

ADVISORY COMMISSION ON CHILDHOOD VACCINES
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September 18, 2018

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***ADVISORY COMMISSION ON
CHILDHOOD VACCINES***

Agenda

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

5600 Fishers Lane, Rockville, MD 20857

Teleconference and Adobe Connect

Thursday, September 6, 2018

(11:00 am Eastern Daylight Time)

Dial-in: 1-800-988-0218

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

Time	Agenda Item	Presenter
11:00 AM	Welcome and Chair Report	Ms. Beth Luthy, Chair
11:10 AM	Public Comment on Agenda Items	Ms. Beth Luthy, Chair
11:15 AM	Approval of June 2018 Minutes	Ms. Beth Luthy, Chair
11:25 AM	ACCV Work Group Update	Mr. John Howie, Work Group Chair
11:50 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Director, DICP
12:10 PM	Report from the Department of Justice	Ms. Heather Pearlman, Trial Attorney, Torts Branch, DOJ
12:30 PM	Break	
1:00 PM	Review of Vaccine Information Statements (VIS's)	Mr. Skip Wolfe Ms. Suzanne Johnson-DeLeon CDC
1:30 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Michael McNeil CDC
1:45 PM	Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH

Time	Agenda Item	Presenter
2:00 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	CDR Valerie Marshall CBER, FDA
2:15 PM	Update from the National Vaccine Program Office (NVPO)	Ms. Ann Aikin NVPO
2:30 PM	Public Comment (follows the preceding topic and may commence earlier or later than 2:30 pm)	
2:45 PM	Future Agenda Items/New Business	Ms. Beth Luthy, Chair
3:00 PM	Adjournment of the September 6, 2018 ACCV Meeting	Ms. Beth Luthy, Chair



Charter



CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

1. Committee's Official Designation: The committee shall be known as the Advisory Commission on Childhood Vaccines ("the Commission").
2. Authority: Required by 42 U.S.C. 300aa-19 of the Public Health Service (PHS) Act. 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.
3. Objectives and Scope of Activities: The ACCV advises and makes recommendations to the Secretary of Health and Human Services on issues relating to the operation of the National Vaccine Injury Compensation Program (VICP). The nine voting members provide oversight of and recommendations how to improve the VICP.
4. 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; and (6) consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act.
5. 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.
6. Support: Management and support services shall be provided by the Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA).
7. 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 \$36,460. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of \$295,043.

8. 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.
9. Estimated Number and Frequency of Meetings: The Commission shall meet no less than four times per year and at the call 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.
10. Duration: Continuing.
11. Termination: Unless renewed by appropriate action prior to its expiration, this charter will expire two years from the date the charter is filed.
12. 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.

13. 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.
14. Recordkeeping: The records of the Commission and its subcommittees shall be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.
15. Filing Date:

Approved:

20 July 2018
Date

/s/

Amy McNulty
Acting Director, Division of the Executive Secretariat



Roster

April 12, 2018

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

5600 Fishers Lane, 08N146B
Rockville, MD 20857

ACCV MEMBERS

Karlen E. (Beth) Luthy, D.N.P., A.R.P.N. (Term Expires 2018)
Chair
Associate Professor
College of Nursing, Brigham Young University
Health Professional

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

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

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

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

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

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

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

Vacant Position
Parent of a Vaccine Injured Child

EX-OFFICIO MEMBERS

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

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

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

Michael McNeil, M.D., M.P.H.
Immunization Safety Office
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OFFICE OF THE GENERAL COUNSEL

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Attorney



2018 & 2019
Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2018 MEETING DATES

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

2019 MEETING DATES

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

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Advisory Commission on Childhood Vaccines

June 15, 2018

106th Meeting

Members Present

Karlen E. (Beth) Luthy, D.N.P., Chair ('18)

H. Cody Meissner, MD, Vice Chair ('19)

Kathleen F. Gaffney, PhD, RN ('19)

Tina Tan, MD ('19)

Alexandra Stewart, J.D. ('18)

Martha Toomey ('18)

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

Narayan Nair, M.D., Acting Director, DICP

Andrea Herzog, Principal Staff Liaison, Advisory Commission on Childhood Vaccines (ACCV)

Welcome and Report of the Ms. Beth Luthy, ACCV Chair

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

Public Comment on Agenda Items, Ms. Beth Luthy

Ms. Luthy invited comments from the public on agenda items. The conference operator informed the commission there were no requests to speak.

Approval of December 2017 and March 2018 Minutes, Ms. Beth Luthy

Ms. Luthy invited approval of the December 8, 2017 and March 8, 2018 meeting minutes. On motion duly made by Dr. Meissner and seconded by Mrs. Toomey, the minutes of the December 2017 meeting were unanimously approved. On motion duly made by Dr. Meissner and seconded by Ms. Toomey, the minutes of the March 2018 meeting were unanimously approved.

Work Group Update, Ms. Alexandra Stewart

Ms. Stewart announced that the ACCV Process Work Group agreed to revise the work group and add new commissioners to the membership. The work group met on April 11, 2018 and May 21, 2018 and officers were appointed at the May meeting: chair, Martha Toomey; vice chair, John Howie; and Ms. Stewart stated that she would serve as secretary. Ms. Toomey, was unable to attend either meeting, so Ms. Stewart agreed to present this meeting summary.

Mr. Howie suggested that existing recommendations (which can be found on the ACCV website) be identified and confirmed before discussion of new recommendations. He also suggested reviewing the funding and staffing issues that have caused the backlog in processing claims. There was some general discussion on how the commission interacts with the public, and some preliminary ideas related to increasing that interaction were briefly mentioned. The changes might include promoting inclusion, transparency and increased program education.

When the work group meets again it will clarify its mission, which would include consideration of process changes that the commission may submit to the new HHS secretary. The date and time for the next meeting has not been announced. It was observed that there has been a steady and dramatic increase in non-autism claims.

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

Dr. Nair reviewed the agenda, which includes his report on the National Vaccine Injury Compensation Program (VICP), a report from the Department of Justice, and reports from the ex officio members (CDC, NIAID, FDA and NVPO). Dr. Nair presented VICP statistics, including data on the number of petitions filed in the current fiscal year, 783 as of June 4, 2018, and total annual filings since FY 2013. The average number of claims for Fiscal Years (FYs) 2008 – 2012 was 410. From FY 2013, following a decade of relatively stable claims, there has been a dramatic increase in non-autism claims filed with the VICP, so far peaking at over 1,200 claims in FY 2017.

Dr. Nair described the administrative funding approved for each fiscal year since 2013, when it was \$6.48 million and when there were 504 claims. Since then the annual claims have risen to 1,243 through FY 2017. In FY 2018 administrative funding increased to \$9.2 million, a 19% increase over the year before.

Dr. Nair discussed the VICP case backlog; all the claims with complete medical records filed in 2017 have been assigned for medical review. For FY 2018, the current backlog is 559 claims awaiting assignment to HRSA medical officers.

The awards paid through June 4, 2018, about 8 months into the current fiscal year, were slightly over \$130 million and attorney's fees and costs were \$19 million. For FY 2017, the amounts were \$252 million and \$30 million respectively. There were 877 adjudications in FY 2017, of which 696 were compensated (80%), and 181 were dismissed. To date in FY 2018, 405 cases have been adjudicated with 288 deemed compensable and 117 dismissed. Specifically, in FY 2017, 26% of adjudicated claims were resolved by concession, 7% by court decisions, 67% were settled by the parties to the case. There were 173 claims not compensated. To date in FY 2018, 35% were conceded, 19% decided by the court, 46 were settled and 100 were not compensated. These figures were slightly skewed by the fact that the reporting period was through June 14, instead of June 4.

In response to a question to clarify what a concession means, Dr. Nair explained that a concession is made by HHS when it is determined that, based on the evidence submitted in the case, it is more likely than not that the vaccine caused the injury or that the basis of the claim and the evidence submitted support the assumption that the injury is covered in the Vaccine Injury Table.

Noting the significant 19% increase in funding authorized for administrative purposes in FY 2018, Ms. Toomey stated that the work group would benefit by an explanation of how that dramatic increase came about. Dr. Nair explained that he did not know the specific detailed process that resulted in the increase, and that the program does not have direct input into the process, but he could look into it. Finally, asked about the term “non-autism,” Dr. Nair briefly explained the history of autism claims, the ultimate determination that the claims would be consolidated in an Omnibus Autism Proceeding (OAP), and the autism claims were separated from the reporting because of the potential of statistically misrepresenting the workload related to processing claims. He added that most autism claims have been dismissed, but that a very few, probably less than ten, are still pending.

Dr. Nair continued his report, noting that the Vaccine Injury Compensation Trust Fund (Trust Fund) stands at \$3.75 billion, and it was increased during the first part of FY 2018 (through March 31st) by \$168 million, \$137 million from excise tax revenues and \$32 million from interest on the fund’s investments.

Regarding program activities, on April 4, 2018, the Notice of Proposed Rulemaking (NPRM) proposing to add the category of vaccines recommended for pregnant women to the Vaccine Injury Table was published in the *Federal Register*. A public hearing is scheduled for September 17, 2018 and members of the public are encouraged to participate. On April 24, 2018 the DICP provided an overview of the program to managers of HRSA regional offices to help them inform grantees about the program.

During the discussion following Dr. Nair’s presentation, Ms. Toomey asked about the integrity of the Trust Fund. Dr. Nair explained that the statute limits disbursement of Trust Fund monies to administration the VICP by HRSA, and funding the Office of Special Masters of the U. S. Court of Federal Claims (CFC), germane programs in the Department of Justice, and compensating petitioners and paying their attorneys’ fees and costs. The statute can only be changed by act of Congress signed by the President.

Dr. Nair closed with an observation that the VICP is one of many programs within HRSA that provide benefits to the public. Other HRSA programs include: supporting poison control center; organ transplantation programs; contributions to the effort to reduce the effects of the opioid epidemic; funding for community health centers; and others. More detail is available on the HRSA web site.

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

Ms. Reeves stated that her data covered claims from February 16, 2018 through May 15, 2018, which is a different reporting period than that discussed by DICP. Ms. Reeves stated that 263 claims were filed during this time period: 240 for adults and 23 on behalf of minors. The total number of cases adjudicated during this time period was 147: 113 compensated (43 conceded by HHS, 70 cases not conceded (68 decisions adopting a settlement; 2 decisions awarding damages)). There were 34 non-compensated cases, all of which were non-Omnibus Autism Proceeding claims. Finally, two claims were voluntarily withdrawn by the petitioners.

Turning to appeals in the U.S. Court of Appeals for the Federal Circuit (CAFC), Ms. Reeves stated that the CAFC issued three decisions during the reporting period: (1) *D’Tiole v. HHS* affirmed a ruling denying entitlement in a claim that flu vaccine caused narcolepsy; (2) *Anderson v. HHS* affirmed a ruling denying entitlement in a claim that flu vaccine caused autism;

and (3) *Galindo v. HHS*, petitioner unsuccessfully sought a writ of mandamus (an order from a court to an inferior government official ordering the government official to properly fulfill his/her official duties or correct an abuse of discretion). Six cases are pending in the CAFC.

In the Court of Federal Claims (CFC), the court issued four decisions following a motion for review filed by the petitioner (all involving entitlement issues), and two decisions following a motion for review filed by HHS. With regard to the motions for review filed by HHS, *McCulloch v. HHS* concerned attorneys' fees and costs, and *Fairchild v. HHS* involved an interim award of damages. The latter decision is of concern, as it has the potential to undermine the Vaccine Act's statutory scheme, which requires that a petitioner elect to accept or reject any compensation awarded on a Vaccine Act petition.

There are 12 motions for review pending in the CFC, 7 filed by petitioners and 5 filed by HHS. Oral arguments have been held in two of those cases. *Boatmon v. HHS*, argued on June 5, 2018 by the Deputy Assistant Attorney General, involved an allegation that a vaccine caused sudden infant death syndrome (SIDS). *Oliver v. HHS* was argued on June 6, 2018. A third case, *Depena v. HHS*, will have oral argument on July 9, 2018.

Finally, Ms. Reeves presented a history of adjudicated settlements showing the time required to reach final adjudication. Four cases took four or more years to reach final adjudication; 53 cases took one year or more; and 14 cases reached final adjudication in nine-to-twelve months. Ms. Reeves explained that in an "adjudicated settlement" the parties file a stipulation that sets forth the terms of their agreed upon settlement. That stipulation is then reviewed by the special master and, if found acceptable, the special master enters a decision that adopts the stipulation. A final judgment thereafter enters. A petitioner may either accept the final judgment and receive a damages award, or reject the final judgment and pursue a civil action.

During the discussion period, Ms. Toomey asked for more detail about *Anderson v. HHS*, the claim involving an allegation of vaccine-caused autism. Ms. Reeves explained that the petitioners in that case alleged that the MMR vaccine aggravated their child's underlying mitochondrial condition that resulted in autism. The special master denied entitlement because he determined that petitioners' evidence that their child had underlying mitochondrial disease was insufficient. In addition, the special master found that the medical records did not support petitioners' allegation that their child had suffered any reaction to the MMR vaccine. Both the CFC and the CAFC affirmed the special master's decision.

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

Dr. Duffy reported that the 48th National Immunization Conference was held May 15-17, 2018 in Atlanta, GA. The ISO staff made four oral presentations: 1) vaccine administration errors; 2) human papillomavirus (HPV) vaccination programs in the U.S.; 3) maternal vaccine safety monitoring at CDC; and 4) updates from the ISO. There were also several posters presented at the conference: 1) the healthcare providers' role in vaccine safety; 2) the safety of the currently licensed hepatitis B vaccine; and 3) the safety of Menactra based on Vaccine Adverse Event Reporting System (VAERS) data.

At the Preventive Medicine Conference on May 23-24, 2018, in Chicago, IL. The ISO had one presentation on unintentional administration of insulin instead of influenza vaccine in about 20 patients. It was deemed to be related to confusion between the two products.

Dr. Duffy announced the upcoming meeting of the Advisory Committee on Immunization Practices (ACIP) on June 20-21, 2018. At this meeting there will be a session devoted to a safety update on the 2017-2018 influenza season, and an update on the CDC-funded Systematic Observational Method for Narcolepsy and Influenza Immunization Assessment (SOMNIA) study of narcolepsy following adjuvanted monovalent pandemic H1N1 flu vaccine. There will also be a pneumococcal session looking at the safety of 13-valent pneumococcal conjugate vaccine in adults 65 and older. Finally, there will be a session on herpes zoster vaccine, including a review of a new inactivated recombinant adjuvanted vaccine.

Dr. Duffy mentioned several recent publications:

- ,Kharbanda, et al. about first trimester influenza inactivated vaccination (IIV) and risks for major structural birth defects in offspring. It was published in the Journal of Pediatrics and was selected as Paper of the Year by the Health Care Systems Research Network (HCSRN). The authors concluded that first trimester maternal IIV exposure was not associated with an increased risk for selected major structural birth defects in a large cohort of singleton live births.
- Markowitz, et al. published a paper in Academic Pediatrics on HPV vaccination in the United States, a vaccine first introduced for females in the United States in 2006. The United States adopted a gender-neutral routine HPV immunization policy in 2011. The safety profile has been well-established from ten years of post-licensure monitoring. Vaccination coverage is increasing, although it remains lower than for other vaccines recommended for adolescents. Despite low coverage, the early positive effects of the HPV vaccination program have exceeded expectations.
- Irving, et al. published a paper in Academic Pediatrics entitled “Human papillomavirus vaccine coverage and prevalence of missed opportunities for vaccination in an integrated healthcare system.” The paper focused on coverage and less on safety.
- Glanz, et al. published a paper in the Journal of the American Medical Association on the association between estimated cumulative vaccine antigen exposure through the first 23 months of life and non-vaccine targeted infections from 24 through 47 months of age. The study looked at effects of vaccines on non-targeted conditions, and there was no significant difference in estimated cumulative vaccine antigen exposure through the first 23 months of life.
- Daley, et al. assessed potential confounding and misclassification bias when studying the safety of the childhood immunization schedule (Academic Pediatrics). The study found that data reported by parents versus EHRs did not differ significantly among children in the vaccination groups studied.
- Liang, et al. published recommendations by the ACIP regarding pertussis, diphtheria and tetanus vaccines.
- Miller, et al. published a comprehensive review of reports to VAERS on post-licensure safety surveillance of zoster vaccine live (Zostavax®). It covered ten years of reports and did not identify any new safety concerns.
- Donahue, et al. published a response to a letter to the Editor of Vaccine dealing with an association between influenza vaccine containing H1N1pdm09 and spontaneous abortion.

The original letter did not claim causation, only an association. It did prompt a response from the authors that included additional information about the study.

Dr. Duffy concluded his remarks. During discussion following Dr. Duffy's presentation, in response to a question about narcolepsy and the H1N1 flu vaccine, Dr. Duffy explained that the issue was first identified in Europe, and there were numerous articles published in that market. For the U.S., the ISO has looked at VAERS reports and found no association with narcolepsy, and the Vaccine Safety Datalink has similarly not identified any issues related to narcolepsy.

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

Ms. Schuster reported that in March 2018, NIAID launched two clinical trials looking at the inactivated 2017 H7N9 influenza vaccine manufactured by Sanofi Pasteur. The two trials are being conducted by the NIAID-funded network of Vaccine and Treatment Evaluation Units (VTEUs) and participants are being enrolled at sites across the U.S. The Phase II trials will enroll up to 570 volunteers ages 19 to 64, and an additional 300 volunteers ages 65 and older. One of the trials is testing various dosages of the inactivated influenza candidate with or without the AS03 adjuvant (manufactured by GSK). This trial is being conducted at VTEU sites in Georgia, Iowa, Maryland, North Carolina and Washington. The second trial is testing the vaccine with adjuvant when co-administered with seasonal influenza vaccine. This trial is being conducted at VTEU sites and one affiliated site in Maryland, Alabama, Ohio and Tennessee. The new vaccine uses an inactivated form of the H7N9 virus collected in 2017 to increase the likelihood that the new vaccine will induce immunity against a newly-evolved strain of H7N9.

Research has revealed that influenza vaccines that effectively target an influenza surface protein, neuraminidase, could provide broad protection against various influenza strains and lessen the severity of the illness. Current vaccines target a more abundant surface protein, hemagglutinin. The new research builds on previous studies of neuraminidase and was conducted by a team of scientists including investigators from the NIAID-supported Centers of Excellence for Influenza Research and Surveillance (CEIRS) program.

At the last ACCV meeting, Dr. Mulach discussed NIAID's new strategic plan for developing a universal influenza vaccine, which would provide durable protection against multiple influenza strains. NIAID will pursue three objectives: 1) improve understanding of transmission, natural history, and pathogenesis of influenza infection; 2) achieve precise characterization of influenza immunity and correlates of immune protection; and 3) support rational design of universal influenza vaccines.

In May 2018, NIAID launched a clinical trial testing a candidate universal influenza vaccine. The trial is testing an experimental vaccine, M-001, developed in Israel, to assess its ability to produce a broad and protective response on its own or in conjunction with a licensed seasonal influenza vaccine. The vaccine contains components known as antigenic peptide sequences shared across a number of different influenza viruses. Six previous trials of M-001 conducted by Biondvax in Israel and Europe indicated that the vaccine was safe, well-tolerated, and able to produce an immune response in a broad range of flu strains. The new study, which will involve four VTEU sites in the U.S., will enroll up to 120 healthy volunteers between the ages of 18 and 49 years. Participating sites include Baylor College of Medicine, Cincinnati

Children's Hospital Medical Center and the University of Iowa. Lab support will be provided by Saint Louis University.

There are currently nine VTEU sites in the United States. The new structure to be launched in 2020, it will include a leadership group and operations center. A recent webinar on NIAID's vision for the VTEU structure can be viewed on YouTube at www.youtube.com/user/niaid.

In May, NIH opened national enrollment for the All of Us research program, that aims to enroll up to a million volunteers and oversample from communities that have been underrepresented in research. There is more information on All of Us at: <https://www.6youtube.com/watch?v=BSq08AduVGA>.

Finally, NIAID launched a Phase I clinical trial of an investigational vaccine developed by researchers and St. Jude Children's Hospital, designed to protect against respiratory syncytial virus (RSV). It will enroll a small group of healthy adults to assess the safety of the vaccine and its efficacy to induce an immune response.

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

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

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

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

The Vaccines and Related Biological Products Committee (VRBPAC) met on May 17, 2018 to discuss approaches for demonstrating effectiveness of Group B Streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant. GBS is a significant cause of early infant morbidity and mortality.

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

CDR Marshall concluded her report and there was no discussion.

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

Ms. Luthy explained that there would not be a report from the NVPO, the last ex officio report on the agenda. She introduced Ann Aiken, who will replace Dr. Bok. Ms. Aiken introduced herself as communications director of the NVPO, stating that she would assume the duties of Karin Bok as ex officio commission member and would be providing reports about NVPO activities in the future.

Public Comment

Ms. Luthy suggested inviting public comment before considering future agenda items and new business. There was concern expressed because the agenda item was scheduled for 1:30 p.m., that this might adversely affect an individual's plan to make a comment. Ms. Andrea Herzog explained that the announcement in the Federal Register clearly stated that the opportunity to make public comment might be changed based on the flow of the meeting. It is also explained on the agenda published on the web prior to the meeting. Finally, public comment may be submitted in writing before or after the meeting, which provides ample opportunity to be heard.

Ms. Luthy invited public comments.

There were no requests to make comments.

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

Ms. Toomey asked about the vacant position on the commission and Ms. Herzog indicated that nominations had been received and nomination packages would be prepared and sent forward for approval in the near future.

Ms. Luthy stated that the next meetings would be on September 6-7, and the last meeting of the year would be on December 6-7. Dr. Nair commented that either meeting could be an in-person meeting, depending on the needs of the commission. Ms. Toomey emphasized the importance of occasional in-person meetings. Dr. Meissner agreed, but also commented that the travel imposes a greater time commitment. Dr. Nair stated that there had been an attempt to hold at least two face-to-face meetings each year, particularly when a new commissioner is joining the ACCV.

Adjournment

There was a consensus to include in the record a special thank you to Ms. Herzog for her contribution and support for the commission, and her part in planning the meetings.

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

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

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

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

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

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

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

Future agenda items

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Public comment

1. Dr. Hooker – Parent/Private Citizen

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

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

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

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

2. Theresa Wrangham – Executive Director, NVIC

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

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

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

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

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

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

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

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

Adjournment

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

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Vaccine Injury Compensation Trust Fund

Balance as of July 31, 2018

\$3,768,655,418

Figures for October 1, 2017 to July 31, 2018

- Excise Tax Revenue: \$193,467,713
- Interest on Investments: \$56,453,067
- Total Income: \$249,920,781
- Interest as a Percentage of Total Income: 19%

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

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Data & Statistics

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

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

What does it mean to be awarded compensation?

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

- Almost 80 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

What reasons might a petition result in a negotiated settlement?

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

How many petitions have been awarded compensation?

According to the CDC, from 2006 to 2016 over 3.1 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 5,517 petitions were adjudicated by the Court, and of those 3,737 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 19,669 petitions have been filed with the VICP. Over that 29-year time period, 17,336 petitions have been adjudicated, with 6,122 of those determined to be compensable, while 11,214 were dismissed. Total compensation paid over the life of the program is approximately \$3.9 billion.

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

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

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2016 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	794,777	1	0	5	6	4	10
DTaP	95,532,634	17	24	99	140	112	252
DTaP-Hep B-IPV	63,245,627	5	11	26	42	46	88
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	21,143,570	0	0	2	2	1	3
DTap-IPV-HIB	56,635,096	3	5	7	15	29	44
DTP	0	1	1	3	5	2	7
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	14,706,195	2	0	15	17	4	21
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	163,305,725	7	7	37	51	30	81
Hepatitis B (Hep B)	172,993,779	6	11	59	76	67	143
HIB	111,200,358	2	1	8	11	10	21
HPV	101,405,935	15	16	97	128	160	288
Influenza	1,372,400,000	442	194	1,853	2,490	395	2,885
IPV	69,510,722	0	0	4	4	3	7
Measles	135,660	0	0	1	1	0	1
Meningococcal	82,762,503	1	5	36	42	8	50

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Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2016 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
MMR	94,815,650	22	15	82	119	115	234
Mumps	110,749	0	0	0	0	0	0
MMR-Varicella	21,349,409	9	1	10	20	14	34
Nonqualified	0	0	0	3	3	35	38
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	206,003,646	10	4	16	30	23	53
Rotavirus	98,664,187	12	6	18	36	10	46
Rubella	422,548	0	1	1	2	0	2
Td	61,869,752	10	8	57	75	24	99
Tdap	225,013,338	74	18	224	316	57	373
Tetanus	3,836,052	8	1	38	47	19	66
Unspecified	0	1	1	4	6	585	591
Varicella	110,095,393	6	8	28	42	18	60
Grand Total	3,153,876,236	657	340	2,739	3,737	1,780	5,517

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2016 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

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

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

distributors.

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

Definitions

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

- **Concession:** HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision:** A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:
 1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
 2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement:** The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner’s alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to

minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.

- **Non-compensable/Dismissed:** The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
 1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
 2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
 3. The injured person voluntarily withdrew his or her petition.

**Petitions Filed, Compensated and Dismissed, by Alleged Vaccine,
 Since the Beginning of VICP, 10/01/1988 through 8/08/2018**

Vaccines	Filed Injury	Filed Death	Filed Grand Total	Compensated	Dismissed
DTaP-IPV	10	0	10	2	1
DT	69	9	78	26	52
DTP	3,286	696	3,982	1,273	2,709
DTP-HIB	20	8	28	7	21
DTaP	446	82	528	221	247
DTaP-Hep B-IPV	81	36	117	42	49
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	43	21	64	12	27
Td	205	3	208	120	74
Tdap	615	6	621	322	64
Tetanus	132	2	134	72	47
Hepatitis A (Hep A)	101	7	108	49	29
Hepatitis B (Hep B)	683	59	742	271	415
Hep A-Hep B	30	0	30	16	5
Hep B-HIB	8	0	8	5	3
HIB	42	3	45	16	20
HPV	373	14	387	124	158
Influenza	4,383	144	4,527	2,603	423
IPV	268	14	282	8	269
OPV	282	28	310	158	151
Measles	143	19	162	55	107
Meningococcal	68	2	70	41	7
MMR	964	61	1,025	400	580
MMR-Varicella	442	2	46	20	12
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	162	15	177	43	45
Rotavirus	92	4	96	56	21
Rubella	190	4	194	71	123
Varicella	98	9	107	62	30
Nonqualified ¹	97	9	106	3	100
Unspecified ²	5,424	9	5,433	8	5,398
Grand Total	18,399	1,270	19,669	6,122	11,214

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

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

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	987
Total	19,669

Adjudications

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

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	329	509
FY 2011	266	1,740	2,006
FY 2012	265	2,533	2,798
FY 2013	369	649	1,018
FY 2014	371	193	564
FY 2015	517	138	655
FY 2016	697	179	876
FY 2017	696	183	879
FY 2018	380	147	527
Total	6,122	11,214	17,336

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Awards Paid

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

5.1

The National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines

September 6, 2018

CAPT Narayan Nair, MD

Director, Division of Injury Compensation Programs

Healthcare Systems Bureau (HSB)

Health Resources and Services Administration (HRSA)



DICP Update

ACCV Meeting Highlights

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



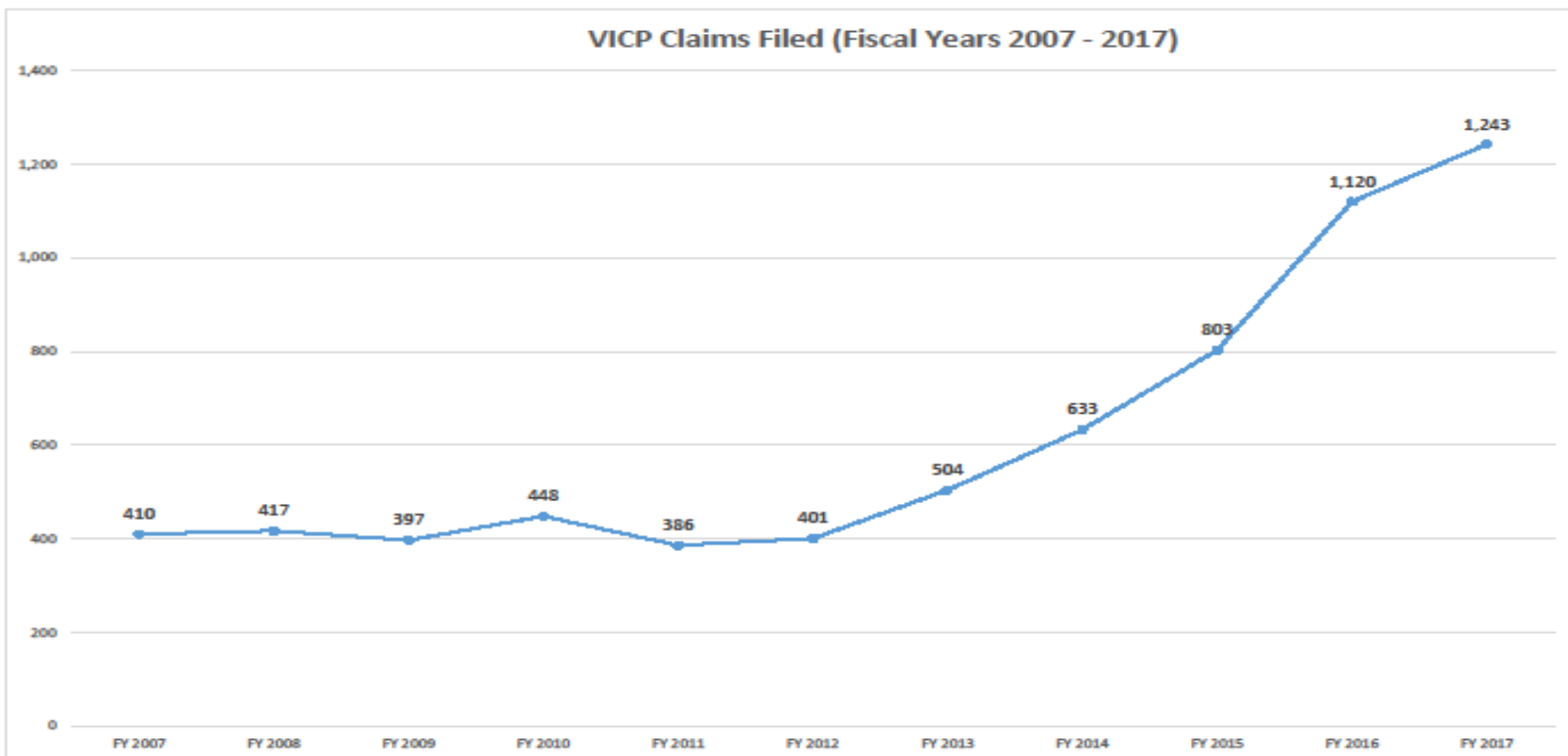
Number of Petitions Filed as of August 6, 2018

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

Fiscal Year	Total
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	977



VICP Claims Filed (Fiscal Years 2007 - 2017)



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

Fiscal Year (FY)	No. of Claims Filed	No. of Claims Percentage Change	Administrative Funding (\$ in millions)	Administrative Funding Percentage Change
2013	504	----	\$6.48	----
2014	633	26%	\$6.46	-0.3%
2015	803	27%	\$7.50	16%
2016	1,120	39%	\$7.50	0%
2017	1,243	11%	\$7.75	3%
2018	977 (As of 8/6/18)	----	\$9.2	19%



Number of Claims Awaiting Review As of 8/7/18

Fiscal Year	Claims Awaiting Review
2017	0
2018	615
Total	615



Award Amounts Paid as of August 6, 2018

<u>Fiscal Year</u>	<u>Petitioners' Award</u>	<u>Attorneys' Fees & Costs</u>
FY 2012	\$163,491,999	\$23,311,362
FY 2013	\$254,666,327	\$22,010,567
FY 2014	\$202,084,196	\$21,479,450
FY 2015	\$204,137,880	\$21,082,059
FY 2016	\$230,140,251	\$22,470,421
FY 2017	\$252,245,933	\$29,850,973
FY 2018	\$152,072,678	\$23,393,394



Number of Adjudications as of August 6, 2018

Fiscal Year	Compensable	Dismissed	Total
FY 2012	265	2,533	2,798
FY 2013	369	649	1,018
FY 2014	371	193	564
FY 2015	517	138	655
FY 2016	697	179	876
FY 2017	696	183	879
FY 2018	375	140	515



DICP Update

Adjudication Categories for Claims*

FY 2015– FY 2018 as of June August 6, 2018

Adjudication Category	FY 2016	FY 2017	FY 2018
Compensable	697 (100%)	696 (100%)	375 (100%)
❖ Concession	204 (29%)	187 (27%)	142 (38%)
❖ Court Decision (includes proffers)	43 (6%)	47 (7%)	49 (13%)
❖ Settlement	450 (65%)	462 (66%)	184 (49%)
Not Compensable	168	175	115
Adjudication Total	865	871	490

***Does not include claims alleging Autism**



DICP Update

Vaccine Injury Compensation Trust Fund

- **Balance as of July 31, 2018**
 - \$3,768,655,418
- **Activity from October 1, 2017 to July 31, 2018**
 - Excise Tax Revenue: \$193,467,713
 - Interest on Investments: \$56,453,067
 - Total Income: \$249,920,781
 - Interest as a Percentage of Total Income: 19%

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



DICP Update

Significant Activities

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



- 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

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5.2

5.3



Centers for Disease Control and Prevention Immunization Safety Office Update

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

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

Disclaimer

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

Topics

- Presentations at June 21-22, ACIP meeting*
- Presentations at recent/upcoming meetings
- Selected publications

ACIP Update – Influenza Vaccines

Vaccine Effectiveness (VE) Summary

- 2017-18 was a flu season with high severity
 - Influenza A(H3N2) viruses predominated
- Influenza vaccination reduced *outpatient visits for influenza-associated acute respiratory illness** by 40% in persons aged 6 months or older
- Among adults, VE estimates were similar for outpatients & inpatient
 - Vaccination reduced *influenza-associated hospitalization*[†] by 22%
- VE estimates against A(H1N1)pdm09 (65%) and B/Yamagata (49%) viruses were higher than against A(H3N2) viruses (24%), similar to previous seasons

*US Flu Vaccine Effectiveness Network Data (Baylor Scott and White Health, University of Michigan and University of Pittsburgh, Vanderbilt University Hospital)

†USHospitalized Influenza Vaccine Effectiveness Network (HAIVEN)

ACIP Update – Influenza Vaccines

Relative Effectiveness of Cell-cultured vs. Egg-based vaccines, 2017-18

- In an analysis by FDA, CMS* and Acumen, LLC, cell-cultured and high-dose vaccines were marginally more effective than egg-based standard dose quadrivalent vaccines for *hospital outcomes among U.S. persons aged ≥ 65 yrs during this season*
 - Cell-cultured quadrivalent vaccines were ~10% more effective than egg-based standard dose quadrivalent vaccines
 - Cell-cultured quadrivalent and egg-based high dose trivalent vaccines were slightly more effective than egg-based quadrivalent standard dose vaccine
 - As the relative VE could vary from season-to-season, monitoring will continue for additional seasons

ACIP Update – Influenza Vaccines End-of-Season Vaccine Safety Monitoring*

- Summary of VAERS monitoring
 - No new safety concerns detected for vaccines used during the 2017-18 influenza season
- FDA did not detect a signal for GBS in its near real-time sequential monitoring in CMS.
- Summary for VSD Rapid Cycle Analysis (RCA)
 - No confirmed RCA signals for pre-specified outcomes of acute disseminated encephalomyelitis (ADEM), anaphylaxis, Bell's palsy, encephalitis, Guillain-Barré syndrome, seizures, or transverse myelitis

ACIP Update – Influenza Vaccines

CISA Project Studies

- Safety and immunogenicity of Fluvad vs. Fluzone High-Dose in older adults
 - Randomized clinical trial in 2017-18 & 2018-19 seasons
 - In progress
- Fever after simultaneous vs. sequential vaccination in young children
 - Randomized clinical trial in children aged 12-16 months
 - Receive either simultaneous (PCV13, DTaP, and IIV4) or sequential (PCV13 & DTaP, then IIV4 2 weeks later) schedules
 - In progress

ACIP Update – Influenza Vaccines

Systematic Observational Method for Narcolepsy and Influenza Immunization Assessment (SOMNIA)

- Assess the risk of Narcolepsy following both AS03- and MF59-adjuvanted 2009 pandemic influenza vaccines: Arepanrix (AS03), Pandemrix (AS03), & Focetria (MF59)
 - International study: 14 study sites
- Incidence rate study data did not show a rise in the rate of narcolepsy following vaccination except in the one signaling country included (Sweden, which used Pandemrix)
- Case-control analyses for AS03-adjuvanted pandemic H1N1 vaccines (Arepanrix and Pandemrix) did not show evidence of an increased risk of narcolepsy, though data were limited for Pandemrix
- Case-coverage analysis for Pandemrix in children in the Netherlands did not show evidence of an increased risk of narcolepsy, but the number of exposed cases was small (N=7)

ACIP Update – Influenza Vaccines

Study of an Adjuvanted Quadrivalent Influenza (aQIV) Vaccine in Young Children

- Presented by Seqirus, the manufacturer of aQIV
- Randomized clinical trial design compared aQIV with FluzoneTIV/QIV
- aQIV has higher rates of local and systemic reactogenicity
- Most reactions started within the first 3 days after vaccination and were mild to moderate and lasted 2-3 days
- Increased incidence of fever, but no increase in febrile convulsions
- Efficacy and immunogenicity
 - aQIV efficacy and immunogenicity superior to comparator vaccine

ACIP Update – Influenza Vaccines

2018-2019 Season Recommendations - Vote

- LAIV4 is an option for persons for whom it is otherwise appropriate
- U.S. influenza vaccine composition already determined by FDA
 - Trivalent vaccines
 - A/Michigan/45/2015 (H1N1)pdm09-like virus
 - A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus-updated
 - B/Colorado/06/2017-like virus (Victoria lineage)-updated
 - Quadrivalent Vaccines
 - Above three plus B/Phuket/3073/2013-like virus (Yamagata lineage)
- Fluarix Quadrivalent (IIV4, GSK) 0.5mL dose licensed for aged ≥ 6 months (previously licensed for aged ≥ 3 years)
- Vote passed: 13 yes, 1 recuse

ACIP Update – HPV Vaccines

- A Biologic License Application (BLA) to expand the age indication for 9vHPV vaccine through age 45 years in males and females was submitted to FDA in April 2018
- FDA is giving this priority review, expected to be completed by October 2018
- Canada and Australia licensed 9vHPV for females aged 9-45 and males aged 9-26
- European Medicines Agency (EMA) approved 9vHPV for use “from the age of 9 years”
- 4vHPV efficacy trial conducted in females aged 24-45 years showed high, statistically significant efficacy against persistent infection
- Bridging efficacy and immunogenicity data accepted for other HPV vaccine approval will inform consideration of the expanded age application

ACIP Update – Mumps Vaccine

- October 2017- ACIP recommendation for use of a 3rd dose of MMR vaccine during mumps outbreak
 - Persons previously vaccinated with 2 doses of a mumps virus-containing vaccine who are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak should receive 3rd dose of mumps virus-containing vaccine to improve protection against mumps disease and related complications
- Mumps cases and outbreaks have increased since 2012
- Proposed CDC updated guidance on use of a 3rd dose of MMR vaccine during an outbreak
 - Identifying groups of persons at risk for acquiring mumps during an outbreak
 - Assessing transmission in the setting to determine if groups are at increased risk
 - Implementing a 3rd dose recommendation

ACIP Update – Recombinant Zoster Vaccine (RZV)

- VAERS Safety Monitoring
 - From October 20, 2017-April 27, 2018 (n= 680 reports)
 - No unusual patterns or unexpected adverse events
- Vaccine Safety Datalink (VSD)
 - As of May 31, 2018, 37,303 total doses of RZV administered at the 6 VSD sites participating in safety monitoring
 - VSD Rapid Cycle Analysis (RCA) protocol under review at VSD sites and to include high priority short-term outcomes (Guillain-Barré syndrome, anaphylaxis, acute myocardial infarction), lower priority short-term outcomes (gout, local and systemic reactions) & longer term outcomes (potential immune-mediated diseases)
- MMWR publication on RZV vaccine administration errors*
- CDC has communication on administration errors and reactogenicity[†]
- Supply-due to high demand, GSK has order limits and shipping delays, GSK has increased number of doses for US markets

*<https://www.cdc.gov/mmwr/volumes/67/wr/mm6720a4.htm>

[†]<https://www.cdc.gov/vaccines/vpd/shingles/hcp/index.html>

ACIP Update – Pneumococcal Vaccines (PCV13)

- 2014: ACIP recommended PCV13 & PPSV23 for adults ≥ 65 years old
 - Long term benefits expected to be limited due to indirect effects from pediatric PCV13 program, planned to reevaluate the policy after 4 years and revise as needed
- Safety of PCV13 in adults ≥ 65
 - VAERS received 5,822 reports from Aug. 1, 2014-Dec. 31, 2017
 - No unexpected data mining findings or safety signals or unexpected patterns observed
 - VSD study
 - Results do not support an increased rate for adverse events studied (cardiovascular events, Bell's palsy, Guillain Barré syndrome, syncope, erythema multiforme, thrombocytopenia, cellulitis and infection, allergic reaction & anaphylaxis) following PCV13 compared to PPSV23

ACIP Update – Pneumococcal Vaccines (PCV13) (Cont'd)

- Findings of studies presented ¹⁻² strongly suggest a direct impact of PCV13 on *vaccine type pneumococcal-community acquired pneumonia (CAP)* beyond pediatric indirect effects which supports direct PCV13 efficacy/effectiveness data against CAP in adults
- While PCV13 uptake is currently around 45% in persons ≥65 years, coverage among persons with lower socioeconomic status and among minorities is markedly lower
- Pneumococcus remains an important cause of CXR+CAP among Native American adults
- Invasive pneumococcal disease (IPD) incidence has dramatically decreased for all racial groups driven by reduction in PCV13-type IPD
- PCVs have nearly eliminated the absolute difference in PCV13-type IPD incidence between blacks and whites, but disparities in IPD remain among non-vaccine type IPD

1. Ramirez JA, et al. Adults Hospitalized With Pneumonia in the United States: Incidence, Epidemiology, and Mortality. [Clin Infect Dis](https://www.ncbi.nlm.nih.gov/pubmed/29020164). 2017 Nov 13;65(11):1806-1812. <https://www.ncbi.nlm.nih.gov/pubmed/29020164>

2. McLaughlin JM, et al. Effectiveness of 13-Valent Pneumococcal Conjugate Vaccine Against Hospitalization for Community-Acquired Pneumonia in Older US Adults: A Test-Negative Design. [Clin Infect Dis](https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy312/5000157). 2018 May 21. <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy312/5000157>

Selected publications

Recent Publication

- Haber P, Amin M, Ng C, Weintraub E, McNeil MM. **Reports of lower respiratory tract infections following dose 1 of RotaTeq and Rotarix vaccines to the Vaccine Adverse Event Reporting System (VAERS), 2008-2016.** Hum Vaccin Immunother. 2018 Jul 11:1-5.
 - Summary: A 2018 manufacturer post-licensure safety study identified a possible association between Rotarix (RV1) rotavirus vaccine and lower respiratory tract infections (LRTI) in infants within 0-6 days following receipt of RV1 dose 1. We reviewed reports to the Vaccine Adverse Event Reporting System (VAERS) of LRTI occurring 0-6 days and 0-29 days post vaccination following RotaTeq (RV5) or Rotarix (RV1) vaccinations in conjunction with either Prevnar (PCV7) or Prevnar 13 (PCV13), in infants aged 6 to 15 weeks. There was no significant difference in LRTI reports to VAERS in the 0-6 days and 0-29 days following receipt of either RV5 or RV1 given with either pneumococcal vaccine
 - Available at <https://www.ncbi.nlm.nih.gov/pubmed/29993327>


5.4

National Institutes of Health Update

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

September 2018




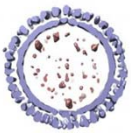



NIH News
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)
<http://www.niaid.nih.gov>
July 11, 2018

NIAID Scientists Create 3D Structure of 1918 Influenza Virus-Like Particles

Details Could Advance Vaccine Development for Several Human Diseases

1 Credit: NIAID

Published online February 28, 2018



The Journal of Infectious Diseases

■ **Three key research areas:**

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


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

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

2 AS Fauci/NIAID

Advancing Universal Influenza Vaccine Research


- July 2018: NIAID announced funding opportunities
 - [PA-18-859 \(R01\)](#)
 - [PA-18-858 \(R21\)](#)
- **Purpose:** To support research activities that will advance areas of interest outlined in "A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases"
 - Improve understanding of transmission, natural history and pathogenesis of influenza virus infection
 - Characterize influenza immunity and correlates of immune protection
 - Support rational design of universal influenza vaccines



3

Collaborative Influenza Vaccine Innovation Centers (CIVICs)


- July 2018: NIAID began soliciting proposals for CIVICs
 - [HHS-NIH-NIAID-BAA2018](#) (due 11/29/2018)
- **Objectives:**
 - Support improvements in immunogenicity and durability of seasonal influenza vaccines
 - Develop innovative influenza vaccine approaches that provide robust, durable, broadly protective mucosal and systemic anti-influenza immunity ("universal influenza vaccines")
 - Support iterative vaccine design based on detailed immunologic assessment of influenza vaccine candidates (pre-clinical studies, clinical trials, healthy volunteer human challenge studies)



4

Program Announcements: Research to Advance Vaccine Safety

- First launched in 2008
- Collaborative effort between NIH and CDC
- Most recent iteration released on July 24, 2018
 - [PA-18-873 \(R01\)](#)
 - [PA-18-872 \(R21\)](#)



5

Research to Advance Vaccine Safety

Focus

- Study physiological and immunological responses to vaccines/components
- Determine how genetic variations affect immune/physiological responses
- Identify risk factors and biological markers
- Create/evaluate statistical methodologies
- Apply genomic technologies and systems biology approaches
- Compare effects of vaccine combinations and different schedules

6



Trans-NIH Pediatric Research Consortium

- Nearly all 27 NIH institutes and centers fund some aspects of child health research
 - Fiscal year 2017: >\$4 billion total support
- This new consortium aims to harmonize these activities, explore gaps and opportunities in the overall pediatric research portfolio, and set priorities
- Project-based interactions and full consortium meetings to discuss scientific opportunities and potential new areas of collaboration

7



5.5

5.6

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

September 6, 2018



CDR Valerie Marshall, MPH, PMP

Immediate Office of the Director

Office of Vaccines Research and Review (OVRR)

Center for Biologics Evaluation and Research (CBER)

Food and Drug Administration (FDA)

Influenza Vaccine Strain Changes

- The FDA approved supplements for the Biologics License Applications (BLA) for seasonal influenza vaccines to include the 2018-2019 United States formulation and associated labeling revisions.

Upcoming Workshop

- On September 17, 2018, the Center for Biologics Evaluation and Research and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) will hold a public workshop entitled,

“Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans”
- The purpose of the public workshop is to exchange information with the scientific community about the clinical, manufacturing, and regulatory considerations associated with live microbiome-based products, when administered to prevent, treat, or cure a disease or condition in humans.



Thank you!



5.7

Update from the National Vaccine Program Office



September 6, 2018

Advisory Commission on Childhood Vaccines

Ann Aikin, MA





U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Vaccine Advisory Committee Updates

NATIONAL VACCINE PROGRAM OFFICE

New NVAC Report

Strengthening the Effectiveness of National, State, and Local Efforts to Improve HPV Vaccination Coverage in the United States

Reports and Recommendations

PUBLIC
HEALTH
Reports

Strengthening the Effectiveness of National, State, and Local Efforts to Improve HPV Vaccination Coverage in the United States: Recommendations From the National Vaccine Advisory Committee

Public Health Reports
Vol. XXX(0) 1-8
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DOI: 10.1177/0033354918793629
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SAGE

Approved by the National Vaccine Advisory Committee on June 25, 2018

Abstract

In February 2018, recognizing the suboptimal rates of human papillomavirus (HPV) vaccination in the United States, the assistant secretary for health of the US Department of Health and Human Services charged the National Vaccine Advisory Committee (NVAC) with providing recommendations on how to strengthen the effectiveness of national, state, and local efforts to improve HPV vaccination coverage rates. In the same month, the NVAC established the HPV Vaccination Implementation Working Group and assigned it to develop these recommendations. The working group sought advice from federal and nonfederal partners. This NVAC report recommends ways to improve HPV vaccination coverage rates by focusing on 4 areas of activity: (1) identifying additional national partners, (2) guiding coalition building for states, (3) engaging integrated health care delivery networks, and (4) addressing provider needs in rural areas.

Keywords

National Vaccine Advisory Committee, human papillomavirus, immunization, coalition, health systems, rural health

Introduction

In June 2015, the National Vaccine Advisory Committee (NVAC) issued the report, "Overcoming Barriers to Low HPV Vaccine Uptake in the United States: Recommendations From the National Vaccine Advisory Committee."¹ The report provided recommendations to the assistant secretary for health (ASH) on strategies to increase human papillomavirus (HPV) vaccine uptake among adolescents by reviewing the current state of HPV immunization, exploring the root causes for low vaccine uptake in both initiation and series completion, and identifying some of the best practices currently in use to attain high immunization coverage. The NVAC endorsed, among other recommendations, the recommendations of a report issued by the President's Cancer Panel, a federal advisory committee of the National Institutes of Health's National Cancer Institute, *Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer*.²

Since the 2015 report, a range of policy and program changes and advances in research have resulted in progress on HPV vaccination.¹ In 2016, the Advisory Committee on

Immunization Practices updated its HPV vaccination guidance to routinely recommend a 2-dose schedule for males and females aged 9-14, while maintaining a 3-dose schedule for those aged ≥ 15 .³ Shortly thereafter, 2 existing Healthcare Effectiveness Data and Information Set measures that assessed the receipt of adolescent vaccines were modified and combined. Specifically, in 2017, the Human Papillomavirus for Female Adolescents measure and the Immunizations for Adolescents measure were combined to report receipt of all recommended vaccines (meningococcal, tetanus-diphtheria-acellular pertussis, and HPV) for both male and female adolescents.^{4,5} The 2-dose schedule and updated Healthcare Effectiveness Data and Information Set measure may increase vaccine uptake among adolescents.

Primary care providers deliver most vaccinations in practice-based settings in the United States, but there is a

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Available on the NVPO website:

<https://www.hhs.gov/nvpo/nvac/reports-and-recommendations/index.html>

Upcoming NVAC Meetings

Upcoming Meeting:

- September 12-13, 2018

Proposed 2019 Meeting Dates:

- February—1/2 Day, Virtual: February 5 in afternoon
- June, 2-Day, In-Person: June 4-5
- September, 2-Day, In-Person: September 17-18

Visit the [NVPO website](#) for more information

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Report to Congress on Encouraging Vaccine Innovation

NATIONAL VACCINE PROGRAM OFFICE

Report Development

December 13, 2016

The 21st Century Cures Act is signed into law. A provision requires the HHS Secretary to submit a report on encouraging vaccine innovation

June 27, 2017

Panel discussion with experts in science, medicine, public health, vaccine safety, patient policy, consumer advocacy, and private sector industry

March 2018

HHS Secretary reviews and submits final report to Congress



**Vaccine Innovation
Steering Committee**

On behalf of the Secretary,
NVPO coordinates with ASPE,
BARDA/ASPR, CDC, FDA, and NIH

Report Development

The VISIC collaborates
to develop the report

Current Status of Vaccine Development



120+

vaccine
candidates
are currently
under
development

The U.S. vaccine enterprise is **well established** and has been **successful** at bringing innovative and new and improved vaccines to the market.

- **Many domestic and global partners are involved** such as government, industry, academia, non-profit, and private sector partners.
- **It is complex** including infectious disease surveillance, basic and applied research, product development, regulatory evaluation and licensure, recommendations for introduction and use, and vaccine uptake.

Challenges



The prevailing business model prioritizes vaccine candidates with large markets; yet market sizes are likely smaller for many remaining targets

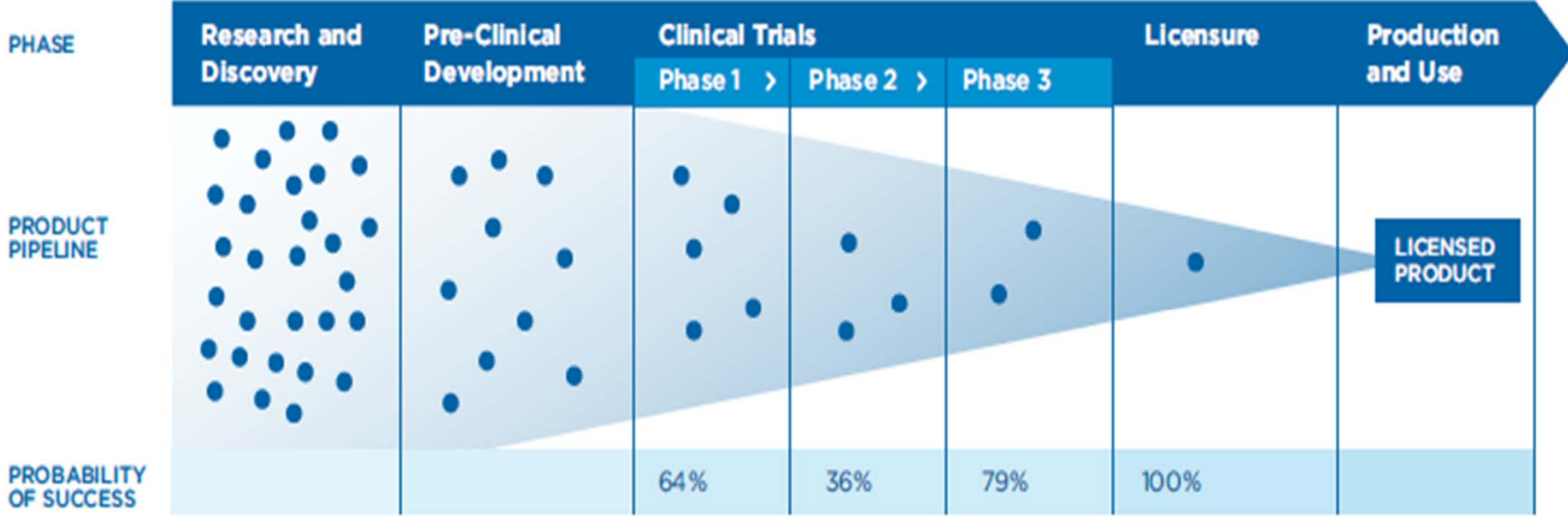


Substantial investment is needed to address the scientific complexity of remaining targets



Uncertainty of the public health priority and demand of some targets may be unclear—increasing uncertainty of potential ROI and therefore investment risk of development

Phases of Vaccine Development

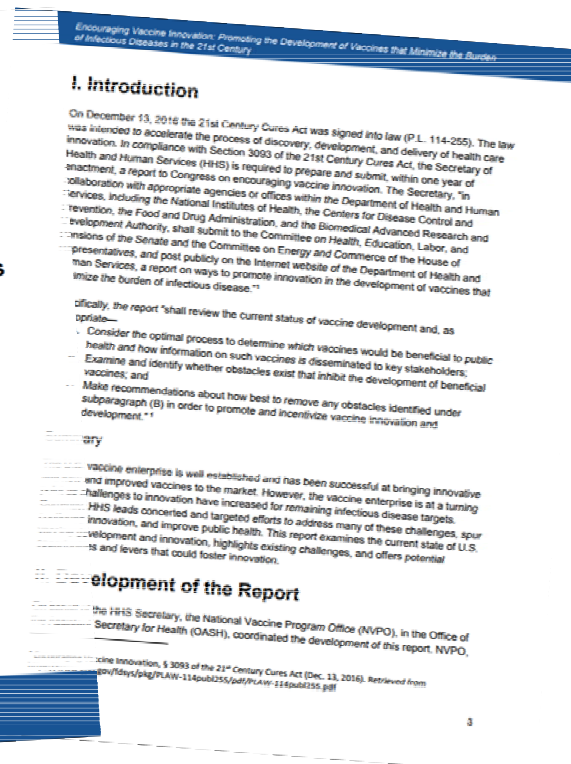
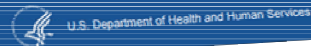


Source: Biotechnology Innovation Organization, BioMedTracker, and Amplion. Clinical Development Success Rates 2006-2015.

Read the Report Online!

Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century Report to Congress

December 2017



Available at: www.hhs.gov/nvpo/featured-priorities/vaccine-innovation



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

New Video Series and Web Content

NATIONAL VACCINE PROGRAM OFFICE

“Your Best Shot” Video Series

Purpose: Educational series to highlight the importance of vaccines across the lifespan.

Each video is...

- ✓ User-tested and approved
- ✓ Easy-to-understand, based on health literacy principles
- ✓ Up-to-date with the latest recommendations
- ✓ Inclusive, featuring diverse characters across the lifespan



Videos and Materials:

www.vaccines.gov/resources/videos_and_tools

Vaccines.gov Content Refresh



- Award-winning website developed in 2011.
- **Mission:** To provide trusted, consumer-friendly information about vaccines and vaccine-preventable diseases that answers questions and directs users to partner sites for in-depth content.
 - A complete portrait of vaccination from how the immune system works to how to pay for vaccines
 - Unprecedented collaboration
 - English & Spanish content

Complete content audit and refresh in 2017-2018



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Thank you!

Ann Aikin, MA
Communications Director
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National Vaccine Program Office

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NATIONAL VACCINE PROGRAM OFFICE

6.1

Vaccine Information Statement

Meningococcal ACWY Vaccine: 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 <http://www.immunize.org/vis>.

1. Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning – even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *N. meningitidis*, called “serogroups.” Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Meningococcal ACWY vaccine can help prevent meningococcal disease caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available to help protect against serogroup B.

2. Meningococcal ACWY Vaccine

Meningococcal conjugate vaccine (**MenACWY**) is licensed by the Food and Drug Administration (FDA) for protection against serogroups A, C, W, and Y

Two doses of MenACWY are routinely recommended for adolescents 11 through 18 years old: the first dose at 11 or 12 years old, with a booster dose at age 16. Some adolescents, including those with HIV, should get additional doses. Ask your health care provider for more information.

In addition to routine vaccination for adolescents, MenACWY vaccine is also recommended for certain groups of people:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- People with HIV
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called “persistent complement component deficiency”
- Anyone taking a drug called eculizumab (also called Soliris[®])
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in dormitories
- U.S. military recruits

Some people need multiple doses for adequate protection. Ask your health care provider about the number and timing of doses, and the need for booster doses.

3. Some people should not get this vaccine

Tell the person who is giving you the vaccine **if you have any severe, life-threatening allergies**. If you have ever had a life-threatening allergic reaction after a previous dose of meningococcal ACWY vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your provider can tell you about the vaccine’s ingredients.

Not much is known about the risks of this vaccine for a pregnant woman or breastfeeding mother. However, pregnancy or breastfeeding are not reasons to avoid MenACWY vaccination. A pregnant or breastfeeding woman should be vaccinated if she is at increased risk of meningococcal disease.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. 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 within a few days, but serious reactions are also possible.

As many as half of the people who get meningococcal ACWY vaccine have **mild problems** following vaccination, such as redness or soreness where the shot was given. If these problems occur, they usually last for 1 or 2 days.

A small percentage of people who receive the vaccine experience muscle or joint pains.

Problems that could happen after any injected 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 doctor if you feel dizzy or lightheaded, or have vision changes.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. 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 reaction?

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 – usually within 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 and get to the nearest hospital. Otherwise, call your doctor.
- 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 web site 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 health care 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

Vaccine Information Statement
Meningococcal ACWY Vaccines
[new date]
42 U.S.C. § 300aa-26

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

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6.2

Vaccine Information Statement

DTaP (Tetanus, Diphtheria, Pertussis) Vaccine: 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?

DTaP vaccine can help protect your child from **diphtheria, tetanus, and pertussis**.

- **DIPHTHERIA (D)** can cause breathing problems, paralysis, and heart failure. Before vaccines, diphtheria killed tens of thousands of children every year in the United States.
- **TETANUS (T)** causes painful tightening of the muscles. It can cause “locking” of the jaw so you cannot open your mouth or swallow. About 1 person out of 5 who get tetanus dies.
- **PERTUSSIS (aP)**, also known as Whooping Cough causes coughing spells so bad that it is hard for infants and children to eat, drink, or breathe. It can cause pneumonia, seizures, brain damage, or death.

Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

2. DTaP vaccine

Children should usually get 5 doses of DTaP vaccine, one dose at each of the following ages:

- 2 months
- 4 months
- 6 months
- 15–18 months
- 4–6 years

DTaP may be given at the same time as other vaccines. Also, sometimes a child can receive DTaP together with one or more other vaccines in a single shot.

3. Some children should not get DTaP vaccine or should wait

DTaP is only for children younger than 7 years old. DTaP vaccine is not appropriate for everyone – a small number of children should receive a different vaccine that contains only diphtheria and tetanus instead of DTaP.

Tell your health care provider if your child:

- Has had an **allergic reaction after a previous dose of DTaP**, or has any **severe, life-threatening allergies**.
- Has had a **coma or long repeated seizures within 7 days after a dose of DTaP**.
- Has **seizures or another nervous system problem**.
- Has had a condition called **Guillain-Barré Syndrome (GBS)**.

- Has had **severe pain or swelling after a previous dose** of DTaP or DT vaccine.

In some cases, your health care provider may decide to postpone your child's DTaP vaccination to a future visit.

Children with minor illnesses, such as a cold, may be vaccinated. Children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness, soreness, swelling, and tenderness where the shot is given are common after DTaP.
- Fever, fussiness, tiredness, poor appetite, and vomiting sometimes happen 1 to 3 days after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, the vaccine is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.
- Long-term seizures, coma, lowered consciousness, or permanent brain damage happen extremely rarely after DTaP vaccination.

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

5. What if there is a serious problem?

An allergic reaction could occur after the child leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the child to the nearest hospital.

For other signs that concern you, call your child's health care provider.

Serious reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor will usually file this report, or you can do it yourself. Visit www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, it does not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit www.hrsa.gov/vaccinecompensation or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7. How can I learn more?

- Ask your health care provider.
- 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 www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
DTaP (Tetanus, Diphtheria, Pertussis) Vaccine
(DATE)
42 U.S.C. § 300aa-26

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

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7.1



Promoting the HPV vaccine doesn't lead to more teen sex, study shows

Health Aug 13, 2018 5:44 PM EDT

Teens are no more sexually promiscuous in states that have passed legislation promoting the HPV vaccine than those living in states that have not, according to a newly published study.

The study, released in the journal *Pediatrics*, compared the District of Columbia and 23 U.S. states that passed legislation to promote the vaccine for human papillomavirus (HPV) with states with no such policies. Researchers then analyzed the results of a **multi-year survey** conducted by the Centers for Disease Control and Prevention to determine whether teens living in states with pro-HPV vaccine policies had more sex. They didn't, the study concluded.

"Concern that legislation will increase risky adolescent sexual behaviors should not be used when deciding to pass HPV legislation," the study said.

In states that promoted vaccines, these policies ranged from in-school awareness programs to incentivizing insurance companies to cover the vaccine's cost, said Erin Cook, the study's primary author who led this research as part of her doctoral dissertation in epidemiology at the Harvard T.H. Chan School of Public Health.

"The big takeaway is that passage of legislation regarding HPV didn't seem to be associated with any changes in adolescent sexual behaviors in the sample of states we were able to look at," Cook said.

The study did not examine how well these policies were implemented but simply used the mere presence or absence of such legislation as an indicator of a state's political will to act on HPV vaccine, cancer prevention and public health, she cautioned.

According to the CDC, some 79 million Americans have HPV; it's the most common sexually transmitted infection in the U.S., this latest study says. Another 14 million people are infected with HPV each year, the CDC says, many of them in their teens and early 20s. Cervical cancer cases **almost always link** back to the human papillomavirus, according to the *Lancet*.

The U.S. approved use of the three-dose HPV vaccine for girls in 2006 and for boys in 2011. By 2014, just a third of U.S. girls — 37 percent — and 13 percent of American boys had completed the vaccination course. By 2016, nearly half of U.S. girls were vaccinated.

Still, half of U.S. states have not implemented policies to promote the vaccine, which scientific research shows can effectively **prevent cancers caused by HPV infection**, according to the CDC.

These findings are not new, despite persistent attitudes that the HPV vaccine could encourage sexual promiscuity. In 2015, *JAMA* published a Harvard Medical School study that showed **no link between the vaccine** and a change in teen sexual behavior.

In 2007, Gary Freed, a pediatrician and professor at the University of Michigan, chaired the National Vaccine Advisory Council, and told **Now on PBS**: “If we have the ability to prevent any cancer deaths, much less a significant number of cancer deaths that affect a segment of our population that historically have not been necessarily as well served as they could have been, then I think it’s incumbent upon society to make sure that we’re able to prevent these cancers.”

Freed said this latest study reinforces the idea that teens are not deciding whether to have sex based on the threat of receiving an HPV infection. This is partly because so few people have heard of HPV, and because “adolescents think in the here and now, not 40 years from now.”

“We as a society need to decide how much we want to prevent cervical cancer for the children of today,” Freed said. “That’s really what this is all about. We can make pap smears a thing of the past.”

The U.S. is not alone in its sluggish implementation of a vaccine that can prevent illness and death as a result of cervical cancer. In 2016, **a study published in the Lancet** reported that out of 64 nations and 12 territories, only 47 million women finished the three-dose HPV vaccine course. Most of those women lived in high-income or upper middle income countries, the study said.

“Access to HPV vaccination in low-income and lower-middle-income countries is almost non-existent, despite these countries carrying most of the burden of cervical cancer cases worldwide,” the report said.

By – **Laura Santhanam**

Laura Santhanam is the Data Producer for the PBS NewsHour. [Follow @LauraSanthanam](#)

7.2



Wider use of rotavirus vaccine urged after 'potent' success of Malawi trial

Dramatic fall in infant deaths prompts calls for national immunisation programmes to incorporate treatment

Global development is supported by

BILL & MELINDA

GATES foundation About this content

Kate Hodal

Mon 13 Aug 2018 02.00 EDT

A rotavirus vaccine introduced in rural Malawi has reduced deaths from infant diarrhoea by more than a third, proving for the first time that a major intervention in a low-income country can be highly effective.

The findings, published in the *Lancet Global Health*, are likely to add further weight to calls by global health experts for rotavirus vaccine to be included in all national immunisation programmes.

“These findings are very, very encouraging indeed,” said Malawi’s chief of health services, Dr Charles Mwansambo.

“Rotavirus is a major problem in Malawi, but since the introduction of the vaccine we’ve seen remarkable drops in hospital admissions, proving that the vaccine is a worthwhile investment.”

Malawi introduced the monovalent rotavirus vaccine (RV1) in October 2012. For four years, scientists from the University of Liverpool, University College London, Johns Hopkins University and partners in Malawi tracked 48,672 infants born after the introduction of the vaccine. The monitoring, which covered more than 1,800 villages, involved documenting the childrens’ vaccination status and recording whether they survived beyond their first birthday.

Infants who received the vaccine had a 34% lower risk of dying from diarrhoea, researchers found - an impact similar to that seen in middle-income countries.

“Rotavirus remains a leading cause of severe diarrhoea and death among infants and young children in many countries in Africa and Asia,” said Professor Nigel Cunliffe from the University of Liverpool’s centre for global vaccine research, who led the study.

“Our findings strongly advocate the incorporation of rotavirus vaccine into the childhood immunisation programmes of countries with high rates of diarrhoea deaths, and support continued use in such countries where a vaccine has been introduced.”

Globally, rotavirus is the leading cause of severe diarrhoea, which claims the lives of an estimated 1,300 children daily, mainly in sub-Saharan Africa. Highly contagious, particularly among babies and young children, rotavirus can be spread by contaminated hands, objects such as toys and surfaces, and water and food. Diarrhoea is the second largest cause of death among infants and children worldwide, primarily in low-income countries, where access to clean water and sanitation is limited.

Although children in the world's poorest countries account for 82% of rotavirus deaths, vaccines make a significant difference. In Mexico, diarrhoeal deaths among children under five declined by as much as 50% after rotavirus vaccines were introduced.

Yet, of the 10 countries with the greatest number of rotavirus-related deaths, only six - Afghanistan, Angola, Ethiopia, India, Kenya and Pakistan - have introduced national rotavirus vaccines or initiated phased introductions, according to the Rota Council.

Through Gavi, the global vaccine alliance, a number of lower-income countries have been able to implement the inoculation nationally. But vaccine support is withdrawn as GDP increases, which has left a number of high-burden countries to choose between continued administration of the vaccine or devoting funds to other key areas.

Researchers believe the data from Malawi is likely to create a positive tipping point, given the significant reduction both in deaths from rotavirus infection and overall deaths from diarrhoea.

“This trial provides potent evidence that, because of the many different effects of the vaccine, it is a worthy public health intervention,” said UCL's Professor Robert Heyderman, who worked on the study.

“The key thing is that when a child gets diarrhoea, it leaves the child debilitated to other illnesses, such as malaria or pneumonia or something else, and that has a knock-on effect which can translate to poor performance in education or, ultimately, death. Although 34% doesn't sound large, it's a large impact on all infant diarrhoeal deaths. When we assessed the direct effect on rotavirus alone, the impact was very big - around 64%.”



A mother shows her baby's vaccination certificate in Rumphu, northern Malawi. Photograph: Danita Delimont/Alamy

The vaccine can also help to improve nutrition, said Dr Carina King, one of the report's lead authors and a senior research associate at UCL's institute for global health.

“Repeated episodes of diarrhoea can contribute to a child becoming malnourished over time. Stopping that cycle allows the child to be better nourished and develop greater immunity, preventing the child from getting sick and dying from something else,” said King.

By the end of the study, researchers noted 92% coverage across Malawi for the rotavirus RV1 vaccine - a very high turnout for one of the poorest nations in the world, said Heyderman.

“We have three regions in Malawi, and 28 district hospitals, each of which acts as a centre for immunisations, so we try as much as we can to get into the remotest parts of the country and get the vaccine to as many people as possible,” said Mwansambo.

“For those countries that haven't introduced the rotavirus vaccination, I don't know what they're waiting for. We know that it's effective and that our children deserve better. They need it.”

7.3



To Your Health

Tdap vaccine given to pregnant women did not increase risk of autism in children, study says

by **Lindsey Bever** August 13

New research has shown that a common childhood vaccination given to pregnant women does not put their children at any increased risk of autism.

A [Kaiser Permanente study](#) published Monday in the journal *Pediatrics* found no association between the prenatal Tdap (for [tetanus](#), [diphtheria and pertussis](#), also known as whooping cough) vaccine and autism spectrum disorder when looking at tens of thousands of children in the hospital system. It is the latest in a long line of studies showing that there is no link between vaccines and autism. Despite the abundant scientific evidence, a persistent conspiracy theory has misled some parents into fearing vaccines.

“If any woman had any hesitancy, she can be reassured,” Tracy Becerra-Culqui, lead author and postdoctoral research fellow with Kaiser Permanente Southern California's department of research and evaluation, told *The Washington Post*. When not vaccinated, she said, “the risk of getting whooping cough is greater than any perceived risk of harm to the baby, so it should be a no-brainer to accept the vaccine.”

The [Centers for Disease Control and Prevention](#), the [American College of Obstetricians and Gynecologists](#), and the [American College of Nurse-Midwives](#) encourage expectant mothers to get the Tdap vaccine in the third trimester of pregnancy to protect babies from bacterial infections that can be fatal for infants.

“Any woman who is pregnant may be concerned with any exposure inside or outside the health-care system,” Becerra-Culqui said, noting that some women who are encouraged by their doctors to get the Tdap vaccine may worry about it causing harm to their unborn babies.

“We wanted to get ahead of any concern — the prevailing concern being, 'Will my child develop some disease like autism?' ”

Childhood vaccinations — and vaccines in general — have been a controversial topic since 1998, when conspiracy theorist Andrew Wakefield [published a fraudulent research paper](#) purporting a connection between the MMR (measles, mumps and rubella) vaccine and autism. Though the British doctor and his research have been repeatedly discredited, the idea triggered inextinguishable worry among some parents who still opt not to get their children immunized.

As [The Post's Lena Sun has reported](#), although most parents in the United States vaccinate their children, “vaccine skepticism and outright refusal in recent years have led to places where there are [communities of undervaccinated children](#) who are more susceptible to disease and pose health risks to the broader public.”

Using electronic medical records from Kaiser Permanente Southern California hospitals, the researchers studied more than 80,000 children from a four-year period to determine whether there were more instances of autism among those whose mothers had been vaccinated during pregnancy.

The research showed that 569 children (or 1.5 percent) whose mothers received the vaccination were later diagnosed with autism, compared with 772 children (or 1.8 percent) whose mothers did not get the shot. Becerra-Culqui said in an email that after taking into account other differences between the vaccinated and unvaccinated groups, “there was no association found between the Tdap vaccine received during pregnancy and autism in children.”

Medical experts agree that vaccinations are needed — even before children are born — to protect the infants.

Texas pediatrician Jason Terk said that because tetanus, diphtheria and pertussis can be such serious illnesses for infants, it is recommended that pregnant women get the Tdap vaccine so that they can develop antibodies and pass them on “to protect the babies in those critical first few months.”

The [CDC recommends](#) that children receive their first DTaP vaccine at 2 months of age, but Terk said the children are not completely covered until after the second dose, which they are supposed to receive at 4 months of age. By giving the Tdap vaccine to pregnant women, doctors hope to protect babies during those first few months — when they are unvaccinated and most vulnerable to disease.

Saad Omer, a professor of global health, epidemiology and pediatrics at Emory University, said the study was comprehensive and well-designed.

The results, he said, are “not surprising” but “very reassuring.”
