 flu season an interim assessment of effectiveness against medically-attended flu was 59%, higher than the previous year's flu season when effectiveness was measured at 30% (when a different vaccine was administered). That number might change for post-season results. The manufacturer of the flu vaccines, Protein Sciences Corporation, released data from an analysis comparing quadrivalent recombinant-IIV (RIV4) with IIV4 and PCR confirmed that incidence of flu-like illness was lower with the recombinant version (2.2% versus 3.3%). Both vaccines had similar safety profiles. Injection site pain and tenderness were lower with the RIV4 formulation.

A review of the scientific literature reveals that in egg-allergic recipients there was a low rate of minor adverse reactions. Rare serious adverse events, and immediate hypersensitivity reactions were similar in both egg-allergic recipients and in recipients who were not egg-allergic. In studies of live attenuated influenza vaccine (LAIV) there were no systemic reactions observed (both LAIV and IIV have very low amounts of egg protein).

Dr. Cano stated that the ACIP formally voted on the following recommendations:

- Annual influenza immunization continues to be recommended for all individuals aged 6 months or older.
- Vaccine should be offered by the end of October, and as long as the virus is circulating and vaccine is available.
- Remove the 30-minute post-inoculation observation, except for a 15-minute period for syncope.
- Persons with egg allergies who have required epinephrine therapy for adverse reactions may receive any licensed flu vaccine.
- Wording requiring a consult for individuals suspected of having an egg allergy, with or without history of allergic reaction to eggs, will be removed. And the algorithm on egg allergy will be removed.

Dr. Cano briefly referred to a number of recent publications:

- Haber et al reported on post-licensure surveillance data from VAERS that indicated that quadrivalent inactivated flu vaccine had a similar safety profile to trivalent inactivated flu vaccine, and most reactions were non-serious. The data were similar to pre-licensure studies. (Vaccine Mar 23, 2016)
- Miller et al, in a similar study of VAERS data on 23-valent pneumococcal polysaccharide vaccine, showed no new or unexpected safety concerns and the data were similar to pre-licensure studies. (Vaccine Apr 14, 2016)
- Baxter et al reported data on various vaccines and risk of optic neuritis that showed no association between any vaccine and the disorder. (Clin Infect Dis. April 10, 2016)
- Li et al, using data from the Vaccine Safety Datalink, showed no increased risk from flu vaccine during the flu seasons from fall 2013 through the 2014-2015 flu seasons. The exception was febrile seizures that were reported previously. (Pharmacoepidemiol Drug Saf, April 1, 2016)
- Gee et al looked at quadrivalent HPV vaccine and confirmed that pre-licensure and post-licensure 4vHPV safety data has been reassuring as to safety. (Hum Vaccine Immunother, Mar 30, 2016)
- Baxter et al analyzed a large database and found no association between influenza vaccine or any other vaccine and sudden-onset sensorineural hearing loss. (Otolaryngol Head Neck Surg. Mar 29, 2016)
- Moro et al relying on VAERS data, found no unexpected adverse events in pregnant women who received Tdap. (Vaccine Mar 22, 2016)
- Schiffer et al described recent developments in the understanding and use of anthrax vaccine absorbed (BioThrax is the only FDA-approved vaccine for prevention of anthrax in humans). (Expert Rev Vaccines, Mar 25, 2016)
- Su et al reviewed an MMWR article describing a VAERS report of inappropriate administration of the meningococcal conjugate vaccine, Menveo, when providers administered only one of two required vaccine components. (MMWR Morb Mortal Wkly Rep, Feb 19, 2016)

Dr. Cano concluded her presentation.

Update from the National Institute of Allergy and Infectious Diseases (NIAID, NIH), Vaccine Activities, Dr. Barbara Mulach, NIAID, NIH

Dr. Mulach began her presentation with background about the Zika virus. As of May 2016, Zika was present in 60 countries and territories, 14 of which have reported infections contracted between 2007 and 2014. Also as of May 2016, there were 591 travel-associated cases in the U.S., but no locally acquired infections. However, in U.S. territories there have been 939 cases reported, 935 of which were locally acquired. NIH has an existing screening program to identify potential therapeutics for flaviviruses, and Zika virus was added to that program. Research has been initiated to look at the biology/structure/evolution of the virus and the nature of the mosquito vectors. NIH will also build on existing research programs to develop vaccines, diagnostics and therapeutics, and to better understand the mechanism of the pathogenesis involved. For example, there is DNA vaccine research built on a platform that developed such a vaccine for West Nile virus, and work on a live attenuated Zika chimera vaccine relying on previous research on a dengue vaccine.

Dr. Mulach explained that the research involves collaboration with other institutions in the U.S. and abroad, looking at the epidemiology and natural history of Zika virus infection, and there is a focus on the incidence and adverse outcomes in infected pregnant women, including a collaboration with NICHD.

Recalling an earlier briefing on dengue fever research, Dr. Mulach commented that a Phase III clinical trial is soon to be initiated in Brazil, and the Commission will be regularly informed of its progress. Finally, Dr. Mulach described a collaboration between NIAID and the manufacturer of a malaria vaccine, PfSPZ, which showed efficacy in a Phase I trial of 101 healthy adults. The vaccine seems to show long-term protection that would be beneficial to travelers and military personnel, and durable protection for populations residing in malaria-endemic regions.

Dr. Mulach announced that NIH had awarded six grants to support research on combination adjuvants to improve vaccine response and effectiveness. There is also research being supported to look at influenza vaccine efficacy. Finally, a large clinical trial (5,400 participants) looking at a combination of two HIV vaccines is expected to begin in South Africa in November 2016.

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

LCDR Marshall addressed FDA vaccine supplement approvals, and emergency preparedness. In April, 2016, the FDA approved a supplement to the biologics license application (BLA) for Trumenba, a meningococcal Group B vaccine for individuals age 10 to 25. The approval included a two-dose schedule (modifying the previous 3-dose schedule) for administration of the vaccine at 1-2 months and at 6 months. Also in April, the FDA approved

several BLA supplements to change product labeling for 14 vaccines. The change involved informing users that the product or product container is not made with natural rubber latex."

In March, 2016, the FDA approved a supplement to the BLA for Afluria, an influenza virus vaccine, to include non-seasonal updates to the package insert, including updates to the post-marketing adverse event terms; and information related to Afluria exposure and surveillance information related to pregnant women. Also in March, the FDA approved a supplement to the BLA for Fluzone quadrivalent vaccine to include the 2016 Southern Hemisphere formulation (recommended by WHO).

LCDRMarshall commented on several issues related to emergency preparedness. In late March, FDA participated in the WHO consultation on a rationale for a vaccine efficacy trial during public health emergencies (integrating infectious disease modeling). In early May, FDA participated in the second WHO consultation on regulatory considerations for the evaluation of Ebola vaccines intended for emergency use. And in early June, FDA will participate in a WHO consultation on potential regulatory approval pathways for Zika vaccine in emergency situations. There are no FDA-approved vaccines for Zika.

LCDR Marshall concluded her report.

Update from the National Vaccine Program Office (NVPO)
Dr. Cristina Herrera, NVPO

Dr. Herrera explained that the vaccine prioritization tool software, SMART Vaccines 2.0, will conduct a stakeholders meeting at the end of June 2016. The tool was developed by the Institute of Medicine and there is collaboration between NVPO and the Fogarty International Center to continue its development.

Dr. Herrera commented that NVPO coordinates and leads the Immunization Safety Task Force (ISTF). The Task Force ensures that all federal efforts relevant to immunization safety are coordinated and integrated and that opportunities to enhance synergies across the federal government in immunization safety are identified. The Task Force has held two meetings, one on chimeric yellow fever dengue vaccines, and one on surveillance of Guillain-Barre syndrome is the U.S as it relates to the Zika virus epidemic.

Dr. Herrera noted that NVPO supported a vaccine safety publication submission for a paper entitled, "Unique Safety Issues Associated with Virus-vectored Vaccines: Potential for and Theoretical Consequences of Recombination with Wild Type Virus Strains."

Finally, Dr. Herrera stated that NVPO is re-establishing the Vaccine Safety Fellowship program, which she will be supervising. NVPO has committed additional funding of $500,000 to support vaccine safety through the NVPO 2017 Cooperative Agreement. THhe NVPO awards for vaccine safety research will be introduced at the June NVAC meeting, to be awarded in September.

Public Comment

Dr. Feemster invited public comment.

Ms. **Theresa** Wrangham, **Executive Director, National Vaccine Information Center (NVIC),** clarified her earlier comment about the value of evidence available in the petitions and claims filed and settled. She felt that such information would be helpful to the Commission's deliberations.

Regarding the adequacy of awards, noting the case of the petitioner who requested review of what was considered an insufficient award, Ms. Wrangham commented that there is no mechanism to assess the satisfaction/dissatisfaction of petitioners who receive awards. There has been no such survey since the 2009 Altarum Report. The announcement of the improved number of settlements and the improved speed with which the cases are being resolved was welcome, but information about the quality of those settlements is lacking. The NVIC request that the Commission revisit the 2009 Altarum Report, the 2010 Banyan report, and the 2014 General Accountability Office (GAO) report and prepare a report on progress made and what is needed to improve awareness of and satisfaction with the VICP.

The NVIC also renews its request that the ACCV issue a statement that the use of vaccines carries a risk of injury and, because of that risk, the ACCV supports the right of every parent to provide informed consent and to make choices about administering vaccines to their children.

Finally, a process should be in place to include the opportunity for those who petition for addition/revision to the Table to provide evidence to clarify the request in the petition.

Dr. Feemster stated that there were no other requests to participate in public comment.

Future agenda items and New Business, Dr. Kristen Feemster, Chair

Dr. Feemster invited suggestions for future agenda items. There was a suggestion that the Commission address the public comment issue on informed consent; and that working group meetings be scheduled. Although not firm, the tentative date for the next meeting is September 20, 2016.

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 August 31, 2016

$3,654,788,832.72

Figures for October 1, 2015 – August 31, 2016

Excise Tax Revenue: $221,407,009.47
Interest on Investments: $50,568,301.71
Total Income: $271,975,311.18
Interest as a Percentage of Total Income: 19%

Source: U.S. Treasury, Bureau of Public Debt
September 12, 2016

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U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

Data & Statistics

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

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

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

- Over 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 2014 over 2.5 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 3,594 petitions were adjudicated by the Court, and of those 2,265 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 17,308 petitions have been filed with the VICP. Over that 27 year time period, 14,971 petitions have been adjudicated, with 4,897 of those determined to be compensable, while 10,074 were dismissed. Total compensation paid over the life of the program is approximately $3.4 billion.

VICP Adjudication Categories, by Alleged Vaccine, For Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 Through 12/31/2014

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 12/31/2014 (Source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
DT	712,347	1		5	6	4	10
DTaP	83,052,184	14	21	90	125	85	210
DTaP-Hep B-IPV	51,305,397	4	7	22	34	39	73
DTaP-HIB	1,135,474			1	1	1	2
DTaP-IPV-HIB	46,401,211	1		7	8	17	25
DTap-IPV	15,490,820						
DTP	0	1	1	3	5	2	7
DTP-HIB	0			3	3	1	4
Hep A-Hep B	12,740,305			10	10	2	12
Hep B-HIB	4,787,457	1	1	1	3	1	4
Hepatitis A (Hep A)	136,935,713	6	3	27	36	23	59
Hepatitis B (Hep B)	143,946,953	2	11	53	66	47	113
HIB	93,160,376		1	4	5	5	10
HPV	77,506,945	12	3	86	101	118	219

Influenza	1,078,000,000	100	98	1,165	1,363	210	1,573
IPV	62,344,612			4	4	2	6
Measles	135,660			1	1		1
Meningococcal	64,004,175	1	4	29	34	5	39
MMR	80,115,475	19	14	68	101	83	184
Mumps	110,749						
MMR-Varicella	14,403,057	8		8	16	9	25
Nonqualified	N/A			3	3	23	26
OPV	0	1			1	3	4
Pneumococcal Conjugate	150,497,243		1	5	6	16	22
Rotavirus	79,636,437	4	4	17	25	7	32
Rubella	422,548		1	1	2		2
Td	57,940,972	7	6	55	68	18	86
Tdap	177,160,298	31	7	130	168	23	191
Tetanus	3,836,052	4		25	29	13	42
Unspecified	N/A	1	2	3	6	560	566
Varicella	96,646,081	4	7	24	35	12	47
Grand Total	**2,532,428,541**	**222**	**193**	**1,850**	**2,265**	**1,329**	**3,594**

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2014 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

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

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

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

Definitions

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

- **Concession**: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
  For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:
  1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
  2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement**: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- **Non-compensable/Dismissed**: The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
  3. The injured person voluntarily withdrew his or her petition.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 09/02/2016

Vaccines	Filed			Compensated	Dismissed
	Injury	Death	Grand Total		
DTaP-IPV	5	0	5	0	1
DT	69	9	78	26	51
DTP	3,286	696	3,982	1,273	2,706
DTP-HIB	20	8	28	7	21
DTaP	410	80	490	205	213
DTaP-Hep B-IPV	66	30	96	34	36
DTaP-HIB	11	1	12	5	3
DTaP-IPV-HIB	36	18	54	8	17
Td	192	3	195	116	67
Tdap	383	2	385	210	30
Tetanus	113	2	115	55	41
Hepatitis A (Hep A)	87	6	93	39	23
Hepatitis B (Hep B)	638	56	694	260	376
Hep A-Hep B	25	0	25	13	2
Hep B-HIB	8	0	8	4	3
HIB	38	3	41	13	16
HPV	314	14	328	101	118
Influenza	2,744	108	2,852	1,671	218
IPV	264	14	278	8	267
OPV	282	28	310	158	151
Measles	143	19	162	55	107
Meningococcal	54	2	56	34	5
MMR	924	58	982	386	516
MMR-Varicella	36	1	37	16	9
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	61	8	69	11	28
Rotavirus	75	1	76	45	19
Rubella	190	4	194	71	123
Varicella	88	9	97	56	22
Nonqualified1	96	9	105	3	94
Unspecified2	5,420	9	5,429	5	4,768
Grand Total	**16,107**	**1,201**	**17,308**	**4,897**	**10,074**

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

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	634
FY 2015	805
FY 2016	986
Total	**17,308**

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	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	232	294
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	123	205
FY 2008	147	132	279
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	371	165	536
FY 2015	513	79	592
FY 2016	556	162	718
Total	**4,897**	**10,074**	**14,971**

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	73	$2,511,313.26	2	$117,265.31	$83,536,901.46
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	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53
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	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,637,927.73
FY 2013	375	$254,666,326.70	$13,333,179.53	703	$6,970,278.84	50	$1,454,851.74	$276,424,636.81
FY 2014	365	$202,084,196.12	$11,990,035.82	504	$6,784,885.79	38	$2,493,460.73	$223,352,578.46
FY 2015	508	$204,137,880.22	$14,408,377.76	109	$3,322,873.36	50	$3,089,497.68	$224,958,629.02
FY 2016	627	$191,390,694.40	$14,784,812.49	71	$1,957,392.18	59	$3,502,709.91	$211,635,608.98

Total	**4,899**	**$3,197,500,089.15**	**$146,371,008.40**	**5,059**	**$69,371,840.27**	**314**	**$24,299,980.70**	**$3,437,542,918.52**

"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
September 20, 2016

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

HRSA Healthcare Systems

DICP Update

ACCV Meeting Highlights

- Update from the Department of Justice Vaccine Litigation Office
- Update on ACCV Process Workgroup Activities and Recommendations
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH

HRSA Healthcare Systems

DICP Update
Number of Petitions Filed as of September 2, 2016

Average annual number of petitions filed during FY 2011-2015 = 546

Fiscal Year	Total
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	805
FY 2016	986

DICP Update
Number of Adjudications as of September 2, 2016

Fiscal Year	Compensable	Dismissed	Total
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	371	166	537
FY 2015	513	79	592
FY 2016	556	162	718

DICP Update

Adjudication Categories for Non-Autism Claims

FY 2014 – FY 2016 as of September 12, 2016

Adjudication Category	FY 2014	FY 2015	FY 2016
Compensable ❖Concession ❖Court Decision (includes proffers) ❖Settlement	371 (100%) 40 (11%) 35 (9%) 296 (80%)	513 (100%) 90 (17%) 35 (7%) 388 (76%)	581(100%) 171 (29%) 41 (7%) 369 (64%)
Not Compensable	122	65	151
Adjudication Total	493	578	732

DICP Update

Award Amounts Paid as of September 1, 2016

Fiscal Year	Petitioners' Award	Attorneys' Fees & Costs
FY 2011	$216,319,428	$17,163,231
FY 2012	$163,491,999	$23,145,929
FY 2013	$254,666,327	$21,758,310
FY 2014	$202,084,196	$21,268,382
FY 2015	$204,137,880	$20,811,802
FY 2016	$191,390,694	$20,244,914

DICP Update
Vaccine Injury Compensation Trust Fund

- **Balance as of August 31, 2016**
  - $3,654,788,832.72
- **Activity from October 1, 2015 to August 31, 2016**
  - Excise Tax Revenue: $221,407,009.47
  - Interest on Investments: $50,568,301.71
  - Income (Tax Revenue and Investments): $271,975,311.18
  - Interest as a Percentage of Income: 19%

Source: U.S. Treasury, Bureau of Public Debt (September 12, 2016)

DICP Update

Significant Activities

- Status of Revisions to Vaccine Injury Table Notice of Proposed Rulemaking (NPRM)
  - Public hearing was held on January 14, 2016
  - Public comment period ended January 25, 2016
  - The final rule has been developed and is being reviewed by Department of Health and Human Services

- Highlights of Recent Outreach Activities
  - On 8/9, Dr. Nair provided an overview of the program to the Association of State and Territorial Health Officials.

DICP Update
ACCV Meeting Information

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

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

DICP Update
Contact Information
Public Comment/Participation in Commission Meetings

Annie Herzog, ACCV Principal Staff Liaison
5600 Fishers Lane, Room 08N146B
Rockville, Maryland 20857
Phone: 301-443-6634
Email: aherzog@hrsa.gov

Web: hrsa.gov/about/organization/bureaus/hsb/
Twitter: twitter.com/HRSAgov
Facebook: facebook.com/HHS.HRSA

5.2

Report from the Department of Justice

September 20, 2016

Catharine E. Reeves
Acting Deputy Director, Torts Branch

Statistics

Reporting Period: 5/16/16 – 8/15/16

I. Total Petitions Filed in the United States Court of Federal Claims this reporting period: 276

A. Minors: 30

B. Adults: 246

Statistics

Reporting Period: 5/16/16 – 8/15/16

II. Total Petitions Adjudicated this reporting period: 233

A. Compensated: 180

i. Cases conceded by HHS: 67

1. Decision awarding damages: 0
2. Decision adopting Proffer: 65
3. Decision adopting Settlement: 2

ii. Cases not conceded by HHS: 113

1. Decision awarding damages: 0
2. Decision adopting Proffer: 0
3. Decision adopting Settlement: 113

B. Not Compensated/Dismissed: 53

i. Decision dismissing Non-OAP: 51

ii. Decision dismissing OAP: 2

Statistics

Reporting Period: 5/16/16 – 8/15/16

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 13

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

Recently Decided Cases

<u>Appeals by Petitioner</u>:

- *Milik v. HHS* (Entitlement): Affirmed per curiam
  - Petitioners filed a combined petition for panel rehearing and en banc hearing, which was denied

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:

- *R.K. v. HHS* (Entitlement)
- *Mora v. HHS* (Relief from Judgment)
- *Contreras v. HHS* (Entitlement)
- *Canuto v. HHS* (Entitlement)
- *R.V. v. HHS* (Entitlement)
- *Culligan v. HHS* (Entitlement-POI)
- *Fishkis v. HHS*: (Entitlement-POI)
- *Meylor v. HHS*: (Entitlement-POI)
- *Meylor v. HHS*: (Entitlement-POI)

*Yellow cases are new this reporting period

Appeals: U.S. Court of Federal Claims

Recently Decided Cases

Appeals by Petitioner:

- *R.V. v. HHS* (Entitlement): Affirmed
- *Marshall v. HHS* (Entitlement): Affirmed
- *Valle v. HHS* (Entitlement): Affirmed
- *Bean-Sasser v. HHS* (Entitlement): Affirmed
- *Murphy v. HHS* (Entitlement): Affirmed

*Yellow cases are new this reporting period

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:

- *H.L. v. HHS* (Entitlement)
- *Tarsell v. HHS* (Entitlement)
- *Spahn v. HHS* (Entitlement)
- *Spahn v. HHS* (Redaction)
- *Holt v. HHS* (Entitlement)
- *Lasnetski v. HHS* (Entitlement)
- *Curran v. HHS* (Attorneys' Fees and Costs)

Appeals by Respondent:

- *Simmons v. HHS (*Attorneys' Fees and Costs)
- *Allicock v. HHS* (Attorneys' Fees and Costs)
- *Copenhaver v. HHS* (Entitlement)
- *Rus v. HHS* (Entitlement)
- *Brannigan v. HHS* (Interim Attorneys' Fees and Costs)
- *Rich v. HHS* (Entitlement)
- *Raymo v. HHS* (Attorneys' Fees and Costs)
- *Reiling v. HHS* (Interim Attorneys' Fees and Costs)
- *Day v. HHS* (Interim Damages)
- *Garrison v. HHS* (Interim Attorneys' Fees and Costs)

*Yellow cases are new this reporting period

Scheduled Oral Arguments

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

- None scheduled at this time.

U.S. Court of Federal Claims:

- None scheduled at this time.

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
1. Dtap; IPV; Hep B; Hib; PCV	Encephalopathy; Seizure Disorder; Profound Developmental Delays	6 Years, 5 Months
2. HPV and Meningococcal Vaccines	Syncopal Seizure; Post-Vaccination Encephalopathy	5 Years, 11 Months
3. Flu	Postural Orthostatic Tachycardia Syndrome	4 Years, 5 Months
4. Flu	Vaccine; Stroke Death	3 Years, 11 Months
5. Flu	Bullous Dermatitis	3 Years, 10 Months
6. Flu	Dermatomyositis	3 Years, 4 Months
7. DtaP	Overlap Syndrome	3 Years, 3 Months
8. Td	SIRVA	3 Years, 2 Months
9. TDaP	Chronic Inflammatory Demyelinating Polyneuropathy	2 Years, 10 Months
11. Flu	GBS; CIDP	2 Years, 9 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
12. Flu	GBS	2 Years, 6 Months
13. Flu	Cellulitis, Pyoderma Gangrenosum, Polyglandular Autoimmune Syndrome	2 Years, 6 Months
14. Tdap	SIRVA	2 Years, 6 Months
15. Meningococcal Vaccine	ADEM, MS	2 Years, 5 Months
16. Hep B	Neurological Injuries, Bilateral Extremity Numbness, Balance Problems, Small Fiber Neurologic Injuries, Peripheral Neuropathy, Essential Tremors	2 Years, 4 Months
17. HPV	Peripheral Neuropathy, Irritable Bowel Syndrome, Fibromyalgia, Myalgias, Chronic Pain, Dizziness, Headaches, Cognitive Impairments, Chronic Debilitating Fatigue	2 Years, 2 Months
18. Flu	ADEM	2 Years, 2 Months
19. HPV	GBS	2 Years, 1 Months
20. Flu	Chronic Uticaria	2 Years, 1 Months
21. Flu	CIDP	2 Years

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
22. Flu	ARDS	1 Year, 11 Months
23. Flu	GBS	1 Year, 9 Months
24. Tdap	TM	1 Year, 9 Months
25. Flu	GBS; CIDP	1 Year, 9 Months
26. Flu	GBS	1 Year, 9 Months
27. Rotavirus	Intussusception	1 Year, 9 Months
28. Tdap	Brachial Neuritis	1 Year, 9 Months
29. Flu	GBS	1 Year, 8 Months
30. Flu	GBS	1 Year, 8 Months
31. Flu	TM	1 Year, 8 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
32. Flu	GBS, TM	1 Year, 8 Months
33. MMR	Peripheral Neuropathy, Neuritis Myalgia	1 Year, 8 Months
34. Flu	MS, Significant Aggravation, Cellulitis	1 Year, 8 Months
35. Flu, TDaP	GBS	1 Year, 7 Months
36. TDaP	GBS	1 Year, 7 Months
37. Flu	GBS, CIDP	1 Year, 7 Months
38. Flu	Pain, Numbness, Weakness, Right Arm	1 Year, 6 Months
39. Flu	TM	1 Year, 5 Months
40. Flu	SIRVA	1 Year, 4 Months
41. Flu	GBS, CIDP	1 Year, 3 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
41. Flu	Radial Neuropathy, Acute Inflammatory Demyelinating Polyneuropathy, Acute Motor Axonal Neuropathy, GBS	1 Year, 3 Months
42. Flu	ADEM	1 Year, 3 Months
43. Flu	GBS	1 Year, 3 Months
44. Flu	Neurological Injury	1 Year, 2 Months
45. Flu	GBS, Death	1 Year, 2 Months
46. Flu	GBS	1 Year, 2 Months
47. Flu	Brachial Neuritis	1 Year, 1 Months
48. Flu	SIRVA	1 Year, 1 Months
49. Flu	GBS	1 Year, 1 Months
50. Flu, Dtap	GBS	1 Year

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
51. Flu	SIRVA	1 Year
52. Flu	Neurological Injury, Suspected Parsonage-Turner Syndrome	1 Year
53. Hepatitis A, Haemophilus influenza type B, Measles-Mumps Rubella, Pneumococcal Conjugate, and Varicella Vaccines	Death	1 Year
54. Meningococcal Vaccine	GBS	1 Year
55. Flu	Adhesive Capsulitis	1 Year
56. Flu	SIRVA	1 Year
57. Flu	GBS	11 Months
58. Flu	Brachial Neuritis, Parsonage Turner Syndrome	11 Months
59. Flu	GBS	11 Months
60. Flu	GBS	11 Months

(continued . . .)

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
61. Hep B	GBS	11 Months
62. Flu	GBS	11 Months
63. Flu	GBS	10 Months
64. Flu, TDaP	GBS	10 Months
65. Flu	GBS	10 Months
66. Flu	GBS	10 Months
67. Flu	GBS	10 Months
68. Flu	GBS	10 Months
69. Flu	GBS	10 Months
70. Flu	Optic Neuritis, Chronic Headaches, Sinusitis	10 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
71. Flu	Spinal Cord Myelitis	10 Months
72. Flu	GBS	10 Months
73. Tdap	GBS	10 Months
74. Flu	GBS	10 Months
75. Flu	SIRVA	10 Months
76. Flu	SIRVA	10 Months
77. Flu	GBS	9 Months
78. Flu	Rheumatoid Arthritis, Bladder Weakness, Loss of Balance	9 Months
79. Flu	SIRVA	9 Months
80. Flu	GBS	9 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
81. Flu	SIRVA	9 Months
82. Flu	Tetanus Diphtheria, Acellular Pertussis, GBS	9 Months
83. Flu	Brachial Radiculopathy	9 Months
84. Flu	GBS, CIDP	9 Months
85. Flu	ADEM	9 Months
86. Flu	GBS	9 Months
87. Flu	Peripheral Neuropathy	9 Months
88. TDaP	SIRVA	9 Months
89. Flu	GBS	8 Months
90. Tdap	SIRVA	8 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
91. Flu	GBS	8 Months
92. Flu	GBS	8 Months
93. Flu	SIRVA	8 Months
94. Flu	SIRVA	8 Months
95. Flu	GBS	8 Months
96. Flu	SIRVA	8 Months
97. Flu	SIRVA	8 Months
98. Flu	GBS	8 Months
99. Tdap	Brachial Neuritis	8 Months
100. Tdap	SIRVA	8 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
101. Flu	GBS	8 Months
102. Flu	TM, AIDP	8 Months
103. Flu, Menactra Meningococcal	GBS	8 Months
104. Flu	SIRVA	7 Months
105. Flu	SIRVA	7 Months
106. Flu	GBS	7 Months
107. Flu	GBS	7 Months
108. DTaP-IPV	Angiomatoid, Fibrous Histiocytoma	7 Months
109. Flu	SIRVA	6 Months
110. Flu	SIRVA	6 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/16 – 8/15/16

1. Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
111. Flu	GBS	6 Months
112. Flu	SIRVA	6 Months
113. Flu	GBS	5 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Appendix

Glossary of Terms

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

Glossary of Terms

- **Settlement:** Petition is resolved via a negotiated settlement between the parties, and results in the filing of a stipulation that memorializes the terms of the settlement.

- **Decision:** Special Master issues decision on the merits of the petition.

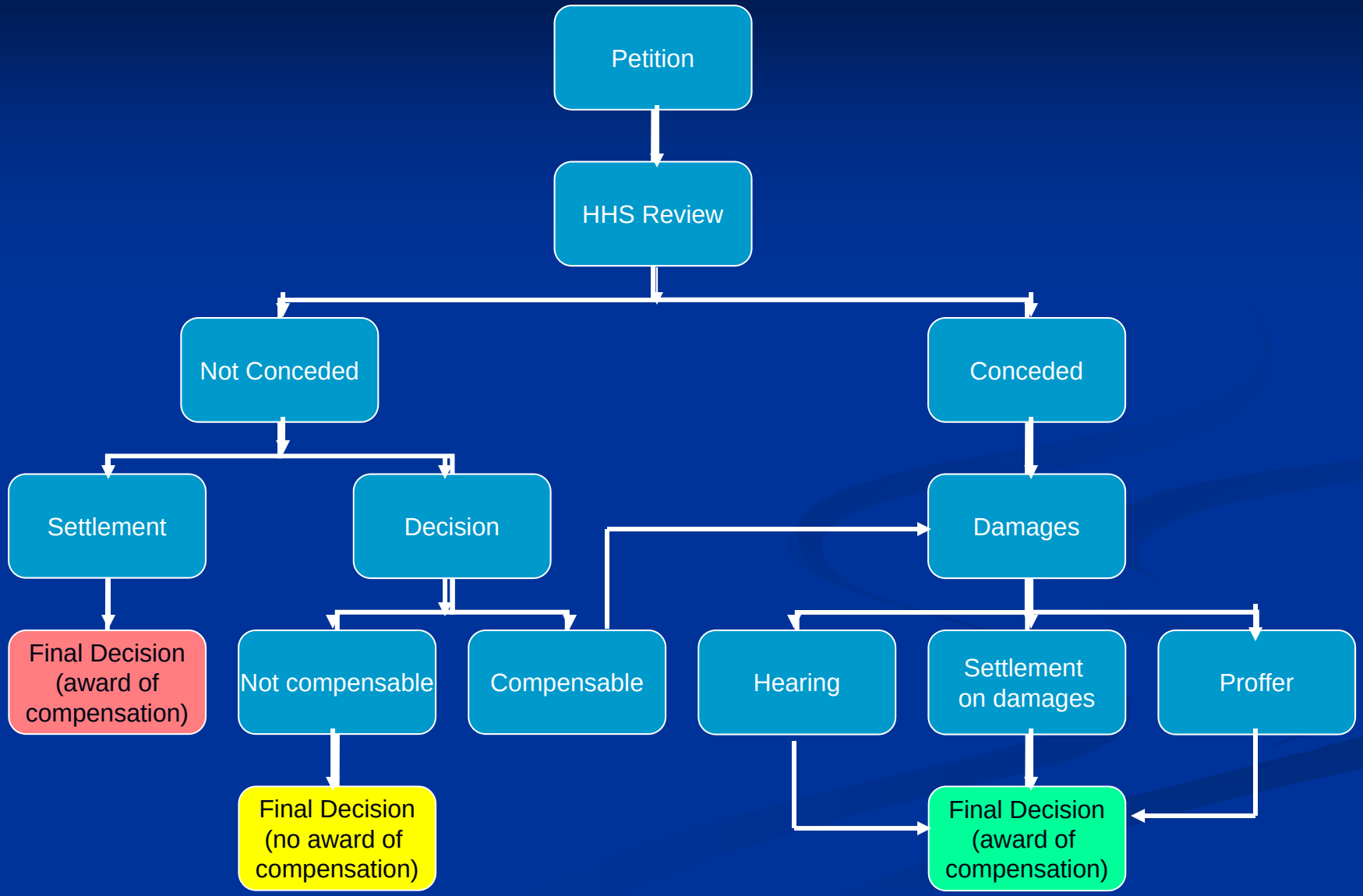
- **Non-compensable/Dismissed:** Petition dismissed.

- **Proffer:** After discussions between the parties regarding a reasonable amount of damages, respondent will file a suggested award of compensation, known within the Program as a "Proffer," which is also agreed to by petitioners and their counsel. The Proffer is reviewed by the presiding special master to determine that it represents a reasonable measure of the amount of the award and describes compensation pursuant to 42 U.S.C. § 300aa-15(a). The special master issues a final decision consistent with the terms of the Proffer.

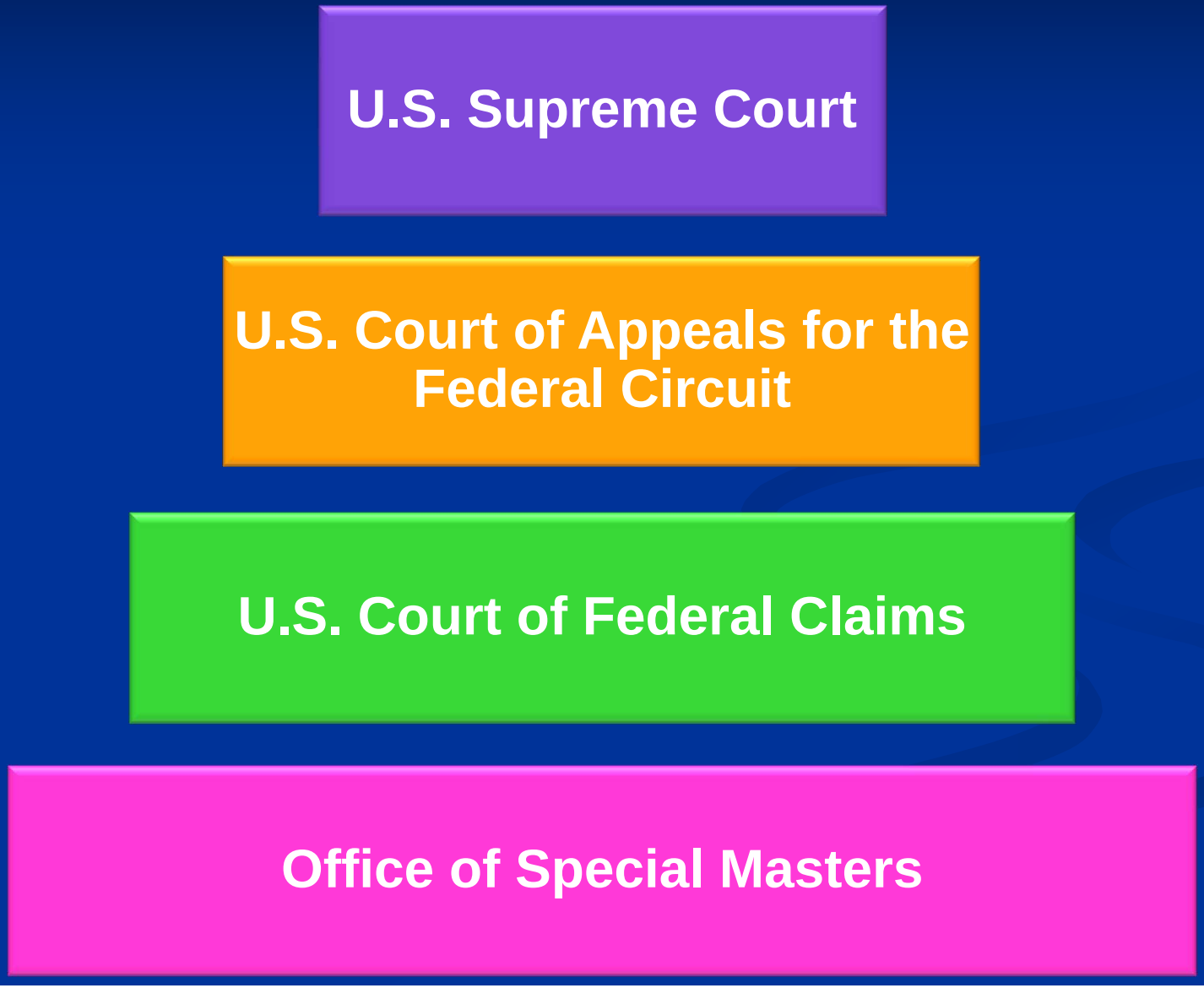
Glossary of Terms

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

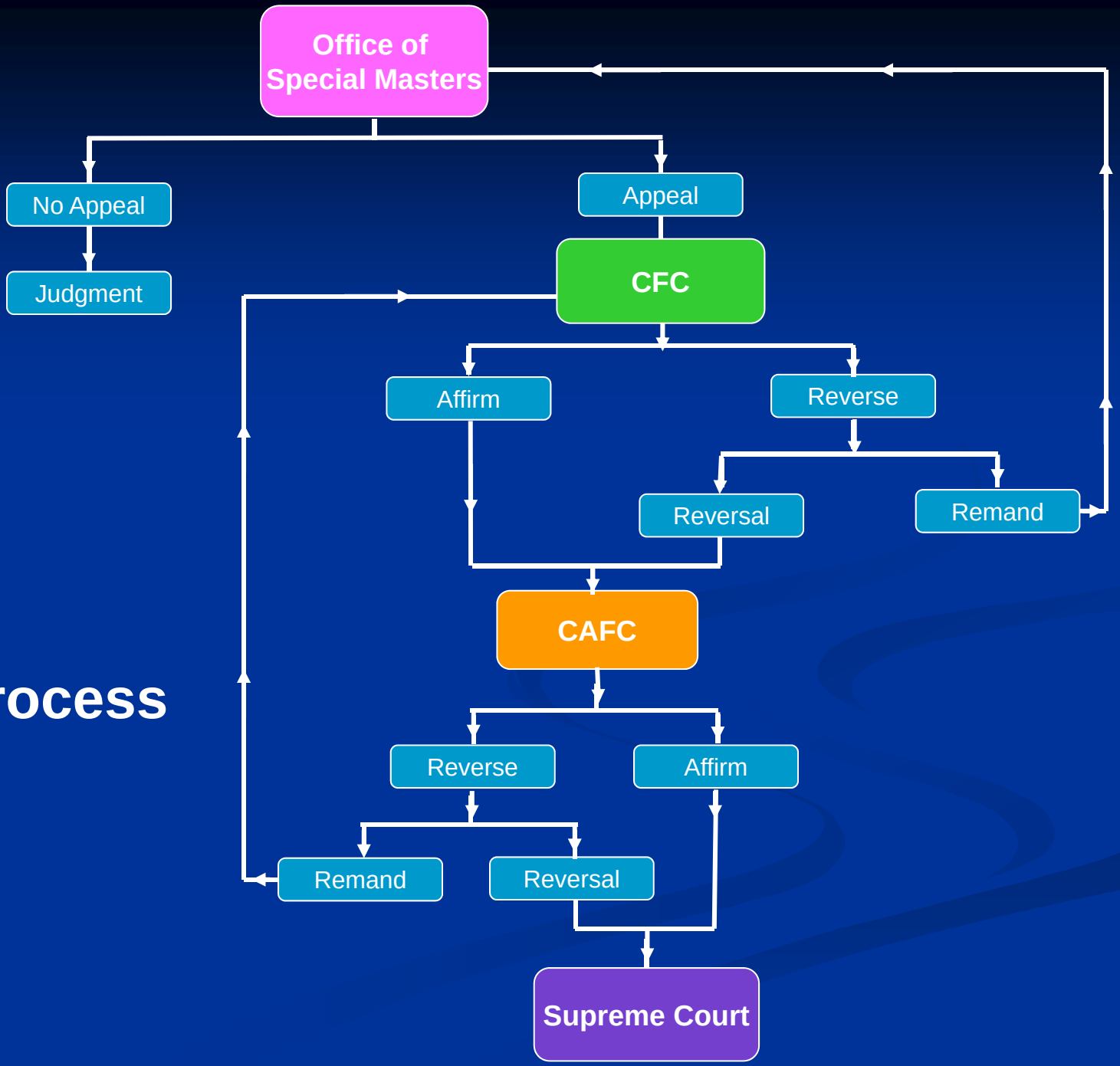
Petition Processing in the Office of Special Masters



Levels of Appeal in Vaccine Act Cases



Appeals Process



5.3

Recommendation to Support an Increase in National Vaccine Injury Compensation Program (VICP) Special Masters, Staffing and/or Funding Resources

Background

After a relatively stable annual average of 200 non-autism VICP claims filed from Calendar Year (CY) 2002 through CY 2008, the number of non-autism claims filed began to significantly increase in CY 2013. From CY 2013 to CY 2015, the number of non-autism claims filed increased from 525 to 945 which is an 80% increase over a three-year period.

Due to the significant increase in VICP claims filed annually, the workload for the Health Resources and Services Administration (HRSA) and Department of Justice (DOJ) and the Office of the Special Masters (OSM), U.S. Court of Federal Claims (Court) staff involved in VICP claims resolution has more than doubled since 2013. HRSA, DOJ and the Court struggle to manage the workload with limited resources; consequently, there is a backlog of unresolved claims which may lead to delays in compensation. The Court is concerned that the gap between the number of claims filed each month as compared to the number of claims that are closed each month will continue to widen.

Inadequate funding and the National Childhood Vaccine Injury Act of 1986 (the Act) provision which currently limits the number of special masters that can be hired, prevents HRSA, DOJ, and the Court from hiring needed medical officers, attorneys and special masters to resolve the backlog of claims and eliminate the potential delay in compensation to vaccine injured persons. The Act limits the number of special masters to a total of eight, and this number has not been changed in 30 years, in spite of the increased workload and increase in the number of vaccines added to the Vaccine Injury Table (Table).

The shortage of resources requires a permanent solution because the HRSA, DOJ and the Court expect the increases in claims filed will continue indefinitely. An estimated 1,200 claims will be filed in 2016, a 27% increase over 2015. The majority of VICP claims being filed are adults claiming seasonal flu vaccine injuries. The Centers for Disease Control and Prevention reports the number of adults and children administered seasonal flu vaccine increases every year; this suggests that the increase in the volume of claims filed with the VICP is permanent, not a temporary surge, and will continue to grow. In addition, HRSA has increased outreach efforts, following the 2014 Government Accountability Office study of the program, which will likely result in permanent increases in VICP claims filed. Furthermore, proposed changes to the Table will allow people who previously missed the VICP filing deadline additional time to file a claim, likely leading to a significant temporary increase in claims filed.

Even though the workload of staff has drastically increased, the staffing and funding resources for HRSA, DOJ, and the Court involved in resolving VICP claims have not had commensurate increases. Without commensurate increases in staffing and funding resources, the rise in the number of claims filed will result in the inability to resolve claims in a timely manner; and thus, delays in compensation to petitioners.

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

Recommendation 1

The ACCV recommends that the Secretary support a legislative proposal to the National Childhood Vaccine Injury Act of 1986, as amended, permitting the hire of eight or more special masters. The current provision states:

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

The proposed provision would state:

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

Recommendation 2

The ACCV recommends that the Secretary support efforts to increase the annual appropriations of the HRSA, DOJ and the OSM of the Court to provide adequate staffing and funding and staffing resources to enable the timely resolution of VICP claims.

5.4

Vaccine Information Statement

MMRV Vaccine (Measles, Mumps, Rubella and Varicella): What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Measles, **mumps**, **rubella**, and **varicella** are diseases that can have serious consequences. Before vaccines they were very common, especially among children.

Measles

- Measles virus causes fever, cough, runny nose, and red, watery eyes, followed by a rash.
- Measles can lead to ear infections, diarrhea, pneumonia, brain damage, and death.

Mumps

- Mumps virus causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen glands in the cheeks and neck.
- Mumps can lead to deafness, encephalitis or meningitis (swelling of the brain and/or spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (also known as **German Measles**)

- Rubella virus causes fever, sore throat, rash, headache, eye irritation, and arthritis (mostly in teenage and adult women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Varicella (also known as **Chickenpox**)

- Varicella causes an itchy rash that usually lasts about a week, in addition to fever, tiredness, loss of appetite, and headache.
- Varicella can lead to pneumonia; inflammation of blood vessels; or infections of the brain and spinal cord coverings, skin, blood, bones, or joints.
- People who get chickenpox often get as painful rash called shingles years later.

These diseases are easily spread from person to person through coughing and sneezing, or through direct contact with an infected person.

2. MMRV Vaccine

MMRV vaccine may be given to children from 12 months through 12 years of age to protect them from these four diseases. Two doses are usually recommended, at:

- 12 through 15 months of age (first dose), and
- 4 through 6 years of age (second dose).

The second dose may be given earlier, but at least 3 months after the first dose.

Children may also get these vaccines as 2 separate shots: **MMR** (measles, mumps and rubella) and **chickenpox** (**varicella**) vaccines. There are separate Vaccine Information Statements for MMR vaccine and varicella vaccine. Ask your doctor for more information.

There are no known risks to getting MMRV vaccine at the same time as other vaccines.

3. Some people should not get this vaccine

Tell the person who is giving your child the vaccine if your child:

- **Has any severe, life-threatening allergies.**
  A person who has ever had a life-threatening allergic reaction after a dose of MMRV vaccine, or have a severe allergy to any part of this vaccine, may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.

- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, steroids, or chemotherapy).

- **Has a history of seizures,** or **has a parent, brother or sister with a history of seizures.**

- **Has a parent, brother or sister with a history of immune system problems.**

- **Has ever had a low platelet** count (or another blood disorder).

- **Might be pregnant.** MMRV vaccine should not be given during pregnancy.

- **Has recently had a blood transfusion or received other blood products**. You might be advised to postpone MMR vaccination of your child for at least three months.

- **Has gotten any other vaccines in the past 4 weeks.** Live vaccines given too close together might not work as well.

- **Is not feeling well.** If your child has a mild illness, such as a cold, he or she can probably get the vaccine today. If your child is moderately or severely ill, you should probably wait until the child recovers. Your doctor can advise you.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Getting MMRV vaccine is much safer than getting measles, mumps, rubella, or chickenpox disease. Most children who get MMRV vaccine do not have any problems with it.

Minor problems following MMRV vaccine include:
- Fever
- Mild rash
- Swelling of glands in the cheeks or neck

If these problems occur, they usually begin within 6 to 14 days after the shot. They occur less often after the second dose.

If you get a rash after vaccination, it might be related to the varicella component of the vaccine. If so, you might be able to spread the vaccine virus to others. But, this is extremely rare. If you have a rash, you should stay away from people with weakened immune systems until the rash goes away.

Moderate problems following MMRV vaccine include:
- Seizure caused by fever.
  - *The risk these seizures is higher after MMRV than after separate MMR and varicella vaccines when given as the first dose of the series. Your doctor can advise you about the most appropriate vaccines for your child.*
- Temporary pain and stiffness in the joints, mostly in teenage or adult women
- Temporary low platelet count, which can cause a bleeding disorder

Several **severe, and very rare, problems** have been reported following MMR vaccine, and might also happen after MMRV. These include:
- Deafness
- Long-term seizures, coma, lowered consciousness
- Permanent brain damage

These reactions happen so rarely that is it difficult to tell whether they are caused by the vaccine.

Other problems that could happen after this vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy, or have vision changes or ringing in the ears.

- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. This happens very rarely.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

5. What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your clinic.

  Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7. How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

42 U.S.C. § 300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention

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5.5

Immunization Safety Office Updates

Centers for Disease Control and Prevention

Mike McNeil, MD, MPH
Immunization Safety Office
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention (CDC)

Advisory Commission on Childhood Vaccines (ACCV)
September 20, 2016

Topics

- Update on selected sessions from the June 2016 Advisory Committee on Immunization Practices (ACIP) meeting
- Selected vaccine safety publications

June 2016 ACIP meeting summary

- **Cholera**
  - **Vaxchora® (live single dose oral vaccine) approved for travelers aged 18-64 years**
  - ***Vibrio cholerae* 01 infection can be severe and rapidly fatal without treatment**
    - **Endemic in >50 countries**
    - **Rehydration can reduce fatality rate to <1%**
  - **Travelers with increased risk of poor clinical outcomes**
    - **Blood type O**
    - **Pregnancy**
    - **Immunocompromising conditions**
    - **Cardiovascular disease, renal disease**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **Vote 1* Cholera Vaccine**
  - **Unanimously voted YES to recommend for travelers to an area of active cholera transmission**
    - **Who are at increased risk of toxigenic *Vibrio cholera* 01 exposure**

      or
    - **Whose individual risk factors or travel situations carry increased risk of poor clinical outcome if infected**

*Language regarding votes is provisional until published in the MMWR

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **Meningococcal B Vaccine (Trumenba®)**
  - **FDA approved revised dosing schedule for Trumenba for 2 doses (0 and 6 months) or 3 doses (0, 1-2 and 6 months)**
    - **Bexsero ® is a 2-dose schedule**
  - **Workgroup preference for 3-dose schedule of Trumenba®**
  - **Additional data will be available at the Oct. 2016 ACIP meeting**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **Vote 2* Meningococcal Conjugate Vaccine**
  - Unanimously voted YES to recommend meningococcal conjugate vaccines be given routinely to all HIV-infected persons aged ≥2 months to prevent meningococcal disease
  - Rationale
    - Increased risk of meningococcal disease in HIV infected persons
    - Meningococcal disease in HIV infected persons primarily due to serogroup C,W, and Y

*Language regarding votes is provisional until published in the MMWR

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

Influenza

- **Flucelvax Quadrivalent**
  - Licensed May 23, 2016 for persons aged ≥4 years
    - Demonstrated immune response and safety and tolerability profile similar to the trivalent product in adults and children
- **FluLaval Quadrivalent**
  - Licensed for persons aged ≥3 years
  - Submitted sBLA to extend the ages to 6-35 months
  - Dose 0.5 ml (same dose for all ages)
  - GSK presented data on safety and immunogenicity compared with Fluzone Quadrivalent among children aged 6-35 month old
    - Immunogenic non-inferiority of FluLaval QIV to Fluzone QIV was demonstrated for all 4 strains
    - Both have similar reactogenicity and safety profiles

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **End of season 2015-2016 influenza safety monitoring**
  - **Vaccine Adverse Event Reporting System (VAERS)**
    - **No new safety concerns detected**
  - **FDA monitoring in the CMS database**
    - **Showed a Guillain-Barré syndrome (GBS) rate following inactivated influenza vaccine (IIV) of 7.25 cases/million compared to average of 5.45 cases/million for the past 3 seasons**
  - **Vaccine Safety Datalink (VSD)**
    - **Identified a signal for GBS following trivalent inactivated influenza vaccine (IIV3) in the self-controlled risk interval design**
    - **Estimated attributable risk is 2.6 GBS cases per million IIV3 doses administered**
  - **Preliminary GBS risk estimate appears consistent with that observed in some previous influenza seasons**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- Influenza vaccine effectiveness (VE) (US flu VE Network)
  - Inactivated influenza vaccine (IIV) VE 63% against influenza A and B among children aged 2-17 year old
  - VE for live attenuated influenza vaccine (LAIV) significantly lower than IIV among children aged 2-17 year olds
    - No significant LAIV effectiveness against A/H1N1pdm09 or B
- Influenza VE study from AstraZeneca in children aged 2-17 years
  - LAIV4: 46%
  - IIV: 65%
  - No explanation for differences compared to CDC VE estimates

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **Vote 3* live attenuated influenza vaccine (LAIV) not to be used in 2016-17 season**
  - **Motion passed (13 yes, 1 no, 1 abstain for conflict of interest): "In light of the evidence for poor effectiveness of LAIV in the US over the last 3 influenza seasons (2013-14 through 2015-16), for the 2016-17 season, ACIP makes the interim recommendation that LAIV should not be used."**
  - **http://www.cdc.gov/media/releases/2016/s0622-laiv-flu.html**
- **VFC vote: Remove LAIV from the Vaccines for Children (VFC) program for the 2016-17 season**

*Language regarding votes is provisional until published in the MMWR

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **Respiratory Syncytial Virus (RSV)**
  - **Common cause of acute respiratory infection in infants and young children**
    - **50% infected in first year of life and virtually all infected by 2 years of age**
  - **Burden in older adults**
    - **~177,000 hospitalizations and ~14,000 deaths annually**
  - **Formalin inactivated vaccine trials (1966-67) caused vaccine-enhanced disease syndrome in RSV-naïve infants**
    - **Non-replicating vaccines unlikely to be used in RSV-naïve infants**
  - **Vaccine candidates in phase 1 clinical trials for older infants and children and in phase 1-3 clinical trials for pregnant women and older adults**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- **Safety of maternal Tdap vaccination**
  - **VAERS monitoring: no new unexpected vaccine safety concerns among pregnant women who received Tdap or their infants**
  - **VSD: maternal Tdap during pregnancy was NOT associated with increased risk for birth defects, including microcephaly, among live birth offspring**
  - **Clinical Immunization Safety Assessment (CISA) Project clinical study**
    - **Tdap was well tolerated in pregnant and non-pregnant women**
    - **Moderate/severe injection-site pain more frequent among pregnant women, but rates were consistent with clinically reported rates for Tdap and did not lead to medical visits**
    - **53% of pregnant women received prior Tdap and rate of moderate/severe reactions were similar in pregnant women receiving the first or repeat Tdap**
    - **Both pregnant and non-pregnant women had significantly higher antibody titers to all antigens after vaccination**
    - **Obstetric and fetal outcome data are being collected**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

June 2016 ACIP meeting summary (cont.)

- Human papillomavirus (HPV) vaccines
  - No evidence of waning protection after a 3-dose HPV vaccine schedule
  - Antibody responses maintained over time after 3-dose schedule
  - 13 studies evaluated 2-dose effectiveness
    - 3 studies found similar outcomes for 2 compared to 3 doses
    - 10 studies found 2 doses not as effective as 3 doses
    - Long term protection data not available from 2-dose trials yet
  - Draft proposed recommendations
    - If vaccine initiated before 15th birthday, ACIP recommends 2 doses of HPV vaccine (0, 6-12 month schedule)
    - If vaccine initiated after the 15th birthday, ACIP recommends 3 doses of HPV vaccine (0,1-2, 6 month schedule)

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-06.html

Selected publications

- Duffy et al. Febrile Seizure Risk After Vaccination in Children 6 to 23 Months. Pediatrics. 2016;138(1). pii: e20160320.
  - The administration of trivalent inactivated influenza vaccine (IIV3) on the same day as either pneumococcal conjugate vaccine (PCV) or a DTaP-containing vaccine was associated with a greater risk of febrile seizure than when IIV3 was given on a separate day.
  - The absolute risk of postvaccination febrile seizure with these vaccine combinations was small.

- Sawyer et al. Vaccines and Febrile Seizures: Quantifying the Risk. Pediatrics. 2016;138(1). pii: e20160976.
  - Commentary on Duffy et al.

Selected publications

- Stockwell et al. Assessing Fever Frequency After Pediatric Live Attenuated Versus Inactivated Influenza Vaccination. J Pediatric Infect Dis Soc. 2016 Jun 14. pii: piw028.
  - Postvaccination fever frequencies were low overall and did not differ according to influenza vaccine type during the 2013-2014 influenza season.
  - The similarity of results when data were limited to text messages lends support to its use for surveillance of vaccine adverse events.

Selected publications

- Moro et al. P, et al. Post-Marketing Surveillance of Human Rabies Diploid Cell Vaccine (Imovax) in the Vaccine Adverse Event Reporting System (VAERS) in the United States, 1990–2015. PLoS Negl Trop Dis. 2016;10(7):e0004846.
  - This 25-year review of VAERS did not identify new or unexpected adverse events after Human Rabies Diploid Cell Vaccine.
  - The vast majority of adverse events were non-serious.
  - Injection site reactions, hypersensitivity reactions, and non-specific constitutional symptoms were most frequently reported, similar to findings in pre-licensure studies.

Selected publications

- Lindsey et al. Adverse event reports following yellow fever vaccination, 2007-13. J Travel Med. 2016;23(5). pii: taw045.
  - The findings reinforce the generally acceptable safety profile of yellow fever (YF) vaccine, but highlight the importance of continued physician and traveler education regarding the risks and benefits of YF vaccination, particularly for older travelers.

- Bardenheier et al. Adverse events following pandemic influenza A (H1N1) 2009 monovalent and seasonal influenza vaccinations during the 2009-2010 season in the active component U.S. military and civilians aged 17-44years reported to the Vaccine Adverse Event Reporting System. Vaccine. 2016;34(37):4406-14.
  - Despite higher vaccination coverage in service personnel, the rate of serious AEs following MIV was about half that in civilians.
  - The rate of GBS reported following MIV was higher in the military.

Selected publications

- Vazquez-Benitez et al. Risk of Preterm or Small-for-Gestational-Age Birth After Influenza Vaccination During Pregnancy: Caveats When Conducting Retrospective Observational Studies. Am J Epidemiol. 2016;184(3):176-86.
  - Found potential biases in the vaccine-birth outcome association that might occur due to variable access to vaccines, the time-dependent nature of exposure to vaccination within pregnancy (immortal time bias), and confounding from baseline differences between vaccinated and unvaccinated women.
  - Investigators conducting studies to evaluate birth outcomes after maternal vaccination should use statistical approaches to minimize potential biases.

Selected publications

- Clogston et al. Unintentional administration of insulin instead of influenza vaccine: a case study and review of reports to US vaccine and drug safety monitoring systems. Drugs Ther Perspective. Aug 2016.
  - The cluster investigation and safety review indicated that deviations from recommended practices likely contributed to the adverse events. Influenza vaccines and insulin mix-ups are events that are potentially serious, but are preventable with proper training and application of standards on storage and handling of vaccines and medicines, proper product administration procedure, and correct documentation.

Selected publications

- Moro and Chen. Obstetrical and neonatal case definitions for immunization safety data. Vaccine. 2016 Aug 20. pii: S0264-410X(16)30698-3.
  - The Global Alignment of Immunization Safety Assessment in pregnancy (GAIA) coalition has developed 10 obstetric and neonatal case definitions. In addition to the case definitions GAIA has developed tools which include guidelines for harmonized data collection, analysis and presentation.

Selected publications

- Vergnano et al. Neonatal infections: Case definition and guidelines for data collection, analysis, and presentation of immunisation safety data. Vaccine. 2016 Aug 1. pii: S0264-410X(16)30029-9.
  - Brighton Collaboration case definition paper.

- DeSilva et al. Congenital anomalies: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2016 Jul 16. pii: S0264-410X(16)30030-5.
  - Brighton Collaboration case definition paper.

Centers for Disease Control and Prevention
Atlanta, GA

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion – Immunization Safety Office

Thank You

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion – Immunization Safety Office

5.6

Vaccine Activities Update

National Institute of Allergy and Infectious Diseases, National Institutes of Health

Claire Schuster, MPH
Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS

September 2016

National Institute of Allergy and Infectious Diseases

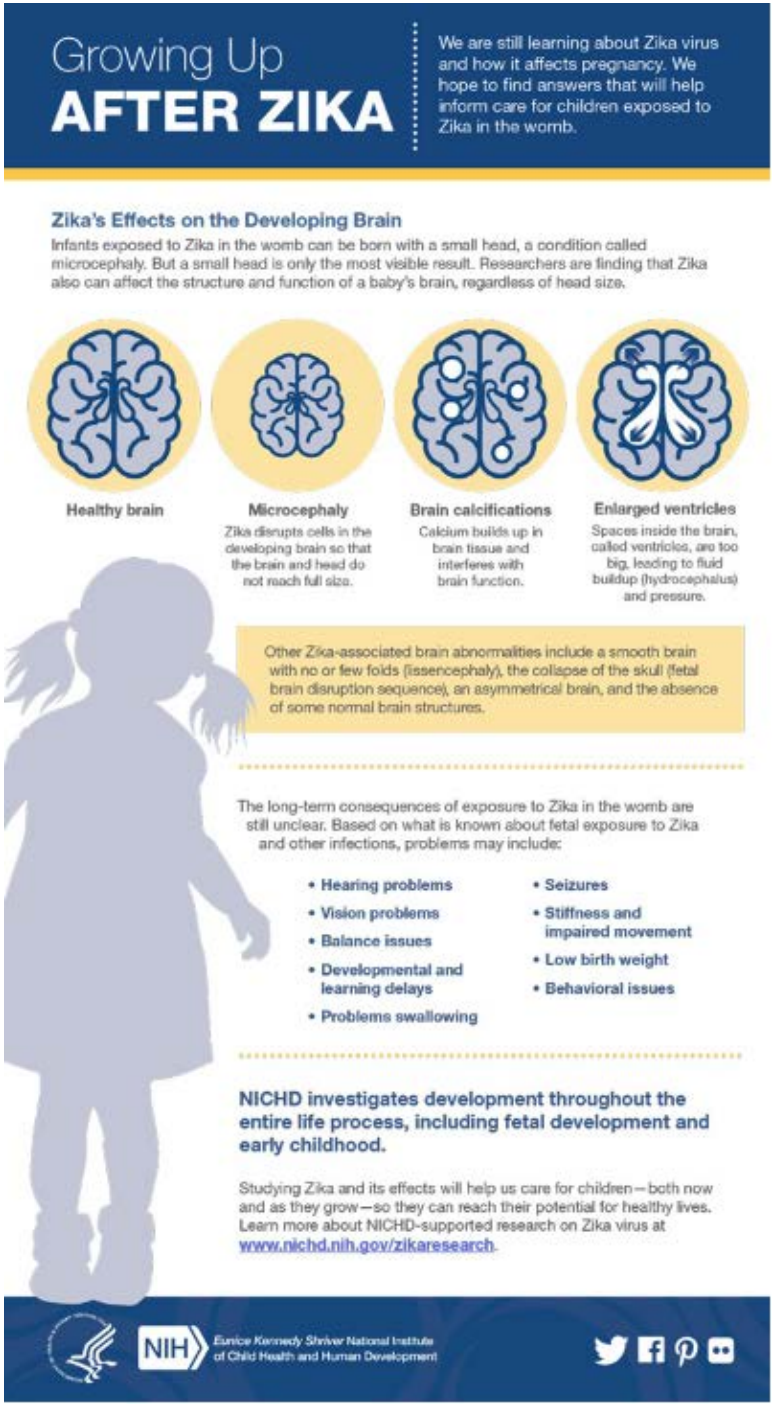

U.S. Department of Health and Human Services
NIH News
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
Tuesday, June 21, 2016
NIH Launches Large Study of Pregnant Women in Areas Affected by Zika Virus
National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
Wednesday, August 3, 2016
NIH Begins Testing Investigational Zika Vaccine in Humans
U.S. Department of Health and Human Services
NIH News
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
Thursday, August 4, 2016
Three Vaccine Approaches Protect Monkeys Against Zika Infection
U.S. Department of Health and Human Services
NIH News
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
Tuesday, June 28, 2016
Zika Vaccines Protect Mice from Infection

Bridging Knowledge Gaps to Understand How ZIKV Exposure and Infection Affects Child Development

September 22-23, 2016

Bethesda, MD

Hosted by Eunice Kennedy Shriver National Institute of Child Health and Human Development



Yellow Fever Vaccine Research

U.S. Department of Health and Human Services
NIH News
National Institutes of Health

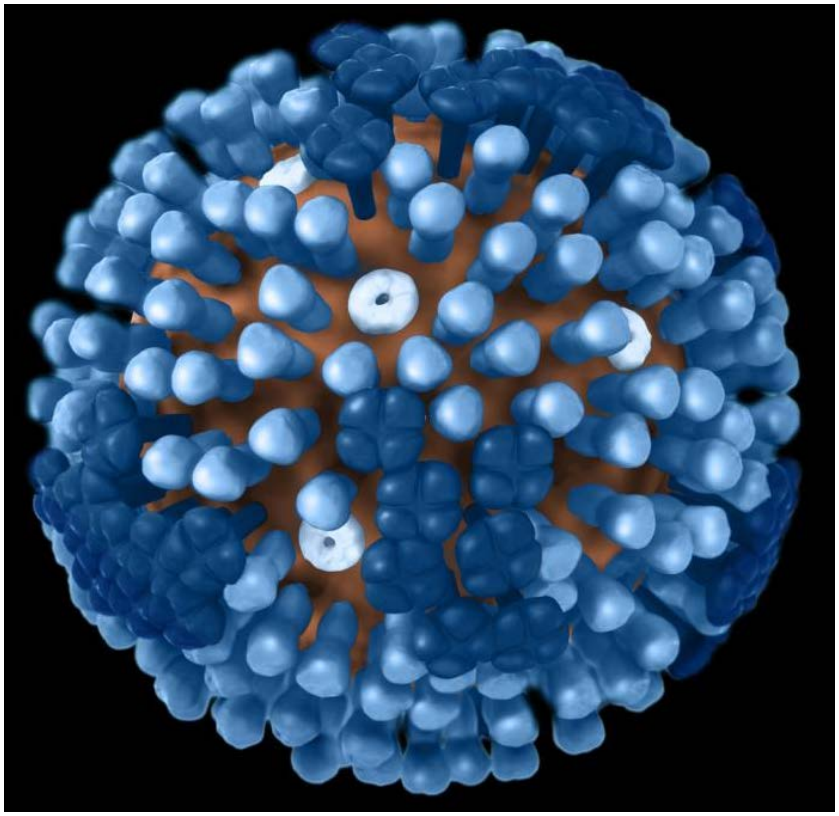
National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov
Wednesday, July 27, 2016

NIH Launches Early-Stage Yellow Fever Vaccine Trial

- 2013: Yellow fever virus caused ~ 84,000-170,000 severe cases of disease and 29,000- 60,000 deaths (WHO)
- Yellow fever virus is transmitted through *Aedes aegypti* mosquitoes
- Phase 1 trial evaluating experimental vaccine's safety, tolerability and potential to prevent yellow fever virus infection
- Conducted by NIAID-funded Vaccine and Treatment Evaluation Units (VTEUs)

Influenza Vaccine Research



Credit: Dan Higgins

U.S. Department of Health and Human Services
NIH News
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov
Friday, July 22, 2016

Vaccine Strategy Induces Antibodies that Can Target Multiple Influenza Viruses

Data May Help Guide Development of a Universal Flu Vaccine

MG Joyce *et al*. Vaccine-Induced Antibodies that Neutralize Group 1 and Group 2 Influenza A Viruses. *Cell* (2016)

NIH National Institute of Allergy and Infectious Diseases

Select Publications

- JN Roberts *et al.* Challenges and opportunities in RSV vaccine development: Meeting report from FDA/NIH workshop. *Vaccine* (2016 Aug 23)

- LM Wetzler *et al.* Summary and recommendations from the National Institute of Allergy and Infectious Diseases (NIAID) workshop "Gonorrhea Vaccines: the Way Forward." *Clin Vaccine Immunol* (2016 Aug 5)

Cancer Moonshot

National Cancer Institute embraces scientific road map to achieve Cancer Moonshot goals

Antimicrobial Resistance Diagnostic Challenge

- Antibiotic resistant bacteria cause at least 2 million infections and 23,000 deaths each year in the U.S.(CDC)
- Federal prize competition seeks innovative ideas to combat antimicrobial resistance
- Contestants will vie for $20 million in prizes to develop new innovative laboratory diagnostic tools that detect and distinguish antibiotic resistant bacteria
- Prize is sponsored by NIH and HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) in support of the National Action Plan for Combating Antibiotic Resistant Bacteria

5.7

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

September 20, 2016

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)

Outline

- Vaccine Approvals
- Upcoming Advisory Committee Meeting
- Emergency Preparedness

Vaccine Approvals

Cholera Vaccine, Live, Oral, Vaxchora

- Approved in June 2016 for the prevention of disease caused by *Vibrio cholerae* serogroup O1 in adults 18 through 64 years of age traveling to cholera-affected areas.
  - Cholera is an acute diarrheal infection caused by ingestion of food or water contaminated with the bacterium *Vibrio cholerae*
- Vaxchora is the only FDA-approved vaccine for the prevention of cholera
- The FDA granted this application fast track designation and priority review status.

Influenza Vaccine, Flucelvax

- In May 2016, the FDA approved a supplement to the biologics license application (BLA) for Influenza Vaccine, Flucelvax, manufactured by Seqirus, to include a quadrivalent formulation.
- Flucelvax Quadrivalent is the first four-strain, cell culture-derived, inactivated seasonal influenza vaccine for indicated for persons four years of age and older.

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein), Prevnar 13

- In July 2016, the FDA approved a supplement to the BLA for Prevnar 13® to expand the indication to include adults 18 through 49 years of age for the prevention of pneumonia and invasive disease caused by caused by the 13 serotypes of *S. pneumoniae* contained in the vaccine
- Prevnar 13 was previously approved for use in the following age groups:
  - Children 6 -17 years of age
  - Adults 50 years of age

Influenza Season

- In July 2016, the FDA approved strain change supplements to the BLAs for licensed influenza vaccines to include the 2016-2017 seasonal vaccine formulation.
- Influenza vaccine lots released by the FDA are available for distribution by the manufacturers.

Advisory Committee Meeting

Upcoming Advisory Committee Meeting

- On October 13, 2016, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2017 southern hemisphere influenza season.
- Committee members will participate via teleconference.

Emergency Preparedness

Emergency Preparedness

- Several investigational zika vaccines are in the early stages of development.
- In June 2016, the FDA authorized the initiation of the first clinical trial for an experimental zika virus vaccine.
- The FDA will work with the vaccine industry to clarify regulatory and data requirements necessary to move products forward in development as quickly as possible.

6.1

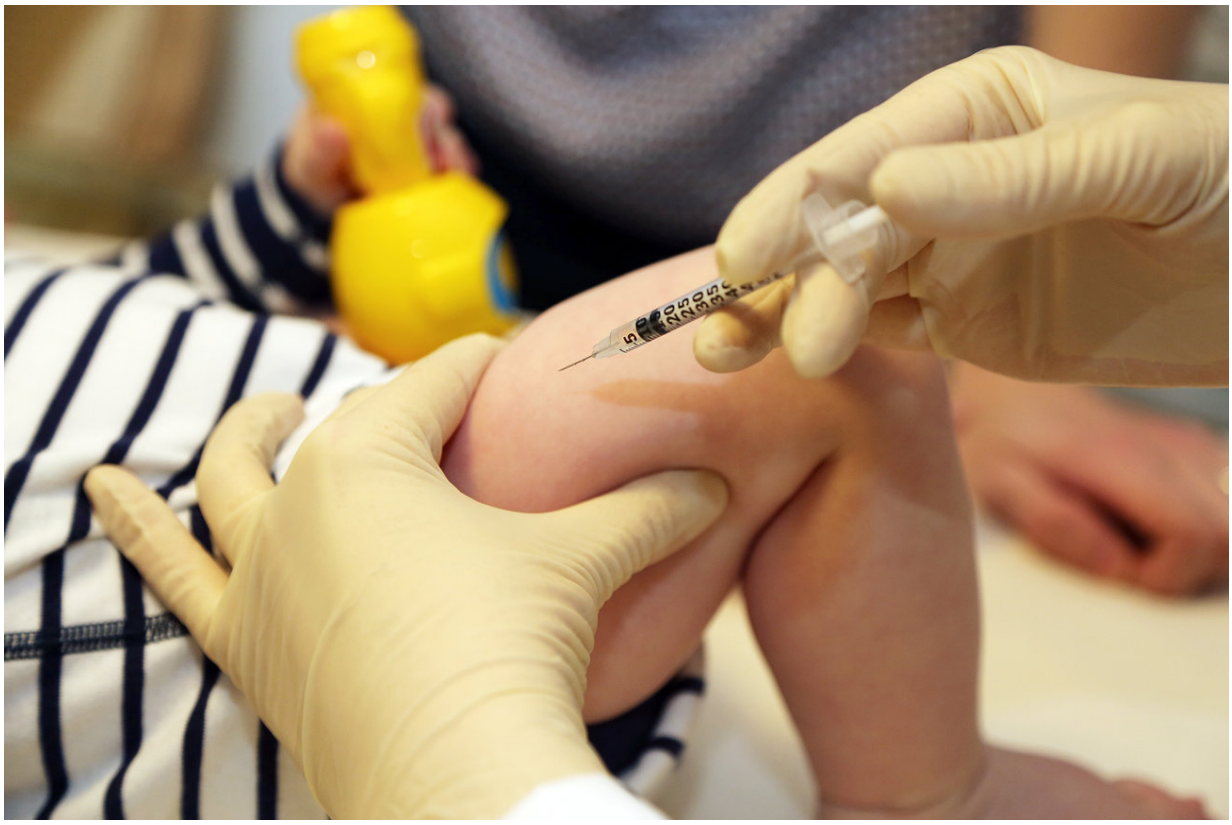
shots

YOUR HEALTH

Febrile Seizures After Childhood Vaccines Are Rare, Study Finds

June 6, 2016 · 6:31 AM ET

TARA HAELLE



Children sometimes can run a fever after getting a vaccine.

Maureen P Sullivan/Getty Images

A seizure caused by a fever in a young child can be terrifying, and some parents worry that the occasional fever that can follow a vaccine may cause one. But febrile seizures after vaccines are rare, a study finds, affecting 3 children out of 10,000. And children almost always recover completely.

The study, published Monday in *Pediatrics*, found that only a few vaccines or vaccine combinations increase the risk of febrile seizures. The pneumococcal vaccine given alone increases the risk, and so does the flu vaccine if given at the same time as either the pneumococcal vaccine or DTaP (diphtheria, tetanus, pertussis) vaccine.

The pneumococcal vaccine, or PCV, protects against pneumococcal disease. The pneumococcus bacteria can cause infections ranging from an ear infection to pneumonia to pneumococcal meningitis, which kills 1 in 15 children under 5 who develop it.

"The basic message is, while there is an increase compared to giving them on separate days, the absolute amount of that risk is so, so very small that for the average person, it won't really affect their chances of having a febrile seizure," lead study author Jonathan Duffy tells Shots.

Febrile seizures, he adds, are considered isolated, benign events with no long-term consequences in the vast majority of children. They occur in approximately 2 to 5 percent of children, caused infections or other conditions that can cause a fever, according to Mark Sawyer, a professor of clinical pediatrics at University of California San Diego School of Medicine and Rady Children's Hospital in San Diego.

"For anybody who's seen a febrile seizure, it is a scary experience," Sawyer says. "People are not responding, sometimes they are not breathing very effectively, and there's uncontrolled twitching of arms and legs, so people assume there must be something major going on in the brain, but fortunately, that's not the case."

Febrile seizures occur most typically in children between 1 and 2 years old — the same ages when children receive a number of vaccines. Sometimes other seizures may follow if the child has a disorder such as epilepsy, but no evidence has suggested that a febrile seizure can cause seizure disorders.

"If you're really concerned about febrile seizures, the smartest strategy is to protect your child against the infection with the vaccine," Mark Schleiss, director of pediatric

infectious diseases at the University of Minnesota, told Shots. About 20 percent of children hospitalized for influenza, for example, experience febrile seizures, he says. "I find this paper reassuring about vaccine safety," he adds.

Duffy, a medical officer in the Centers for Disease Control and Prevention Immunization Safety Office, says they conducted the study to follow up on reports five years ago that found an increased risk of febrile seizures when the flu and pneumococcal vaccines were given the same day.

This study used the Vaccine Safety Datalink, a massive database that tracks millions of children receiving vaccines in nine health systems across the U.S. The very large population size — approximately 9.8 million for this study — ensures the highest quality data possible in assessing vaccine safety. It's the largest vaccine safety surveillance program of its kind.

The researchers identified all children between 6 and 23 months old who had a febrile seizure within 20 days of at least one vaccine between 2006 and 2011. They compared the number of seizures occurring the day of or after a vaccine with those occurring 14 to 20 days after the vaccine in the same children. The first 24 hours is the time a febrile seizure caused by inactivated vaccines is biologically possible.

The researchers skipped days 2 to 14 because febrile seizures from live vaccines, such as the measles-mumps-rubella and chickenpox vaccines, are biologically likely then. The risk of a febrile seizure from these vaccines is already known to be 1 in 3,000 doses.

Among 333 febrile seizures that occurred following nearly 2 million vaccinations, half the children had had a previous febrile seizure. Those not caused by a vaccine resulted from respiratory tract infections, urinary tract infections, ear infections and viral infections.

A slightly increased risk of 3 febrile seizures per 10,000 children existed when receiving the PCV vaccine by itself, the inactivated trivalent influenza vaccine with

either the PCV or DTaP vaccine, or all three vaccines together. A commentary accompanying the study, co-authored by Sawyer, calculated that this risk translates to approximately 1 child with a vaccine-caused febrile seizure every 5 to 10 years in the practice of an average pediatrician, seeing 1,000 children under 5 each year.

"While we've done all this work to quantify this risk, what we've found is that even at the highest risk we've seen [it] is still very small in absolute terms," Duffy says. "The pneumococcal vaccine prevents life-threatening conditions such as blood infections and meningitis, so the benefits of getting that vaccine are so much greater than the very small risk of getting a febrile seizure, which does not have the potential to cause long-term damage such as those infections can."

Though parents of children with a history of febrile seizures might want to discuss separating these vaccines with their child's doctor, that's not the wisest plan overall, Sawyer told Shots.

"What we know from many years of experience is that every time you skip a vaccine, a certain percentage of those kids will never get that vaccine or the doctor doesn't realize they didn't get that vaccine," Sawyer says. "Parents are going to naturally assume 'That's not me, of course I'll bring my child back,' but not everybody does, and then we have susceptible children in our community." Separating these vaccines also leaves children susceptible to those illnesses for longer, he added.

"It's kind of like not wearing a seat belt for two weeks," Sawyer says. "If you end up in a car accident in those two weeks, you're going to wish you had been wearing your seat belt."

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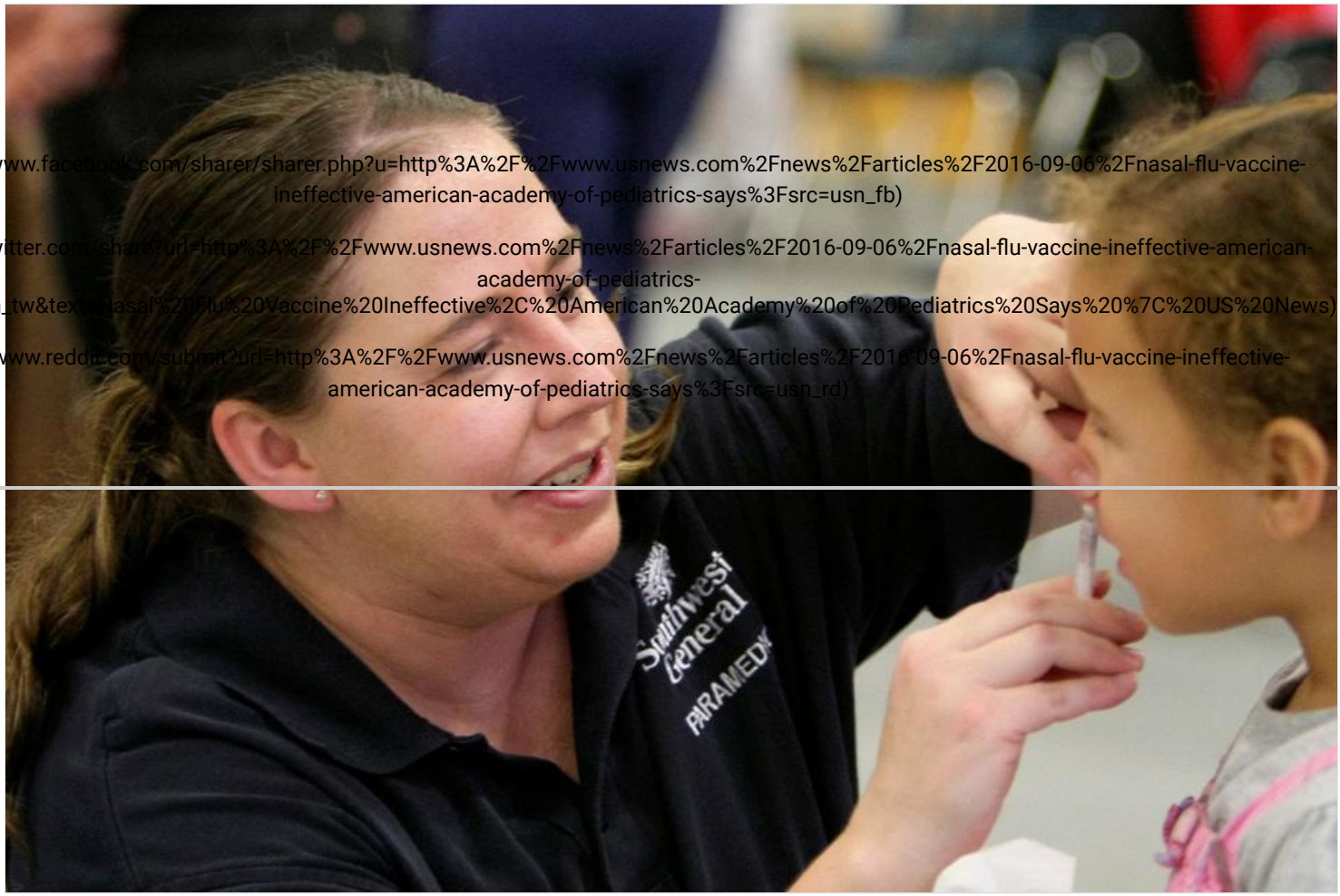
6.2

Nasal Flu Vaccine Ineffective, American Academy of Pediatrics Says

The nasal spray is less effective than the shot at preventing the flu, says the American Academy of Pediatrics.

By Kimberly Leonard (/topics/author/kimberly_leonard) | Staff Writer

Sept. 6, 2016, at 11:22 a.m.



A paramedic administers the nasal flu vaccine to a child at Olmsted Falls Middle School on Nov. 15, 2009, in Olmsted Falls, Ohio. (MARK DUNCAN/AP)

The nasal spray version of the flu vaccine has for years been the go-to for parents whose children are afraid of needles, but this year the nation's leading pediatrics group is advising parents against it (http://pediatrics.aappublications.org/content/early/2016/09/01/peds.2016-2527).

In a policy statement (http://pediatrics.aappublications.org/content/early/2016/09/01/peds.2016-2527) released Tuesday by the American Academy of Pediatrics, the group recommended (http://health.usnews.com/health-care/articles/2016-06-23/cdc-panel-says-flumist-nasal-flu-vaccine-ineffective) children over six months old receive the flu shot rather than the FluMist vaccine, which federal health officials have recently discovered (http://www.usnews.com/news/articles/2016-06-23/cdc-recommends-against-flumist-vaccine) was not effective in preventing the flu during the past three seasons. About a third of children who are vaccinated against the flu each year receive FluMist.

"As a parent it hurts," Dr. James Lozada, an anesthesiologist based in Houston, said of the guidance on Twitter (https://twitter.com/DrJLozada/status/773165359746527232). "But as a doctor I want what's best for my patients, so injection it is!"

[**MORE:** Flu Shot or Not? Majority Say No to the Needle (//www.usnews.com/news/articles/2015/09/17/flu-shot-or-not-majority-say-no-to-the-needle)]

The announcement came just as many children across the country were returning to school from summer vacation. The guidance echoes those from federal health officials, who said in June that the nasal vaccine would be ineffective this year.

The Centers for Disease Control and Prevention found that among children ages 2 to 17 during the 2015 to 2016 flu season, effectiveness for the nasal spray was at 3 percent, whereas it reached 63 percent for the shot. The shot uses an inactive virus to stimulate the immune system to create antibodies against certain strains of the flu, while the nasal spray relies on a live, but weakened, virus.

"New research shows that the flu shot provided significantly better protection in recent flu seasons compared with the nasal spray vaccine," Henry Bernstein, coauthor of the policy statement, said in a statement. "We want to provide children with the best protection possible against flu, and these recent studies show the flu shot is likely to provide a higher level of protection."

AstraZeneca, the company that manufacturers FluMist, previously said in a statement (https://www.astrazeneca.com/media-centre/press-releases/2016/astrazeneca-provides-update-on-flumist-quadrivalent-vaccine-in-the-us-for-the-2016-17-influenza-season-23062016.html) that it disputes the CDC's findings that the spray was nearly ineffective. Their data, company spokespeople have said, indicates an effectiveness rate of 46 percent to 58 percent.

[**MORE:** MMR Vaccine Is Less Effective for Mumps Than Measles, Rubella (//www.usnews.com/news/articles/2015/02/06/mmr-vaccine-is-less-effective-for-mumps-than-measles-rubella)]

Guidance about the nasal spray could change next flu season. The flu has hundreds of strains and each year officials work to predict the ones that will be most prevalent during the flu season. The process begins around February, but the flu season begins in October, making it difficult to accurately predict (http://www.usnews.com/news/newsgram/articles/2014/12/04/influenza-vaccine-could-be-ineffective-against-unpredictable-flu-virus) which strains the vaccine should protect against.

Adherence to the flu vaccine tends to be lower than that of other vaccines, (http://www.usnews.com/news/articles/2015/09/17/flu-shot-or-not-majority-say-no-to-the-needle) even though children are particularly vulnerable to the flu, serious complications from which can lead to pneumonia, bronchitis or sinus infections. Each year, about 20,000 children under age 5 are hospitalized because of complications related to the flu and about 100 children die, according to the CDC.

6.3

The Washington Post

On Parenting

Refuse to vaccinate? You may be told to seek care elsewhere.

By Bonnie Miller Rubin August 29

Say a family comes into your pediatrician's office for a regular checkup. And say this is also a family that refuses to vaccinate their children. Your doctor can tell them to take their business elsewhere. And in fact, the American Academy of Pediatrics today recommends that action.

"Parents, pediatricians and policymakers all have a role in protecting children from diseases like measles and whooping cough," said Benard Dreyer, president of the AAP, which is taking a stronger position on this issue than ever before. "No child should have to suffer through a disease that could have been prevented by a vaccine."

In an effort to address the anti-vaccine trend, the AAP issued a new policy statement today opposing all nonmedical exemptions for vaccines. If, after counseling, skeptical parents still choose to opt out, doctors may request "that they seek care elsewhere."

Bayla Sandman, a mother of two sets of twins, ages 5 and 2, applauds the new recommendations. "I think it's great," said the paralegal, who lives in New Haven, Conn. "People read all this stuff on the Internet and it's not based on any science. It's based on nothing."

Anxiety about immunizations has increased in recent years, according to survey findings, also included in the latest report. Of about 630 pediatricians polled in a 2013 survey, 87 percent had encountered vaccine refusal, up from 75 percent in 2006. Top concerns include: the child's pain, too many injections at a single visit — causing some parents to delay rather than refuse vaccines — and a fear of autism. Many have a mistrust of health-care professionals.

Likewise, the number of providers who dismiss families for noncompliance nearly doubled between the two time periods, reported the AAP.

Despite the new position, Todd Ochs won't change the way he has interacted with skeptics for the past 30 years. "Why should I punish a child for a parent's bad decision?" the Chicago pediatrician said. "If I kick out these families, there will always be

some homeopath or alternative medicine practitioner who will give parents exactly what they want. I'd much rather have an ongoing conversation with them than isolate them."

To counter vaccine-hesitant parents, more providers are implementing an office policy requiring that all patients comply with the AAP vaccine schedule, which recommends two MMR vaccines at 12 to 15 months and a second dose at 4 to 6 years. This way, pediatricians are not really severing ties with families, but declining to treat them at all.

After a national measles outbreak last year, Anita Chandra-Puri, a pediatrician who also practices in Chicago, has tried to walk a more nuanced path. If after six months of counseling a family is still undecided on whether to immunize, she will recommend they seek care elsewhere.

"You just can't take part of my advice. If you trust me when your child has a fever or a rash, you should trust me on this, too," she said. "If after six months, you still aren't convinced, then we don't really have a working relationship."

As for delaying vaccines, "There is no alternative schedule," said Chandra-Puri. "There is only one schedule. … The rest is parental choice."

High community immunization rates protect vulnerable individuals — those who are too young to get vaccinated or can't be vaccinated because of medical problems, such as undergoing chemotherapy. Those people are protected by the majority who are inoculated, called herd immunity.

For example, when the vaccination rate for measles drops below 95 percent, a community loses its herd immunity to highly infectious diseases, explained Kathryn Edwards, one of the co-authors of the report and a professor of pediatrics at Vanderbilt University.

Measles was all but eradicated in 2000, but last year, the disease came roaring back, with many cases linked to the Disneyland outbreak in California, where an estimated 3 percent of kindergartners had a nonmedical or philosophical exemption from the MMR.

Later, California responded by passing legislation that ended exemptions for nonmedical reasons. West Virginia and Mississippi are the only other states that have similar requirements, according to the Centers for Disease Control and Prevention.

The AAP has called for all nonmedical exemptions to be eliminated and recommends that public health officials release immunization rate data for individual schools and communities, so parents can make informed decisions about their children's safety in those settings.

Sandman, the New Haven mother, said that the vaccine debate is most heated among those who spend a lot of time on social media, debating the merits of everything from sleep training to home schooling.

“There’s so much pressure to be perfect. I was nervous because there was so much from the anti-vaccine people on the Internet, like doctors were being paid by the pharmaceutical companies,” she said. “I eventually stopped reading and searching … because what you really need to find is a doctor you can trust.”

Bonnie Miller Rubin is a former reporter at the Chicago Tribune. Follow her at bonniemillerrubin.com or on Twitter @bmrubin.

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6.4

Study: HPV vaccine can benefit older women

By Olivier Uyttebrouck / Journal Staff Writer

Monday**, August 15th, 2016 at 12:05am**

ALBUQUERQUE, N.M. — A new study co-authored by a University of New Mexico researcher strengthens the argument that older women can benefit from a vaccine that blocks viral infections that cause cervical cancers.

The human papillomavirus vaccine prevented infections from the most dangerous virus types among women over 26 who had not been previously infected, the seven-year study of thousands of women found.

“If a person has not been exposed to a virus type before, the vaccine is highly efficacious in a broad age range of women,” said Cosette Wheeler, lead author of a June 28 report published in the online edition of Lancet Infectious Diseases.

The human papillomavirus, or HPV, vaccine is FDA-approved for women only through age 26, although doctors can legally offer the shot to older women as an “off-label” use.

The primary target for HPV vaccinations is boys and girls ages 11 and 12 for routine vaccinations and for “touch-up” vaccinations up to 21 for males and 26 for females, Wheeler said.

HPV is among the most common sexually transmitted diseases, and more than 40 types can infect male and female genitalia. Half of U.S. residents will be infected with HPV in their lifetimes, the Centers for Disease Control and Prevention estimates.

Infections from five types of HPV cause about 85 percent of invasive cervical cancers.

The decision to target children in their early teens is primarily one of cost versus benefit, Wheeler said.

Officials who want the greatest benefit from limited public-health dollars urge vaccinating children before they become sexually active.

“The vaccine is more efficacious prior to exposure,” she said.

The high cost of HPV vaccine is a key factor in the discussion.

A single dose of the vaccine costs $130 to $150, and insurance is unlikely to cover it for off-label uses. For children, the CDC recommends a three-dose sequence.

Among those who are not vaccinated, many develop natural immunity through exposure to HPV after they become sexually active. As a result, HPV infection rates decline as the population ages, she said.

In other words, society gets the greatest bang for its health-care dollars by vaccinating children before they become sexually active.

“It does not change the fact that older women benefit from vaccinations,” though in smaller numbers, she said. “The benefit may be small, but if we really wanted to eradicate cervical cancer like we did smallpox, you would vaccinate as many people as you could afford to.”

The study, which tracked women ages 26 to 45 for seven years, found that the vaccine was about 90 percent effective in preventing infection from two of the most dangerous HPV types.

The study draws no conclusions about what groups of older women could benefit the most from the vaccine. Nor does it recommend any changes in the FDA guidelines for the vaccine.