ADVISORY COMMISSION ON CHILDHOOD VACCINES
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September 8, 2017

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

July 14, 2017

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

5600 Fishers Lane, Room 5N54
Rockville, MD 20857
Teleconference and Adobe Connect
Friday, September 8, 2017
(10:00 am Eastern Daylight Time)

Dial in:1-800-369-1833
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Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Ms. Beth Luthy, Interim Chair
10:10 AM	Public Comment on Agenda Items	Ms. Beth Luthy, Interim Chair
10:15 AM	Approval of December 2016 Minutes	Ms. Beth Luthy, Interim Chair
10:20 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Director, DICP
10:50 AM	Overview of Maternal Immunization Provisions and Proposed Changes to the Vaccine Injury Table	Dr. Narayan Nair Director, DICP
11:30 AM	Report from the Department of Justice	Ms. Sarah Duncan, Trial Attorney, Torts Branch, DOJ
12:00 PM	Lunch	
1:00 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimbakuro CDC
1:15 PM	Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Claire Schuster, MPH NIAID, NIH

Time	Agenda Item	Presenter
1:30 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	LCDR Valerie Marshall CBER, FDA
1:45 PM	Update from the National Vaccine Program Office (NVPO)	Dr. Karin Bok NVPO
2:00 PM	Public Comment (follows the preceding topic and may commence earlier or later than 2:00 pm)	
2:15 PM	Future Agenda Items/New Business	Ms. Beth Luthy, Interim Chair
2:30 PM	Adjournment of the September 8, 2017 ACCV Meeting	Ms. Beth Luthy, Interim Chair

Charter

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

42 U.S.C. 300aa-19, Section 2119 of the Public Health Service (PHS) Act. The Advisory Commission on Childhood Vaccines (hereinafter refen-ed to as the "Commission") is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. App. 2), which sets f01ih standards for the formation of advisory committees.

Objectives and Scope of Activities

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

Description of Duties

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

Agency or Official to Whom the Commission Reports

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

Supp01i

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

Estimated Annual Operating Costs and Staff Years

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

Designated Federal Official

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

Estimated Number and Frequency of Meetings

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

Duration

Continuing.

Termination

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

Membership and Designation

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

The Commission shall be composed of the following:

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

(A) tlnee 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) tlnee 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 Drng 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 Govermnent Employees. The ex officio members shall be Regular Government Employees.

Subcommittees

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

Recordkeeping

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

4 -ACCV Charter

Filing Date

July 21, 2016

Approved:

JUL 20 2016

Date

Roster

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2017 & 2018
Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2017 MEETING DATES

September 8, 2017
December 7 & 8, 2017

2018 MEETING DATES

March 8 & 9, 2018
June 14 & 15, 2018
September 6 & 7, 2018
December 6 & 7, 2018

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Advisory Commission on Childhood Vaccines (ACCV)

December 2, 2016
102nd Meeting

Members Present
Kristen A. Feemster, M.D., Chair ('16)
Jason Smith, J.D., Vice Chair ('16)
Charlene Douglas, Ph.D. ('16)
Edward Kraus, J.D. ('16)
Luisita dela Rosa, Ph.D. ('16)
Karlen E. Luthy, ('18)
Martha Toomey ('18)
Alexandra Stewart, ('18)

Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)
Narayan Nair, M.D., Director, DICP
Andrea Herzog, Principal Staff Liaison, ACCV

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

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

Public Comment on the Agenda Items

Dr. Feemster invited public comments concerning the agenda; there was none.

Approval of December 2016 ACCV Meeting Minutes

Dr. Feemster invited approval of the December 2016 meeting minutes. On motion duly made by Mr. Kraus, and seconded by Ms. Toomey, the minutes were approved unanimously.

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

Dr. Nair outlined the meeting agenda, noting that after his presentation Ms. Catharine Reeves would present information from the Department of Justice Vaccine Litigation Office; and Ms. Toomey, Chair of the ACCV Process Work Group, would provide an update; followed by update reports from the ACCV ex officio members from FDA, CDC, NIH, and NVPO.

Dr. Nair reported that for the years 2011 through 2016 the DICP received an average of 546 petitions per year. The yearly filings have increased annually and in fiscal year (FY) 2016,

1,120 petitions were filed, a significant increase over the prior year. The number of petitions received in FY 2017, through November 1, 2016, was 115.

Adjudications in FY 2016 totaled 837, of which 659 were deemed compensable and 178 were dismissed. So far in FY 2017 only 18 cases have been adjudicated, all of which were deemed compensable. In FY 2017, through November 14, 2016, 42 cases have been resolved: 10 through concessions by HHS; 1 decision handed down by the court; and 31 resolved by settlement agreement between the parties involved. Unlike previous years, all cases were non-autism claims. In FY 2016, the total petitioners' award was $228 million and attorneys received $21.6 million in fees and costs. To date in FY 2017, the total petitioners' awards are $17 million and attorneys' fees and costs are $2.5 million.

Dr. Nair reported that the Vaccine Injury Compensation Trust Fund (Trust Fund) stands at $3.6 billion. Excise tax added nearly $291 million and interest on the added nearly $99 million (25% of total revenues). In response to a clarifying question, Dr. Nair stated that, by statute, the money in the Trust Fund could only be used for petitioners' awards, attorney's fees and costs, and administrative expenses of the program.

Concerning program activities, Dr. Nair noted that a Notice of Proposed Rulemaking (NPRM) on revisions to the Vaccine Injury Table has reached the final rule stage and is being reviewed by HHS. Asked about a timeline, Dr. Nair said that the date of final approval is difficult to predict, but that his office is hopeful of an expeditious process.

Recent outreach activities included a presentation to the Association of State and Territorial Health Officials that resulted in the association mentioning the program in its regular newsletter, and adding a link on its web site so that interested individuals may look for information on the program. In September, an overview of the program was provided to the Public Health Service Physicians Professional Advisory Committee; and in October, the DICP participated in a webinar series entitled "Topics in Public Health."

Finally, Dr. Nair stated that a bill passed in the House of Representatives that would provide program coverage of vaccines recommended for routine use in pregnant women. That bill would have to clear the Senate as well, and then be signed into law by the President. He added that only the vaccines for pregnant women is included in the bill, and there were no other recommendations by the ACCV included in the bill (such as increasing the cap for pain and suffering, and expanding the statute of limitations).

There was a brief discussion about the timeline for nominations to fill the pending vacancies on the Commission and the appointment of a pediatrician to the Commission.

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

Ms. Reeves welcomed the commissioners. Ms. Reeves noted that the reporting period for the Department of Justice (DOJ) is different from that of the Division of Injury Compensation Programs. Ms. Reeves referenced the DOJ Power Point materials as part of her presentation for the three-month period from August 16, 2016 to November 15, 2016. During this reporting period, 355 petitions were filed, which is an increase of 79 petitions compared to last period. Of those 355, 34 were filed on behalf of children (10%) and 321 were filed by adults (90%). (DOJ PP at 2).

With regard to total cases adjudicated, Ms. Reeves noted that 222 claims were adjudicated this quarter. (DOJ PP at 3). There were 178 cases compensated. Of those 178

cases, 47 were conceded by HHS. Of those 47 conceded cases, all 47 were resolved by a decision adopting a proffer. Ms. Reeves noted that 11 fewer cases were adjudicated this period than last period. There were 131 cases compensated but not conceded by HHS. Of those, all 131 cases were resolved by a decision adopting a settlement stipulation. (DOJ PP at 3). There were 44 cases dismissed. Of those, 42 non-OAP cases were resolved by decisions dismissing the petition, and 2 were dismissed from the OAP. (DOJ PP at 3). There were 10 petitions voluntarily withdrawn, which Ms. Reeves remarked was a decrease of 3 compared to last period. (DOJ PP at 4).

Turning to appeals, four cases filed by petitioners at the U.S. Court of Appeals for the Federal Circuit (CAFC) were quickly voluntarily dismissed because they had not been heard by the Court of Federal Claims (CFC) and therefore the CAFC did not have jurisdiction to hear the appeals. (DOJ PP at 5). A fifth case, *R.V. v. HHS*, was also voluntarily dismissed by petitioners. In addition to four appeals filed by petitioners that are pending, three new appeals were filed by petitioners in *Murphy v. HHS*, *H.L. v. HHS*, and *Lasnetski v. HHS.* (DOJ PP at 6). In *Canuto v. HHS*, one of the four pending cases, a petition for panel re-hearing was denied, which effectively ended the appeal. Petitioners may choose to file for certiorari at the Supreme Court.

Ms. Reeves discussed appeals at the CFC, and noted that three appeals filed by petitioners were decided by the CFC. (DOJ PP at 7). One of the three appeals concerned attorneys' fees and costs and two concerned entitlement. The court affirmed the special master's decisions in the cases concerning entitlement. In *Reiling v. HHS*, petitioner's attorney filed a motion for review after he had withdrawn his appearance as attorney for petitioner, and the CFC dismissed the motion for lack of jurisdiction. Ms. Reeves reported that the CFC also decided three appeals filed by respondent. (DOJ PP at 7). In *Garrison v. HHS*, the special master's award of forum rates to petitioner's attorney was affirmed. In *Allicock v. HHS*, the CFC affirmed the special master's decision finding reasonable basis to award attorneys' fees and costs. In *Simmons v. HHS*, the CFC reversed the special master's decision finding reasonable basis to award attorneys' fees and costs. Ms. Reeves noted that petitioners filed six new appeals to the CFC, 4 of which involve entitlement, and 2 of which involve attorneys' fees and costs. (DOJ PP at 8). Nine cases remain pending at the CFC. (DOJ PP 8).

One oral argument is scheduled at the CAFC in *R.K v. HHS*. There was an oral argument in *Rich v. HHS* before the CFC and the decision is pending. (DOJ PP at 9).

Ms. Reeves noted the history of adjudicated settlements, which are listed in order of the time they took to resolve. (DOJ PP at 10-23). Most of the cases involved influenza vaccine and injuries related to Guillain-Barré Syndrome and shoulder injury related to vaccine administration (SIRVA).

Update from the ACCV Process Work Group, Martha Toomey, Work Group Chair, ACCV Member

Ms. Toomey reported that the Process Work Group recommendation regarding increasing resources did not specify when recommendation was submitted to the Secretary of the Department of Health and Human Services. Ms. Herzog commented that the cover letter and recommendation required signatures from the ACCV Chair and Vice Chair before submission and informed the ACCV that the recommendation was circulated for signatures. Mr. Jason Smith, Vice Chair, ACCV, stated that he had signed and sent the signed document to Dr. Nair's office via UPS the previous day, so the signed letter and recommendation should be ready for

delivery soon. Ms. Toomey informed the ACCV that the Process Work Group discussed other recommendations under consideration and agreed to delay submitting those recommendations until after the inauguration. Ms. Toomey stated that her report was concluded.

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

Dr. McNeil stated that he would review the recent October meeting of the Advisory Committee on Immunization Practices (ACIP), and briefly discuss several vaccine-related publications not previously addressed in ACCV meetings. The ACIP in a session on hepatitis B vaccine considered the recommendations of the American Association for the Study of Liver Disease. The modified ACIP recommendations included the following: 1) antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg+ pregnant women; 2) removal of permissive language for delaying a birth dose for all medically stable infants weighing 2,000 grams or more, noting that the hepatitis B vaccine should be administered within 24 hours of birth; and 3) hepatitis B vaccine for those with existing hepatitis C infection. There was a vote to accept the updated hepatitis B recommendations and the Vaccine for Children (VFC) resolution.

Turning to pertussis vaccine, Dr. McNeil commented that there was a vote to accept the updated statement in "Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States," as recommended by ACIP. There were no new vaccine recommendations. There was discussion of timing of vaccinations and, although there is variance in other countries, the ACIP agreed that the current recommendation should be followed – Tdap administered between 27 and 36 weeks of gestation. There is some data that indicate that vaccination in the early part of that time window will maximize passive antibody transfer to the infant.

The ISO has assessed data from three surveillance systems with regard to maternal Tdap safety. The Vaccine Adverse Event Reporting System (VAERS) conducts ongoing monitoring through voluntary reports of adverse events from several sources – clinics, physicians, and private individuals. The Vaccine Safety Datalink (VSD) has provided data on preterm delivery and small for gestational age infants, other vaccine-related adverse events, obstetric adverse events and birth defects. The VSD has access to electronic medical records from several large healthcare services for their statistical analysis. The Clinical Immunization Safety Assessment (CISA) project monitors vaccine safety in pregnant women and assessed the safety of simultaneous Tdap and inactivate influenza vaccine (IIV) immunization in pregnant women.

In summary, data to date are reassuring, VAERS shows that the pattern of adverse events in women receiving Tdap is consistent with expectations. In the VSD, a study of 50,000 women who received Tdap during pregnancy showed no increased risk. In the CISA project, Tdap was well tolerated in both pregnant and non-pregnant women.

Moving to human papillomavirus vaccines, the ACIP work group proposed a dose modification in the recommendation for young people who initiate inoculation age 9 to 14 years. The FDA approved a 2-dose series of 9vHPV for that population, and trials of the immune response with that schedule proved as good as the prior 3-dose regimen (although the recommendation stands for a 3-dose regimen for individuals beginning immunization after age 15). There was a vote in the ACIP to endorse 2 dose HPV immunization regimen before the 15th birthday, with the second of two doses administered 6 to 12 months after the first dose. For those 15 years and older the recommendation is for three doses, with the second dose at 1-2 months and the third at 6 months. There was a brief discussion about the rationale for a two-

dose regimen for those under 15 and a three-dose regimen for those 15 and older. Dr. Feemster commented that trials had shown that the immune response in the younger individuals reached about the same efficacy level as the immune response in the older group for those respective vaccine schedules. Therefore, it indicated that a third dose was not constructive for the younger individuals.

With regard to meningococcal vaccines, Dr. McNeil noted that there were two licensed vaccines in the U.S. for people 10 to 25 years of age. The ACIP modified its recommendation for Trumemba (Pfizer), which is licensed as a three-dose regimen for individuals at higher risk of meningococcal virus infections and for anyone who is in an outbreak area; to allow for it to be given as a two-dose regimen for healthy adolescents. There was a vote in the AICP to accept the recommendation and Vaccine for Children resolution.

Dr. McNeil commented on a new herpes zoster vaccine developed by GSK, an adjuvanted, subunit zoster vaccine with a two-dose schedule (0 and 2 months) for persons 50 years of age and older. GSK will submit a biologic license application (BLA) by the end of the year. Efficacy is excellent – 97% in the 50-59 age group, 91% for those 80 and older. Efficacy of greater than 85% is maintained through four years for all ages. Adverse reactions are relatively common, but are mainly minor injection site problems and nonspecific systemic effects.

An interagency working group has been established to address the Zika virus issues. It will evaluate candidate vaccines with an objective of developing one or more candidate vaccines that would be available by 2018. There are several candidate vaccines in preclinical development or Phase I trials now, and Phase II studies are scheduled for 2017. The ACIP will include a session on Zika virus at its February 2017 meeting.

The ACIP called the development and use of pneumococcal vaccine PCV13 a success story. Introduction of PCV13 in 2014 in the childhood schedule had markedly reduced the incidence of invasive pneumococcal disease in adults 65 and older, and the reduction suggests that benefits observed to date are largely due to indirect PCV13 effects. Most of the remaining burden of disease in adults can be traced to non-PCV13 serotypes.

The ACIP addressed influenza vaccines, noting that there is a low level of influenza activity in the US and the infections are mainly H3N2 strains (90%), although the pandemic H1N1 and H3N2 continue to circulate worldwide. The recent recommended components of the 2017 Southern Hemisphere vaccine include an updated H1N1 component, the first change for that strain since the 2009 pandemic. Labs worldwide continue to indicate that most currently circulating virus strains are antigenically similar to the vaccine viruses included in the 2016-2017 vaccines, which is good news. There are two newly icensed flu vaccines – Afluria quadrivalent (Seqirus) and Flublok quadrivalent (Protein Science). The latter is an insect cell line formulation and considered egg free.

The ACIP discussed respiratory syncytial virus. Respiratory syncytial virus (RSV) is an important factor in lower respiratory tract infections causing hospitalization in older adults. Novavax developed an RSV F-protein recombinant nanoparticle vaccine that fared well in Phase II trials in older adults, but failed to show efficacy in a subsequent Phase III trial. The company is trying to discover the reason for that failure. There is also a different RSV formulation prototype vaccine with an aluminum adjuvant being tested in pregnant women.

Dr. McNeil briefly mentioned a number of recent publications.

- Grohskopf et al. published in the MMWR updated ACIP recommendations on prevention and control of seasonal flu with vaccine recommendations. (MMWR Recomm Rep. 2016; 65 (5): 1-54)

- Bardenheier et al evaluated anthrax vaccine adsorbed given to US military personnel, and found an association with recent onset rheumatoid arthritis (RA); however, it did not increase the risk of RA in the long term. Nor was it associated with onset of systemic lupus erythematosus. The vaccine may have triggered RA earlier than expected, but it is thought likely that the condition would have eventually developed even without the vaccine. (Mil. Med. 2016; 181(10):1348-1356)

- Lauren et al. published a case report of subcutaneous nodules and sterile abscesses due to delayed type hypersensitivity to aluminum-containing vaccines. Anaphylaxis is a risk for any inoculation, but the delayed type hypersensitivity is relatively rare. (Pediatrics 2016. Epub ahead of print)

- Baxter et al. looked at acute demyelinating events following vaccination and found no association between transverse myelitis and prior immunization, although there was a possible association of acute disseminated encephalomyelitis (ADEM) with Tdap vaccine (probably no more than 1.16 cases per million vaccines administered). (Clin Infect Dis. 2016. – Epub ahead of print)

- DeSilva et al published a report based on Vaccine Safety Datalink data that showed that maternal Tdap was not significantly associated with increased risk of microcephaly for inoculations occurring at less than 14 weeks of gestation. (JAMA 2016; 316(17): 1823-1825)

Dr. McNeil concluded his report.

Update from the National Institute of Allergy and Infectious Diseases (NIAID, NIH), Vaccine Activities, Claire Schuster, NIAID, NIH

Ms. Schuster announced an early stage investigational trial of Zika Purified Inactivated Virus (ZPIV) vaccine that is based on technology that was developed at the Walter Reed Army Institute of Research (WRAIR) in Maryland. The technology is based on earlier work in 2009 by WRAIR to develop a vaccine for another flavivirus, Japanese encephalitis. The inactivated Zika virus vaccine cannot replicate and cause infection in humans. WRAIR, NIAID and the HHS Biomedical Advanced R&D Authority (BARDA) have established a collaboration to pursue development of the vaccine. A Phase I trial is underway at WRAIR to test the vaccine's safety and ability to generate an immune response. It will recruit individuals from 18 to 49 years of age with no previous infection by a flavivirus (e.g., Zika, yellow fever, dengue, Japanese encephalitis, and West Nile virus).

Another Phase 1 trial of this investigational vaccine is being conducted at the NIAID-funded Vaccine and Treatment Evaluation Unit at St. Louis University. In addition, a WRAIR-funded trial at the Center for Virology and Vaccine Research, part of Beth Israel Deaconess

Medical Center, and Harvard Medical School, is recruiting participants for a trial. Additional trials of the ZPIV vaccine are being planned.

Recent Zika-related publications include a paper by Dowd et al, Rapid Developments of a DNA Vaccine for Zika Virus (Science October 14, 2016); and Marston et al, Considerations for Developing a Zika Virus Vaccine (New England Journal of Medicine September 29, 2016).

NIH is supporting research to develop a patch to administer flu vaccine. The patch contains tiny microneedles that contain the vaccine, which dissolve in the skin. After application, the patch is removed and discarded. Nearly a hundred individuals participated in a trial to assess the appeal of the patch. Of participants who had not planned to get a flu vaccine, 35% opted to accept vaccination using the patch. The patch can be self-administered, requires no refrigeration, and remains stable until used. The November 4th issue of the NIH Record described the patch.

Another patch was developed that delivers a small amount of peanut protein through the skin to treat peanut allergies. The treatment is called epicutaneous immunotherapy and was shown to be effective, safe and well-tolerated. Seventy-four peanut-allergic volunteers between 4 and 25 years of age participated in a randomized placebo controlled trial that consisted of a low-dose and high-dose cohort. After one year, the investigators tested tolerance of each individual to consume ten times the peanut volume than before treatment. The study found that 46% of the low-dose group and 48% of the high-dose group achieved treatment success compared with 12% of the placebo group.

A different NIAID-supported study involves the hypothesis that the infant gut microbiome may influence the immune response to allergies and asthma in early childhood. Researchers at the University of California – San Francisco and the Henry Ford Health System in Detroit, studied microbiota that reside in the infant digestive tract. They identified a type of microbiota composition that appears to play a role in this process. The high-risk group identified by the researchers had a relatively lower abundance of certain bacteria and an increased abundance of specific fungi. Fujimura et al. in Nature Medicine reported the study.

Finally, Ms. Schuster reported that a large study of HIV vaccine efficacy (HVTN702) is being launched in South Africa, with support from NIAID, the Bill and Melinda Gates Foundation, and the South African Medical Council. It will build on the modest success of another HIV vaccine study (RV144) completed in Thailand. Ms. Schuster ended her report.

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

LCDR Marshall addressed FDA vaccine supplement approvals. In September, the FDA approved a supplement to the biological license application (BLA) for Daptacel to add immunogenicity and safety data to support the co-administration of Meningococcal (Groups A, C, Y and W-135) polysaccharide diphtheria toxoid conjugate vaccine (Menactra) with a fifth dose of Daptacel for children 4 through 6 years of age. Also in September, FDA approved a supplement to the BLA for Q-Pan to extend the age range of the vaccine to include persons 6 months through 17 years of age at increased risk of exposure to influenza A virus H5N1 subtype contained in the vaccine. The vaccine was previously approved for use in persons 18 years of age and older. The vaccine is not intended for commercial availability and was purchased for the national vaccine stockpile to be distributed in the event of a pandemic.

LCDR Marshall discussed two FDA publications. The first, by Khurana et al, in Nature Medicine (October 2016), was entitled "Human antibody repertoire following VSV-Ebola vaccination identified novel targets and virus neutralizing IgM antibodies." The FDA researchers demonstrated novel immune system targets on Ebola virus and identified the major type of vaccine-triggered antibodies that neutralize the virus. The findings also demonstrate that selection of the appropriate assay may be important for evaluating effective vaccines against the Ebola virus.

The second publication, "Zika (PRVABC59) infections associated with T-cell infiltration and neurodegeneration of the central nervous system in immunocompetent neonatal mice," looks at the use of neonatal C57Bl/6 mice to explore potential activity of Zika virus vaccines and therapeutics. This mouse model provides a platform for potentially improving and expediting studies to understand the causes and effect of the Zika virus. LCDR Marshall concluded her presentation.

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

Dr. Bok provided an update on the NVPO's pilot project on cooperative agreements for vaccine safety and the decision to extend the agreement based on initial positive results. The rationale for the agreement is to strengthen vaccine safety research in areas for which national surveillance system intervention or pre-clinical funding would not be suitable. The program funds exploratory research and early programmatic interventions that might influence scientific advancement and policy. It supports the objectives of the Assistant Secretary for Health in defining public health policy, and links NVPO with the vaccine safety community to address vaccine safety research hurdles and gaps.

NVPO funded two cooperative agreements for $250,000 each to help determine safety profiles of new vaccines in early development; modifying existing vaccines to improve their safety profiles; support applied research that will inform the current vaccine safety monitoring system; and conduct research that will promote consensus definitions of vaccine safety outcomes. One of those agreements, creation and analysis of a maternal-neonatal vaccine safety database, was awarded to Kaiser Hospital Foundation in Oakland. They have published one study and are currently completing a second analysis of alternative benefits of influenza vaccine during pregnancy. The cooperative agreement will also fund, at a different branch of the Kaiser Foundation in Portland, a program to prevent injection site pain and syncope associated with pre-teen and teen vaccinations.

Based on the success of the pilot program, a decision was made to renew the program with the FY 2017 Cooperative Agreement Program, with increased funding up to $750,000 per award. The objectives of the FY 2017 Cooperative Agreement Program is:

1. Research to better understand immunization safety in older adults; prediction of safety profiles of vaccines during early development before testing in humans;
2. Improvement of safety of existing vaccines; research to improve vaccine surveillance systems;
3. Research to improve the safety of currently marketed vaccines; and
4. Support for the Assistant Secretary for Health in analyzing bio-specimens to understand differences in genetic or metabolic profiles that may correlate with an individual's predisposition to immunization-related adverse outcomes.

The invitation to submit proposals will be released in January with responses due in March.

Finally, Dr. Bok announced that on September 20, 2016 the National Vaccine Advisory Committee voted on new recommendations to the Assistant Secretary for Health related to overcoming barriers and identifying opportunities for developing maternal immunizations.

Dr. Bok concluded her comments.

Public Comment

Dr. Feemster invited public comment. Hearing no requests to speak, she moved to the agenda item inviting Commission members to suggest new agenda topics for the next meeting.

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

Dr. Feemster invited comments. Mr. Kraus suggested adding time for a report on legislation that amends the Vaccine Act to include the maternal immunization changes. There was a suggestion that a presentation on the vaccine manufacturing process might be of interest, since the Commission generally focuses on post-licensure issues. There was consensus that the discussion would be helpful, and Mr. Smith, the ACCV member who serves as the vaccine manufacturer's attorney, offered to inquire about the possibility that his company could provide support for the discussion. Dr. Nair expressed interest in whether the presentation should focus on the FDA perspective or from the industry perspective. There was a comment that combining both would be more informative. There was a suggestion that including a brief discussion about the patch device discussed earlier in the meeting would be appropriate. Finally, there was a comment that a briefing would be informative on the transition in the White House and changes in Congress, and the prospects for future legislation.

Adjournment

There being no other comments from Commission members, on motion duly made by Mr. Kraus and seconded by Ms. Toomey, the Commission unanimously approved adjournment.

3

Vaccine Injury Compensation Trust Fund

Balance as of July 31, 2017

$3,633,889,437

Figures for October 1, 2016 to July 31, 2017

- Excise Tax Revenue: $181,464,471
- Interest on Investments: $46,928,638
- Total Income: $228,393,110
- Interest as a Percentage of Total Income: 20.5%

Source: U.S. Treasury, Bureau of Public Debt
August 31, 2017

4

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

Data & Statistics

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

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

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

- 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 2015 over 2.8 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 4,528 petitions were adjudicated by the Court, and of those 2,962 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 18,426 petitions have been filed with the VICP. Over that 29-year time period, 16,555 petitions have been adjudicated, with 5,581 of those determined to be compensable, while 10,974 were dismissed. Total compensation paid over the life of the program is approximately $3.7 billion.

VICP Adjudication Categories, by Alleged Vaccine, For Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 Through 12/31/2015

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 12/31/2015 (Source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
DT	756,377	1		5	6	4	10
DTaP	88,814,104	15	23	98	136	99	235
DTaP-Hep B-IPV	56,700,877	4	8	24	36	42	78
DTaP-HIB	1,135,474		1	2	3	2	5
DTaP-IPV	18,613,490			2	2	1	3
DTap-IPV-HIB	52,242,336	2	2	7	11	23	34
DTP	0	1	1	3	5	2	7
DTP-HIB	0			3	3	1	4
Hep A-Hep B	13,767,345			15	15	3	18
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	150,276,481	5	4	33	42	26	68
Hepatitis B (Hep B)	158,988,970	4	11	57	72	57	129
HIB	101,459,227	1	1	5	7	8	15
HPV	89,696,704	15	13	95	123	140	263

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 12/31/2015 (Source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
Influenza	1,226,400,000	232	138	1,528	1,898	299	2,197
IPV	65,399,472			4	4	3	7
Measles	135,660			1	1		1
Meningococcal	70,797,701	1	4	31	36	7	43
MMR	87,990,038	20	16	77	113	96	209
Mumps	110,749						
MMR-Varicella	18,023,247	8	1	9	18	10	28
Nonqualified	N/A			3	3	28	31
OPV	0	1			1	5	6
Pneumococcal Conjugate	180,357,916		1	7	8	20	28
Rotavirus	89,501,227	8	4	17	29	10	39
Rubella	422,548		1	1	2		2
Td	60,068,722	8	7	55	70	23	93
Tdap	202,021,173	50	13	1742	237	41	278
Tetanus	3,836,052	5	1	29	35	18	53
Unspecified	N/A	1	1	3	5	580	585
Varicella	103,643,469	4	8	25	37	17	54
Grand Total	**2,845,946,816**	**387**	**260**	**2,315**	**2,962**	**1,566**	**4,528**

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2015 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 08/01/2017

Vaccines	Filed			Compensated	Dismissed
	Injury	Death	Grand Total		
DTaP-IPV	8	0	8	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	429	81	510	217	238
DTaP-Hep B-IPV	73	32	105	37	43
DTaP-HIB	11	1	12	6	3
DTaP-IPV-HIB	39	19	58	11	22
Td	199	3	202	117	73
Tdap	484	3	487	276	44
Tetanus	124	2	126	63	45
Hepatitis A (Hep A)	95	6	101	43	27
Hepatitis B (Hep B)	665	57	722	266	400
Hep A-Hep B	26	0	26	16	4
Hep B-HIB	8	0	8	5	3
HIB	42	3	45	14	19
HPV	343	14	357	119	137
Influenza	3,519	127	3,646	2,186	321
IPV	265	14	279	8	269
OPV	282	28	310	158	151
Measles	143	19	162	55	107
Meningococcal	60	2	62	37	6
MMR	948	61	1,009	396	555
MMR-Varicella	39	1	40	19	11
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	107	10	117	23	37
Rotavirus	79	4	83	51	21
Rubella	190	4	194	71	123
Varicella	92	9	101	60	29
Nonqualified1	97	9	106	3	97
Unspecified2	5,421	9	5,430	7	5,383
Grand Total	**17,192**	**1,234**	**18,426**	**5,581**	**10,974**

[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	987
Total	**18,426**

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	2,534	2,799
FY 2013	369	649	1,018
FY 2014	371	195	566
FY 2015	517	114	631
FY 2016	696	179	875
FY 2017	536	111	647
Total	**5,581**	**10,974**	**16,555**

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	91	$2,430,293.74	59	$3,502,709.91	$252,299,135.97

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2017	610	$232,667,154.63	$19,115,679.76	108	$3,783,818.42	46	$3,153,930.53	$258,720,583.34
Total	**5,571**	**$3,468,916,800.58**	**$167,545,317.02**	**5,207**	**$73,968,458.84**	**360**	**$27,453,911.23**	**$3,737,884,487.67**

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals,

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.

5.1

The National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines

September 8, 2017

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
- Presentation: 21st Century Cures Act
- Presentation: Proposed Changes to the VICP Injury Table
- Update from the Department of Justice Vaccine Litigation Office
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH, NVPO

HRSA Healthcare Systems

DICP Update
Number of Petitions Filed as of August 1, 2017

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

Fiscal Year	Total
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	987

DICP Update
Number of Adjudications as of August 1, 2017

Fiscal Year	Compensable	Dismissed	Total
FY 2011	266	1,740	2,006
FY 2012	265	2,534	2,799
FY 2013	369	649	1,018
FY 2014	371	195	566
FY 2015	517	114	631
FY 2016	696	179	875
FY 2017	536	111	647

DICP Update

Adjudication Categories for Non-Autism Claims
FY 2015– FY 2017 as of August 19, 2017

Adjudication Category	FY 2015	FY 2016	FY 2017
Compensable ❖Concession ❖Court Decision (includes proffers) ❖Settlement	517 (100%) 89 (17%) 38 (7%) 390 (75%)	697 (100%) 204 (29%) 44 (6%) 449 (64%)	595 (100%) 156 (26%) 40 (7%) 399 (67%)
Not Compensable	119	168	135
Adjudication Total	636	865	730

DICP Update
Award Amounts Paid as of August 1, 2017

Fiscal Year	Petitioners' Award	Attorneys' Fees & Costs
FY 2011	$216,319,428	$17,163,231
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	$22,158,885
FY 2017	$232,667,155	$26,053,429

DICP Update
Vaccine Injury Compensation Trust Fund

- **Balance as of July 31, 2017**
  - $3,633,889,437
- **Activity from October 1, 2016 to June 30, 2017**
  - Excise Tax Revenue: $181,464,471
  - Interest on Investments: $46,928,638
  - Net Income: $228,393,109
  - Interest as a Percentage of Net Income: 20.5%

Source: U.S. Treasury, Bureau of Public Debt (August 31, 2017)

HRSA Healthcare Systems

DICP Update
Significant Activities

- **Status of Revisions to Vaccine Injury Table Notice of Proposed Rulemaking (NPRM)**
  - Revisions to the Vaccine Injury Table Final Rule went into effect on March 21, 2017

- **Implementation of Maternal Immunization Provisions**
  - Updated VICP Website
  - Planned consultation with ACCV regarding revising the Vaccine Injury Table

- **Highlights of Recent Outreach Activities**
  - Presented overview of maternal immunization provisions at the National Vaccine Advisory Committee Meeting in February
  - Presented at Johns Hopkins University

DICP Update
ACCV Meeting Information

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

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

DICP Update
Contact Information
Public Comment/Participation in Commission Meetings

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5.2

The 21st Century Cures Act and the National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs

Advisory Commission on Childhood Vaccines

September 8, 2017

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

HRSA Healthcare Systems

VICP Update– 21st Century Cures Act
Overview

- 21st Century Cures Act enacted on December 13, 2016
- Discussion of 21st Century Cures Act provisions which amend the National Childhood Vaccine Injury Act of 1986

VICP Update– 21st Century Cures Act

Maternal Immunization Provisions

- The 21st Century Cures Act amends the National Childhood Vaccine Injury Act to require that the Secretary revise the Vaccine Injury Table to include vaccines recommended by the CDC for routine administration in pregnant women - (42 U.S.C. 300aa-14(e)(3))

VICP Update – 21st Century Cures Act
Maternal Immunization Provisions

- Both a woman who received the vaccine while pregnant and any child who was in utero at the time shall be considered persons to whom the vaccine was administered and persons who received the covered vaccines - (42 U.S.C. 300aa-11(f)(1))
- The 21st Century Cures Act provides a specific definition for the term "child," as used in the Vaccine Act with respect to maternal immunization, which requires that the child be born alive - (42 U.S.C. 300aa-11(f)(2))

VICP Update – 21st Century Cures Act
Maternal Immunization Provisions

- A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine (42 U.S.C. 300aa-11(b)(2))

Contact Information

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HRSA
Healthcare Systems

The National Vaccine Injury Compensation Program (VICP)

Proposed Changes to the Vaccine Injury Table to Add Vaccines Recommended by the CDC for Routine Administration to Pregnant Women

Advisory Commission on Childhood Vaccines

September 8, 2017

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

HRSA Healthcare Systems

Proposed Changes to the Vaccine Injury Table
Overview

- 21st Century Cures Act enacted on December 13, 2016

- Discussion of proposed changes to the Vaccine Injury Table based on a provision in the 21st Century Cures Act

Proposed Changes to the Vaccine Injury Table
21st Century Cures Act – Maternal Immunization Provision

- **The 21st Century Cures Act amends the National Childhood Vaccine Injury Act of 1986 to require that the Secretary revise the Vaccine Injury Table to include vaccines recommended by the CDC for routine administration in pregnant women**
    - Develop a Notice of Proposed Rulemaking (NPRM) to revise the Table

Proposed Changes to the Vaccine Injury Table

Option 1

- **Option 1: Revise Category XVII (New Vaccines) to add "and/or pregnant women"**

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage	No Condition Specified	Not applicable.

Proposed Changes to the Vaccine Injury Table

Option 2

- **Option 2: Create a Category XVIII (New Vaccines for Pregnant Women)**

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
XVIII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to pregnant women, after publication by the Secretary of a notice of coverage	No Condition Specified	Not applicable.

Proposed Changes to the Vaccine Injury Table

Option 3

- **Option 3: Present Options 1 and 2 in NPRM to obtain public comments regarding both options**

Contact Information

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HRSA Healthcare Systems

5.3

Report from the Department of Justice

September 8, 2017

Sarah C. Duncan
Trial Attorney

Statistics

Reporting Period: 11/16/16 – 8/15/17

I. Total Petitions Filed in the United States Court of Federal Claims this reporting period: 856

A. Minors: 103

B. Adults: 753

Statistics

Reporting Period: 11/16/16 – 8/15/17

II. Total Petitions Adjudicated this reporting period: 593

A. Compensated: 485

i. Cases conceded by HHS: 153

1. Decision awarding damages: 0
2. Decision adopting Proffer: 153
3. Decision adopting Settlement: 0

ii. Cases not conceded by HHS: 332

1. Decision awarding damages: 0
2. Decision adopting Proffer: 0
3. Decision adopting Settlement: 332

B. Not Compensated/Dismissed: 108

i. Decision dismissing Non-OAP: 103

ii. Decision dismissing OAP: 5

Statistics

Reporting Period: 11/16/16 – 8/15/17

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 45

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

Recently Decided Cases

Appeals by Petitioner:

- *R.K. v. HHS* (Entitlement): Affirmed per curiam
- *Contreras v. HHS* (Entitlement): Remanded
  - Parties reached a tentative settlement agreement; approval is pending
- *Murphy v. HHS* (Entitlement): Voluntarily Dismissed
- *G.G.M. v. HHS* (Entitlement): Dismissed
  - CAFC ruled appellant could file another RCFC 60(b) motion raising argument raised in amicus brief; petitioner filed a new motion for 60(b) relief which was granted by SM Millman on 5/25/2017
- *Osele v. HHS* (Entitlement): Dismissed
- *Moriarty v. HHS* (Entitlement): Remanded
- *Lasnetski v. HHS* (Entitlement): Affirmed

Appeals by Respondent:

- *Allicock v. HHS* (Attys' Fees and Costs): Voluntarily Dismissed

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

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

Pending Cases

Appeals by Petitioner:

- *H.L. v. HHS* (Entitlement)
- *Simmons v. HHS* (Attys' Fees and Costs)
- *D'Tiole v. HHS* (Entitlement)
- *Anderson v. HHS* (Entitlement)

*Yellow[illegible] are new this reporting period

Appeals: U.S. Court of Federal Claims

Recently Decided Cases

Appeals by Petitioner:

- *Curran v. HHS* (Attys' Fees and Costs): Affirmed in part
  - Remanded for "wind up" expenses
- *Brannigan v. HHS* (Interim Attys' Fees): Affirmed
- *Rich v. HHS* (Entitlement): Affirmed
- *Raymo v. HHS* (Attys' Fees and Costs): Affirmed
- *Mounts v. HHS* (Attys' Fees and Costs): Affirmed
- *Cunningham v. HHS* (Entitlement): Affirmed
- *Rus v. HHS* (Entitlement): Affirmed
- *Rehn v. HHS* (Attys' Fees and Costs): Affirmed
- *Tarsell v. HHS* (Entitlement): Remanded

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

Appeals: U.S. Court of Federal Claims

Recently Decided Cases (cont'd)

Appeals by Petitioner (cont'd) :

- *Loutos v. HHS* (Entitlement): Dismissed as Untimely
- *K.T. v. HHS* (Entitlement): Affirmed
- *Mondello v. HHS* (Entitlement): Remanded
- *Phillips, Ivan v. HHS* (Entitlement): Affirmed
- *Phillips, Ivana v. HHS* (Entitlement): Affirmed
- *Phillips, Ivanka v. HHS* (Entitlement): Affirmed
- *Anthony v. HHS* (Attys' Fees and Costs): Voluntarily Dismissed
- *Holt v. HHS* (Entitlement): Affirmed
- *Mette v. HHS* (Entitlement): Affirmed
- *Spahn v. HHS* (Entitlement): Affirmed in part
  - Remanded issue of interim fees and costs

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

Appeals: U.S. Court of Federal Claims

Recently Decided Cases (cont'd)

Appeals by Petitioner (cont'd):

- *Carter v. HHS (*Attys' Fees and Costs): Affirmed
- *Oliver v. HHS* (Entitlement): Affirmed
- *Depena v. HHS* (Entitlement): Affirmed
- *K.L. v. HHS* (Attys' Fees and Costs): Affirmed
- *Garner v. HHS* (Entitlement): Affirmed
- *Anderson v. HHS* (Entitlement): Affirmed
- *D'Tiole v. HHS* (Entitlement): Affirmed

Appeals by Respondent:

- *Day v. HHS* (Interim Damages): Affirmed

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

Appeals: U.S. Court of Federal Claims

Pending Cases

Appeals by Petitioner:

- *Cottingham v. HHS* (Attys' Fees and Costs)
- *Abbott v. HHS* (Attys' Fees and Costs)
- *Erxleben v. HHS* (Entitlement)
- *Dean v. HHS* (Entitlement)
- *Santacroce v. HHS* (Attys' Fees and Costs)
- *Olson v. HHS* (Entitlement)

*Yellow[illegible]s are new this reporting period

Scheduled Oral Arguments

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

- *H.L. v. HHS* (Entitlement): 10/3/2017
- *Simmons v. HHS* (Attys' Fees and Costs): 10/4/2017

U.S. Court of Federal Claims:

- None scheduled at this time.

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
1. DTaP	Developmental Delays	11 years, 2 months
2. Hep B	Multiple Sclerosis (MS)	8 years, 4 months
3. Flu	Encephalitis	7 years
4. Hep A; Hep B	GBS	4 years, 9 months
5. Flu	Acute Hemorrhagic Leukoencephalomyelitis	4 years, 4 months
6. Flu	Transverse Myelitis	4 years, 4 months
7. Flu	GBS	4 years, 3 months
8. Flu	Demyelinating Injury	4 years, 2 months
9. Flu	Chronic Inflammatory Demyelinating Neuropathy	4 years, 2 months
10. Flu	GBS	4 years, 1 month
11. Flu	Demyelinating Disorder	3 years, 7 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
12. Flu	Stevens Johnson Syndrome; Fibromyalgia	3 years, 4 months
13. TDaP; IPV; MMR; HPV	Acute Disseminated Encephalomyelitis; GBS	4 years
14. Hep B	Demyelinating Polyneuropathy	3 years, 8 months
15. Flu	GBS	3 years, 3 months
16. Flu	Acute Disseminated Encephalomyelitis	3 years
17. MMR; DTaP; IPV; Varicella Vaccine	Encephalitis	3 years
18. Flu	Bilateral upper extremity weakness; Difficulty breathing; Torso and bilateral upper extremity paresthesia; Fatigue	3 years, 2 months
19. Flu	GBS	3 years
20. Flu; Hepatitis A	Myoclonic Seizures	2 years, 9 months
21. Flu	CIDP	2 years, 8 months
22. Flu	Peripheral Neuropathy	2 years, 5 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
23. TDAP	TM	2 years, 8 months
24. DTaP; Hib	Acute Liver Failure; Autoimmune Hepatitis Type 2	2 years, 7 months
25. Flu	GBS; Acute Renal Failure; Wegener's Granulomatosis	2 years, 5 months
26. Flu; Hep A; Hep B; Polio; DTAP	Anaphylactic Reaction; Weakness; Parsonage Turner Syndrome; Peripheral Neuropathy; TM	2 years, 4 months
27. DTaP; PCV-13; Hib; RTQ; IPV; Flu	Seizure Disorder	2 years, 4 months
28. Flu	GBS	2 years, 3 months
29. Flu	SIRVA	2 years, 3 months
30. Flu	Bell's Palsy	2 years, 3 months
31. Flu	Pityriasis Lichenoides et Varioliformis Acuta (PLEVA)	2 years, 2 months
32. Meningitis; Varicella; DTaP	Brachial Neuritis	2 years, 3 months
33. MMR	GBS	2 years, 3 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
34. TDAP	GBS	2 years, 3 months
35. Flu	Acute Disseminated Encephalomyelitis	2 years, 3 months
36. Flu	Anaphylaxis; Vocal Cord Paralysis	2 years, 3 months
37. Flu	Rheumatoid Arthritis	2 years, 3 months
38. Flu	Small Fiber Neuropathy	2 years, 3 months
39. Flu	Parsonage Turner Syndrome	2 years, 3 months
40. Flu	SIRVA	2 years, 3 months
41. Flu	GBS	2 years 2 months
42. Flu	GBS; Lambert Eaton Myasthenic Syndrome; Death	2 years
43. Flu	TM	1 year, 9 months
44. Flu	TM	1 year, 8 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
45. Flu	GBS; CIDP	1 year, 8 months
46. MMR	Arthralgia; Bilateral Bursitis; Numbness; Tingling; Pain	2 year, 2 months
47. Flu	GBS; CIDP	1 year, 8 months
48. Flu	TM	1 year, 8 months
49. Flu	Urticaria	1 year, 8 months
50. Flu	SIRVA	1 year, 7 months
51. Flu	Brachial Plexopathy	1 year, 7 months
52. Flu	ADEM	1 year, 7 months
53. Flu	CIDP; Polyradiculoneuropathy	1 year, 7 months
54. Flu	SIRVA	1 year, 7 months
55. Flu	CIDP	1 year, 7 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
56. MMR	Sensorineural Hearing Loss	1 year 9 months
57. Flu	GBS	1 year, 7 months
58. Flu	GBS	1 year, 7 months
59. Flu	GBS	1 year, 7 months
60. Hep A; Pneumococcal conjugate vaccine;	Febrile convulsions; Developmental delays	1 year, 8 months
61. Flu	GBS	1 year, 7 months
62. Flu	GBS	1 year, 6 months
63. HPV	MS	1 year, 8 months
64. TDaP	Neuropathy; Thrombocytopenia; Lymphadenopathy; Central Vestibular System Impairment	1 year 7 months
65. MMR	TM	1 year, 7 months
66. Flu	GBS; TM; Kidney Failure; Death	1 year, 6 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
67. Flu	GBS	1 year, 6 months
68. Flu	CIDP	1 year, 6 months
69. Flu	GBS	1 year, 6 months
70. TDaP	Sjogren's syndrome; UCTD	1 year, 7 months
71. Flu	Sixth Cranial Nerve Palsy	1 year, 6 months
72. Flu	GBS	1 year, 5 months
73. TDaP	Neurological Injuries	1 year, 7 months
74. Flu	GBS	1 year, 5 months
75. TDaP	SIRVA	1 year, 7 months
76. Flu; TDaP	GBS	1 year, 5 months
77. Flu	GBS	1 year, 5 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
78. Flu	SIRVA	1 year, 5 months
79. Flu	TM	1 year, 5 months
80. Flu	SIRVA	1 year, 5 months
81. Flu	TM	1 year, 5 months
82. TDaP	Brachial Neuritis	1 year, 6 months
83. Flu	CIDP	1 year, 5 months
84. Flu	SIRVA; Adhesive Capsulitis	1 year, 5 months
85. Flu	GBS	1 year, 5 months
86. Flu	TDaP; ADEM	1 year, 5 months
87. Flu	GBS	1 year, 5 months
88. TDaP	TM	1 year, 6 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
89. Flu	Bell's Palsy; Facial Spasms; Dystonia	1 year, 5 months
90. Flu	Dermatofibrosarcoma Protuberans	1 year, 5 months
91. Flu	SIRVA	1 year, 5 months
92. Flu	Anaphylaxis; Hypotension; Cholecystitis; Cholecystectomy	1 year, 4 months
93. Flu	Peripheral Neuropathy; Mononeuritis Multiplex	1 year, 4 months
94. Flu	TM	1 year, 4 months
95. Flu	Brachial Neuritis	1 year 4 Months
96. Flu	SIRVA	1 year, 4 months
97. Flu	Vaccine Neuropathy	1 year, 4 months
98. Flu	SIRVA; Rotator Cuff Tear; Adhesive Capsulitis	1 year, 4 months
99. Flu	GBS	1 year, 4 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
100. Flu	Small Fiber Neuropathy	1 year, 3 months
101. Flu	Optic Neuritis; Vision Loss	1 year, 3 months
102. Flu	Limbic Encephalitis	1 year, 3 months
103. TDaP	TM	1 year, 5 months
104. Flu	SIRVA	1 year, 3 months
105. Flu	GBS	1 year, 3 months
106. TDaP	Bell's Palsy	1 year, 5 months
107. Flu	Bell's palsy	1 year, 3 months
108. Flu	SIRVA	1 year, 3 months
109. Flu	SIRVA	1 year, 3 months
110. Flu	GBS	1 Year 3 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
111. Flu	SIRVA	1 year. 3 months
112. TDAP	GBS	1 year, 5 months
113. Flu	GBS	1 year, 3 months
114. Flu	SIRVA	1 year, 3 months
115. TDaP	Brachial Neuritis	1 year, 5 months
116. Flu	Encephalitis; Death	1 year, 3 months
117. TDaP	CIDP	1 year, 5 months
118. Flu	TM	1 year, 2 months
119. Flu	GBS	1 year, 2 months
120. Flu	SIRVA; Neuropathy of the Medial and Radial Nerves	1 year, 2 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
121. Flu	SIRVA	1 year, 2 months
122. DTaP; MCV	CIDP	1 year, 4 months
123. Flu	SIRVA	1 year, 2 months
124. Flu	Brachial Neuritis; Parsonage-Turner	1 Year 2 months
125. Flu	SIRVA	1 year, 2 months
126. Flu	Brachial Neuritis	1 year, 2 months
127. Flu	GBS	1 year, 2 months
128. TDaP	SIRVA	1 year, 4 months
129. Flu	GBS	1 year, 2 months
130. MMR	Thrombocytopenic Purpura	1 year, 4 months
131. Flu; PCV	SIRVA	1 year, 2 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
132. Flu	GBS	1 year, 2 months
133. Hep A; Flu; IPV	SIRVA	1 year, 2 months
134. Flu	TM	1 year, 1 month
135. Flu	Bell's Palsy; Hearing Loss	1 year, 1 month
136. Flu	SIRVA	1 year, 1 month
137. Flu	GBS	1 year, 1 month
138. Flu	GBS	1 year, 1 month
139. Flu	GBS	1 year, 1 month
140. Flu	GBS	1 year, 1 month
141. Flu	Trigeminal Neuralgia	1 year, 1 month
142. Flu	GBS	1 year

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
143. DTaP; PCV	Transverse Myelitis	1 year, 3 months
144. Flu	GBS	1 year
145. Flu	GBS	1 year
146. Flu	GBS	1 year
147. Flu	GBS	1 year
148. Flu	SIRVA	1 year
149. Flu	GBS	1 year
150. Flu	SIRVA	1 year
151. Flu	SIRVA	1 year
152. Flu	SIRVA	1 year
153. Flu	Rotator Cuff Tear (SIRVA)	1 year

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
154. Flu	MG; GBS	11 months
155. Flu	GBS	11 months
156. Flu	GBS	11 months
157. Flu	GBS	11 months
158. Flu	SIRVA	11 months
159. Flu	Bell's Palsy	11 months
160. Flu	SIRVA	11 months
161. Flu	SIRVA	11 months
162. Flu	GBS	11 months
163. Flu	CIDP; Anti-MAG Neuropathy	11 months
164. TDaP	GBS	1 year, 2 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
165. Flu	GBS	11 months
166. Flu	Parsonage Turner Syndrome	11 months
167. Flu; TDaP	GBS	11 months
168. Flu	GBS	11 months
169. MMR	ITP	1 year, 2 months
170. Flu	GBS	11 months
171. Flu	GBS	11 months
172. TDaP	SIRVA	1 year, 1 month
173. Flu	SIRVA	10 months
174. Flu	Rotator Cuff Syndrome; Carpal Tunnel Syndrome	10 months
175. TDaP; MMR	SIRVA	1 year, 1 month

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
176. Flu	GBS	10 months
177. Flu	CIDP	10 months
178. Flu	GBS	10 months
179. Flu	SIRVA	10 months
180. Flu	SIRVA	10 months
181. Flu	SIRVA	10 months
182. MMR	Hearing Loss; Tinnitus	1 year, 1 month
183. TDaP	SIRVA	1 year, 1 month
184. Flu	GBS	10 months
185. Flu	SIRVA	10 months
186. Flu	SIRVA	10 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
187. Flu	SIRVA	10 months
188. Flu	SIRVA	9 months
189. Flu	GBS	9 months
190. TDaP; Flu	GBS; Death	8 months
191. Flu	TDaP; GBS	8 months
192. Flu	SIRVA	8 months
193. Flu	GBS	8 months
194. Flu	GBS; CIDP	8 months
195. TDaP	SIRVA	1 year
196. Flu	SIRVA	8 months
197. Flu	SIRVA	8 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
198. TD	GBS	1 year
199. Flu	GBS	8 months
200. Flu	SIRVA	8 months
201. Flu	GBS	8 months
202. Flu	GBS	8 months
203. Flu	SIRVA	8 months
204. Flu	GBS	8 months
205. Flu	SIRVA	8 months
206. Flu	TM; ADEM	8 months
207. TDaP	SIRVA	1 year
208. Flu	GBS	8 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
209. Flu	GBS	8 months
210. Flu	SIRVA	8 months
211. Flu	SIRVA	7 months
212. Flu	TM; Acute Neurogenic Bladder Dysfunction	7 months
213. Flu	Cerebellar Ataxia; Speech Problems	7 months
214. Flu	GBS	7 months
215. Flu	SIRVA	7 months
216. Flu	SIRVA	7 months
217. TDaP	GBS	11 months
218. Flu	SIRVA	7 months
219. Flu	CIDP	7 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
220. Flu	SIRVA	7 months
221. Hep B	Bell's palsy	11 months
222. TDaP	GBS; Bell's Palsy	11 months
223. Flu	Parsonage Turner Syndrome; SIRVA	7 months
224. TDaP; Meningococcal Vaccine	SIRVA	11 months
225. TDaP	SIRVA	11 months
226. Flu	SIRVA	7 months
227. Flu	GBS	7 months
228. Flu	Bell's Palsy	7 months
229. TDaP	GBS	11 months
230. Flu	SIRVA	7 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
231. Flu	GBS	6 months
232. Flu	GBS	6 months
233. Flu	TM	6 months
234. Flu	GBS	6 months
235. Flu	Optic Neuritis	6 months
236. Flu	GBS	6 months
237. Flu	GBS	6 months
238. Flu	GBS	6 months
239. Flu; TDaP	Parsonage Turner Syndrome; Brachial Neuritis	5 months
240. Flu	GBS	5 months
241. Flu	Bell's palsy	5 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
242. Flu	SIRVA	5 months
243. Flu	Chronic Pain; Myalgia	5 months
244. Flu	Allergic Encephalomyelitis; Neuropathy	4 years, 8 months
245. Flu	TM	4 years, 7 months
246. TDaP	SIRVA	10 months
247. Flu	GBS	4 months
248. TDaP	SIRVA	10 months
249. Flu	SIRVA	2 years, 5 months
250. Flu	TM	2 years, 2 months
251. TDaP	SIRVA	10 months
252. Flu	GBS; Necrotizing Myositis (NM)	2 years, 2 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
253. Flu	Vasovagal Syncope	2 years
254. Flu	SIRVA	2 years
255. TDaP	Rheumatoid Arthritis	9 months
256. Flu	ADEM	2 years
257. Flu	GBS	2 years
258. Flu	Encephalitis	1 year, 8 months
259. TDaP	SIRVA	9 months
260. Flu	GBS	1 year, 8 months
261. Flu	GBS	1 year, 7 months
262. Flu	GBS; CIDP	1 year, 7 months
263. Flu	GBS	1 year, 7 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
264. Flu	Ischemic Optic Neuropathy	1 year, 6 months
265. Flu	TM	1 year, 6 months
266. Flu	GBS	1 year, 6 months
267. Flu	GBS	1 year, 5 months
268. Flu	TM	1 year, 5 months
269. Flu	SIRVA	1 year, 5 months
270. Varicella Vaccine	Hives	8 months
271. Flu	GBS	1 year, 5 months
272. TDaP	SIRVA	8 months
273. Flu	Amplified Pain Syndrome	1 year, 5 months
274. Flu	GBS	1 year, 5 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
275. Flu	GBS	1 year, 4 months
276. DTaP; Hep B; IPV; Hib; PCV	Encephalopathy; Death	8 months
277. Flu	SIRVA	1 year, 4 months
278. TDaP	GBS	8 months
279. Flu	CIDP	1 year, 3 months
280. Flu	ADEM	1 year, 3 months
281. Flu	SIRVA	1 year, 3 months
282. Flu	SIRVA	1 year, 3 months
283. Flu	GBS	1 year, 3 months
284. Flu	GBS	1 year, 3 months
285. Flu	SIRVA	1 year, 3 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
286. Flu	SIRVA	1 year, 2 months
287. Flu	SIRVA	1 year, 2 months
288. TDaP	GBS	8 months
289. Flu	SIRVA	1 year, 1 month
290. Flu	SIRVA	1 year, 1 month
291. Flu	SIRVA	1 year, 1 month
292. Flu	GBS; Miller Fisher Variant; Tibial Nerve Palsy	1 year
293. Flu	SIRVA	1 year
294. Flu	Bell's Palsy; Internuclear Ophthalmoplegia and/or optic neuritis	1 year
295. Flu	SIRVA	1 year
296. Flu	CIDP	1 year

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
297. Flu	GBS	1 year
298. Flu	SIRVA	1 year
299. Flu	GBS	1 year
300. Flu	SIRVA	1 year
301. TDaP	GBS	7 months
302. Flu	GBS	11 months
303. Flu	SIRVA	11 months
304. Flu	SIRVA	11 months
305. Flu	SIRVA	11 months
306. Flu	SIRVA	11 months
307. Flu	SIRVA	10 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
308. Flu	SIRVA	10 months
309. Flu	GBS	10 months
310. Flu	SIRVA	10 months
311. Flu	SIRVA	10 months
312. Flu	GBS	10 months
313. Flu	Post-Vaccine Syndrome with Demyelinating Features	10 months
314. Flu	SIRVA	9 months
315. Flu	ADEM	9 months
316. Flu	GBS	9 months
317. Flu	SIRVA; Axillary nerve injury	9 months
318. Flu	GBS	9 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
319. Flu	SIRVA	9 months
320. Flu	SIRVA	8 months
321. Flu	Optic Neuritis	8 months
322. Flu; TDaP	Bell's Palsy	8 months
323. Flu	SIRVA	8 months
324. Flu	GBS	8 months
325. Flu	TM	8 months
326. Flu	SIRVA	8 months
327. PCV	SIRVA	5 months
328. Flu	SIRVA	8 months
329. TDaP	SIRVA	10 months

*Terms of compensated settlements memorialized by Stipulation

Adjudicated Settlements*

Reporting Period: 11/16/16 – 8/15/17

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
330. Flu	GBS	7 months
331. Flu	SIRVA	7 months
332. Flu	GBS	6 months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Appendix

Glossary of Terms

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

Glossary of Terms

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

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

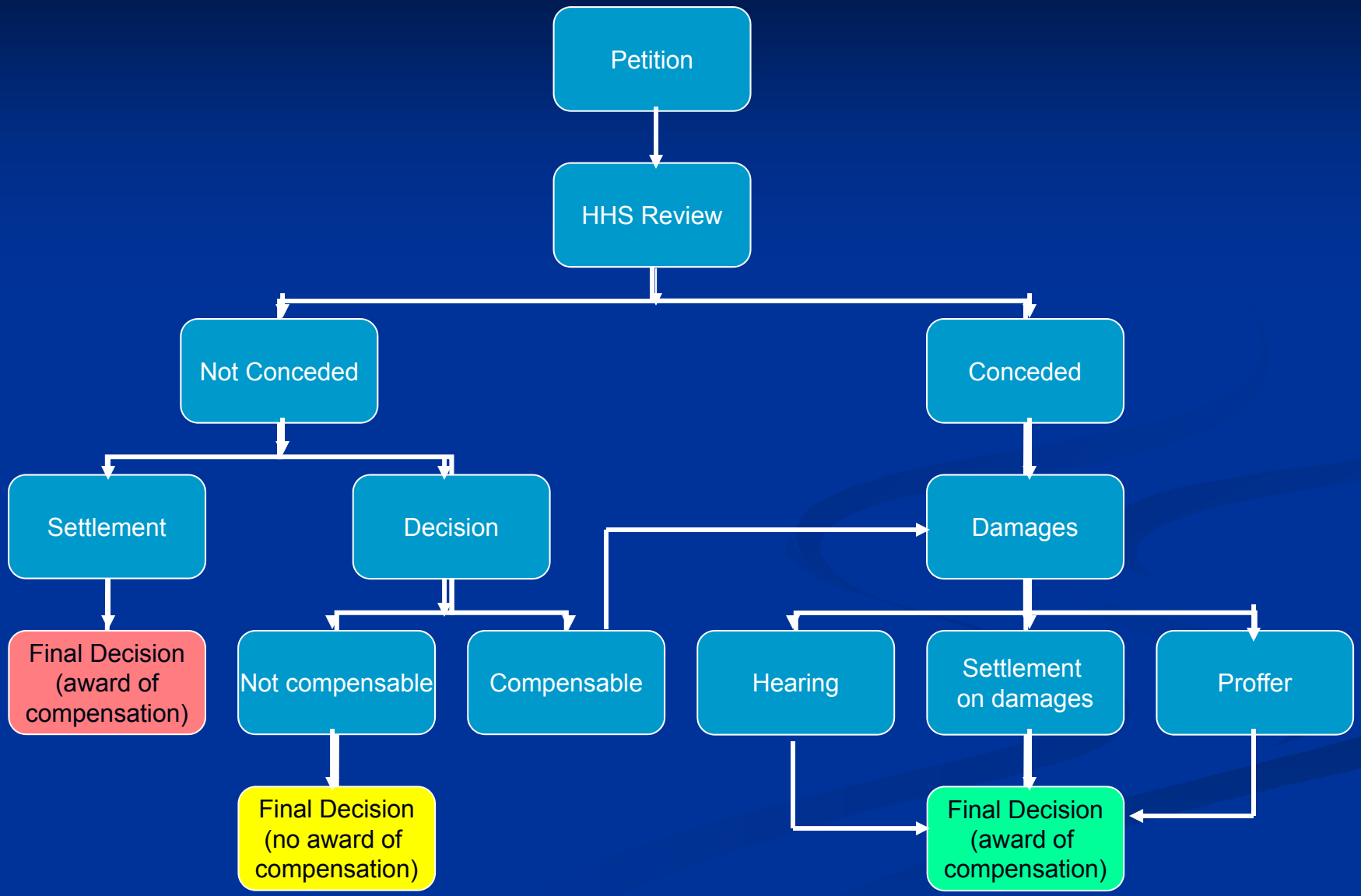
- **Non-compensable/Dismissed:** Petition dismissed.

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

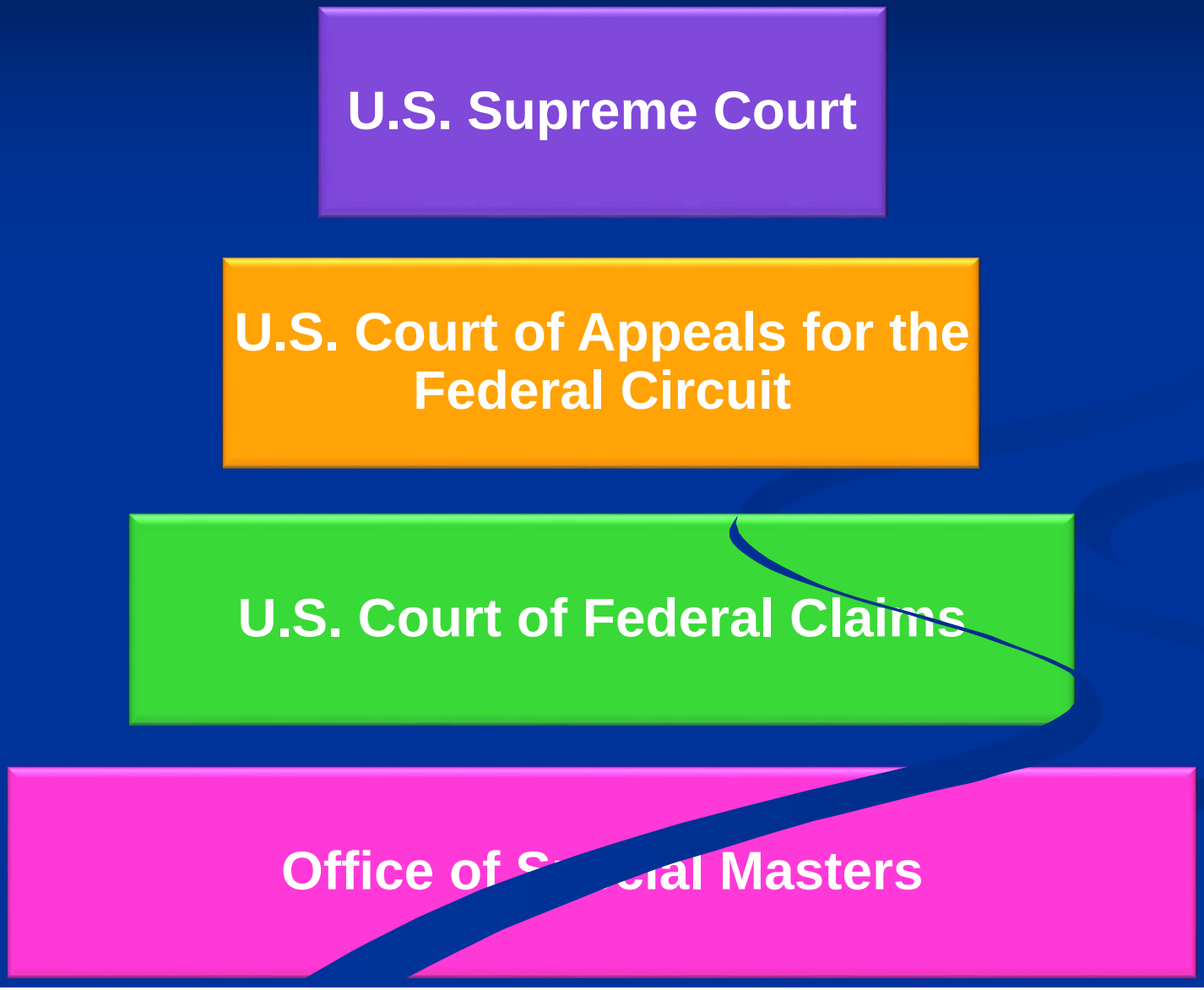
Glossary of Terms

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

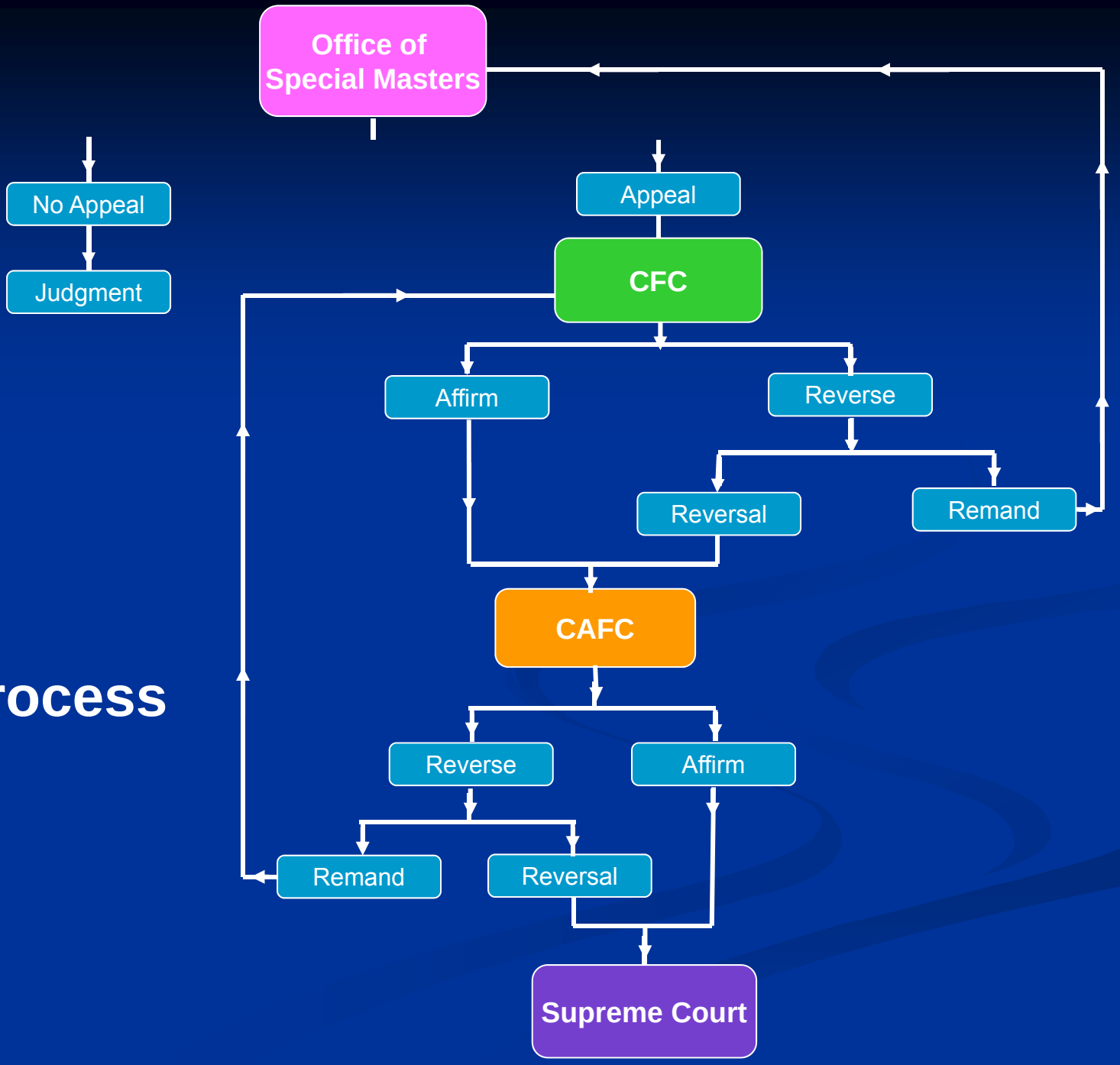
Petition Processing in the Office of Special Masters



Levels of Appeal in Vaccine Act Cases



Appeals Process



5.4

CDC Immunization Safety Office Updates

Centers for Disease Control and Prevention

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

Advisory Commission on Childhood Vaccines (ACCV)
September 8, 2017

Disclaimer

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

Topics

- Transition to the Vaccine Adverse Event Reporting System (VAERS) 2.0 reporting process
- Selected vaccine safety publications

Vaccine Adverse Event Reporting System (VAERS) 2.0

Vaccine Adverse Event Reporting System (VAERS)

- VAERS is the national spontaneous reporting system for monitoring the safety of U.S.-licensed vaccines
- VAERS is co-managed by CDC and FDA
- The VAERS-1 form had been in use since 1990 (prior to June 30, 2017, when VAERS 2.0 was released)
- The paper version* of the VAERS-1 form had to be filled out by hand and mailed or faxed
- An online reporting tool allowed for web-based reporting

*The VAERS-1 form was a PDF that did not have writable and savable features

VAERS-1 form circa 1990 (now obsolete)

WEBSITE: www.vaers.hhs.gov E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name: Last First M.I.
Address
City State Zip
Telephone no. (___) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (___) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (___) _____

1. State | 2. County where administered | 3. Date of birth mm dd yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm dd yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm dd yy Time _____ AM PM

11. Adverse event onset mm dd yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under
22. Birth weight _____ lb. _____ oz.
23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project
24. Mfr./imm. proj. report no.
25. Date received by mfr./imm.proj.
26. 15 day report? ☐ Yes ☐ No
27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(FDA)

Vaccine Adverse Event Reporting System (VAERS) 2.0

- **VAERS 2.0 consists of two major initiatives**
  - **A new VAERS form with revised data elements**
    - **VAERS 2.0 reporting form**
  - **An updated processes for submitting VAERS reports**
    - **Option 1: updated online reporting tool**
    - **Option 2: writable PDF form combined with electronic document upload capability**
    - **See https://www.youtube.com/watch?v=sbCWhcQADFE**

VAERS 2.0 development

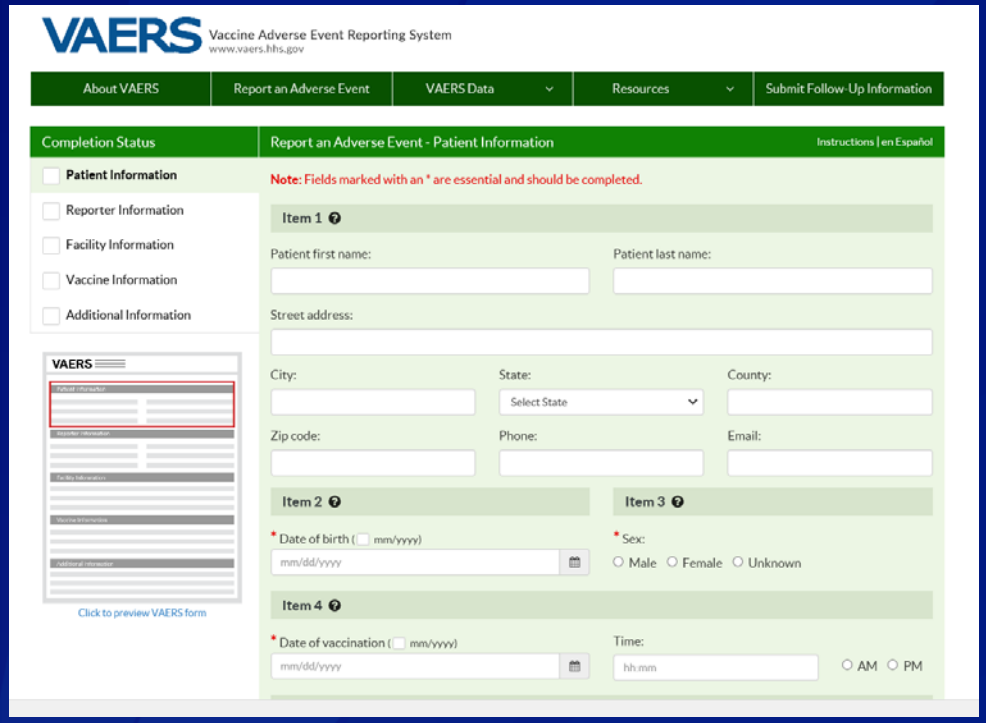
- Proposed changes to the VAERS-1 form were first presented to ACIP, NVAC and ACCV in September and October 2014
- Proposed changes were also posted on the Federal Register for public comment in November 2014 (https://www.federalregister.gov/documents/2014/11/24/2014-27678/request-for-comment-on-draft-vaccines-adverse-event-reporting-system-vaers-20-form)
- CDC conducted extensive user testing during development
- Changes to the VAERS form were finalized in 2016
- The new VAERS 2.0 form has updated data elements (e.g. pregnancy status, race and ethnicity) and new features including writable and savable options
- IT upgrades to the VAERS website were completed in 2017 to incorporate new data elements into a reconfigured online reporting tool and to accommodate a new electronic document upload process

Reporting using the VAERS 2.0 form

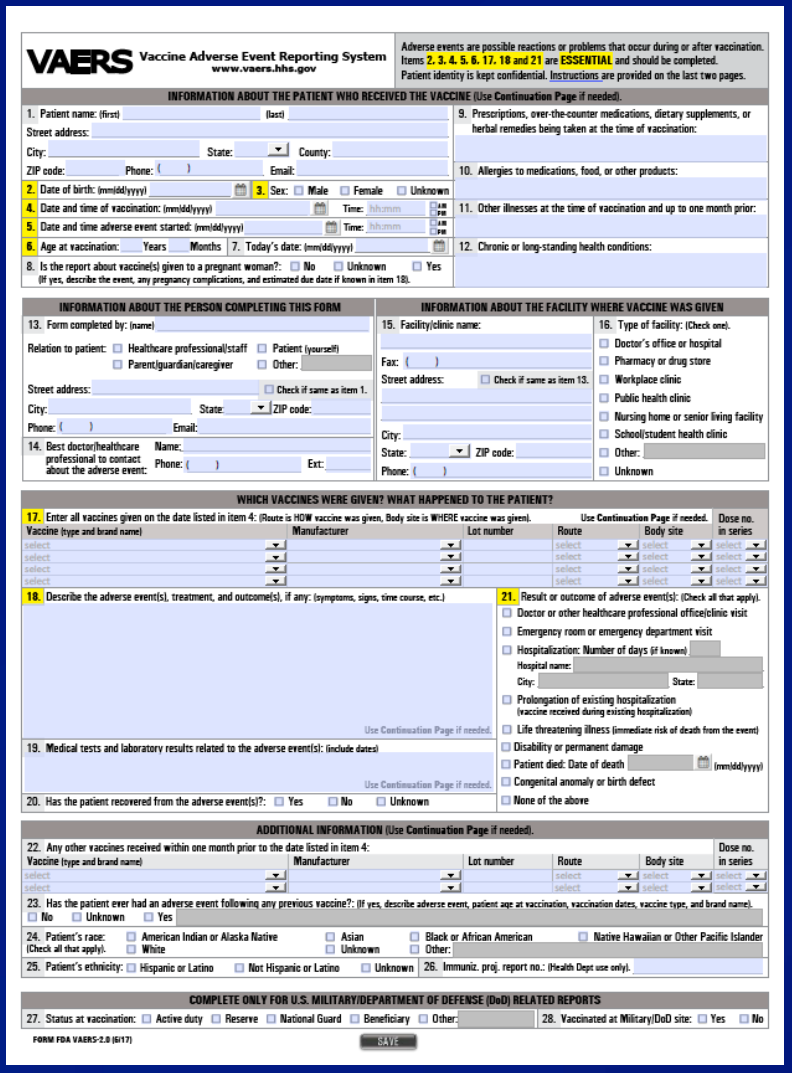
- Starting June 30, 2017, and extending through the end of December 2017, CDC and FDA are implementing the VAERS 2.0 form and phasing out the VAERS-1 form
- VAERS 2.0 is for reporting by:
  - Healthcare professionals, patients, parents, guardians, caregivers, and other non-manufacturer reporters
- Reporters can:
  - Use the VAERS 2.0 online reporting tool to submit reports (i.e., direct online reporting)

    or
  - Download and complete the writable and savable VAERS 2.0 form and submit using an electronic document upload feature
- Vaccine manufacturers report through a different process using the FDA Electronic Submissions Gateway

Partial screen shot of VAERS 2.0 online reporting tool (direct online reporting)



VAERS 2.0 form (writable, savable and uploadable onto the VAERS website)



- "Essential" items (high value data elements) are highlighted with asterisks in the online reporting tool and with yellow boxes in the writable PDF form

VAERS 2.0 form (additional information)

- Instructions for reporting to VAERS are available at https://vaers.hhs.gov/reportevent.html and https://www.youtube.com/watch?v=sbCWhcQADFE
- Additional assistance is available via email at info@vaers.org or by phone at 1-800-822-7967
- Transition to the VAERS 2.0 form is expected to be completed by the end of December 2017
- Accommodations will be made for individuals unable to submit reports electronically

Selected publications

- **Stockwell et al. Feasibility of Text Message Influenza Vaccine Safety Monitoring During Pregnancy. Am J Prev Med. 2017. pii: S0749-3797(17)30204-0.**
  - **This study demonstrated the feasibility of text messaging for influenza vaccine safety surveillance sustained throughout pregnancy. In these women receiving inactivated influenza vaccination during pregnancy, post-vaccination fever was infrequent and a typical pattern of maternal and neonatal health outcomes was observed.**
- **Moro et al. Major Birth Defects after Vaccination Reported to the Vaccine Adverse Event Reporting System (VAERS), 1990 to 2014. Birth Defects Res. 2017;109(13):1057-1062.**
  - **This review of the VAERS database found that major birth defects were infrequently reported, with no particular condition reported disproportionally. Birth defects after routine maternal vaccination will continue to be monitored in VAERS for signals to prompt future studies.**

Selected publications

- Lipkind et al. Maternal and Infant Outcomes After Human Papillomavirus Vaccination in the Periconceptional Period or During Pregnancy. Obstetrics & Gynecology. 2017. doi: 10.1097/AOG.0000000000002191.
  - Quadrivalent HPV vaccine inadvertently administered in pregnancy or during the periconceptional period was not associated with adverse pregnancy or birth outcomes.

ACIP updates

- June 2017 ACIP meeting presentations available at https://www.cdc.gov/vaccines/acip/meetings/slides-2017-06.html

Centers for Disease Control and Prevention
Atlanta, GA

Thank You

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

5.5

National Institutes of Health Update

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

September 2017

Respiratory Syncytial Virus (RSV)

- Common respiratory virus that can be serious for infants and older adults
- No vaccine to prevent RSV infection or drug to treat it
- February 2017: NIH announced Phase 1 clinical trial for investigational RSV vaccine
  - Vaccine developed by NIH scientists
  - To test safety and tolerability & assess vaccine's ability to prompt an immune response
  - Conducted at NIH Clinical Center, Bethesda, Maryland

Zika Research

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
June 21, 2016

NIH Launches Large Study of Pregnant Women in Areas Affected by Zika Virus

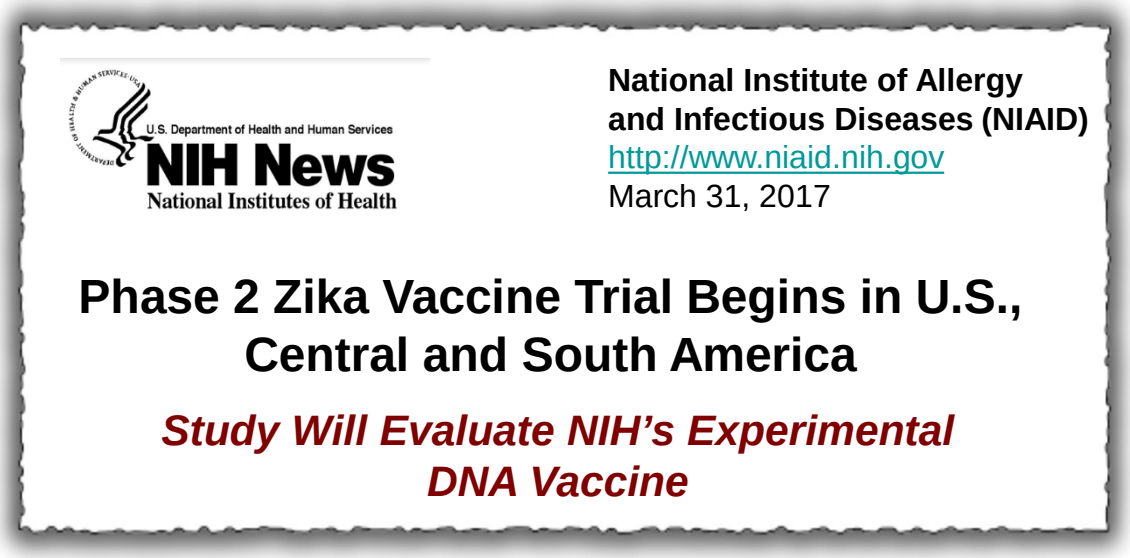
International Effort to Enroll Approximately 10,000 Women

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
June 19, 2017

Study to Examine Effects of Zika Infection in Guatemalan Infants and Children

NIH-Funded Study Will Characterize Outcomes of Infection Acquired After Birth

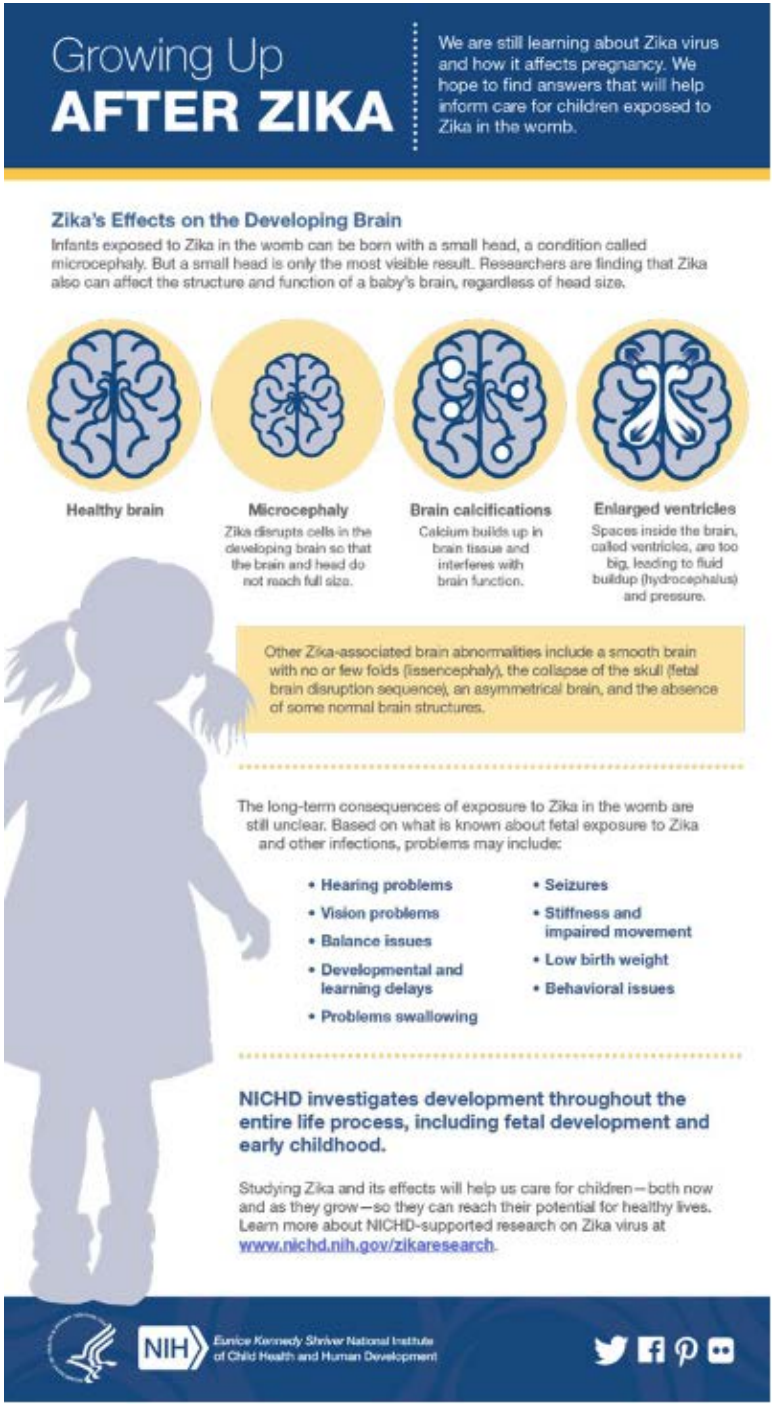
Zika Research



- To evaluate experimental Zika vaccine's safety and ability to stimulate an immune response
- To assess optimal dose for administration
- Will attempt to determine if the vaccine can prevent disease caused by Zika infection

Bridging Knowledge Gaps to Understand How Zika Virus Exposure and Infection Affect Child Development

BG Kapogiannis, N Chakhtoura, R Hazra, CY Spong. *JAMA Pediatrics* (May 2017)



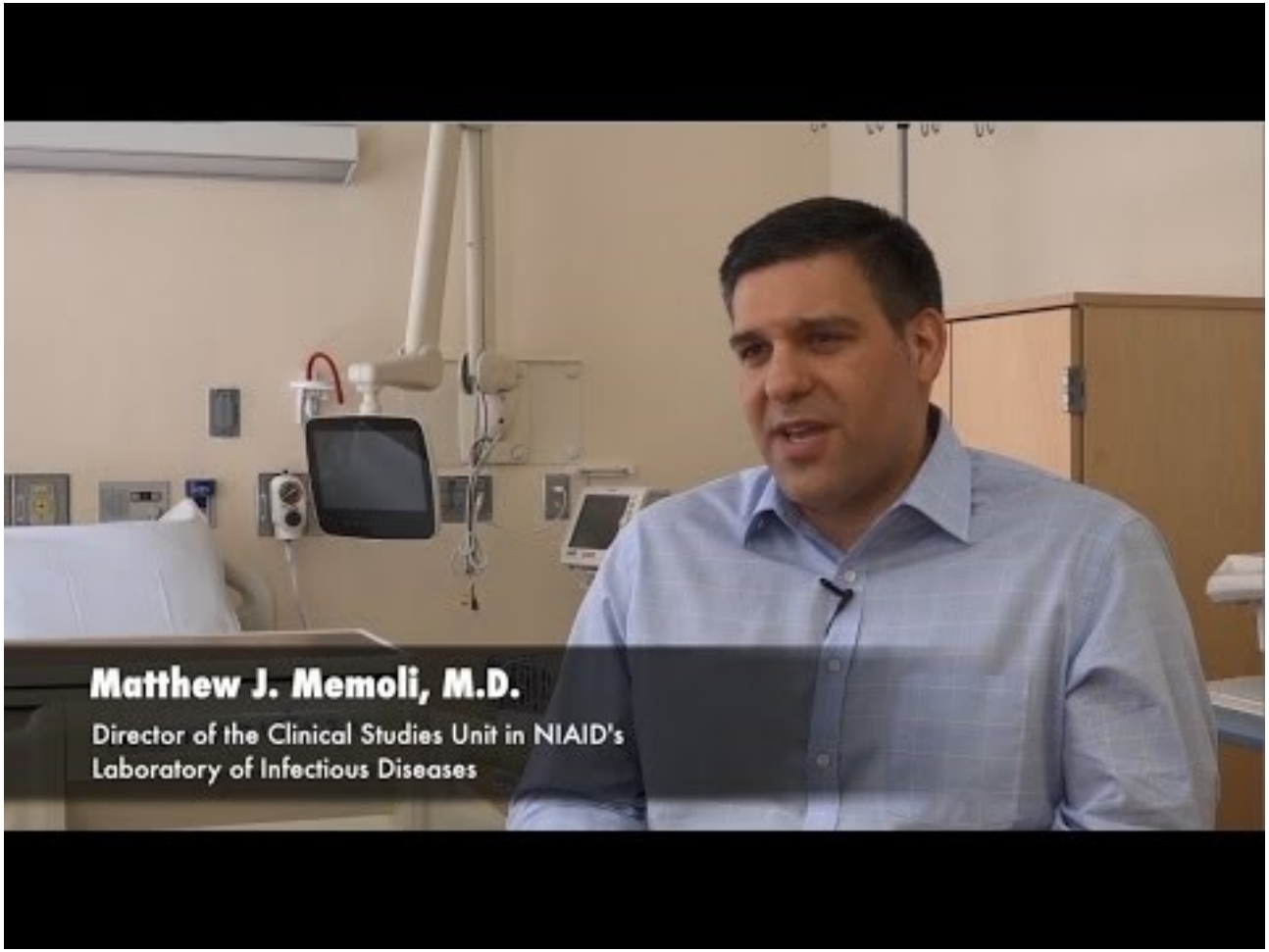
Protecting Against Mosquito-Borne Diseases

Credit: NIAID

- February 2017: NIH announced Phase 1 clinical trial of investigational vaccine to protect against mosquito-transmitted diseases, e.g.:
  - Zika
  - Malaria
  - West Nile fever
  - Dengue fever
- To examine safety and ability to generate an immune response
- Experimental vaccine targets mosquito saliva
- Conducted at the NIH Clinical Center, Bethesda, Maryland

NIH National Institute of Allergy and Infectious Diseases

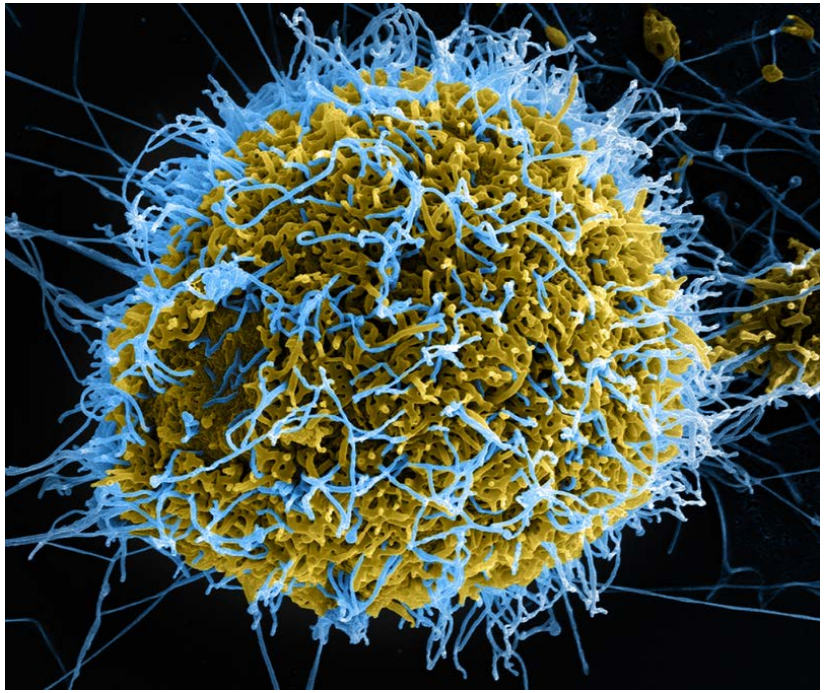
Protecting Against Mosquito-Borne Diseases



https://www.youtube.com/watch?v=KK0fWXT2Ttk

NIH National Institute of Allergy and Infectious Diseases

Ebola Vaccine Research



Credit: NIAID

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

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
April 6, 2017

Ebola: New Trial Launched in West Africa to Evaluate Three Vaccination Strategies

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

National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov
March 14, 2017

Experimental Ebola Vaccine Regimen Induced Durable Immune Response, Study Finds

Antibodies to Ebola Present in all Participants One Year after Vaccination

R Winslow *et al*. Immune Responses to Novel Adenovirus Type 26 and Modified Vaccinia Virus Ankara-Vectored Ebola Vaccines at 1 Year. *JAMA* (2017 Mar 14)

Recent Publications

- NG Rouphael, *et al*. The Safety, Immunogenicity, and Acceptability of Inactivated Influenza Vaccine Delivered by Microneedle Patch (TIV-MNP 2015): A Randomised, Partly Blinded, Placebo-controlled, Phase 1 Trial. *Lancet* (2017 Aug 12)

- Poland GA, *et al*. Personalized Vaccinology: A Review. *Vaccine* (2017 Jul 31)

- XX Gu, *et al*. Waning Immunity and Microbial Vaccines-Workshop of the National Institute of Allergy and Infectious Diseases. *Clin Vaccine Immunol* (2017 Jul 5)

All of Us RESEARCH PROGRAM

The Future of Health Begins With You

- The All of Us Research Program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health.
- By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine.

https://allofus.nih.gov/
https://www.joinallofus.org/

5.6

U.S. FOOD & DRUG ADMINISTRATION

Office of Vaccines Research and Review (OVRR)

ACCV Update

CDR Valerie Marshall

September 8, 2017

Vaccines and Related Products Advisory Committee Meeting:
An Update

Past Meetings

- On March 9, 2017, the committee met to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2017-2018 influenza season.
- On May 17, 2017, the committee met to discuss considerations for evaluation of Respiratory Syncytial Virus (RSV) vaccine candidates in seronegative infants.
- On July 28, 2017, the committee met to discuss and make recommendations on the safety and efficacy of a Hepatitis B Vaccine manufactured by Dynavax.

Upcoming

- On September 13, 2017, the committee will meet to discuss and make recommendations on the safety and effectiveness of Zoster Vaccine Recombinant (Adjuvanted) [Shingrix], manufactured by GlaxoSmithKline Biologicals.


FDA
U.S. FOOD & DRUG
ADMINISTRATION

5.7

THE NATIONAL VACCINE PROGRAM OFFICE

NATIONAL VACCINE PROGRAM OFFICE UPDATE

ACCV, SEPTEMBER 8, 2017

Dr. Karin Bok
Senior Vaccine Science Advisor

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FY17 COOPERATIVE AGREEMENT ON VACCINE SAFETY #1

- **Awardee:** Cincinnati Children's Hospital Medical Center
  Principal Investigator: Steven Black, MD

- **Description:** This project aims to validate the Global Alignment of Immunization Safety Assessment in pregnancy (GAIA) maternal and neonatal outcome definitions to standardize the evaluation of the safety of vaccines.(US, Australia and UK)

FY17 COOPERATIVE AGREEMENT ON VACCINE SAFETY #2

- **Awardee:** Kaiser Foundation Hospitals
  Principal Investigator: Nicola Klein, MD, PhD

- **Description:** This project focuses on adversomics. It aims to identify inherited, immunologic, and clinical factors that may predict the occurrence of febrile seizures after measles vaccination.

FY17 COOPERATIVE AGREEMENT ON VACCINE SAFETY #3

- **Awardee:** The Rockefeller University
  Principal Investigator: Jean-Laurent Casanova, MD, PhD

  Description: This project focuses on precision medicine. It aims to analyze the genetic determinants of the immune response following yellow fever vaccination among individuals who experience serious adverse events.

21ST CENTURY CURES ACT: VACCINE INNOVATION REPORT TO CONGRESS

The Vaccine Innovation Steering Committee will:

- Consider the optimal process to determine which vaccines would be beneficial to public health and how information on such vaccines is disseminated to key stakeholders;
- Examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and
- Make recommendations about how best to remove any obstacles in order to promote and incentivize vaccine innovation and development.

21ST CENTURY CURES ACT: TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN

The Task Force shall provide advice and guidance

to the Secretary regarding **Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities**

The task force will report:

(A) A plan to identify and address gaps in knowledge and research regarding pregnant women (B) Ethical issues surrounding the inclusion of pregnant women in clinical research. (C) Effective communication strategies with health care providers and the public (D) Identification of Federal activities, including—(i) the state of research on pregnancy and lactation; (iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities. (E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

THE VACCINE CONFIDENCE MEETING

THE VACCINE CONFIDENCE MEETING

Collaborating to Advance Vaccine Confidence

August 15-16, 2017 at Emory University in Atlanta, Georgia

About the Meeting

The Vaccine Confidence Meeting is the first of its kind to bring together researchers, government agencies, and health care organizations to examine the latest insights from research and practice on increasing vaccine confidence in the United States.

Co-sponsored by the National Vaccine Program Office (NVPO) and Emory University, this meeting joins NVPO's leadership with Emory's academic excellence.

Coming Together for Collaboration

What is vaccine confidence?

The trust that parents, patients, or providers have in:

- recommended vaccines;
- providers who administer vaccines; and
- processes and policies that lead to vaccine development, licensure, and recommendations for use.

UPSHOT AWARDS: VACCINE SAFETY

Excellence in Vaccine Safety

- **Awardee: Roger Baxter, MD**, Co-director, Kaiser Permanente Vaccine Study Center, Infectious Disease Physician, Kaiser Permanente Oakland Medical Center, Research Scientist, Kaiser Permanente Northern California Division of Research

  Dr. Baxter was awarded posthumously in recognition of his prolific contributions to advancing vaccine safety research including his instrumental role in the case-centered approach and the dynamic pregnancy neonate registry.

THANK YOU

Karin Bok
Karin.Bok@hhs.gov
202-690-1191

http://www.hhs.gov/nvpo/
http://www.vaccines.gov/

6.1

smaller, needles in our future?

Some companies and academic labs are working to make those things happen.

They're refining technologies that involve tiny needles, less than a millimeter long, and needle-free injectors that can send a dose of vaccine through your skin in a fraction of a second.

Some of these technologies are already available on the market, while others are still being tested.

One hundred very tiny needles

A flu vaccine patch is not yet available to the public. But one version developed by Georgia Tech's Laboratory for Drug Delivery showed promising results in its first human clinical trial, according to a study published in *The Lancet* in June.

The patch, about the size of a small square bandage, has tiny, dissolvable needles filled with a dose of flu vaccine. It's placed on the arm and activated through pressure. The microneedles dissolve into the skin, releasing the vaccine.

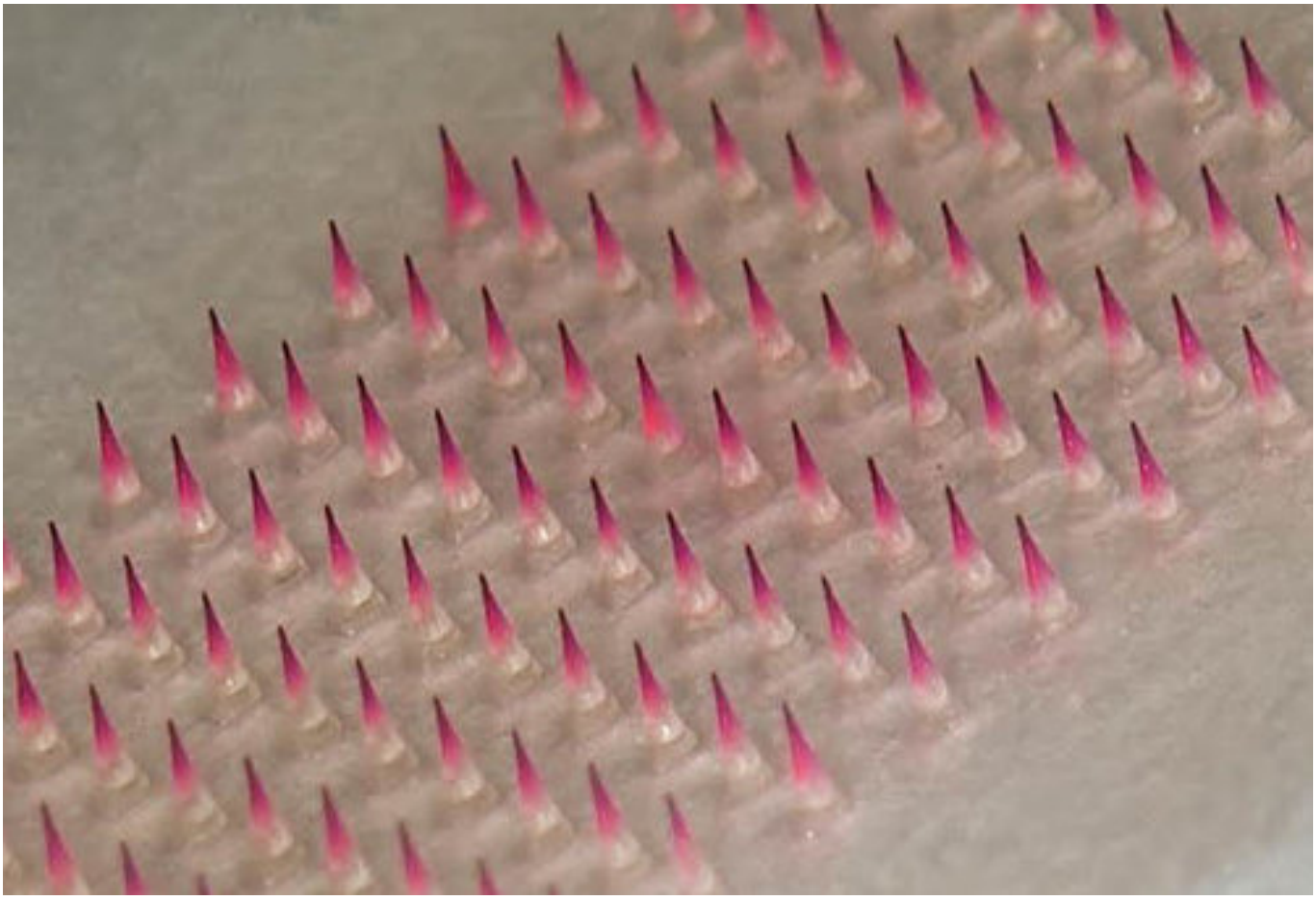
In the study, 100 participants received either the flu vaccine patch, a standard flu shot or a placebo via a patch.

Six months later, no one involved in the study had gotten the flu. People in the microneedle patch groups reported some redness, itching and tenderness but no serious side effects.

People who received the flu patch had comparable immune responses to people who had gotten the flu shot.

About 70 percent of the patients in the study preferred the patch to the regular shot, says Yasmine Gomaa, the lab's associate director.

Now, Gomaa's lab is looking beyond the flu vaccine. She says the microneedle patch could be particularly helpful in developing countries because it uses a form of vaccines that doesn't need to be kept as cold as regular vaccines. It can be stored at temperatures as high as 104 degrees Fahrenheit for up to a year, she says.



The microneedles attached to this patch dissolve after being pressed into skin, releasing a dose of vaccine. Each microneedle is less than a millimeter in length.

Courtesy of Georgia Institute of Technology

And the patch can be administered by people who aren't trained health professionals. A number of the people in the flu patch study applied it to themselves.

In 2015, Georgia Tech and the pharmaceutical company Micron Biomedical won $2.5 million in grants from the Bill and Melinda Gates Foundation to develop a patch for polio immunization.

Gomaa's hope is that vaccine patches will cost less than vaccinations do now.

A 2016 study from the Centers for Disease Control and Prevention found that the use of vaccine patches could save on cooling costs and could cut down on waste. Its analysis concluded that a dose of measles vaccine with the patch would cost just under $1, while a typical shot would cost $1.65. But that didn't take into account the costs of getting the patch to market.

The potential cost savings wouldn't happen until the patches were in "routine use," the CDC noted.

A twist on Star Trek technology

Others in the vaccine-delivery business are taking a different approach, using a new twist on a needle-free device called a jet injector that has been around for more than half a century.

Star Trek featured such a device, calling it a "hypospray."

Portal Instruments, a company that is developing jet injectors, uses technology based on work done by Ian Hunter at the Massachusetts Institute of Technology.

SHOTS - HEALTH NEWS

MIT Builds A Needle-Free Drug Injector

"Initially, we worked on microneedles," says the company's CEO Patrick Anquetil. "And then Ian realized that why don't we just remove the needle altogether? And that's how this project came to be."

Needle-free jet injectors were actually used in the 1960s in mass smallpox vaccination campaigns. As described by the CDC, these devices use a high-pressure, narrow stream of fluid to penetrate the skin. The diameter of the stream is comparable to a mosquito bite.

The devices were used to quickly vaccinate large numbers of people, including members of the armed forces.

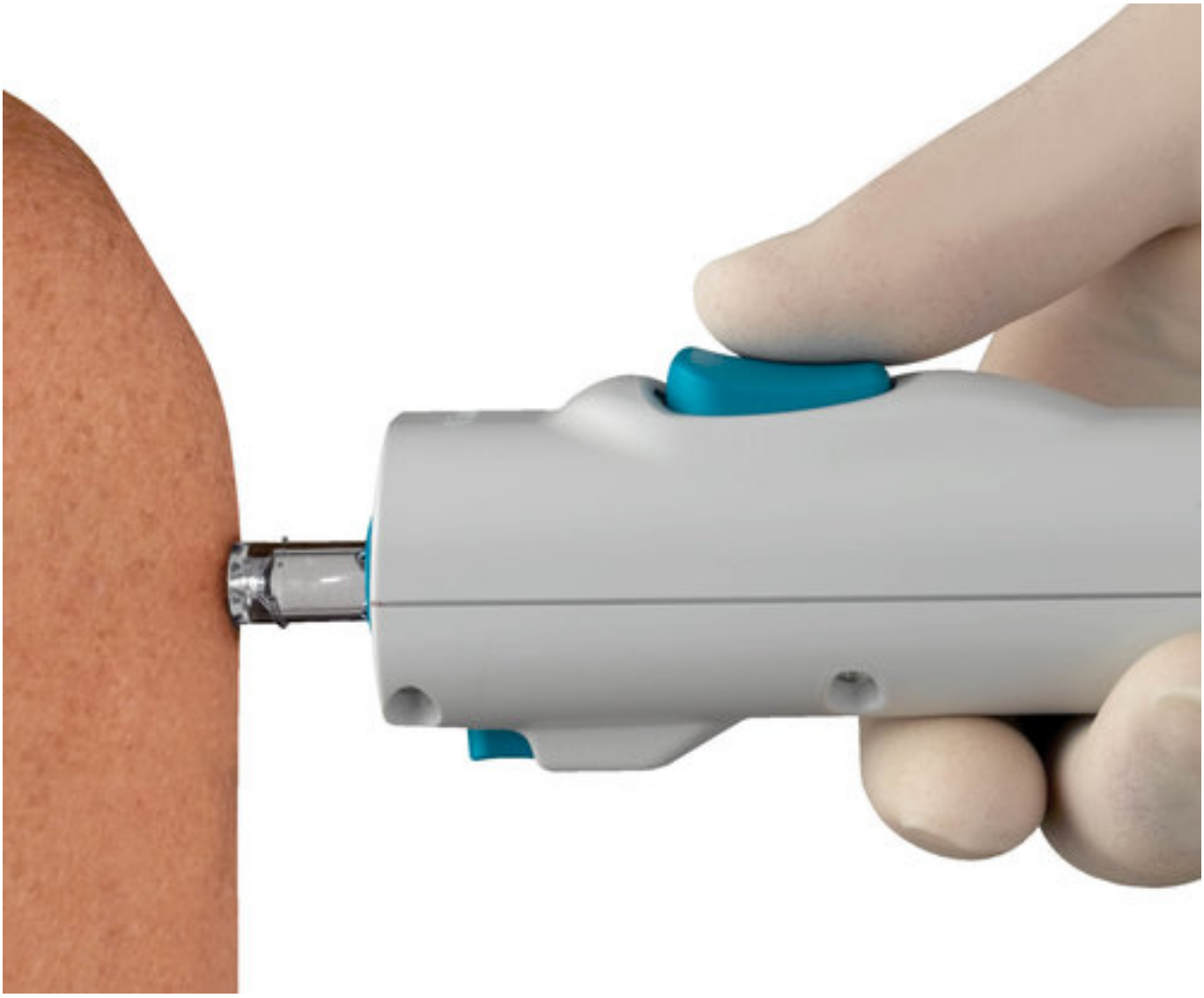
Anquetil notes that the older devices sometimes made patients feel as if they had been punched.

"To create the jet, you have to instantaneously create 100 times more pressure than you've got in the tire of a car," he says. "Patients actually hated them because they were more painful than a needle and syringe."

Others echo that sentiment.

"My 85-year-old neighbor still remembers how painful it was," says Ron Lowy, CEO of PharmaJet, a company that makes an FDA-approved jet injector that administers a flu vaccine.

The older devices had another problem. They used the same nozzle for multiple injections, leading to concerns about the transmission of bloodborne pathogens between patients.



Needle-free jet injectors push a narrow stream of liquid into the skin.

Courtesy of PharmaJet

Today's devices have made a lot of progress, Lowy says. Now, the syringe is changed for each patient and the injections are gentler.

"It feels like somebody snapped me with a rubber band," he says, adding that the injection happens too fast for some patients to register any sensation at all. It lasts about one-tenth of a second.

He says hundreds of thousands of people in the U.S. have already received the flu vaccine via one of PharmaJet's injectors.

"If you have your choice, you want to get poked with a needle or you want to try this? Most of the people say, 'Yeah, I'll try that,' " he says.

Cost remains an issue for some jet injectors. Portal is aiming to get its cost down to $3 or $4 per injection.

"In vaccines, what's really hard is that there's a very, very high volume, and you're competing with a needle and syringe, which is tremendously low cost," Anquetil says.

PharmaJet says the ability to give precise doses helps to save money. The company says its flu vaccine "starter kit," which can vaccinate 500 people, costs $900.

Nasal spray hits a roadblock

FluMist, an FDA-approved flu vaccine delivered through a nasal spray, was widely used in the U.S. and, at one point, was even the preferred method of vaccination for children.

Then last year, in a sharp turnaround, the CDC recommended that it not be used during the 2016-17 flu season after a study found it had not been very effective in the previous year, particularly among kids.

SHOTS - HEALTH NEWS

How FluMist Slipped From Preferred To Passe

The vaccine's effectiveness was just 3 percent, so low that "no protective benefit could be measured" for children ages 2 to 17, the CDC said in a statement.

In contrast, the effectiveness of the flu shot was about 63 percent for kids in that age group.

AstraZeneca, the parent company behind FluMist, says the CDC's data contradicts data from several other studies, which show the vaccine was about 48 percent effective during the same flu season. And the same vaccine continues to be recommended and used in European Union markets, AstraZeneca says.

In the U.S., the CDC continues to recommend against the nasal spray vaccine for the upcoming flu season. AstraZeneca hopes to reverse that decision before flu season

begins.

"We continue to pursue a broad-based investigation to identify potential causes of lower effectiveness" in recent years, the company said in a statement, adding that one of the four flu virus strains it used in the vaccine during the past two flu seasons may have been the problem.

The company has chosen a new strain of live virus that is similar to other strains that have proven effective in studies and clinical trials.

Correction

July 24, 2017

An earlier version of this story incorrectly referred to Ron Lowy as Ron Lowry. It also referred to a "nozzle" being changed for every new patient. The correct word is "syringe."

flumist flu shots vaccination vaccines

More Stories From NPR

6.2

HEALTHY LIVING 08/15/2017 09:00 am ET

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Hope in a Vial – The Journey Behind Vaccines

Pfizer Vaccines' innovative approach is helping the whole world live more healthfully.

By Susan Silbermann

A while back, I was traveling abroad on business and as is often the case in my line of work, found myself chatting with a group of mothers. Just like the moms I know back home in the U.S., they worry about their kids. But there was a major difference. These moms lived in a small village in Rwanda where access to health care is often difficult to come by. Even if they hadn't personally lost a child – even an infant - to disease, they knew someone who had. The heartbreaking truth is that moms there often wait to name their babies until after they've gotten vaccinated.

That made two things devastatingly clear to me. First, every day, these families are fighting off diseases that many people in the U.S. have never heard of or forgotten are deadly. And second, while access to vaccines is common in many parts of the world, it is by no means guaranteed for these mothers or their children.

In the world we live in today, no one should lose their life to a vaccine-preventable illness. I believe that it is our collective responsibility, and it's something I've made my personal mission as the head of Pfizer's vaccine division.

For Pfizer, solving this global public health challenge will come through innovation.

Picture a small vaccine vial, something you might remember seeing at the doctor's office. What's harder to envision are the hours in the lab, the hundreds of quality tests it goes through, and the thousands of people who pour their hearts into creating that single dose.

So, let's break it down.

Every dose of one of our Pfizer vaccines requires about 400 raw materials. Here, about 1,700 employees will be involved in taking the next 580 steps to turn those ingredients into a vaccine. Then, researchers and scientists will perform 678 quality tests to make sure it will be effective once it reaches your child.

Watch this video to learn more about what goes into making a vaccine.

For each complete batch, from start to finish, the process takes two and a half years. That's all for a single dose of one vaccine. That tiny vaccine vial is an incredible testament to scientific innovation – and to the passion and perseverance of the many people behind it.

But even after that long, complex process, our job isn't done – far from it. Vaccines are only as effective as our ability to get them to the people in need. That includes those living in some of the most remote places in the world.

It is also tricky to transport vaccines. They have to be refrigerated and kept at precise temperatures — no easy feat when reaching people who live in deserts with hundred-degree temperatures or places without paved roads or on the side of a mountain. Today, 19 million kids around the world don't have the vaccines they need in part because they are difficult to reach.[1] Just like the women I talked with in Rwanda, moms around the globe are willing to travel dozens of miles to get their children vaccinated. We owe it to them to make sure the vaccines are there when they arrive.

Think of all the life milestones you'll reach in the next 2.5 years – and know that in that same time we are spending every day making a new batch of a vaccine to help babies, parents and grandparents avoid infections to help them live their healthiest life possible and reach their dreams. So we're working on solutions to get vaccines to people faster and more efficiently. For example, we've innovated ways to fit more doses into a single vaccine vial so it takes up less storage space and makes for easier transport to remote regions in many developing countries.

When I think about the journey of a vaccine – from the inventive mind of a scientist, to the skillful hands of a manufacturing expert carefully creating each dose – traveling across thousands of miles of roads and rivers to some of the world's hardest to reach places, I think again about those mothers in Rwanda, waiting and counting on us to deliver on the promise of health and hope. This journey will culminate only when every child, teen, and adult can live to their potential with the help of disease-preventing vaccines.

Better public health is our shared challenge. Innovation is a critical part of the solution, and it's our hope for a healthier world.

At Pfizer Vaccines, we help protect as many people as possible from life-threatening illness with quality vaccines that make an impact across all stages of life. Our employees combine unrelenting passion, global impact, and an enduring quest for progress to unlock the promise and value that vaccines hold for our world. Learn more at www.pfizer.com/science/vaccines.

6.3

HEALTH & FITNESS

The truth about your child's vaccines: No alternative facts allowed

BY SARAH HATFIELD AND LISA GWYNN, D.O.
UHealthSystem.com

AUGUST 07, 2017 3:39 PM

From the time they can barely walk, children learn that a trip to the doctor's office may easily end with shots. Amidst your child's nervous cries, parents often question whether vaccines are the right choice. "Are they safe? Are we giving too many too fast? Are they even necessary?"

This hesitancy is understandable — it's your child and you should ask questions. But over the past few decades, pediatricians have seen a rising number of parents forgoing vaccinations. They've heard stories about the side effects, and whispers about their safety. Why risk it when these diseases are all but extinct, right?

With misinformation frequently circulating in our communities, parents may struggle with the decision to vaccinate, unsure what they should believe. To aid this decision, we've chosen to expose the fiction and highlight the truth about vaccines – no alternative facts allowed.

The bottom line is that the vaccines we use today are incredibly safe. They undergo years of testing before they're released for use and are continuously monitored once they're on the market. Anyone can submit concerns about vaccine safety to the Vaccine Adverse Event Reporting System, assuring that any unforeseen complications do not continue unchecked. These extensive safety protocols have made serious complications incredibly rare. The risk of a severe reaction for most vaccines is less than one in a million. In comparison, the risk of death for infants with whooping cough is one in a hundred, a 10,000 percent increase.

Unfortunately, despite their safety, many myths persist. One of the most common is that the measles, mumps and rubella (MMR) vaccine causes autism. This idea was first proposed in 1998 by a British physician whose claims were rapidly disproven. When he was found accepting money from lawyers suing the vaccine manufacturers, he was accused of fraud and banned from practicing medicine. In the almost 20 years since his paper was published, the medical community has invested tremendous resources to evaluate the vaccine's safety. The results are unanimous — there is absolutely no link between the MMR vaccine and autism.

The doubt and uncertainty surrounding vaccines is undeserved, but more importantly, it obscures the fact that vaccines save lives — two to three million every year, according to the World Health Organization. Diseases that once ran rampant in our communities are now so uncommon in the United States that most physicians have never seen actual cases.

However, since these diseases are so rare, some question whether the vaccines are still necessary. Experience has shown us that the answer is a resounding yes. Despite their elimination in the United States, these diseases are common in other countries and will return if enough people remain unvaccinated. Measles was successfully eliminated from the United States in 2000, but low vaccination rates have caused large outbreaks in recent

years. In Venezuela, vaccine shortages resulted in 324 cases of diphtheria last year, claiming the life of a 9-year-old girl. This deadly disease hadn't been seen within that country in decades but is now a major public health concern there.

Even if you personally think that vaccines are unnecessary, there are other reasons to vaccinate. Vaccines protect not only the people who receive them, but also the vulnerable members of our society who cannot be vaccinated for medical reasons. This is known as herd immunity; when enough of the population is vaccinated, the disease can no longer spread, protecting those at greatest risk. However, for this protection to work, almost everyone must be vaccinated — about 95 percent of the population.

Infants, cancer patients, pregnant women and the elderly are all protected when everyone is vaccinated, and suffer the consequences when they're not.

Currently, Miami-Dade County has some of the lowest vaccination rates in the state with just 91.6 percent of our kindergarten students fully vaccinated, and 90.8 percent of our seventh-grade students. This issue is by no means unique to Florida; schools everywhere are struggling to ensure their students are vaccinated.

We know that vaccines are the single best way of protecting our children from preventable diseases, but as a community, we've fallen short. We need to partner with parents, schools, pediatricians and the health department so that every child is immunized and these deadly diseases are finally eliminated.

As school approaches, we urge parents to make sure their child is fully vaccinated. For those wishing to learn more, the Centers for Disease Control and Prevent has reliable information available online, and your child's pediatrician is also an excellent resource.

We know that parents only want what's best for their child, and figuring out just what that is isn't an easy task. Make use of the credible evidence available and empower yourself with knowledge when deciding whether to vaccinate. Your child's health depends on it.

Sarah Hatfield, is a candidate M.D./MPH for the Class of 2020 at the University of Miami Miller School of Medicine, and Lisa Gwynn, D.O., is associate division director of general pediatrics at the University of Miami Health System. For more information, visit UHealthSystem.com/patients/pediatrics.

7.1

Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

* * * * *

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 14. Section 73.16 is amended by revising paragraph (l)(1) to read as follows:

§ 73.16 Transfers.

* * * * *

(l) * * *

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*e.g.,* prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

* * * * *

■ 15. Section 73.17 is amended as follows:

■ a. In paragraphs (a)(1)(iii) and (a)(3)(v) by adding ''or other storage container'' after ''freezer''.

■ b. By revising paragraph (a)(1)(v).

■ c. By adding paragraph (a)(8).

■ d . By revising paragraph (b).

■ e. By revising paragraph (c).

The revision and additions read as follows:

§ 73.17 Records.

(a) * * *

(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition,

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

* * * * *

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Dated: January 9, 2017.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2017–00726 Filed 1–18–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB01

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

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

ACTION: Final rule.

SUMMARY: On July 29, 2015, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) to amend the regulations governing the National Vaccine Injury Compensation Program (VICP or program) by proposing revisions to the Vaccine Injury Table (Table). The Secretary based the Table revisions primarily on the 2012 Institute of Medicine (IOM) report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the work of nine HHS workgroups who reviewed the IOM findings, and consideration of the Advisory Commission on Childhood Vaccines' (ACCV) recommendations. The Secretary amends the Table through the changes in this final rule. These changes will apply only to petitions for compensation under the VICP filed after this final rule becomes effective.

DATE: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Narayan Nair, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8N146B, Rockville, MD 20857, or by telephone (855) 266–2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–10 *et seq.*), established the VICP, a Federal

compensation program for persons thought to be injured by vaccines. The statute governing the VICP has been amended several times since 1986 and is hereinafter referred to as ''the Act.'' Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is designated as the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes decisions as to eligibility for, and the amount of, compensation.

To gain entitlement to compensation under this program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a ''Table Injury.'' That is, a petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the ''Vaccine Injury Table''—corresponding to the vaccination in question and that the onset of such injury took place within a time period also specified in the Table. If so, the injury is presumed to have been caused by the vaccination and the petitioner is entitled to compensation (assuming that other requirements are satisfied) unless the Respondent affirmatively shows that the injury was caused by some factor other than the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a)).

In prior Table revisions, the Secretary determined that the appropriate framework for making changes to the Table is to make specific findings as to the illnesses or conditions that can reasonably be determined, in some circumstances, to be caused or significantly aggravated by the vaccines under review and the circumstances under which such causation or aggravation can reasonably be determined to occur. The Secretary continues this approach through the use of the 2012 IOM report, the work of the nine workgroups who reviewed the IOM findings, and consideration of the ACCV's recommendations. After consultation with the ACCV, the Secretary may modify the Table by promulgating regulations, with notice and opportunity for a public hearing and at least 180 days of public comment. *See* 42 U.S.C. 300aa–14(c) and (d).

II. Summary of the Final Rule

After the IOM released its 2012 report, 9 HHS workgroups comprising HRSA and Centers for Disease Control and Prevention (CDC) medical staff reviewed IOM's conclusions for 158 vaccine-adverse events, as well as any newly published scientific literature not contained in the report, and developed a set of proposed changes to the Table and its definitional counterpart, the Qualifications and Aids to Interpretation (QAI). For the vast majority of the vaccine-adverse event pairs reviewed (135), the IOM determined that the evidence was inadequate to accept or reject a causal relationship. Considering the remaining IOM conclusions and the ACCV Guiding Principles, the Secretary in this final rule is adopting certain additions or changes to the Table where the scientific evidence either convincingly supports or favors acceptance of a causal relationship between certain conditions and covered vaccines, which are unchanged from the proposed rule. As required by the Act, the changes in the proposed rule were presented to the ACCV, which reviewed and concurred with the Table changes set forth in this final rule.

Additionally, the Secretary, following the recommendation of the ACCV, is finalizing the Table change, as proposed, to add the injury of Guillain-Barré Syndrome (GBS) for seasonal influenza vaccinations, which is consistent with the approach taken in the Countermeasures Injury Compensation Program (CICP). Studies have demonstrated a causal association between the monovalent 2009 H1N1 vaccine and the 1976 swine flu vaccine and GBS. These causal associations were the basis of the 2015 decision by the Secretary in the CICP Pandemic Influenza A Countermeasures Injury Table Final Rule (80 FR 47411) to include GBS as an injury associated with the 2009 H1N1 influenza. With respect to that vaccine, the Secretary found that there was compelling, reliable, and valid medical and scientific evidence of an association between the 2009 H1N1 vaccine and GBS, which is required to add an injury to the CICP's Injury Table. To date, the H1N1 antigen has been included in all seasonal influenza vaccines beginning with the 2010–2011 flu season. HHS notes that seasonal influenza vaccine formulations, unlike other vaccines, include multiple antigens that change from year-to-year, and enhanced surveillance activities to detect the incidence of GBS that occurred during the 2009 H1N1 pandemic may not occur with each virus strain change. In light of this information and other information as discussed in the proposed rule, the ACCV recommended that the Secretary add GBS consistent with one of its Guiding Principles: That where there is credible evidence to both support and reject a change to the Table, the change should, whenever possible, be made to the benefit of petitioners.

In addition, in the final rule, the Secretary adopts the proposed rule's new paragraph (b), *Provision that applies to all vaccines listed.* To streamline the Table, this paragraph includes any acute complication or sequela, including death, of the illness, disability, injury, or condition listed, as a Table injury (absent an exclusion as set forth under the QAI) rather than adding the provision to every line of the Table. To further streamline the Table, the Secretary deleted redundant wording in the various definitions, particularly with regard to any references to the presumption of causation, and the importance of the entire medical record. These elements have been included in paragraph (b) and are unchanged from the proposed rule. Finally, in this final rule, the Secretary adopts changes in the proposed rule that simplify and expand applicability of a provision that previously applied only to an encephalopathy. This provision, which indicates that idiopathic conditions do not rebut the Table presumption, now applies (through inclusion in paragraph (b)), to all injuries, while continuing to apply to an encephalopathy.

In this final rule, in addition to the changes described in the proposed rule, the Secretary has made the following non-substantive changes to the proposed rule for purposes of clarity:

a. Added headings to (c)(2)(ii) and (c)(3)(ii).

b. Moved text from the end of paragraph (c)(3)(ii)(C) to create a new (c)(3)(ii)(D).

c. Changed paragraphs (c)(11) and (12) by revising the sentence regarding organs other than the skin by adding ''the'' before '' disease'', inserting ''and'' after ''organ'', and moving '', not just mildly abnormal laboratory values'' to the end of the sentence.

d. Revised paragraph (c)(15)(i) by changing ''nine weeks'' to ''9 weeks''.

e. Changed paragraph (e)(1) (''Coverage Provisions'') for purpose of clarity and consistency with 42 U.S.C. 300aa–14(c)(4) by adding ''only'' before ''to petitions for compensation.''

The modified Table applies only to petitions filed under the VICP after the effective date of this final rule. Also, petitions must be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed under the VICP, set forth in 42 U.S.C. 300aa–16(a),

continues to apply. However, the statute identifies a specific exception to this statute of limitations that applies when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this exception, an individual who may be eligible to file a petition based on the revised Table may file the petition for compensation not later than 2 years after the effective date of the revision if the alleged injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)). This is true even if such individual previously filed a petition for compensation, and is thus an exception to the ''one petition per injury'' limitation of 42 U.S.C. 300aa–11(b)(2).

For any vaccine-adverse event pairs for which future scientific evidence develops to support a finding of a causal relationship, the Secretary will consider future rulemaking to revise the Table accordingly.

III. Comments and Responses

The NPRM provided a 180-day comment period that resulted in the receipt of 14 written comments—13 from individuals and one from a national organization. In addition, a public hearing on the proposed rule was held on January 14, 2016, during which a representative from the above mentioned national organization presented comments. The organization's oral comments were an expansion of the organization's previously submitted written comments. The Secretary carefully considered all received comments in the development of this final rule. Below is a summary of the comments and the Secretary's responses:

Comment: One commenter suggested that vaccines are unsafe, disagreed with the process for predicting vaccine harm to humans, and disagreed with the makeup of the ''group assembled to force changes in this Table,'' calling it a biased group.

Response: The United States has a long-standing vaccine safety program that closely monitors the safety of vaccines on an ongoing basis. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side effects and conduct studies to determine whether health problems are caused by vaccines. CDC's ISO data show that the current U.S. vaccine supply is the safest in history.[1] Also, regulating clinical research and reviewing the safety of vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

As previously indicated, the Table revisions were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: Pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.

Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

Comment: A commenter recommends revising the statute of limitations for filing complex cases, with additional consideration given to the aggravation of preexisting conditions not active until post vaccine(s).

Response: Revision of the statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: A commenter stated that there is a problem with the VICP's 3-year statute of limitations for filing a claim and the military's 5-year program titled, Temporary Disabled Retirement Listing (TDRL), where active duty military personnel injured by vaccines are placed. The commenter stated that the rules need to be amended and/or waivers granted to military personnel who are severely injured by vaccines so they can seek compensation for damages.

Response: Amending the Act's statute of limitations is not within the scope of this final rule.

Comment: A commenter recommended the addition of SIRVA to the vaccine court [sic]. The commenter also indicated a belief that SIRVA is due to lack of education on proper injection technique. The commenter further stated that the CDC should make SIRVA, which the commenter believes is 100 percent preventable, a priority.

Response: This final rule will add SIRVA as an injury associated with certain vaccines on the Table. In the VICP, claims are adjudicated by special masters in the Court. SIRVA prevention activities are not within the scope of this final rule.

Comment: A commenter recommended that the VICP transfer a fraction of its compensation responsibilities to pharmaceutical companies, which would incentivize these companies to develop safer vaccines to avoid claim compensation.

Response: The source of funding for the VICP is the Vaccine Injury Compensation Trust Fund (Trust Fund). The Trust Fund is funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

Comment: A commenter agreed with the Secretary's proposal that SIRVA injuries be added to the Table for the

[1] *http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html*

measles, mumps, and rubella (MMR) and varicella vaccines that are currently administered only by percutaneous injection in case an intramuscular injection is available in the future. The commenter suggested that the Table make clear that SIRVA only pertains to intramuscular injection so there is no confusion with respect to vaccines administered using a different method. The commenter also suggested that syncope be added as an injury for vaccines that are administered by jet injectors. The commenter expressed support for the revision of the Table based on new medical findings and for the organizational changes to paragraph (b) of the Table.

Response: The Secretary agrees that SIRVA should be an injury listed on the Table for potential future formulations of MMR and varicella vaccines that are administered by intramuscular injection, and, therefore, has added SIRVA to the Table for those vaccines despite the fact that currently there are no MMR or varicella vaccines that are administered by intramuscular injection. As such, if an intramuscular formulation of those vaccines is developed in the future, the Table will not need to be amended to allow petitioners to potentially meet the definition for SIRVA in the QAI with respect to those vaccines. The QAI specifically states that SIRVA is a condition related to ''administration of a vaccine intended for intramuscular administration in the upper arm.'' Thus, the Secretary believes it is clear that to meet the definition of SIRVA in the QAI, the vaccine administered must be one intended for intramuscular injection in the upper arm.

The Secretary is not aware of any reliable and persuasive evidence demonstrating that syncope occurs following administration of a vaccine via a needleless jet device. While it may be plausible for syncope to occur with this route of administration, given the lack of evidence of syncope following administration of a vaccine via a needleless jet device, the Secretary will not include syncope as a Table injury for vaccines that are administered by a needleless jet device at this time. However, this does not preclude a claim alleging syncope after the administration of a vaccine via needleless jet device from being filed with the program as a non-Table injury.

Comment: One commenter opposed the revision of the Vaccine Injury Table's QAI for encephalopathy, stating that it is not based on sound science and that it creates a restrictive and exclusionary guideline that unfairly discriminates against children and adults born with certain genes or pre-existing conditions (which may be triggered or significantly aggravated following vaccination). The commenter further contends that due to lack of knowledge about biological mechanisms and high risk factors for vaccine injury, the proposed changes are without ethical, scientific, or legal justification.

Response: The Secretary respectfully disagrees with the comment that the revised definition for encephalopathy and the new definition for encephalitis in the QAI are not based on firm science. The previous definition of encephalopathy in the QAI was imprecise and did not include the comprehensive criteria used by medical providers, particularly specialists, to diagnose encephalopathy or encephalitis. In addition, the previous QAI did not include any definition for encephalitis, and, therefore, new and more accurate criteria and definitions were necessary. To develop precise definitions for the QAI, an extensive literature search was conducted for reliable, reputable, evidence-based criteria consistently used by medical specialists in the fields of infectious disease and neurology. The Secretary also evaluated information from organizations and publications to formulate definitions, including those responsible for publishing case definitions for the Vaccine Adverse Event Reporting System (2002) and other significant guidelines.

The commenter also stated that the proposed revisions create a restrictive and exclusionary guideline, unfairly discriminating against children and adults born with certain genes or pre-existing conditions which may be triggered or significantly aggravated following vaccination. The Secretary understands these concerns and agrees that individuals should not be disqualified from potentially receiving VICP compensation due to biodiversity and individual susceptibilities. Certain individuals may not meet the QAI definition, as it is impossible to develop a scientifically sound definition that allows for inclusion of every circumstance, particularly those that may arise when unique and sometimes complex pre-vaccination medical conditions exist.[2] However, individuals who do not meet the Table criteria are not precluded from filing a petition, and may be found entitled to receive compensation if they demonstrate that their condition was caused or significantly aggravated by a covered vaccine.

[2] 2012 IOM Report, pp. 52, and 82–84.

Comment: One commenter also noted that, historically, acute and chronic encephalopathy have been acknowledged as a serious complication of pertussis, measles and measles containing vaccines, and have been reported following receipt of other vaccines.

Response: With regard to this comment, it is important to note that the initial Table and QAI set forth in the 1986 Act reflected Congress's initial determination of vaccine-related injuries for whole cell diphtheria, tetanus, and pertussis (DTwP) vaccine, which is no longer used. Additionally, modifications to the Table and QAI by the Secretary in 1995 were based on scientific findings—the National Childhood Encephalopathy Study and its 10-year follow-up study—related to DTwP vaccine. The IOM committee's conclusions in both 1991 and 1994 were mixed regarding the statistically significant findings of encephalopathy in these studies. After reviewing the evidence, the National Vaccine Advisory Committee (NVAC) voted to remove encephalopathy from the Table. However, in the end, the Secretary, for both scientific and policy reasons, and with support of the ACCV, retained the condition on the Table, but clarified the definition of encephalopathy to make it more clinically precise.

While the initial Table and QAI were based on studies using DTwP vaccine, the acellular (aP) diphtheria, tetanus, and pertussis (DTaP) vaccine has been the primary formulation used in the United States since 1997 when it was recommended for routine use in children younger than 7 years of age. Current DTaP vaccines were developed because of concerns of reactogenicity with whole cell pertussis.

To date, no adequate scientific study has been published that demonstrates a causal relationship between either acellular pertussis vaccines or MMR vaccines and encephalopathy or encephalitis. As a result, in its most recent evaluation of adverse events after vaccines (2012), the IOM found that the evidence was inadequate to accept or reject a causal association between either acellular pertussis containing vaccines or MMR vaccines and encephalopathy or encephalitis. Of the large scale studies that have been conducted on DTaP, none have shown an increased risk of encephalopathy or encephalitis after receiving the DTaP vaccine. Furthermore, these studies have demonstrated a significant reduction in the number of common adverse events with acellular pertussis, such as crying and fevers, and less common ones, such as febrile seizures.

With regard to the MMR vaccine, because natural infection of measles, mumps and/or rubella virus is thought to lead to neurologic illness by damaging neurons through direct viral infection and/or reactivation, it is theorized that the same mechanisms may be responsible for vaccine-associated encephalopathy and encephalitis. However, of the studies examined and described by the IOM in its 2012 report, none identified causality between the MMR vaccine and encephalopathy or encephalitis. Similarly, the IOM concluded that the mechanistic evidence for an association is weak, based on knowledge about natural infection and only a few case reports. Accordingly, the Secretary does not agree that brain inflammation or acute and chronic encephalopathy have been acknowledged as a serious complication of either the DTaP or MMR vaccines. However, for the reasons discussed in the NPRM, the Secretary chose to retain these conditions in the revisions to the Table and QAI.

Comment: One commenter, when conveying views on acute encephalopathy as ''one of the most serious complications of vaccination . . .'' also referenced both encephalitis and encephalomyelitis in the discussion.

Response: The Secretary would like to clarify that encephalitis and encephalomyelitis (which is referred to as acute disseminated encephalomyelitis or ADEM) are distinct conditions. While they share some clinical characteristics, ADEM is a demyelinating condition with distinct differences from other types of encephalitis, as demonstrated on brain magnetic resonance imaging (MRI). The type of encephalitis that was initially attributed to DTwP was not described as demyelinating. Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on an MRI are distinct, with only ADEM displaying evidence of acute demyelination. For scientific accuracy, we have excluded ADEM from the Table definition of encephalitis.

Comment: One commenter, while applauding the expansion of the Vaccine Injury Table and agreeing with the IOM's recommendations, stated that the Table remains wholly inadequate to properly address ''the widespread epidemic of vaccine adverse events.'' The commenter stated that the reason for this is that science has been corrupted by commercial interests, by financial ties between industry, regulators, and academic institutions and that health care delivery has been compromised by financial ties between industry, physicians, and their trade publications.

Response: The Secretary believes that the revisions to the Table and QAI increase clarity and scientific accuracy regarding those injuries that will be afforded the Table's presumption of vaccine causation. As previously indicated, the revisions to the Table and QAI were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: One commenter stated that the Secretary should not make changes to the Vaccine Injury Table that would make it more difficult for ''victims'' to be compensated.

Response: The Secretary believes that the revisions to the Table and QAI set forth in this final rule, such as the addition of injuries, will make it easier for petitioners alleging injuries that meet the criteria in the Table and QAI to receive the Table's presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury). This will make it easier for such petitioners to receive compensation under the VICP.

Comment: One commenter asked that additional consideration be given to the human papillomavirus (HPV) vaccination as a cause of postural orthostatic tachycardia syndrome (POTS), a condition where individuals can experience fainting and lightheadedness. The commenter also stated that the ''review period'' should be indefinite for the HPV vaccine.

Response: Like all vaccines used in the United States, HPV vaccines are required to go through years of safety testing before they are approved by the FDA. After they are approved and made available to the public, CDC and FDA continue to evaluate vaccines to ensure their safety. To date, there is no medical or scientific evidence that the HPV vaccine causes POTS and safety monitoring has not shown any other problems. Extending the review period for alleged injuries due to the HPV vaccine would require a statutory amendment to the Act's statute of limitations which is not within the scope of the final rule.

Comment: A commenter requested that food allergies be added to the Table asserting that food proteins that are present in vaccines cause the development of food allergies. The commenter also requested removal of the time limit that compensation is not provided for injuries or death that occurred more than ''8 years before the effective date of the revision of the Table'' because the commenter believes that ''food proteins in vaccines have been causing injury for decades.''

Response: The Secretary does not agree that food allergies should be added to the Table as injuries. HHS conducted a literature search of the major medical databases for any articles linking the development of food allergies to vaccinations (81 FR 17423, March 29, 2016). Despite an extensive search, HHS found no published research addressing any linkages or potential causality between vaccinations covered by VICP and the development of food allergies in any population. In addition, revision of the Act's statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: One commenter suggested that autism spectrum disorders be added to the Vaccine Injury Table. The commenter also requested removal of the time limit that compensation not be provided for injuries or death that occurred more than ''8 years before the effective date of the revision of the Table'' because the commenter believes that ''bovine milk contaminated vaccines have been causing injury for decades.''

Response: The Secretary does not agree that autism spectrum disorders should be added as an injury to the Table. The 2012 IOM report found that the epidemiologic and mechanistic evidence favored rejection of a causal relationship between the MMR vaccine and autism. Moreover, in opinions that were upheld on appeal to the U.S. Court of Appeals for the Federal Circuit, special masters of the U.S. Court of Federal Claims held that the MMR, whether administered alone or in conjunction with thimerosal-containing vaccines, is not a causal factor in the development of autism or autism spectrum disorders. In addition, revision of the Act's statute of limitations would require a statutory

amendment and thus is not within the purview of this final rule.

Comment: One commenter stated that thimerosal (a preservative added to vaccines) causes nerve damage.

Response: The Secretary disagrees with the comment that thimerosal in vaccines causes nerve damage to immunized individuals. Currently, no childhood vaccines used in the U.S. include thimerosal as a preservative, except for some formulations of influenza vaccine in multi-dose vials. When exposure to thimerosal occurs through vaccination, it is at a very low dose, which is readily eliminated from the body. Thimerosal has been used safely in vaccines since the 1930s. According to the CDC, scientists have been studying the use of thimerosal in vaccines for many years. They have not found any evidence that thimerosal causes any harm. Thimerosal use in medical products has a record of being very safe. Data from many studies show no evidence of harm caused by low doses of thimerosal in vaccines.[3]

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this rule. Compensation will be made in the same manner. This final rule only lessens the burden of proof for potential petitioners. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this final rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the final rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

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

This rule is not being treated as a ''significant regulatory action'' as defined under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

As stated above, this final rule will modify the Vaccine Injury Table and its Qualifications and Aids to Interpretation based on legal authority.

Impact of the New Rule

This final rule will have the effect of making it easier for future petitioners alleging injuries that meet the criteria in the Vaccine Injury Table to receive the Table's presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury).

Paperwork Reduction Act of 1995

This final rule has no information collection requirements.

Dated: January 6, 2017.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: January 9, 2017.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

Therefore, for the reasons stated in the preamble, the Department of Health and Human Services amends 42 CFR part 100 as follows:

PART 100—VACCINE INJURY COMPENSATION

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

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

■ 2. Revise § 100.3 to read as follows:

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such

[3] Following are referenced thimerosal studies:

1. Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association by Nick Andrews et al. Pediatrics. September 2004. Vol 114: pp. 584–591. *http://pediatrics.aappublications.org/cgi/content/full/114/3/584.*

2. Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations by Eric Frombonne et al. Pediatriacs. July 2006. Vol 118: e139–e150. *http://pediatrics.aappublications.org/cgi/content/full/118/1/e139.*

3. Association between Thimerosal-Containing Vaccine and Autism by Anders Hviid et al. Journal of the American Medical Association. October 2003. Vol 290: pp. 1763–1766. *http://jama.ama-assn.org/cgi/content/full/290/13/1763.*

4. Immunization Safety Review: Vaccines and Autism. Institute of Medicine. The National Academies Press: 2004. *http://www.iom.edu/Reports/2004/Immunization-SafetyReview-Vaccines-and-Autism.aspx.*

5. Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism by Cristofer Price et al. Pediatrics. September 2010. Vol 126: pp. 656–664, *http://pediatrics.aappublications.org/cgi/reprint* peds. 20100309v1.

6. Continuing Increases in Autism Reported to California's Developmental Services System by Robert Schechter et al. Archives of General Psychiatry. January 2008. Vol 65: pp. 19–24. *http://archpsyc.ama-assn.org/cgi/content/full/65/1/19.*

7. Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years by William Thompson et al. The New England Journal of Medicine. September 2007. Vol 357: pages 1281–1292. *http://www.nejm.org/doi/pdf/10.1056/NEJMoa071434.*

injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (*e.g.,* DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	2–28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.,* DTP, DTaP, P, DTP-Hib).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.,* MMR, MM, MMRV).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	5–15 days (not less than 5 days and not more than 15 days).
	C. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
IV. Vaccines containing rubella virus (*e.g.,* MMR, MMRV).	A. Chronic arthritis	7–42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (*e.g.,* MMR, MM, MMRV).	A. Thrombocytopenic purpura	7–30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient.	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive.	≤12 months.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio.	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection.	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
VII. Vaccines containing polio inactivated virus (*e.g.,* IPV).	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
IX. Haemophilus influenzae type b (Hib) vaccines.	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
X. Varicella vaccines	A. Anaphylaxis	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease.	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive.	7–42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	Not applicable.
	D. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	E. Vasovagal syncope	≤1 hour.
XI. Rotavirus vaccines	A. Intussusception	1–21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	B. Vasovagal syncope	≤1 hour.
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
	D. Guillain-Barré Syndrome	3–42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1hour.

(b) *Provisions that apply to all conditions listed.* (1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(c) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Encephalopathy.* A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalopathy.* (A) For children less than 18 months of age who present:

(*1*) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.

(*2*) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:

(*1*) A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis);

(*2*) A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and

(*3*) A seizure associated with loss of consciousness.

(C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.

(ii) *Exclusionary criteria for encephalopathy.* Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or

perinatal central nervous system (CNS) injury); or

(B) An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

(3) *Encephalitis.* A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalitis.* Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

(A) Evidence of neurologic dysfunction consists of either:

(*1*) One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

(*2*) An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.

(B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm^3 in children >2 months of age and adults; >15 WBC/mm3 in children <2 months of age); or at least two of the following:

(*1*) Fever (temperature ≥ 100.4 degrees Fahrenheit);

(*2*) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(*3*) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.

(ii) *Exclusionary criteria for encephalitis.* Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:

(A) An underlying malignancy that led to a paraneoplastic encephalitis;

(B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or

(C) Acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) *Intussusception.* (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

(5) *Chronic arthritis.* Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation recorded within 30 days after the onset of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.

(6) *Brachial neuritis.* This term is defined as dysfunction limited to the upper extremity nerve plexus (*i.e.,* its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is

typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;

(ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

(7) *Thrombocytopenic purpura.* This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3 with normal red and white blood cell indices. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) *Vaccine-strain measles viral disease.* This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) *Vaccine-strain polio viral infection.* This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(10) *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (*e.g.* tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

(11) *Disseminated varicella vaccine-strain viral disease.* Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7– 42 days after vaccination.

(12) *Varicella vaccine-strain viral reactivation disease.* Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type

varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.

(13) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.

(14) *Immunodeficient recipient.* Immunodeficient recipient is defined as an individual with an identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.

(15) *Guillain-Barré Syndrome (GBS).* (i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:

(A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;

(B) A monophasic illness pattern;

(C) An interval between onset and nadir of weakness between 12 hours and 28 days;

(D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,

(E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:

(A) Bilateral ophthalmoparesis;

(B) Bilateral reduced or absent tendon reflexes;

(C) Ataxia;

(D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);

(E) A monophasic illness pattern;

(F) An interval between onset and nadir of weakness between 12 hours and 28 days;

(G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);

(H) No alteration in consciousness;

(I) No corticospinal track signs; and

(J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.

(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) *Glossary for purposes of paragraph (c) of this section*—(1) *Chronic encephalopathy.* (i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.

(2) *Injected* refers to the intramuscular, intradermal, or

subcutaneous needle administration of a vaccine.

(3) *Sequela* means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(4) *Significantly decreased level of consciousness* is indicated by the presence of one or more of the following clinical signs:

(i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(5) *Seizure* includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(e) *Coverage provisions.* (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the United States Court of Federal Claims on or after February 21, 2017.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the **Federal Register** to announce the effective date of such a tax.

[FR Doc. 2017–00701 Filed 1–18–17; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[17X.LLWO310000.L13100000.PP0000]

RIN 1004–AE49

Onshore Oil and Gas Operations—Annual Civil Penalties Inflation Adjustments

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This rule adjusts the level of civil monetary penalties contained in the Bureau of Land Management's regulations governing onshore oil and gas operations as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the ''Act''). The adjustments made by this final rule constitute the annual inflation adjustments contemplated by the Act, and are consistent with applicable Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Wells, Division Chief, Fluid Minerals Division, 202–912–7143, for information regarding the BLM's Fluid Minerals Program. For questions relating to regulatory process issues, please contact Jennifer Noe, Division of Regulatory Affairs, at 202–912–7442. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week to contact the above individuals.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed the Act into law (Sec. 701 of Pub. L. 114–74). The Act requires agencies to:

1. Adjust the level of civil monetary penalties with an initial ''catch-up'' adjustment through an interim final rulemaking in 2016;

2. Make subsequent annual adjustments for inflation beginning in 2017; and

3. Report annually in Agency Financial Reports on these inflation adjustments.

In July 2016, the BLM issued an interim final rule that adjusted the level of civil monetary penalties with the initial ''catch-up'' adjustment, which is reflected in the table below in the ''Previous Penalty'' column.

With this final rule, the BLM is adjusting civil monetary penalties for inflation. The adjustments made by this rule are consistent with the requirements of the Act and OMB guidance.

The purpose of these adjustments is to maintain the deterrent effect of civil penalties found in existing regulations, in order to further the policy goals of the underlying statutes. The BLM has reviewed its existing regulations and determined that only the civil monetary penalties found at 43 CFR 3163.2 are subject to the Act's requirements.

The adjustments made by this final rule constitute the first annual adjustment contemplated by the Act, and include the following changes to the penalties:

CFR Citation	Description of the penalty	Previous penalty	Adjusted penalty
43 CFR 3163.2(a)	Failure to comply	$1,031	$1,048
43 CFR 3163.2(b)	If corrective action is not taken	10,314	10,483
43 CFR 3163.2(d)	If transporter fails to permit inspection for documentation	1,031	1,048
43 CFR 3163.2(e)	Failure to permit inspection, failure to notify	20,628	20,965
43 CFR 3163.2(f)	False or inaccurate documents; unlawful transfer or purchase	51,570	52,414
43 CFR 3163.2(g)(1)	Initial penalty under 43 CFR 3163.2(a) for a major violation	1,031	1,048
43 CFR 3163.2(g)(1)	Maximum penalty under 43 CFR 3163.2(a) for a major violation	2,063	2,097

7.2

Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not impose substantial direct costs on tribal governments or preempt tribal law. This SIP revision is not approved to apply in Indian reservations in the State, or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: January 4, 2017.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2017–01090 Filed 1–18–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting a Rulemaking Proceeding

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

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa–14(c)(2)(B), notice is hereby given concerning the reasons for not conducting a rulemaking proceeding to add neurological disorders or conditions as injuries associated with seasonal influenza vaccines to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT: Narayan Nair, MD, Director, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 8N146B, Rockville, Maryland 20857, or by telephone 301–443–6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, (Vaccine Act), Title III of Public Law 99–660, established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines.[1] Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. To gain entitlement to compensation under VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death in one of the following ways (unless another cause is found): (1) By proving that the first symptom of an injury or condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine; (2) by proving vaccine causation, if the injury or condition is not on the Table or did not occur within the time period specified on the Table; or (3) by proving that the vaccine significantly aggravated a pre-existing condition.

The statute authorizing VICP provides for the inclusion of additional vaccines in VICP when they are recommended by the Centers for Disease Control and Prevention for routine administration to children.[2] Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines.[3] The statute authorizing VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table.[4] Finally, the Vaccine Act provides that:

> [a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—
>
> (A) Receipt of any recommendation of the Commission, or
>
> (B) 180 days after the date of the referral to the Commission,
>
> whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish

[1] 42 U.S.C. 300 aa–10 et seq.

[2] Section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(e)(2).

[3] 42 CFR 100.3(c)(8).

[4] Sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c) and 300aa–14(e)(2).

in the **Federal Register** a statement or reasons for not conducting such proceeding.[5]

On January 28, 2016, a private citizen submitted a petition to the Department of Health and Human Services (HHS) requesting that: (1) Any adverse neurological disorder or condition be added to the Table for the seasonal influenza vaccines; and (2) if any adverse neurological disorder or condition was too broad in scope, then at least anaphylaxis, Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, multiple sclerosis (MS), Guillain-Barré Syndrome (GBS), transverse myelitis (TM), and myelitis be added to the Table for the seasonal influenza vaccine. The petitioner asserted that based on Vaccine Adverse Event Reporting System (VAERS) data and Department of Justice (DOJ) quarterly reports on vaccine settlements, which were presented at Commission meetings, there is sufficient evidence to add these conditions as injuries associated with the seasonal influenza vaccine to the Table. The petitioner did not provide any medical or scientific literature to accompany the request.

Pursuant to the Vaccine Act, the petition was referred to the Commission on June 3, 2016. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table to include ''any adverse neurological disorder or condition,'' MS, TM, or myelitis as injuries associated with seasonal influenza vaccines as requested in the petition.

The petitioner requested the addition of any adverse neurological disorder or condition to the Table for the seasonal influenza vaccine. The petitioner alleged that the DOJ quarterly reports on vaccine settlement cases and VAERS data support the inclusion of all of these conditions to the Table. However, neither of these sources of data is sufficient to modify the Table. The DOJ quarterly report is the report that DOJ provides and discusses at the quarterly Commission meetings and is made available to the public at *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/meetings.html.* The report includes a list of adjudicated settlements for the applicable quarter by vaccine and alleged injury, and time frame from petition filing to settlement filing. In negotiated settlements between the parties, HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury. These settlements are not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injury, and, in settled cases, the Court does not determine that the vaccine caused the injury. Therefore, a settlement cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Thus, information from negotiated settlements cannot be used to establish that vaccines cause certain injuries.

The purposes of VAERS data are to: Detect new, unusual, or rare vaccine adverse events; identify potential patient risk factors for particular types of adverse events; identify vaccine lots with increased numbers or types of reported adverse events; and assess the safety of newly licensed vaccines. The VAERS data are considered a useful tool in vaccine safety, but VAERS reports by themselves generally cannot demonstrate that vaccines cause injuries.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiologic, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by VICP. The results of this review were published in the 2012 IOM Report, ''*Adverse Effects of Vaccines: Evidence and Causality.*'' This report reviewed 8 of the 12 vaccines covered by the VICP and provided 158 causality conclusions. The 2012 IOM Report reviewed the medical and scientific literature regarding a causal relationship between seasonal influenza vaccines and the following conditions: Encephalopathy, encephalitis, seizures, acute disseminated encephalomyelitis, TM, optic neuritis, neuromyelitis optica, MS, MS relapse, GBS, chronic inflammatory demyelinating polyneuropathy, Bell's palsy, brachial neuritis, and small fiber neuropathy. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and the above conditions. Therefore, ''any adverse neurological disorder or condition,'' as suggested by the petitioner will not be added as injuries caused by the seasonal influenza vaccine to the Table since the medical and scientific literature is not sufficient to support this change.

The petitioner also requested that certain conditions be added to the Table if ''any adverse neurological disorder or condition'' could not be added to the Table. These conditions include: Anaphylaxis, SIRVA, vasovagal syncope, MS, GBS, TM, and myelitis. The petitioner stated that VAERS and settlement data from quarterly reports support the inclusion of these conditions for seasonal influenza vaccines to the Table. However, as explained above, the VAERS data and the DOJ quarterly report do not demonstrate that vaccines cause injuries and do not establish causality. As stated previously, the 2012 IOM Report reviewed the medical and scientific literature regarding causal relationships between seasonal influenza vaccines and MS, TM, and myelitis. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and these conditions.

More recent studies support the lack of an association between the seasonal influenza vaccine and neurologic conditions, such as MS. The Williamson, et al. study found no substantiation to reports suggesting a link between MS and vaccines and that most of the studies that purported an increased risk of MS or relapse of MS after vaccination were small case series, which are methodologically less robust than other epidemiologic studies.[6] In addition, Langer-Gould, et al. conducted a nested case control study that found no long-term association between vaccines and MS or other central nervous system acquired demyelinating syndromes.[7] Therefore, MS, TM, and myelitis will not be added to the Table as injuries associated with the seasonal influenza vaccine since the medical and scientific literature is not sufficient to support those changes.

HHS proposed certain changes to the Vaccine Injury Table in a Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on July 29, 2015 (80 Fed. Reg. 45132 (July 29, 2015)). Among other proposed changes, anaphylaxis, SIRVA, GBS, and vasovagal syncope were proposed to be added as injuries for seasonal influenza vaccines. HHS is adding these injuries with the final rule, titled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,'' concurrently publishing in the **Federal Register**.

In conclusion, there is no reliable evidence to support the addition of ''any adverse neurological disorder or condition,'' MS, TM, or myelitis to the Table as injuries associated with the seasonal influenza vaccine. Therefore, the Table will not be amended at this time to include those injuries on the Table.

[5] Section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2).

[6] Williamson et al. Vaccines in Multiple Sclerosis, Curr Neurol Neurosci Rep 2016 16:36.

[7] Langer-Gould et al., Vaccines and the risk of MS and other CNS Demyelinating Diseases, JAMA Neurol. 2014:71(12): 1506–13.

Dated: January 9, 2017.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–00700 Filed 1–18–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

48 CFR Parts 3001, 3002, 3024, and 3052

[Docket No. DHS–2017–0008]

RIN 1601–AA79

Homeland Security Acquisition Regulation (HSAR); Privacy Training (HSAR Case 2015–003)

AGENCY: Office of the Chief Procurement Officer, Department of Homeland Security (DHS).

ACTION: Proposed rule.

SUMMARY: DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR) to add a new subpart, update an existing clause, and add a new contract clause to require contractors to complete training that addresses the protection of privacy, in accordance with the Privacy Act of 1974, and the handling and safeguarding of Personally Identifiable Information and Sensitive Personally Identifiable Information.

DATES: Interested parties should submit written comments to one of the addresses shown below on or before March 20, 2017, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by HSAR Case 2015–003, Privacy Training, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by entering ''HSAR Case 2015–003'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''HSAR Case 2015–003.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''HSAR Case 2015–003'' on your attached document.

- *Fax:* (202) 447–0520
- *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, ATTN: Ms. Candace Lightfoot, 245 Murray Drive, Bldg. 410 (RDS), Washington, DC 20528.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *http://www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Candace Lightfoot, Procurement Analyst, DHS, Office of the Chief Procurement Officer, Acquisition Policy and Legislation at (202) 447–0882 or email *HSAR@hq.dhs.gov.* When using email, include HSAR Case 2015–003 in the ''Subject'' line.

SUPPLEMENTARY INFORMATION:

I. Background

DHS contracts currently require contractor and subcontractor employees to complete privacy training before accessing a Government system of records; handling Personally Identifiable Information (PII) or Sensitive PII (SPII); or designing, developing, maintaining, or operating a Government system of records. This training is completed upon award of the procurement and at least annually thereafter.

DHS is proposing to (1) include Privacy training requirements in the HSAR and (2) make the training more easily accessible by hosting it on a public Web site. This approach ensures all applicable DHS contractors and subcontractors are subject to the same requirements while removing the need for Government intervention to provide access to the Privacy training.

This proposed rule standardizes the Privacy training requirement across all DHS contracts by amending the HSAR to:

(1) Add the terms ''personally identifiable information'' and ''sensitive personally identifiable information'' at HSAR 3002.1, Definitions. The definition of ''personally identifiable information'' is taken from OMB Circular A–130 Managing Information as a Strategic Resource,[1] published July 27, 2016. The definition of ''sensitive personally identifiable information'' is derived from the DHS lexicon, Privacy Incident Handling Guidance, and the Handbook for Safeguarding Sensitive Personally Identifiable Information. These definitions are necessary because these terms appear in proposed HSAR 3024.70, Privacy Training and HSAR 3052.224–7X, Privacy Training.

(2) Add a new subpart at HSAR 3024.70, Privacy Training addressing the requirements for privacy training. HSAR 3024.7001, Scope identifies the applicability of the subpart to contracts and subcontracts. HSAR 3024.7002, Definitions defines the term ''handling.'' The definition of ''handling'' was developed based upon a review of definitions for the term developed by other Federal agencies. HSAR 3024.7003, Policy identifies when contractors and subcontracts are required to complete the DHS privacy training. This subsection also requires the submission of training completion certificates for all contractor and subcontractor employees as a record of compliance. HSAR 3024.7004, Contract Clause, identifies when Contracting Officers must insert HSAR 3052.224–7X Privacy Training in solicitations and contracts. DHS welcomes respondents to offer their views on the following questions in particular:

A. What burden, if any, is associated with the requirement to complete DHS-developed privacy training?

B. What value, if any, is associated with providing industry the flexibility to develop its own privacy training given a unique set of Government requirements?

(3) Amend sub paragraph (b) of the HSAR 3052.212–70, Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items to add HSAR 3052.224–7X, Privacy Training. This change is necessary because HSAR 3052.224–7X is applicable to the acquisition of commercial items; and

(4) Add a new subsection at HSAR 3052.224–7X, Privacy Training to provide the text of the proposed clause. The proposed clause requires contractor and subcontractor employees to complete privacy training before accessing a Government system of records; handling Personally Identifiable Information (PII) or Sensitive PII (SPII); or designing, developing, maintaining, or operating a Government system of records. The training shall be completed within thirty (30) days of contract award and on an annual basis thereafter. The contractor shall maintain copies of training certificates for all contractor and subcontractor employees as a record of compliance and provide copies of the training certificates to the contracting officer. Subsequent training certificates to satisfy the annual privacy training requirement shall be submitted via email notification not later than October 31st of each year. The contractor shall attach training certificates to the email

[1] OMB Circular A–130 *Managing Information as a Strategic Resource* is accessible at *https://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf.*

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From: barbara sachau <bsachau@gmail.com>
Sent: Monday, August 07, 2017 3:35 PM
To: Johnson, Ashyia (HRSA); Herzog, Andrea (HRSA); McNulty, Amy (HRSA); americanvoices@mail.house.gov
Subject: Re: comment

public comment for the meeting.

as a u.s. citizen I am disappointed in the failure of this committee to take any action to stop the use and pushing of vaccines on the aemrican public when we can all see the vast massive number of children increasingly being harmed by these vaccines. the far too aggressive schedule on these vaccins, the fact that you want doctors to push them on kids whose parent sknow that some kids cannot take such insidious toxic chemicals into their system show s complete disregard for the safety and health of our future citizens. it is terrorism of the worst kind.
you all should be responsible financially for the harmyou are causing to so many many American and other lives on this planet. this comment is for the public record. please receipt. jean publiee jeanpublic1@gmail.com certainly those who want the vaccines should be able to take them, but in no way should those who have misgivings about these harmful toxins be forced to take them. every body is different. you are acting like dr. Mengele in forcing people who don't want this to be injected. dog cells, aluminum, eggs, mercury., and other metals, and so many other factors such as temperature and perhaps manufacturing that is less than faultless can influence the harm from thiese vaccines.

On Mon, Aug 7, 2017 at 9:15 AM, Jean Public <jeanpublic1@yahoo.com> wrote:

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[Federal Register Volume 82, Number 150 (Monday, August 7, 2017)]
[Notices]
[Page 36805]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2017-16582]



[[Page 36805]]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration


Meeting of the Advisory Commission on Childhood Vaccines

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

ACTION: Notice of meeting.

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SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory
Committee Act, notice is hereby given that a meeting is scheduled for
the Advisory Commission on Childhood Vaccines (ACCV). This meeting will
be open to the public. Information about the ACCV and the agenda for
this meeting can be obtained by accessing the following Web site:
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http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.

DATES: The meeting will be held on September 8, 2017, at 10:00 a.m. EDT.

ADDRESSES: The address for the meeting is 5600 Fishers Lane, Rockville, MD, Conference Room 5N54. The public can join the meeting by:

1. (In Person) Persons interested in attending the meeting in person are encouraged to submit a written notification to: Annie Herzog, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), HRSA, Rm. 8N146B, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Since this meeting is held in a federal government building, attendees will need to go through a security check to enter the building and participate in the meeting. This written notification is encouraged so that a list of attendees can be provided to make entry through security quicker. Persons may attend in person without providing written notification, but their entry into the building may be delayed due to security checks and the requirement to be escorted to the meeting by a federal government employee. To request an escort to the meeting after entering the building, call Amber Johnson at (301) 443-0129.

2. (Audio Portion) Call the conference phone number (800) 369-1833 and providing the following information:

Leader Name: Dr. Narayan Nair

Password: 6706374

3. (Visual Portion) Connect to the ACCV Adobe Connect Pro Meeting using the following URL: https://hrsa.connectsolutions.com/accv/. Participants should call and connect 15 minutes prior to the meeting to allow time for the logistics to be set-up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm.

Get a quick overview of the software at: http://www.adobe.com/go/connectpro_overview.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACCV should contact Annie Herzog, Program Analyst, DICP, HRSA in one of three ways: (1) Send a request to the following address: Annie Herzog, Program Analyst, DICP, HRSA, 5600 Fishers Lane, 8N146B, Rockville, Maryland 20857; (2) call (301) 443-6593; or (3) send an email to aherzog@hrsa.gov.

The ACCV will meet on Friday, September 8, 2017, beginning at 10:00 a.m. in the 5600 Fishers Lane Building, Rockville, Maryland 20857; however, meeting times and locations could change. For the latest information regarding meeting start time and location, please check the ACCV Web site: http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa-19), as enacted by Public Law (Pub. L.) 99-660, and as subsequently amended, and advises the Secretary of HHS (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

Activities of the ACCV also include: Recommending changes to the Vaccine Injury Table on its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with

childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The agenda items for the meeting will include, but are not limited to, updates from DICP, Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html) prior to the meeting. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACCV should be sent to Annie Herzog using the address and phone number above by September 4, 2017. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Annie Herzog, using the address and phone number above at least 10 days prior to the meeting.

Amy McNulty,
Acting Director, Division of the Executive Secretariat.
[FR Doc. 2017-16582 Filed 8-4-17; 8:45 am]
BILLING CODE 4165-15-P