ADVISORY COMMISSION ON CHILDHOOD VACCINES
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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

August 18, 2015

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)
Parklawn Building, 5600 Fishers Lane, Conference Room 10-65
Rockville, Maryland 20857

Teleconference and Adobe Connect

September 3, 2015
(9:00 am – 2:30 pm Eastern Daylight Time)
Dial in: 1-877-917-4913
Passcode: ACCV
https://hrsa.connectsolutions.com/accv/

Time	Agenda Item	Presenter
9:00 AM	Welcome and Chair Report	Mr. Jason Smith, Vice-Chair
9:10 AM	Public Comment on Agenda Items	Mr. Jason Smith, Vice-Chair
9:15 AM	Approval of June 2015 Minutes	Mr. Jason Smith, Vice-Chair
9:20 AM	Report from the Division of Injury Compensation Programs	Dr. A. Melissa Houston Director, DICP
9:50 AM	Report from the Department of Justice	Mr. Vince Matanoski Assistant Director Torts Branch, DOJ
10:20 AM	Report from the Adult Immunization Workgroup	Dr. Sylvia Villarreal, ACCV Member
10:40 AM	Break	
11:00 AM	Discussion of Follow-up Items from June 2015 ACCV Meeting -VICP Administrative Funding -Prevention of SIRVA	Mr. Jason Smith, Vice-Chair
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 Shimabukuro CDC

Time	Agenda Item	Presenter
1:15 PM	Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Ms. Claire Schuster NIAID, NIH
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	Mr. Jason Smith, Vice-Chair
2:30 PM	Adjournment of the September ACCV Meeting	Mr. Jason Smith, Vice-Chair

Charter

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Resources and Services Administration

Rockville, Maryland 20857

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

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

Objectives and Scope of Activities

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

Description of Duties

The Commission shall: (1) advise the Secretary on the implementation of the Program; (2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table; (3) advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; (4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of Section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; (5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program; and (6) consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act.

Agency or Official to Whom the Commission Reports

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

Support

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

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 $39,795. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $256,377.

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, approve all of the Commission or subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Commission reports. The DFO or his/her designee shall be present at all meetings of the full Commission and subcommittees.

Estimated Number and Frequency of Meetings

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

Duration

Continuing.

Termination

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

Membership and Designation

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

The Commission shall be composed of the following:

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

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

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

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

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

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

Subcommittees

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

Recordkeeping

The records of the Commission, formally established subcommittees, or other subgroups of the Commission, shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

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Filing Date

July 21, 2014

Approved:

JUL 1 2014

Date

Bahar Niakan
Acting Director, Office of Management

Roster

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New Member Information

Advisory Commission on Childhood Vaccines (ACCV)
New Member Information
Class of 2015

Martha Jean Toomey (parent of vaccine-injured child)
Box 236
Orlean, VA 20128

Ms. Toomey is the mother of a child who received a DPT shot, and subsequently experienced encephalopathy. In 1998, she filed a claim with the National Vaccine Injury Compensation Program on behalf of her son, and was awarded compensation for her son's vaccine-related injury in October 2009.

Karlen E. (Beth) Luthy, D.N.P, A.P.R.N (health professional)
Assistant Professor
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Dr. Luthy is currently an Assistant Professor for the College of Nursing at Brigham Young University. Dr. Luthy has worked as a public health nurse where she gained experience in epidemiology, etiology, and the prevention of childhood diseases. During her employment, she primarily has worked on health promotion and prevention of communicable disease among the pediatric population with school-aged children in local preschools and daycare facilities. For the past 8 years, Dr. Luthy has been involved with vaccine-related research, focusing her efforts on understanding issues related to vaccination compliance. She has served as Chair of the Utah County Immunization Coalition leading county-wide vaccination education efforts in her local community, completed a 2-year term as Vice President of Sigma Theta Tau, the honor society for nurses and most recently as editor and then Co-Chair for the National Association of Pediatric Nurse Practitioners (NAPNAP) Immunization Special Interest Group.

Alexandra Stewart, J.D. (attorney, non-affiliated)
The George Washington University, School of Public Health and Health Services
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Ms. Stewart is an Assistant Professor in the Department of Health Policy at The George Washington University, School of Public Health and Health Services, in Washington, DC. Her primary research and academic interest is in the area of U.S. vaccine policy and practice. Professor Stewart has developed and is lead professor for a graduate-level

course that focuses on all aspects of U.S. vaccine policy. She has conducted research on the intersection of immunization law and policy, and how law can support public health goals regarding vaccination for all populations in the U.S. Her work considers all aspects of vaccines from initial research and development, regulation, administration recommendations, financing, access, safety monitoring, and injury compensation. She has presented the results of her research throughout the country. She has published in national and international peer-reviewed journals, law reviews and textbooks.

2015 & 2016 Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2015 MEETING DATES

September 3, 2015
December 3 & 4, 2015

2016 MEETING DATES

March 3 & 4, 2016
June 2 & 3, 2016
September 1 & 2, 2016
December 1 & 2, 2016

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Advisory Commission on Childhood Vaccines (ACCV)

Minutes

June 4, 2015

96th Meeting

DRAFT

Members Present

Kirsten Feemster, M.D., M.P.H., M.S.H.P. ('15)
Charlene Douglas, Ph.D. ('15)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('15)
Luisita dela Rosa, Ph.D. ('15)
Jason Smith, J.D. ('14)
David King ('15)

Division of Injury Compensation Programs (DICP)

A. Melissa Houston, M.D., Director, DICP
Andrea Herzog, Staff Liaison

Welcome, Report of the Chair, Dr. Kristen Feemster, ACCV Chair

Dr. Feemster called the 96th meeting of the ACCV to order and, after roll call introductions, briefly reviewed the agenda. Dr. Feemster noted that Commission members Sylvia Villarreal and Michelle Williams would not be attending the meeting. She also noted that Dr. Shimabukuro submitted an updated presentation that was sent to Commission members before the meeting. The Department of Justice presentation would be made by Ms. Catharine Reeves (Mr. Vince Matanoski was not able to attend). In addition to the usual reports, the agenda included a welcome from Mr. James Macrae, the Acting Administrator of HRSA; and discussion of several action items from the last meeting – recommendations related to vaccine administration, including Shoulder Injury Related to Vaccine Administration (SIRVA), and a discussion of an increase in funding for the National Vaccine Injury Compensation Program to support a more efficient claims process.

Public Comment on Agenda Items

Dr. Feemster invited public comment on the agenda. Theresa Wrangham, National Vaccine Information Center, commented that the information on the ACCV and VICP web sites should be kept current, not only for ACCV members but for the public as well. She noted that the statistical information on awards was not up to date.

There were no other requests for comment

Approval of March 2015 minutes

Dr. Feemster invited approval of the March 2015 meeting minutes. On motion duly made by Mr. King and seconded by Mr. Smith, the minutes were unanimously approved.

Dr. Feemster invited the report from the Division of Injury Compensation Programs (DICP).

Report from the Division of Injury Compensation Programs, Dr. A. Melissa Houston, Director, DICP

Dr. Houston welcomed those present on the teleconference and briefly reviewed the meeting agenda. The agenda includes an update from the Department of Justice (DOJ), a presentation on SIRVA, a review of Vaccine Information Statements, and finally updates from the ex officio members from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and the National Vaccine Program Office (NVPO). A previously scheduled report by the Adult Immunization Workgroup will be postponed until the next ACCV meeting. Dr. Houston added that data on the DICP web site is current, posted as of June 1, 2015. The statistics discussed at this meeting are current as of May 4, 2015.

Looking at petitions and adjudications, Dr. Houston stated, as of May 4, 2015, the Division had received 401 petitions and the projection, based on that number is about 700 petitions may be filed before the end of this fiscal year. The total adjudications for the current report period is 317, which projects to about 543 claims to be adjudicated in Fiscal Year (FY) 2015, more than the previous fiscal year. About 81% are anticipated to be compensated with 19% being dismissed. There have been awards of $146.5 million to petitioners, and about $12 million to petitioners' for attorney's fees and costs. It is anticipated that the totals for FY 2015 will be $250 million for petitioners' and $20 million for attorney's fees and costs. The Trust Fund stands at $3.5 billion as of March 31, 2015. Of the $127 million net income to the Trust Fund, $96 million came from tax revenue and $31 million from interest on the Trust Fund.

Dr. Houston stated that there were several activities since the last ACCV meeting. The VICP regulations, which include changes to the Vaccine Injury Table, are going through final review and clearance. The nominations for incoming ACCV commissioners have been approved and will be released when those nominees have submitted formal acceptance. The National Vaccine Advisory Committee (NVAC) will meet in Washington, DC, on June 9-10, 2015 and the Advisory Committee on Immunization Practices (ACIP) will meet in Atlanta on June 24-25, 2015.

Dr. Houston provided information for obtaining additional information on the web about the DICP and the ACCV. Dr. Houston invited discussion.

Mr. King asked about the status of nominations for new commission members and Dr. Houston indicated that three nominees have been approved. A second solicitation has been published in the Federal Register and responses are pending. She indicated that the new

members are expected to begin their terms in time for the September meeting. If that occurs, current commissioners whose terms have expired and have been extended would not participate in the September meeting. The retiring commissioners are Mr. King, Ms. Williams and Dr. Pron.

Discussion of Program Funding, Dr. Kristen Feemster, Chair

Dr. Feemster noted that this topic was discussed at the last meeting. It involves the allocation of funds to support the program and the possibility of increasing funding. She suggested that the initial discussion might look at next steps and the possibility of setting up a working group to develop a more detailed plan. Mr. King observed that it might be appropriate to wait until the three new commissioners are on board before making those decisions, since there are commissioners absent who might be interested in contributing comments. Dr. Feemster agreed, inviting consensus from those present to defer the discussion until the September meeting. There were no objections and Dr. Feemster stated that the discussion would be added to the September meeting agenda. The new commissioners, if any are on board at that time, would be appropriately briefed beforehand in order to participate in the discussion.

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

Ms. Reeves explained that Vince Matanoski, who usually provides DOJ's report to the Commission, is on temporary military duty in the Democratic Republic of the Congo. Ms. Reeves referenced the Department of Justice Power Point materials (DOJ PP), as part of her presentation for the reporting period February 16, 2015 - May 15, 2015. During this reporting period, 178 petitions were filed. (DOJ PP at 2). This is 54 more petitions than the same period in FY 2014, and 24 more petitions than the immediate past reporting period (November 16, 2014 – February 15, 2015). Of the 178 petitions, 30 were filed on behalf of minors and 148 petitions were filed by adults. Ms. Reeves predicted that approximately 800 petitions will be filed for FY 2015. There were 163 adjudications, 21 more than the last reporting period (November 16, 2014 – February 15, 2015). (DOJ PP at 3). Of those, 136 were compensated, with 32 cases conceded by HHS resolved by a decision adopting a proffer. There were 104 cases resolved that were not conceded. Of those, 103 were settled followed by a decision adopting a stipulation, and one case was resolved by a decision adopting a proffer. There were 27 cases not compensated/dismissed. Of those, 23 were resolved by decisions dismissing claims. These were non-Omnibus Autism Proceeding (OAP) claims. There were 4 petitions dismissed from the OAP. (DOJ PP at 3). There were 8 petitions voluntarily withdrawn. (DOJ PP at 4).

Turning to appeals, three cases were decided by the Court of Appeals for the Federal Circuit (CAFC) (DOJ PP 5). Two appeals were filed by petitioners, *Simanski v. HHS* and *Griffin v. HHS*, and in both, the special masters' decisions were affirmed by the CAFC. In *Simanski*, the CAFC affirmed the special master's decision denying entitlement. As Ms. Reeves noted, *Simanksi* has been discussed at prior meetings, and has a lengthy procedural history. In *Griffin*, which involved a discrete legal issue about whether or not petitioner satisfied statutory requirements, the CAFC affirmed the special master's finding that a federal contractor working in Afghanistan was not eligible to receive compensation under the Act.

Griffin was decided *per curiam*, likely because the Court views the issue addressed in its decision as relatively non- controversial and therefore unlikely to come up again. In *Paluck v. HHS*, another case with a lengthy procedural history that has been discussed at prior ACCV meetings, the CAFC, on appeal by respondent, affirmed the decision by the Court of Federal Claims (CFC) that the special master was arbitrary and capricious in weighing evidence in the case; and, therefore, petitioner was entitled to compensation under the Act. Turning to pending CAFC appeals, petitioners filed two new ones. (DOJ PP at 6). In *Greenberg v. HHS*, petitioners appealed the CFC's affirmance of the special master's dismissal on entitlement and denial of a motion for reconsideration based on untimely filing. In *Moriarty v. HHS*, an OAP case that was stayed for seven years pending the outcome of the OAP, petitioners appealed the CFC's affirmance of the special master's decision dismissing petitioners' claim that their child's injuries were vaccine- related based on a different theory from that relied upon in the OAP litigation.

Turning to the CFC, Ms. Reeves reported that four cases were recently decided by the CFC. (DOJ PP at 7). In *Guerrero v. HHS*, a case involving attorneys' fees and costs, the CFC remanded the claim to the special master to re-evaluate his reduction of attorneys' fees and provide a more detailed explanation for his decision. In *Somosot v. HHS*, the CFC affirmed the special master's decision denying attorneys' fees and costs as the petition, filed untimely, lacked good faith and a reasonable basis. In *Contreras v. HHS*, this was discussed at the last ACCV
meeting, the CFC affirmed the original decision by the special master denying entitlement, after a second remand. In *Milik v. HHS*, the Chief Judge of the CFC affirmed the special master's decision denying entitlement based on evidence that the onset of petitioner's injury preceded vaccination and petitioner failed to prove significant aggravation of a preexisting condition under *Althen*.

There were five new motions for review filed at the CFC, all filed by petitioners. . (DOJ PP at 8). In *Nuttall v. HHS*, the special master denied petitioners' claim that the MMR vaccine caused a Table injury, finding respondent's expert more persuasive with regard to a diagnosis. In *McLeod-Hunt v. HHS*, the special master denied petitioner's claim that vaccines significantly aggravated a child's preexisting condition, finding respondent's expert more convincing in establishing that the injuries began too early to be vaccine-related. In *Mora v. HHS*, the special master denied petitioner's motion for relief from judgment, finding petitioner's counsel's negligence insufficient to demonstrate extraordinary circumstances sufficient to set aside the judgment. In *Hodge v. HHS*, the special master dismissed petitioner's claim as untimely, and determined that petitioner was not entitled to equitable tolling. In *Padmanabhan v. HHS*, the special master dismissed petitioner's case for lack of prosecution after petitioner ignored multiple court orders. Ms. Reeves noted that oral arguments were scheduled at the CAFC for *Stillwell v HHS*, on June 4, 2015, and *Crutchfield v. HHS*, on June 5, 2015. No arguments were scheduled in the CFC. (DOJ PP at 9).

Consistent with the DOJ's past practice of providing information about settlement timelines, Ms. Reeves discussed the compilation of adjudicated settlements reflected by decisions adopting stipulations. (DOJ PP at 10-20). This reporting period reflected 103 cases

resolved by stipulations. Ms. Reeves noted the Appendix containing the glossary of terms and flow charts for the appeals processes. (DOJ PP at 21-27).

Dr. Pron submitted a question via e-mail noting that within adjudicated settlements, a case involving a hepatitis B vaccine apparently took 15 years to settle. She asked about the reasons for the duration. Ms. Reeves responded that the case was filed on July 13, 1999 (at about the same time a large number of similar hepatitis B vaccine claims were filed); the claim eventually became part of the OAP, and was stayed at the petitioner's request until November 23, 2011. At that time, the petition was amended by the petitioner, processed in the usual course, and eventually a settlement was reached.

Dr. Feemster, noting the fact that the meeting was ahead of schedule, suggested that the SIRVA presentation be moved up on the agenda. Because of an unanticipated issue with construction noise at Parklawn, a recess was taken to move the conference call to a more suitable room. Upon reassembling for the call, an issue arose concerning assuring that a quorum was always present at the meeting, a quorum being required to conduct any ACCV meeting. After discussion, Ms. Herzog agreed to investigate whether or not the conference call contractor could maintain a running and continuously updated list of members on the phone, which would provide the assurance that a quorum was properly maintained. Dr. Feemster confirmed that a quorum was present so that the presentation on SIRVA could occur.

Feasibility of SIRVA Prevention, Dr. Terry Dalle-Tezze, Pediatrics Team Lead, DICP

Noting that SIRVA stands for Shoulder Injury Related to Vaccine Administration, Dr. Dalle-Tezze explained that the presentation would look at whether SIRVA could be prevented as an adverse event related to vaccination. In one study, two subjects who experienced shoulder injury within two days of injection were examined using ultrasound to map the anatomy of the shoulder and it was determined that the bursa which underlies the upper third of the deltoid muscle (into which the vaccine was injected using needles 1" to 1.5" in length) was vulnerable to damage. Therefore, the investigators recommended injection into the lower two-thirds of the deltoid muscle.

In a second study by Lippert et al in Pediatrics in 2008, in pediatric subjects, it was determined that using the recommended needle length for injection resulted in a risk of 11% to 61% needle penetration beyond the margins of the deltoid muscle, which could cause injury. In a third study in Britain in 1962, antigen (fibrin) was injected into joint space, with a likelihood that inflammation would occur.

Dr. Dalle-Tezze stated that at the time of the Bodor paper, clinicians at DICP noticed an increase in shoulder-related problems following vaccination, and a study led by Drs. Sarah Atanosoff, Thomas Ryan and Rosemary Johann–Liang, looked at 13 injury claims that occurred between 2006 and 2010, which resulted in significant shoulder pain and dysfunction. All 13 subjects, mostly females, filed program claims for shoulder pain, the onset of which occurred in less than 24 hours in 12 of the 13 subjects (in half of them the pain occurred immediately after injection). About half of the patients suggested that the injection location was too high on the arm. Symptoms included pain and decreased range of motion. The investigators confirmed that

the injury was confined to the vaccinated shoulder, and symptoms were consistent with a local inflammatory shoulder injury. Finally, the investigators agreed that the injection could unintentionally reach and injure musculoskeletal structures outside the deltoid muscle, and that the injection site should be confined to the lower two-thirds of the deltoid muscle, preferably administered to a patient in a seated position.

Dr. Dalle-Tezze stated that, based on this evidence and the findings of the DICP study, a recommendation was made to include SIRVA as an injury on the Vaccine Injury Table. He noted that, since 2011, 136 claims have been adjudicated for SIRVA, with settlements totaling $22.7 million. The proposed criteria for inclusion in the Vaccine Injury Table include: 1) No prior history of pain or dysfunction of the affected shoulder; 2) pain occurs within 48 hours of vaccination; 3) pain and reduced range of motion are limited to the shoulder in which the vaccine was injected; and 4) no other conditions or abnormality is present that could explain the symptoms.

In the past, Dr. Dalle-Tezze noted that vaccines were administered by trained medical personnel (physicians, nurses, nurse assistants, medical assistants) who were certified under state board criteria (although there has been no certification specifically for injecting vaccines or other medicines). The skill was acquired through normal school instruction and on-the-job training.

In the Healthy People 2010 report published in 2000, it was noted that the elderly and those in lower income situations were not being vaccinated at the desired 90% level set in the report. Reasons were related to patient attitudes and awareness, misunderstanding about risks of vaccines, and clinic-related issues such as inadequate staffing and service hours. In 1993 DHHS Secretary Donna Shalala challenged the American Pharmacists Association (APhA) to develop a program to train pharmacists to deliver vaccinations, and in 1996 the APhA called on pharmacists to take on one or more of three roles: advocate, facilitator, and immunizer. Answering that call, pharmacists initially focused on flu shots and pneumococcal immunizations. The program significantly expanded during the 2009 H1N1 flu pandemic.

Dr. Dalle-Tezze noted that today over 200,000 pharmacists in every state and U.S. territory are trained and licensed to provide vaccinations. Individual states set standards for that licensure. A gauge of the program's success can be seen in the 5% rate of vaccines given by pharmacists in 1999 versus the 18% administered by pharmacists in 2010-2011. In 2012 a survey showed that 20% of adults received vaccinations in pharmacies and 33% in doctors' offices. One effect of this program has been a notable increase in vaccinations given to the elderly (over 65 years of age). The CDC has issued guidelines regarding vaccine injection techniques that include the angle of injection into the deltoid muscle (90 degrees), and needle length depending on the age of the recipient. The American Academy of Pediatrics (AAP) and the APhA also published statements related to injection technique, with similar recommendations.

Dr. Dalle-Tezze suggested several recommendations to enhance the prevention of SIRVA:

- Universal certification for all vaccine administrators.

- Inclusion of SIRVA as a subject in all health care education programs (nursing, medical assistant, pharmacy).
- Alternative vaccination routes to avoid the problems related to deltoid muscle injection.

Dr. Dalle-Tezze discussed the pros and cons of each recommendation, noting that each has both positive and negative aspects. He mentioned that the CDC has a Vaccination Error Stakeholders Focus Group that includes partnerships with most major national health organizations. The Focus Group includes a SIRVA subgroup. Dr. Dalle-Tezze recommended updating all germane guidelines to include SIRVA, including needle size, position of administrator and recipient, and injection site. Finally, he suggested that DICP could work with nursing schools to develop guidelines, and join the CDC Vaccination Errors Stakeholders Focus Group as an active partner

Dr. Feemster expressed appreciation for a very thorough presentation. She invited discussion. Mr. King suggested that a brief comment might be included on vaccine information statements for vaccines that are injected into the shoulder area. It might even include a brief summary of the three guidelines – injection angle, standing/sitting position and needle length. Dr. Shimabukuro commented that, although a universal certification is an interesting idea, it may be difficult to justify a certification process only for injections and not for many other similar invasive procedures, such as inserting an IV line or a central line. Also, based on the passive reporting in the Vaccine Adverse Event Reporting System (VAERS), a valid risk level for a shoulder injection has not been determined, and it would be helpful to have a more valid evidence-based risk assessment. Mr. Kraus agreed that it would be helpful to have a more definitive quantitatively-based risk assessment of SIRVA injuries. Nonetheless he felt it was clear that SIRVA injuries are a part of the vaccination environment, and that many individuals may be unaware of the connection between their shoulder pain and a recent flu shot. He suggested that, since the issue is so complex, that a discussion of the SIRVA presentation be included on the agenda of the next ACCV meeting in September. Dr. Feemster agreed that it was an appropriate suggestion, and the agenda would include a discussion of SIRVA.

The Commission recessed for lunch.

Welcome Mr. James Macrae, Acting Administrator, HRSA

Mr. Macrae expressed how important the work of the ACCV was to HRSA in helping to identify what is working, what improvements can be made, and what actions would be appropriate. He felt advice on childhood vaccines was very important. He also solicited suggestions about what could be done to better support the ACCV, including one suggestion he had heard about trying to have more in-person meetings. He said there had been concrete accomplishments, including inclusion of information about the program in the vaccine injury statements, and useful proposals concerning improvements to the Vaccine Injury Table. Aware of the Commission's interest in how the recommendation process works, he stated that he would make every attempt to provide that kind of elucidation. He stated that he was aware of the recommendations made by the ACCV. An initial acknowledgment of the recommendations and the work done by the Commission is made, and then there are internal discussions with the

Secretary. He stated that the transition from Secretary Sebelius to Secretary Burwell may have caused some delays, but Secretary Burwell is interested in responding to the recommendations. The Secretary is very involved with maternal immunizations, although there have been no final actions taken to date.

Mr. McCrae commented that the Secretary is interested in focusing on the science related to the issues, and providing substantive data on the science is helpful. He invited questions or recommendation from the Commission. Mr. King reiterated his interest in the benefits of face-to-face meetings. He noted that the frequency of face-to-face meetings was more like once a year, or three virtual meetings to one face-to-face meeting. Mr. Kraus supported Mr. King's recommendation, noting that he was speaking for the Commission as a whole. He also expressed appreciation that the Secretary was apparently interested in responding to the Commission's concerns. Dr. Feemster expressed the Commission's appreciation for Mr. Macrae's appearance at the meeting and the positive comments that he made.

Review of Vaccine Information Statements (VIS), Mr. Skip Wolf CDC

Dr. Feemster stated that the review of VIS's would include meningococcal serotypes A, B, C, W and Y; and the MMR vaccine.

Mr. Smith recused himself from discussion regarding the meningococcal serotypes A, B, C, W and Y VIS. Dr. Pron stated that she would recuse herself from review of the MMR VIS. She added that she would be interested in discussing all intramuscular injections given in the arm. Dr. Feemster suggested that the Commission review each VIS and then, at the end of the discussion, turn to the previous discussion about the SIRVA injections issue.

VIS for Meningococcal Vaccine (Serogroups ACWY)

Mr. Wolfe stated that he would highlight the recommended changes to each VIS. He noted that the two meningococcal VISs had been harmonized as much as possible. In response to a question about the statement that serotypes A, B, C, W and Y might suggest that the vaccine does not cover serotype B, Mr. Wolfe agreed that the statement at the bottom of the paragraph (that B is covered under a separate VIS) would be moved into juxtaposition with the statement about A, B, C, W and Y.

In paragraph 2, Mr. Wolfe stated that the subject matter experts recommended revising the recommendation for immunizing lab personnel to read "microbiologists, who routinely work with isolates of N. meningitis," which would be the same for both VISs. Dr. Douglas commented that the phrase would be too technical for most readers of the VIS and that CDC should consider whether or not such language is counterproductive to the purpose of the document. Noting that the VIS is for individuals who are imminently anticipating vaccination, Mr. Wolfe suggested that he refer it back to the subject matter experts. Dr. Shimabukuro suggested reordering the list to place those who most commonly receive the vaccine at the top of the list and others, like lab personnel and military recruits, at the bottom.

In paragraph 3, Dr. Houston asked whether the use of generic language concerning allergens versus a more specific list had been discussed. Mr. Wolfe stated common allergen that apply to any vaccine are usually listed (e.g., egg, yeast) and that he would check to make sure the common allergens did not apply to this vaccine. Dr. Feemster asked about the use of MCV4 in pregnant women, and the statement that "it should be used only if clearly indicated" might be confusing. Mr. Wolfe responded that the wording was taken from the Advisory Commission on Immunization Practices (ACIP) recommendation and the drug labeling, and its use in pregnant women would probably be at the direction of a qualified health care provider. Mr. Wolfe asked for better wording for the term "working spleen" in the last sentence of the paragraph. Dr. Shimabukuro suggested "children with a damaged spleen or whose spleen has been removed."

In paragraph 4, Mr. Wolfe commented that the vaccine reactions are typical of most vaccinations. He also pointed out that the statistic concerning severe allergic reactions (such as anaphylaxis) was changed from "one in a million" to "about one in a million." That change would be made in all VISs.

Mr. Wolfe stated that the last three paragraphs were not changed.

VIS for Meningococcal Vaccine (Serogroup B)

Mr. Wolfe stated that the Serotype B VIS was very similar to the VIS for serotypes A, C, W and Y, and that all of the revisions made for the latter would be made in the serotype B VIS. He added that language, such as the words for a damaged or missing spleen, would be made in all applicable VISs. He noted that the addition of a schedule in paragraph 2 was made to avoid having to develop more than one VIS for the B serotype, since there is more than one generic vaccine available. He invited comments and there were no suggestions for further revisions.

VIS for MMR Vaccine (Measles, Mumps, Rubella)

Mr. Wolfe noted that this is the last review of an interim VIS before it becomes final. He invited discussion of paragraph 1. Ms. dela Rosa suggested that cerebral meningitis would be a more specific description for meningitis that affects the brain. Dr. Feemster commented that meningitis is generally considered by the medical community to be a general term for infection or inflammation of the central nervous system, which would include the brain and spinal column. Dr. Feemster noted that inflammation is more accurate than infection. Ms. dela Rosa also asked if seizures should be included under the bullet point for mumps. She added that her daughter had an intractable seizure disorder that arose from a mumps infection. Mr. Wolfe agreed to check with medical experts on that issue.

Dr. Shimabukuro suggested revising the mode of spreading the disease by using the words "coughing and sneezing" as being more specific and appropriately descriptive. Dr. Feemster agreed, noting that droplets can remain in the air. Dr. Shimabukuro suggested "measles can spread from person to person through coughing or sneezing and by direct contact."

Mr. Kraus asked for a brief explanation of the rationale for administering the three vaccines in one injection. Dr. Wolfe said that he would look into it, and that it would probably

fit best in paragraph 2. However, it was noted that there was more than one such combination vaccine. Dr. Shimabukuro suggested that a generic explanation might be appropriate since there are several combination vaccines (DTaP and others), where typically minimal risks involved, and the reasons for the combination is usually programmatic efficiency and reduction of needle sticks. Mr. Wolfe agreed, stating that if there are higher risks (as in MMR plus varicella), the risks can be covered in the VIS.

Asked about the last two sentences in paragraph 1 concerning the effect of reduced vaccination rates, there was agreement that incidents of infection would rise if vaccinations decreased. However, there was consensus that the word "but" should be deleted from the last sentence. There was also a suggestion that wording could be added to indicate the extent of the return of measles if vaccinations were reduced (e.g., to former levels before universal vaccinations).

Mr. Wolfe noted there were no comments on paragraphs 2 and 3. In paragraph 4, there was a brief discussion about severe problems following MMR vaccines and possible severe problems that might be related (deafness, neurological problems, brain damage), and the difficulty of establishing a link to the vaccine. Dr. Shimabukuro recommended wording previously proposed by Mr. Kraus – because these happen so rarely it is difficult to determine with certainty whether they were caused by the vaccine or not. Mr. Wolfe agreed to adapt that language to the VIS.

Mr. Wolfe noted that paragraphs 5, 6 and 7 were the same as other VISs. Dr. Feemster asked Mr. King to discuss the earlier comment about including some kind of information about SIRVA in any VIS that involves a shoulder injection. Mr. King commented that such information would enhance awareness of the risks related to shoulder injections that sometimes result in SIRVA. He suggested that it might reinforce to providers the importance of following guidelines when administering such injections. Mr. Wolfe responded with a concern that the focus of the VIS is about patient information and not providing education to providers. He was also concerned about whether a patient could comfortably instruct a doctor on how to administer an injection. Finally, he noted that provider guidelines are prepared for many VISs and all new VISs are available to providers on the same web site as the patient vaccine information sheets. Mr. Kraus agreed that the VIS might not be the best vehicle for educating providers and that provider guidance would be more appropriate. Ms. Smith agreed with that opinion.

Dr. Feemster invited further discussion and hearing none, moved onto the presentations by ex officio members.

Update on the Immunization Safety Office (ISO), CDC Vaccine Activities, Dr. Tom Shimabukuro

ISO continues to work with the Food and Drug Administration (FDA) to prepare for implementation of manufacturer reporting to the Vaccine Adverse Event Reporting System (VAERS) using the E2B(R3) message standard. Implementation is scheduled for June 10, 2015.

ISO will present a 2014-15 end-of-season analysis of influenza vaccine safety at the June 2015 ACIP meeting on June 24, 2015. At the ACIP meeting there will also be a session on meningococcal vaccines, including a discussion of policy options for routine use of meningococcal group B (MenB) vaccines in adolescents, a GRADE presentation on evidence for use of MenB vaccine in adolescents and college students, considerations for routine use of MenB vaccines in adolescents, and a vote on proposed recommendations. The influenza session will include an influenza surveillance update, an influenza vaccine safety update, a high dose influenza vaccine update and a vote on proposed recommendations. The influenza A (H5N1) session will include an influenza A (H5N1) epidemiology update and a vote on proposed recommendations. The pertussis session there will include be a discussion on cocooning and diphtheria, tetanus and acellular pertussis (DTaP) vaccination, and acellular pertussis vaccine effectiveness among children in the setting of pertactin-deficient B. pertussis in Vermont, 2011-2013. The pneumococcal vaccines session will include a discussion on intervals between 13-valent pneumococcal conjugate (PCV13) and 23-valent pneumococcal polysaccharide (PPSV23) vaccines, and supporting evidence and rationale for change, and a vote on proposed recommendations. Finally in the herpes zoster session there will be an update on herpes zoster epidemiology and vaccine uptake, and a presentation of the results of GSK Phase 3 study of an investigational adjuvant-based zoster vaccine.

Dr. Shimabukuro mentioned several recent publications:

- Petrosky et al; Centers for Disease Control and Prevention (CDC). Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the advisory committee on immunization practices. MMWR Morb Mortal Wkly Rep. 2015 Mar 27;64(11):300-4.

- Iqbal et al. Relationship between Guillain-Barré syndrome, influenza-related hospitalizations, and influenza vaccine coverage. Vaccine. 2015 Apr 21;33(17):2045-9. The main findings were that pneumonia and influenza hospitalization rates were significantly correlated with hospitalization rates for Guillain-Barré syndrome, and vaccine coverage did not significantly affect the rates of Guillain-Barré syndrome hospitalization at the population level.

- McNamara et al. First Use of a Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak. Pediatrics. 2015 May;135(5):798-804. The main findings were that no serogroup B meningococcal disease cases occurred in persons who received 1 or more doses of 4CMenB vaccine, suggesting 4CMenB may have protected vaccinated individuals from disease. However, a case occurred in an unvaccinated close contact of a vaccinated university student demonstrating that carriage of serogroup B Neisseria meningitidis among vaccinated persons was not eliminated.

- Datwani et al. Chorioamnionitis following vaccination in the Vaccine Adverse Event Reporting System. Vaccine. 2015 May 11. [Epub ahead of print]. The main findings were that chorioamnionitis was found to be uncommonly reported, representing 1% of pregnancy reports to VAERS; a majority of reports had at least one risk factor for chorioamnionitis.

- Hibbs et al. Vaccination errors reported to the vaccine adverse event reporting system, United States, 2000–2013. Vaccine (2015), http://dx.doi.org/10.1016/j.vaccine.2015.05.006. The main findings were that vaccination error reports to VAERS have increased substantially from 2000-2013 and contributing factors might include changes in reporting practices, increasing complexity of the immunization schedule, availability of products with similar sounding names or acronyms, and increased attention to storage and temperature lapses.

- Miller et al. Deaths following vaccination: What does the evidence show? Vaccine. 2015 May 21. [Epub ahead of print]. This article reviewed the data on deaths following vaccination and reported that vaccines are rigorously tested and monitored and are among the safest medical products we use. Millions of vaccinations are administered to children and adults in the United States each year. Serious adverse reactions are uncommon and deaths caused by vaccines are very rare. Rare cases where a known or plausible theoretical risk of death following vaccination exists include anaphylaxis, vaccine-strain systemic infection after administration of live vaccines to severely immunocompromised persons, intussusception after rotavirus vaccine, Guillain-Barré syndrome after inactivated influenza vaccine, fall-related injuries associated with syncope after vaccination, yellow fever vaccine-associated viscerotropic disease or associated neurologic disease, serious complications from smallpox vaccine including eczema vaccinatum, progressive vaccinia, postvaccinal encephalitis, myocarditis, and dilated cardiomyopathy, and vaccine-associated paralytic poliomyelitis from oral poliovirus vaccine. The evidence for the safety and effectiveness of vaccines routinely given to children and adults in the Unites States is overwhelmingly favorable.

During discussion, Dr. Douglas asked about the age recommendations for children receiving HPV, suggesting that if the ACIP age is 11 it would be helpful to lower it further to 10 or even 9 to harmonize with DTaP immunizations. Dr. Feemster stated that the ACIP recommendation is age 12, but allows vaccination at age 9.

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

Ms. Schuster reported that a trial of the VSV-ZEBOV Ebola vaccine candidate has shown safety with strong antibody response in 40 study participants. The trial was conducted at NIH and the Walter Reed Army Institute of Research. The Phase I PREVAIL trial conducted in Liberia looked at the VSV-ZEBOV and cAd3-EBOZ Ebola vaccine candidates. The preliminary findings suggest vaccine safety in more than 600 subjects. The Phase II portion of the PREVAIL trial reached its enrollment target of 1,500 participants in May 2015.

Ms. Schuster noted that there is no commercially available human vaccine for West Nile virus. Investigators at Oregon Health and Science University have developed a peroxide-based platform that demonstrates the ability of hydrogen peroxide to inactivate the virus while maintaining key structures that trigger the immune system. A Phase I trial, supported by NIAID, is under way at Duke University.

As part of President Obama's Precision Medicine Initiative, there is a plan to establish a million-person cohort of individuals who will share biological, environment and lifestyle data. A group of experts has been convened to advance this study. The first preliminary report is planned for September 2015.

Finally, Ms. Schuster announced that the National Institute of Child Health and Human Development (NICHD) launched a Pinterest site containing information on NICHD research and educational resources. The web address is https://pinterest.com/NICHD_NIH.

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

LCDR Marshall reported that on March 24, 2015 the FDA approved the use of a single dose of Quadracel for children 4 through 6 years of age as the fifth and final vaccine in the DTaP series; and as a fourth and fifth dose in the inactivated poliovirus (IPV) series, in children who have received four doses of Pentacel and/or DAPTACEL vaccine. The vaccine is indicated for active immunization against diphtheria, tetanus, pertussis and poliomyelitis.

On April 30, the FDA approved a supplement for Fluzone, Fluzone High Dose, Fluzone Intradermal, and Fluzone Quadrivalent vaccines, to update the package insert to include efficacy data for children 6 to 24 months and for adults 18 to 49 years of age.

Earlier in April, FDA approved a BLA Supplement for human papillomavirus quadrivalent vaccine, recombinant (Gardasil), adding a new subsection, "Long-term follow-up studies" to the clinical studies section of the package insert.

LCDR Marshall mentioned two meetings, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on May 12, 2015 to discuss the development and licensure of Ebola vaccines. On June 1-2, 2015 the FDA participated in a Respiratory Syncytial Virus (RSV) Vaccine Workshop. The purpose of the workshop was to identify obstacles to RSV vaccine development, discuss approaches to alleviating them, and identify gaps in research that could be addressed to enable vaccine development.

Finally, LCDR Marshall noted the continued activity among federal partners, the medical and scientific community, industry, and international organizations and regulators to assess investigational products and provide regulatory pathways that may expedite the development and availability of Ebola products.

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

Dr. Bok reported that the Cooperative Agreement on Research, Monitoring and Outcomes Definitions for Vaccine Safety had received eight applications from a solicitation published in April, 2015. After selection, two one-year awards of $250,000 each will be made.

The SMART Vaccines (Strategic Multi-Attribute Ranking Tool for Vaccines) is being moved to the NVPO. The new software will; provision the capabilities to transform the existing SMART Vaccines tool to a web-based platform that can be supported and sustained for public access; include iterative adaptation and refinement of the tool; expand and update of the data warehouse and standardized formats for data sharing; disseminate and use the tool supported by direct engagement and training of the public sector, academic, and private sector stakeholders and decision-makers associated with vaccine development, purchasing, and deployment/implementation programs; safety profile; and host the tool that is sustainable and provides global access to the tool by embedding it an infrastructure that utilizes existing resources for maintenance of standards and capabilities

Public Comment

Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC), focused her comments on the need for greater transparency in sharing the data related to the VICP. She referenced a piece by Sharyl Attkisson, entitled "Government Wipes Recent Vaccine Data from Website," that indicated that the website has changed since February 2015. The current information was truncated to 2013. Ms. Wrangham expressed concern about what changed since February to cause the deletion of data. She noted that NVIC first raised the issue of transparency in 2012. She stated that the information should include what injuries were reported, the vaccines involved, in total and by year, and the number of cases dismissed because of the statute of limitations of the Act. During the September 2014 ACCV meeting the DICP indicated that the Division had appropriately and sufficiently informed the public. New information has been added to the data and statistics report, such as doses of vaccines distributed versus the number of compensation claims made. The report does not include reports to VAERS or discuss the contention that a majority of vaccine injuries are unreported.

Information to which the public should have access is not easy to obtain, requiring visits to a number of web sites to collect raw data and piece it together. The NVIC encourages the ACCV to consider recommendations to report information authorized by law and to provide a higher level of transparency. The NVIC also recommends that the ACCV meet face to face as do the other vaccine-related FACA committees. The NVIC commends the Commission for the SIRVA report, and endorses the proposal for a universal certification for those who administer injections.

With regard to the VIS discussion, Ms. Wrangham expressed concern when the phrase recommends use "when clearly necessary," when the vaccines have not been licensed for the purpose described (e.g., in pregnant women).

Ms. Wrangham expressed appreciation for being able to comment.

Dr. Feemster noted there were no additional public comment requests.

Future Agenda Items

Dr. Feemster noted two items for inclusion in the next meeting agenda: discussion of funding opportunities; and continuation of the SIRVA prevention discussion.

Drs. Houston and Feemster expressed appreciation to Mr. King, Dr. Pron and Ms. Williams for their dedicated service and for their willingness to extend their terms to accommodate the process for selecting replacement commissioners.

Adjournment

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

DRAFT

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Vaccine Injury Compensation Trust Fund

Balance as of June 30, 2015

$3,500,317,015.57

Figures for October 1, 2014 – June 30, 2015

Excise Tax Revenue: $136,378,807
Interest on Investments: $45,248,692
Net Income: $181,627,499
Interest as a Percentage of Net Income: 25%

Source: U.S. Treasury, Bureau of Public Debt
August 10, 2015

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

Data & Statistics

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

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

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

- Over 80 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.

What reasons might a claim result in a negotiated settlement?

- Prior to a decision by the U.S. Court of Federal Claims, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The need to resolve a case quickly

How many claims have been awarded compensation?
From 2006 to 2014, over 2.5 billion doses of covered vaccines were distributed in the U.S. according to the CDC. 3,169 claims were adjudicated by the Court for claims filed in this time period and of those 1,939 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 16,113 claims have been filed with the VICP. Over that 27 year time period, 14,117 claims have been adjudicated, with 4,205 of these determined to be compensable, while 9,912 were dismissed. Total compensation paid over the life of the program is approximately $3.2 billion.

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

VICP Adjudication Categories, by Alleged Vaccine, For Claims Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/06/2006 Through 12/31/2014

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2014 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	712,347	1		4	5	4	9
DTaP	83,052,184	13	19	78	110	78	188
DTaP-Hep B-IPV	51,305,397	4	7	18	29	38	67
DTaP-HIB	1,135,474					1	1
DTaP-IPV-HIB	46,401,211			7	7	12	19
DTap-IPV	15,490,820						
DTP	0	1	1	2	4	2	6
DTP-HIB	0			3	3	1	4
Hep A-Hep B	12,740,305			9	9	2	11
Hep B-HIB	4,787,457	1	1	1	3	1	4
Hepatitis A (Hep A)	136,935,713	6	3	23	32	22	54
Hepatitis B (Hep B)	143,946,953	2	11	45	58	38	96
HIB	93,160,376		1	4	5	5	10
HPV	77,506,945	11		69	80	92	172
Influenza	1,078,000,000	90	88	974	1,152	186	1,338
IPV	62,344,612			4	4	2	6

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2014 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
Measles	135,660			1	1		1
Meningococcal	64,004,175	1	4	25	30	4	34
MMR	80,115,475	18	13	59	90	77	167
Mumps	110,749						
MMR-Varicella	14,403,057	8		8	16	8	24
Nonqualified	N/A			2	2	22	24
OPV	0	1			1	3	4
Pneumococcal Conjugate	150,497,243		1	5	6	14	20
Rotavirus	79,636,437	4	3	15	22	7	29
Rubella	422,548		1		1		1
Td	57,940,972	7	6	53	66	18	84
Tdap	177,160,298	27	6	107	140	18	158
Tetanus	3,836,052	4		21	25	11	36
Unspecified	N/A	1	1	2	4	554	558
Varicella	96,646,081	4	7	23	34	10	44
Grand Total	**2,532,428,541**	**204**	**173**	**1,562**	**1,939**	**1,230**	**3,169**

Notes on the Adjudication Categories Table

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

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

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

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

Definitions

Compensable – The injured person who filed a claim 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 claim 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 claims, 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. Claims 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 claim was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the claim 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 claim 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 claim.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 08/01/2015

Vaccines	Filed Injury	Filed Death	Filed Grand Total	Compensated	Dismissed
DTaP-IPV	3	0	3	0	0
DT	69	9	78	25	51
DTP	3,286	696	3,982	1,271	2,706
DTP-HIB	20	8	28	7	21
DTaP	386	79	465	185	205
DTaP-Hep B-IPV	63	25	88	30	34
DTaP-HIB	11	1	12	4	3
DTaP-IPV-HIB	32	17	49	7	12
Td	187	3	190	111	66
Tdap	269	1	270	137	15
Tetanus	99	2	101	48	37
Hepatitis A (Hep A)	73	6	79	30	22
Hepatitis B (Hep B)	625	54	679	245	364
Hep A-Hep B	23	0	23	9	2
Hep B-HIB	8	0	8	4	3
HIB	31	3	34	12	15
HPV	275	13	288	80	92
Influenza	1,911	90	2,001	1,170	168
IPV	264	15	279	8	267
OPV	281	28	309	158	150
Measles	143	19	162	55	107
Meningococcal	45	2	47	30	4
MMR	898	57	955	371	506
MMR-Varicella	32	1	33	16	8
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	41	6	47	10	27
Rotavirus	69	1	70	40	18
Rubella	190	4	194	70	123
Varicella	82	7	89	53	20
Nonqualified1	89	9	98	2	87
Unspecified2	5,412	8	5,420	4	4,756
Grand Total	**14,946**	**1,167**	**16,113**	**4,205**	**9,912**

[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	597
Total	**16,113**

Adjudications

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

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	232	294
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	123	205
FY 2008	147	134	279
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	370	167	537
FY 2015	378	77	455
Total	**4,205**	**9,912**	**14,117**

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	73	$2,511,313.26	2	$117,265.31	$83,536,901.46
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,637,927.73
FY 2013	375	$254,666,326.70	$13,333,179.53	703	$6,970,278.84	50	$1,454,851.74	$276,424,636.81
FY 2014	365	$202,084,196.12	$11,973,575.82	505	$6,801,345.79	38	$2,493,460.73	$223,352,578.46
FY 2015	432	$187,949,982.00	$11,488,089.35	86	$2,447,135.86	41	$1,943,085.28	$203,828,292.49
Total	**4,196**	**$2,989,921,496.53**	**$128,649,447.50**	**4,966**	**$66,555,170.59**	**246**	**$19,650,858.39**	**$3,204,776,973.01**

"Compensated" are claims 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/claims 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 claim, whether or not the petition/claim 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.

Due to the populations receiving vaccines added to the VICP in recent years, the proportion of adults to children seeking compensation has changed. Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult claims related to that vaccine have been filed.

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5.1

The National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines
September 3, 2015
A. Melissa Houston, M.D., M.P.H., F.A.A.P

Department of Health and Human Services
Health Resources and Services Administration

ACCV Meeting Highlights

- Update from the Department of Justice Vaccine Litigation Office
- Report from the ACCV Adult Immunization Workgroup
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH, NVPO

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Number of Petitions Filed as of August 1, 2015

Average annual number of petitions filed during FY 2010-2014 = 474

Fiscal Year	Total
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	597

Number of Adjudications as of August 1, 2015

Fiscal Year	Compensable	Dismissed	Total
FY 2010	180	293	473
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	370	167	537
FY 2015	378	77	455

Adjudication Categories for Non-Autism Claims FY 2013 – FY 2015 as of August 10, 2015

Adjudication Category	FY 2013	FY 2014	FY 2015
Compensable	367 (100%)	371 (100%)	398 (100%)
❖Concession	21 (6%)	40 (11%)	73 (18%)
❖Court Decision (includes proffers)	19 (5%)	34 (9%)	27 (7%)
❖Settlement	327 (89%)	297 (80%)	298 (75%)
Not Compensable	88	123	63
Adjudication Total	455	494	461

Award Amounts Paid as of August 1, 2015

Fiscal Year	Petitioners' Award	Attorneys' Fees & Costs
FY 2010	$179,387,341	$9,826,788
FY 2011	$216,319,428	$17,163,229
FY 2012	$163,491,999	$23,145,927
FY 2013	$254,666,327	$21,758,310
FY 2014	$202,084,196	$21,268,383
FY 2015	$187,949,982	$15,878,310

Vaccine Injury Compensation Trust Fund

- Balance as of June 30, 2015
  - $3,500,317,015.57
- Activity from October 1, 2014 to June 30, 2015
  - Excise Tax Revenue: $136,378,807
  - Interest on Investments: $45,248,692
  - Net Income: $181,627,499
  - Interest as a Percentage of Net Income: 25%

Source: U.S. Treasury, Bureau of Public Debt (August 10, 2015)

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Significant Activities

- Status of Revisions to Vaccine Injury Table Notice of Proposed Rulemaking (NPRM)
  - Published in the Federal Register on July 29, 2015
  - Public comment period ends January 25, 2016
  - Public hearing will be announced in the Federal Register
- Outreach Activities
  - The Office of Women's Health, Food and Drug Administration attended the National Association of County & City Health Officials on July 7 – 9, 2015 where 1, 300 Local Health Department Leaders and Public Health Partners Participated
  - The Indian Health Service distributed information regarding the VICP to 385 of it's providers through their July newsletter

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Significant Activities

- The Bureau of Primary Health Care distributed information regarding the VICP to 5,000 of it's Health Centers in their July newsletter
- National Vaccine Advisory Committee
  - September 9 – 10, 2015
- Advisory Committee on Immunization Practices
  - October 21 – 22, 2015
- Information on ACCV meetings, presentations and minutes can be found at http://www.hrsa.gov/vaccinecompensation/commissionchildvaccines.html

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Public Comment/Participation in Commission Meetings

Annie Herzog
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, Maryland 20857
Phone: 301-443-6634
Email: aherzog@hrsa.gov

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5.2

Report from the Department of Justice

September 3, 2015

Vincent J. Matanoski
Deputy Director, Torts Branch

1

Statistics

Reporting Period: 5/16/15 – 8/15/15

I. **Total Petitions Filed in the United States Court of Federal Claims this reporting period: 211**
   A. Minors: 36
   B. Adults: 175

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Statistics

Reporting Period: 5/16/15 – 8/15/15

II. Total Petitions Adjudicated this reporting period: 156

A. Compensated: 115

i. Cases conceded by HHS: 29

1. Decision awarding damages: 0
2. Decision adopting Proffer: 28
3. Decision adopting Settlement: 1

ii. Cases not conceded by HHS: 86

1. Decision awarding damages: 0
2. Decision adopting Proffer: 1
3. Decision adopting Settlement: 85

B. Not Compensated/Dismissed: 41

i. Decision dismissing Non-OAP: 36

ii. Decision dismissing OAP: 5

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Statistics

Reporting Period: 5/16/15 – 8/15/15

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 11

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

Recently Decided Cases

Appeals by Petitioner:

- *Stillwell v. HHS*: Affirmed
- *Crutchfield v. HHS*: Affirmed
- *Greenberg v. HHS*: Transferred to CFC

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

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

Pending Cases

Appeals by Petitioner:

- *Contreras v. HHS** (Entitlement)
- *Milik v. HHS** (Entilement)
- *Rowan v. HHS** (Entitlement)
- *Moriarty v. HHS* (Entitlement)
- *Hirmiz v. HHS* (Entitlement)

*Yellow cases are new this reporting period

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Appeals: U.S. Court of Federal Claims

Recently Decided Cases

Appeals by Petitioner:

- *D'Angiolini v. HHS*: Affirmed (Entitlement)
- *Godfrey v. HHS*: Granted in part; Remanded for consideration of *Koehn* (Entitlement)
- *Rowan v. HHS*: Affirmed (Entitlement)
- *Santini v. HHS:* Affirmed (Entitlement)
- *Barclay v. HHS*: Affirmed (Entitlement)
- *Padmanabhan v. HHS*: Affirmed (Entitlement)
- *Mora v.* HHS: Relief Denied (Relief from Judgment)
- *Nutall v. HHS*: Affirmed (Entitlement)
- *McLeod-Hunt v. HHS*: Affirmed (Entitlement)
- *Whitney v. HHS*: Vacated and Remanded

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

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Appeals: U.S. Court of Federal Claims

Pending Cases

Appeals by Petitioner:

- *Scharfenberger v. HHS** (Attorneys' Fees and Costs)
- *Guerrero v. HHS** (Attorneys' Fees and Costs)
- *Greenberg v. HHS** (Entitlement)
- *Holt v. HHS** (Entitlement)
- *Waterman v. HHS** (Entitlement)
- *Hodge v. HHS* (Entitlement)
- *Spahn v. HHS* (Entitlement)

*Yellow cases are new this reporting period

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Scheduled Oral Arguments

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

- *Hirmiz v. HHS*: October 8, 2015

U.S. Court of Federal Claims:

- *Hodge v. HHS*: September 3, 2015

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Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Optic Neuritis	3 Years, 9 Months
Tdap	Shoulder Injury	9 Months
Flu	GBS	9 Months
Flu	Transverse Myelitis/ Neuromyelitis Optica	1 Year, 3 Months
Flu	GBS	1 Year, 6 Months
HPV	Chronic Urticaria	1 Year, 3 Months
Tdap, Flu	Pupuric Lesions/ Vasculitis/ Panniculitis	1 Year, 1 Month
Flu	Transverse Myelitis	11 Months
Tdap	GBS	1 Year, 4 Months
Flu	Frozen Shoulder Syndrome/ Pain/Loss of Motion/Stiffness/Weakness	6 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

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Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Tdap, Hep A	Brachial Plexus Neuritis	1 Year
Flu	GBS	1 Year, 3 Months
DTaP, Hib	Ataxia,	2 Years
MMR	ITP	1 Year 7 Months
Tdap	Shoulder Injury	5 Months
Flu	Bell's Palsy	1 Year, 2 Months
Flu	Myelitis	11 Months
Flu	GBS	11 Months
Flu	Transverse Myelitis	11 Months
Flu	GBS	10 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .) 11

Adjudicated Settlements*

Reporting Period:5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	GBS	10 Months
Flu	Chronic Urticaria	9 Months
Flu	GBS	10 Months
Flu	GBS	2 Years, 6 Months
Flu	Brachial Neuritis	11 Months
Flu	GBS	1 Year, 8 Months
Flu	Lipoma	8 Months
Flu	GBS	11 Months
Flu	GBS	2 Years, 6 Months
Flu	GBS/CIDP	4 Years, 4 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .) 12

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	CIDP	1 Year, 8 Months
Flu	Transverse Myelitis	3 Years, 8 Months
Flu	Intractable Headaches	1 Year, 9 Months
Tdap, Flu	Transverse Myelitis	7 Months
Flu	GBS	6 Months
Flu	GBS	11 Months
Flu	GBS	11 Months
Flu	Shoulder Injury	10 Months
Flu	Shoulder Injury	9 Months
Hep B, DTaP, Hib, PCV13, Inactivated Polio	Infantile Spasms/ Related Seuelae	4 Years, 1 Month

*Terms of compensated settlements memorialized by Stipulation

(continued . . .) 13

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Neurological Defects	2 Years, 8 Months
Flu	GBS	1 Year, 8 Months
Flu	GBS	8 Months
HPV	Polyarthritis, Polyarthralgia, Seronegative Rheumatoid Arthritis	1 Year, 1 Month
Flu	Shoulder Injury	1 Year
Flu	SIRVA	1 Year, 4 Months
Tdap, HPV	Pemphigus Vulgaris	1 Year, 5 Months
Flu	GBS	1 Year, 5 Months
Flu	Brachial Neuritis	9 Months
Flu	CIDP	11 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .) 14

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Transverse Myelitis	1 Year, 10 Months
Flu	GBS	1 Year, 9 Months
Flu	Transverse Myelitis	6 Months
Tdap	Allergic Reaction/ Immune-Mediated Condition	1 Year, 2 Months
Flu	Adhesive Capsulitis	11 Months
Flu	SIRVA	1 Year, 8 Months
Flu	ITP	1 Year, 2 Months
Flu	GBS	5 Months
Hep B	Autoimmune Disorder/UCTD	2 Years
Flu	Shoulder Injury	8 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	GBS	10 Months
MMR	ITP	1 Year, 3 Months
Flu	SIRVA	10 Months
Hep B	Rheumatoid Arthritis/ Arthritis/ Fatigue	2 Years, 6 Months
Td	GBS	4 Years, 11 Months
Flu	Brachial Neuritis	1 Year
Flu	GBS	1 Year
Flu	Brachial Neuritis	5 Months
HPV	Cerebral Vasculitis/ Death	5 Years, 5 Months
Flu	GBS	7 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .)

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Hep B	Transverse Myelitis / Chronic Pain Syndrome/Neuropathic Pain	1 Year, 10 Months
Flu	GBS	9 Months
Flu	Brachial Plexopathy	10 Months
Flu	Transverse Myelitis/Death	10 Months
Flu	GBS	10 Months
Meningococcal	Transverse Myelitis	2 Years, 2 Months
Flu	ADEM	1 Year, 4 Months
Tdap	Seizure Condition	11 Months
Flu	SIRVA	11 Months
Flu	Arm Pain	10 Months

*Terms of compensated settlements memorialized by Stipulation

(continued . . .) 17

Adjudicated Settlements*

Reporting Period: 5/16/15 – 8/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Tdap, Flu	ADEM	1 Year, 4 Months
Flu	Infection/ Sepsis/ Neurological Injuries	7 Months
DTaP	Encephalopathy/ Other Neurological Injuries	8 Years, 8 Months
Flu	GBS/Death	2 Years, 11 Months
Flu	SIRVA	1 Year
Flu	GBS	11 Months

Total Number of Judgments Adopting Settlement this reporting period: 86

*Terms of compensated settlements memorialized by Stipulation

(continued . . .) 18

Appendix

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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.

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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.

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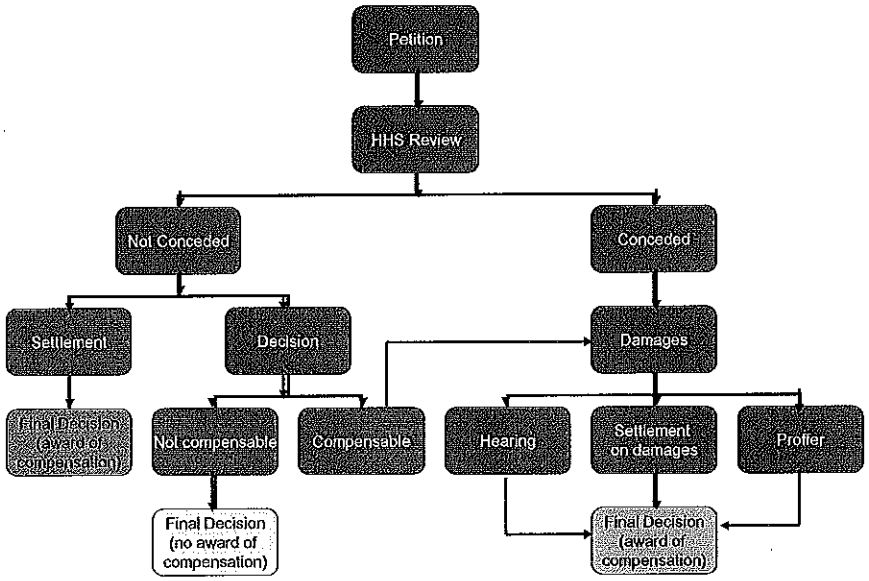
Glossary of Terms

- **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.

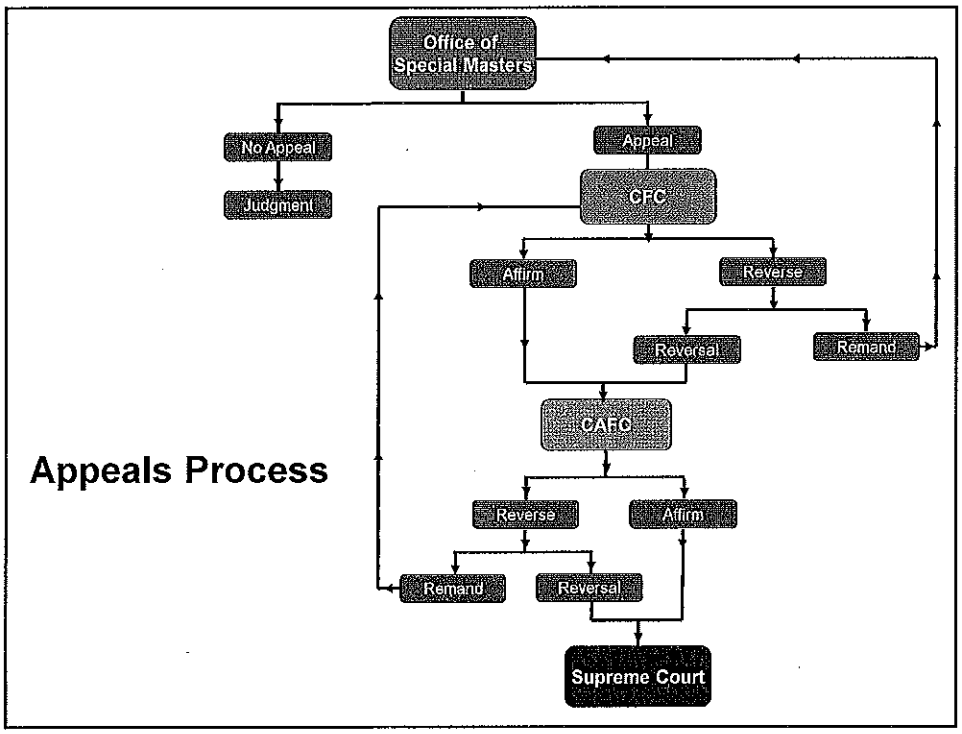
22

Petition Processing in the Office of Special Masters



23

Levels of Appeal in Vaccine Act Cases


Appeals Process
Office of Special Masters
No Appeal
Judgment
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CFC
Affirm
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Reversal
Remand
CAFC
Reverse
Affirm
Remand
Reversal
Supreme Court

5.3

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 3, 2015

Topics

- Update on selected sessions from the June 2015 Advisory Committee on Immunization Practices (ACIP) meeting
- Selected vaccine safety publications

June 2015 ACIP meeting summary

- Meningococcal vaccines (vote)
  - Serogroup B meningococcal (MenB) vaccine series may be administered to persons 16 - 23 years of age to provide short term protection against most strains of serogroup B meningococcal disease
  - Preferred age for MenB vaccination is 16 - 18 years
  - Category B recommendation (made for individual clinical decision making)

http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html

3

June 2015 ACIP meeting summary (cont.)

- Influenza (vote)
  - Algorithm for determining which children aged 6 months - 8 years need 2 doses of influenza vaccine was updated
  - New products incorporated into recommendations
    - Quadrivalent inactivated influenza vaccine (IIV)
    - Intradermal IIV
    - Trivalent recombinant influenza vaccine (FluBlok ®) recommendation expended to ages 18 and older
    - AFLURIA® recommended via jet injector for ages 18 - 64 years

http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html

4

June 2015 ACIP meeting summary (cont.)

- Influenza (vote)
  - Endorsed strain selection for the 2015-16 season, made previously by WHO and FDA
    - A/California/7/2009 (H1N1) pdm09-like virus
    - A/Switzerland/9715293/2013 (H3N2)-like virus
    - B/Phuket/3073/2013-like virus (a B/Yamagata lineage virus)
    - 2015-2016 quadrivalent flu vaccine also includes an additional B virus (B/Brisbane/60/2008-like virus, a B/Victoria lineage virus)

http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html

5

June 2015 ACIP meeting summary (cont.)

- Influenza (vaccine safety presentation)
  - 2014-2015 end-of-season update
  - Update on the Vaccine Safety Datalink (VSD) study:
    - Donahue* et al. "Evaluating the risk of spontaneous abortion following administration of influenza vaccines containing H1N1pdm09 and H3N2 viral antigens"

http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html
http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2015-06/flu-04-shimabukuro.pdf

6

June 2015 ACIP meeting summary (cont.)

- Pneumococcal vaccines (vote)
  - Change interval between PCV13 and PPSV23 in adults aged ≥65 years to:

    "A dose of PPSV23 should be given at least 1 year following a dose of PCV13. The two vaccines should not be co-administered. If a dose of PPSV23 is given earlier than the recommended interval, the dose need not be repeated."
  - Previously the interval in adults from PCV13 to PPV23 was 6 - 12 months

http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html

7

June 2015 ACIP meeting summary (cont.)

- Smallpox vaccine (vote)
  - Updated the smallpox vaccine recommendations (last update was in 2001 and since then ACAM2000 replaced Dryvax)
    - Healthcare personnel (e.g., physicians and nurses) that currently treat or anticipate treating patients with vaccinia virus infections whose contact with replication-competent vaccinia viruses is limited to contaminated materials (e.g., dressings) and persons administering ACAM2000 smallpox vaccine who adhere to appropriate infection prevention measures can be offered vaccination with ACAM2000 (category B recommendation)

http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html

8

Selected publications

- Sukumaran et al. Demographic characteristics of members of the Vaccine Safety Datalink (VSD): A comparison with the United States population. Vaccine. 2015 Jul 23. pii: S0264-410X(15)00984-6. [Epub ahead of print]
  - The VSD population is representative of the general US population on several key demographic and socioeconomic variables.
  - Despite a few specific groups being underrepresented in the VSD compared to the US, the absolute number of VSD members is large enough to ensure significant representation of these groups in vaccine safety studies that use VSD data.

9

Selected publications

- Miller et al. Vaccine Safety Resources for Nurses. Am J Nurs. 2015 Aug;115(8):55-8.
  - Describes the CDC's vaccine safety monitoring systems, explain how nurses and others can access the CDC's inquiry channels and other resources, and give examples of recent inquiries and their resolution.
- Grohskopf et al. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2015-16 Influenza Season. MMWR Morb Mortal Wkly Rep. 2015 Aug 7;64(30):818-25.

10

Selected publications

- Shimabukuro et al. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). Vaccine. 2015 Jul 22. pii: S0264-410X(15)00982-2. [Epub ahead of print]
  - We describe fundamental vaccine safety concepts, provide an overview of VAERS for healthcare professionals who provide vaccinations and might want to report or better understand a vaccine adverse event, and explain how CDC and FDA analyze VAERS data.
  - We also describe strengths and limitations, and address common misconceptions about VAERS. Information in this review will be helpful for healthcare professionals counseling patients, parents, and others on vaccine safety and benefit-risk balance of vaccination.

11

Selected publications

- Baker et al. Advanced Clinical Decision Support for Vaccine Adverse Event Detection and Reporting. Clin Infect Dis. 2015 Jun 9. pii: civ430. [Epub ahead of print]
  - We developed an open-source, generalizable clinical decision support system called Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP-VAERS) to assist clinicians with AE detection and reporting.
  - An open-source, electronic health record-based clinical decision support system can increase AE detection and reporting rates in VAERS.

12

Selected publications

- Moro et al. Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013. Clin Infect Dis. 2015 May 28. pii: civ423. [Epub ahead of print]
  - No concerning pattern was noted among death reports submitted to VAERS during 1997-2013. The main causes of death were consistent with the most common causes of death in the US population.
- Haber et al. Intussusception after monovalent rotavirus vaccine-United States, Vaccine Adverse Event Reporting System (VAERS), 2008-2014. Vaccine. 2015 Aug 11. pii: S0264-410X(15)01015-4. [Epub ahead of print]
  - We observed a significant increased risk of intussusception 3–6 days after dose 1 of RV1. The excess risk ranged from 1.2 to 2.8 per 100,000 in sensitivity analysis.
  - The estimated small number of intussusception cases attributable to RV1 is outweighed by the benefits of rotavirus vaccination.

13

Selected publications

- Iqbal et al. Preparation for global introduction of inactivated poliovirus vaccine: safety evidence from the US Vaccine Adverse Event Reporting System, 2000-12. The Lancet Infectious Diseases. 2015. doi: 10.1016/S1473-3099(15)00059-6.
  - Fairly few adverse events were reported for the more than 250 million IPV doses distributed between 2000 and 2012.
  - Sudden infant death syndrome reports after IPV were consistent with reporting patterns for other vaccines.
  - No new or unexpected vaccine safety problems were identified for fatal, non-fatal serious, and non-serious reports in this assessment of adverse events after IPV.

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Centers for Disease Control and Prevention
Atlanta, GA

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

Thank You

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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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

5.4

Vaccine Activities Update

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

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

September 2015

National Institute of Allergy and Infectious Diseases

National Institute of Allergy and Infectious Diseases

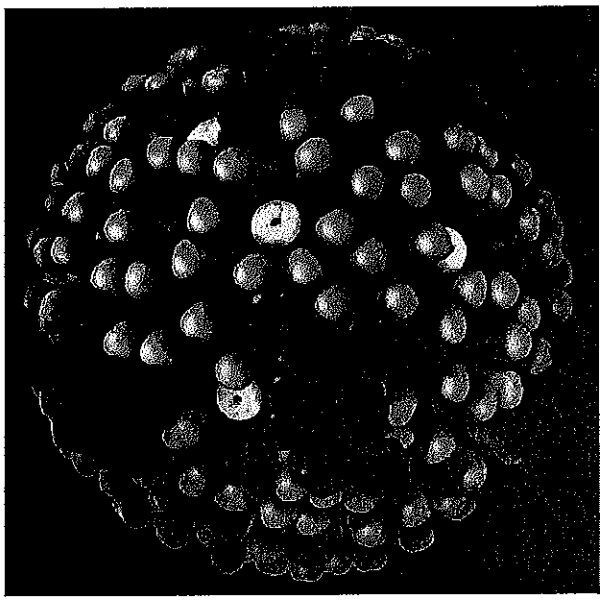
Environmental Influences on Child Health Outcomes (ECHO) Program

- NIH recently invited comments and suggestions on ECHO (the National Children's Study Alternative)
- Leverage existing cohorts to study environmental exposures on pediatric health outcomes
- Focus areas:
  - Obesity
  - Birth defects and other early outcomes
  - Neurodevelopment disorders
  - Airway diseases

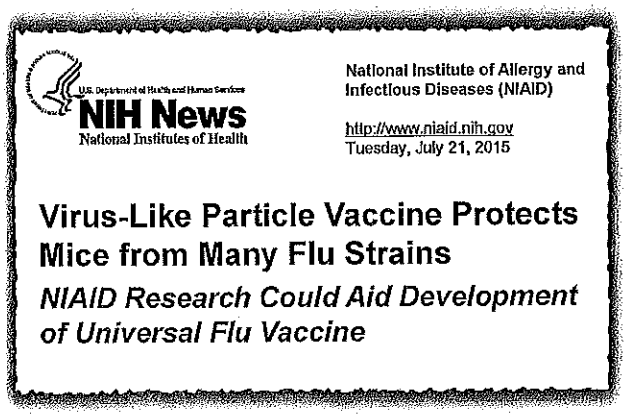
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-117.html

National Institute of Allergy and Infectious Diseases

NIAID Research: Influenza Vaccine



Credit: Dan Higgins



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

National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov
Tuesday, July 21, 2015

Virus-Like Particle Vaccine Protects Mice from Many Flu Strains

NIAID Research Could Aid Development of Universal Flu Vaccine

2 LM Schwartzman *et al.* An intranasal virus-like particle vaccine broadly protects mice from multiple subtypes of Influenza A virus. *mBio* (2015).

National Institute of Allergy and Infectious Diseases

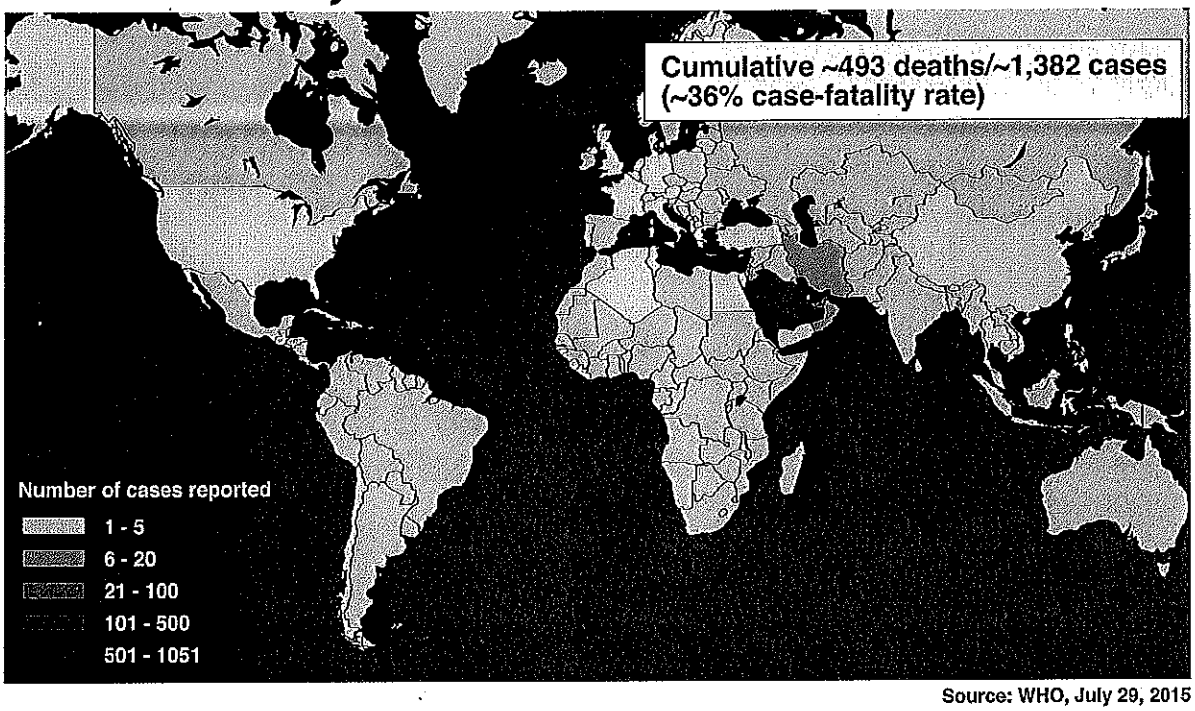
NIAID Research: Epstein-Barr Virus

- Epstein-Barr virus affects 9 out of 10 people during lifetime
  - Major cause of mononucleosis
  - Associated with 200,000 cases of cancer each year
- Experimental nanoparticle-based vaccine
  - Developed using structure-based design
  - Elicited potent neutralizing antibodies in animals
- Nanoparticle vaccine design could be used to create or redesign vaccines against other pathogens

3 M Kanekiyo *et al.* Rational Design of an Epstein-Barr Virus Vaccine Targeting the Receptor-Binding Site. *Cell* (2015).

National Institute of Allergy and Infectious Diseases

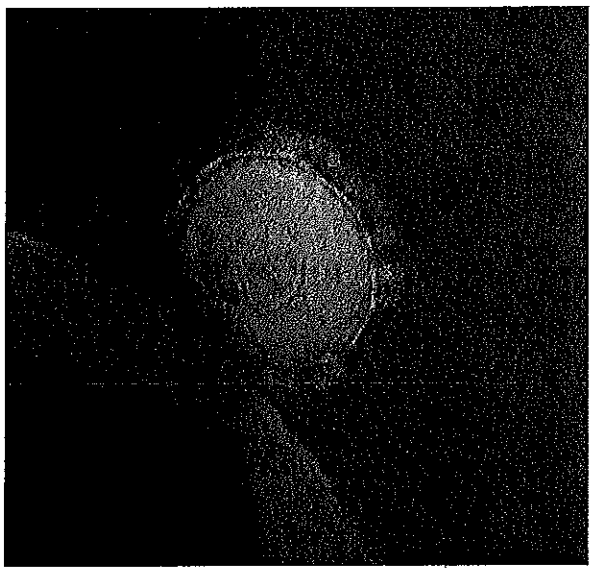
Countries with Confirmed Cases of MERS-CoV, 2012-2015



Source: WHO, July 29, 2015

AS Fauci/NIAID

Middle East Respiratory Syndrome (MERS)



Credit: NIAID

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

National Institute of Allergy and Infectious Diseases (NIAID)

Wednesday, August 19, 2015

NIH Scientists and Colleagues Successfully Test MERS Vaccine in Monkeys and Camels

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

National Institute of Allergy and Infectious Diseases (NIAID)

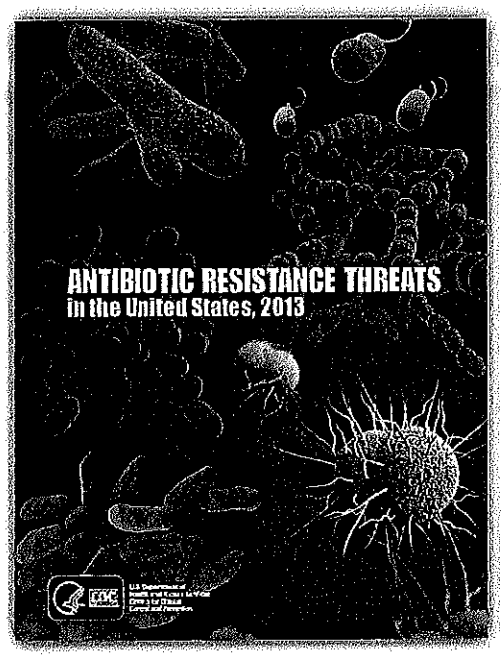
Tuesday, July 28, 2015

Experimental MERS Vaccine Shows Promise in Animal Studies

K. Muthumani *et al.* A synthetic consensus anti-Spike protein DNA vaccine induces protective immunity against Middle East Respiratory Syndrome Coronavirus in non-human primates. *Science Translational Medicine* (2015).

L Wang *et al.* Evaluation of candidate vaccine approaches for MERS-CoV. *Nature Communications* (2105).

Antimicrobial Resistance in the U.S. Results in Lost Lives and Dollars



- 2 M drug-resistant infections, 23,000 deaths/yr
- Annual costs:
  - $20 B in excess healthcare costs
  - $35 B in lost productivity

Increasing White House Emphasis on Antibiotic-Resistant Bacteria

"We now have a national strategy to combat antibiotic-resistant bacteria, to better protect our children and grandchildren from the reemergence of diseases and infections that the world conquered decades ago."

– President Barack Obama,
Global Health Security
Agenda Summit,
September 26, 2014

Credit: MSNBC.com

Vaccines: Innovative Approach to Combating Antimicrobial Resistance

- Unique characteristics of the organisms of concern
  - Many are hospital-associated infections
  - Small, localized, unanticipated outbreaks
- Challenges to vaccine development
  - Many of these pathogens associated with healthy human flora
- Complex regulatory, policy, and implementation issues for vaccines
- Potential solution: "Prophylactic Immune Interventions"
  - Targeted intervention for at-risk populations
  - Preventive approach for infectious disease control

C Heilman. Vaccines: An Innovative Approach to Combating Antimicrobial Resistance. *Infectious Disease News.* (2015)

5.5

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Vaccine Approvals

Prevnar 13 (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed])

- **BLA Supplement Approved: May 22, 2015**
  - To update the package insert to include data from the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) confirmatory efficacy study in adults.
  - The study demonstrated that Prevnar 13 prevented a first episode of vaccine-type community-acquired pneumonia (CAP) in adults 65 years of age and older.

Licensed Seasonal Influenza Vaccines

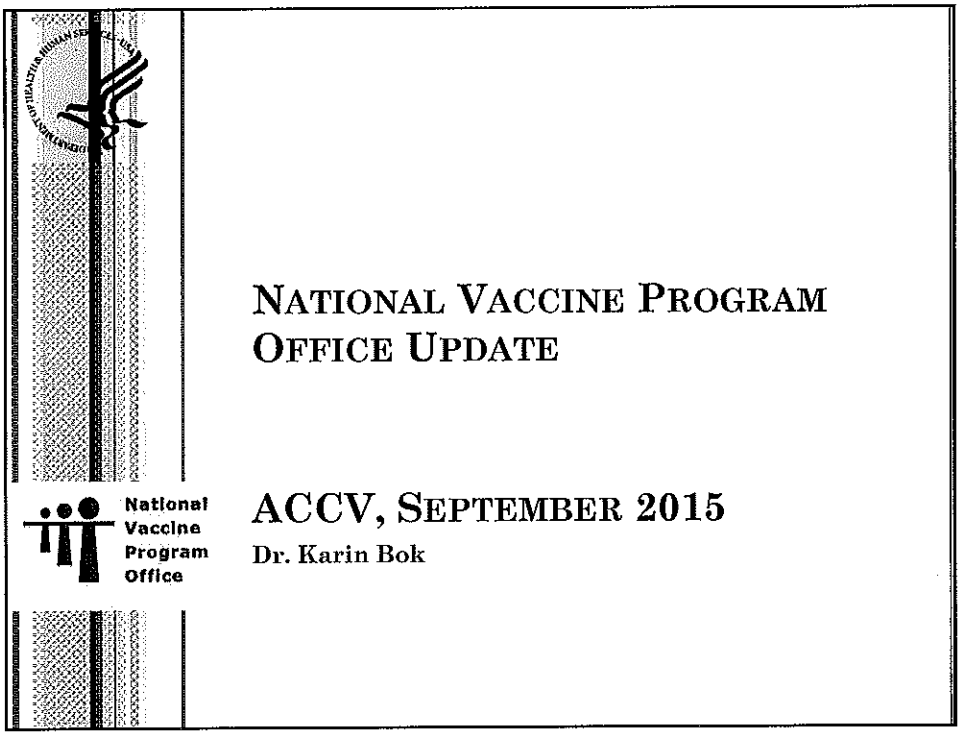
- **BLA Supplements Approved: June and July 2015**
  - To include the 2015-2016 influenza formulation
  - FDA's Vaccines and Related Biological Products Committee recommended that the trivalent formulation for the U.S. 2015-2016 influenza season contain the following:
    - an A/California/7/2009 (H1N1)-like virus
    - an A/Switzerland/9715293/2013 (H3N2)-like virus
    - a B/Phuket/3073/2013-like virus
    - The committee also recommended that quadrivalent influenza vaccines contain the above three strains and the following additional B strain:
    - a B/Brisbane/60/2008-like virus

Upcoming Meetings

Advisory Committee Meeting

- On September 15, 2015, the Vaccines and Related Biological Products Committee (VRBPAC) will meet in open session to discuss and make recommendations on the safety and immunogenicity of Seasonal Trivalent Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59 (FLUAD) manufactured by Novartis.

5.6



NVPO AND ISTF 2015-2016 VACCINE SAFETY INITIATIVES

- Evaluation of Federal Vaccine Safety Systems Ability to Test and Survey the Safety of Vaccines Administered During Pregnancy ($500 K)
- Clinical Study of the Safety of Simultaneous Administration of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and Inactivated Influenza Vaccine (IIV) in Pregnant Women ($200 K)

National Vaccine Program Office

Cooperative agreement: Research, Monitoring and Outcomes Definitions for Vaccine Safety

- **Two awardees with a start date of August 1st, 2015**
  - Establishment of a vaccine safety pregnancy database
  - Prevention of injection site pain and syncope associated with preteen and teen vaccination

National Vaccine Program Office

Thank you

National Vaccine Program Office

6

6.1

"Exclusive". This document removes MR series 11000 and 12000 from being designated as "Exclusive". All other parameters of the Final Rule remain the same as published on June 5, 2015.

DATES: Effective June 23, 2015.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–2118.

SUPPLEMENTARY INFORMATION: This document corrects § 51–6.4 by removing MR series 11000 and 12000 from paragraphs (b), (c)(4), and (d) so the series are no longer designated as "Exclusive". All other parameters of the Final Rule remain the same as published on June 5, 2015.

List of Subjects in 41 CFR Part 51–6 Procurement procedures.

For the reasons set out in the preamble, the Committee amends 41 CFR part 51–6 as follows:

PART 51–6—PROCUREMENT PROCEDURES

■ 1. The authority citation for part 51–6 continues to read as follows:

Authority: 41 U.S.C. 8501–8506.

§ 51–6.4 [Amended]

■ 2. In § 51–6.4, in paragraphs (b), (c)(4), and (d), remove ", 11000 (11000–11999); 12000 (12000–12999)".

Dated: June 17, 2015.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–15284 Filed 6–22–15; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB00

National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table

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

ACTION: Final rule.

SUMMARY: On July 24, 2013, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) proposing changes to the regulations governing the National Vaccine Injury Compensation Program (VICP). Specifically, the Secretary proposed revisions to the Vaccine Injury Table (Table). The basis for this change is consistent with the Secretary's findings that intussusceptions can reasonably be determined in some circumstances to be caused by rotavirus vaccines. The Secretary is now making this amendment to the Table and to the Qualifications and Aids to Interpretation (QAI), described below under Background Information, as proposed in the NPRM. These regulations will apply only to petitions for compensation under the VICP filed after this final rule becomes effective.

DATES: This final rule is effective July 23, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Avril M. Houston, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–06, 5600 Fishers Lane, Rockville, MD 20857, or by telephone: (800) 338–2382. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background Information

Under Title XXI of the Public Health Service Act, as amended (PHS Act), individuals who demonstrate a vaccine-related injury or death may receive compensation through the VICP. To be eligible for compensation from the VICP, a petitioner must demonstrate that the injured or deceased individual received a vaccine set forth in the Table (a "covered vaccine") and sustained a vaccine-related injury or death. A petitioner can prove a vaccine-related injury or death in three ways. First, the petitioner can show, by a preponderance of the evidence, that the vaccine recipient suffered an injury listed in the Table corresponding with the vaccine received, that the onset of such injury occurred within the timeframe specified in the Table, and that the injury meets the requirements set forth in the Table's QAI. A Table injury or death is given the legal presumption that it was caused by the vaccination. Sections 2111(c)(1)(C)(i), 2113(a)(1)(B), and 2114(a) of the PHS Act. Second, if the petitioner cannot demonstrate a Table injury, the petitioner can prevail by proving, by a preponderance of the evidence, that the vaccine caused the injury or death (off-Table injury). Third, a petitioner can prevail by proving, by a preponderance of the evidence, that the vaccine significantly aggravated a pre-existing condition. In all three cases, a petitioner must also show that the injury was sufficiently severe by demonstrating that such person suffered the residual effects of the injury for more than 6 months; died from the administration of the vaccine; or that the alleged injury resulted in inpatient hospitalization and surgical intervention. Section 2111(c)(1)(D) of the PHS Act. If the petitioner can prove a Table injury, off-Table injury, or significant aggravation of a pre-existing condition, the petitioner is entitled to compensation unless it is affirmatively shown that the injury was caused by some factor unrelated to the vaccination.

Under section 2114(e)(2) of the PHS Act, when the Centers for Disease Control and Prevention (CDC) recommends a vaccine for routine administration to children, the Secretary is required to amend the Table to include such vaccine. Coverage becomes effective when an excise tax is imposed on the vaccine. Additionally, the Secretary is authorized to include specific injuries on the Table with respect to each covered vaccine, including the timeframe when the first symptom or manifestation of the onset of such adverse event may occur. The Secretary may also define such injuries through the QAI. Under section 2114(c) of the PHS Act, the Secretary may make such modifications to the Table by promulgating regulations, with notice and opportunity for a public hearing, and at least 180 days of public comment.

II. Discussion of the Final Rule

As discussed in the NPRM (78 FR 44512, July 24, 2013), the Secretary has reviewed the currently available data regarding the Rotarix and RotaTeq vaccines and the risk of intussusception. The background of the RotaShield experience in the U.S. and the published literature from Mexico, Brazil, Australia, and the U.S. supports a small attributable risk of intussusception after the first and second doses of Rotarix and RotaTeq (with a greater amount of data supporting an association with the first dose of both vaccines). Evidence shows the increased risk within the 1–7 days following immunization with peaks in the fourth and fifth days. As a consequence, the Secretary is amending the Table to add the injury of intussusception to the general Table category of "rotavirus vaccines" to allow a presumption of causation for claims that meet the requirements set forth in the Table for that injury. To allow for a generous timeframe that will capture any cases related to the vaccine after day 7, the Secretary has assigned an onset interval of 1–21 days under sections 2114(c) and (e) of the PHS Act.

The Secretary will stay informed of new information in the scientific and medical field about intussusception and

rotavirus vaccines and may propose changes in the future if such information warrants changes to the Table. In addition, the Secretary recognizes that one goal of the VICP is to provide compensation to petitioners harmed by vaccines through a less adversarial system. Therefore, the Secretary feels that adding the Table injury of intussusception after the first and second doses of rotavirus vaccines with a window of 1–21 days is appropriate.

The QAI section of the Table defines the injury of "intussusception" as 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. The definition for presumption of vaccine causation only applies to the first and second dose of vaccine, and excludes intussusception occurring with or after the third dose. The third dose of rotavirus vaccines lacks sufficient evidence showing risk.

The definition also delineates the alternative causes of intussusception which, if present in a case, would prevent it from qualifying as a Table injury. The alternative causes were classified into four categories: infectious diseases; anatomic lead points; anatomic bowel abnormalities; and underlying gastrointestinal or systemic diseases. Cases of intussusception where the onset was within 14 days after an infectious disease secondary to non-enteric or enteric adenovirus, other enteric viruses (such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides) would not qualify as a Table injury. Proof of these alternate causes may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing.

Cases of intussusception in a person with a pre-existing condition identified as the lead point for intussusception, such as intestinal masses and cystic structures (*e.g.*, polyps; tumors; Meckel's diverticulum; lymphoma; or duplication cysts), would not qualify as a Table injury. Additionally, cases of intussusception 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 in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease) would not qualify as a Table injury.

Petitioners may be eligible for compensation for vaccine-related cases of intussusception in which the onset is before 1 day or beyond 21 days, or where the condition does not satisfy the criteria under the QAI for intussusception (an "off-Table" claim); however, the petitioners will be required to prove causation-in-fact. Regardless of whether the claim satisfies the criteria in the Table, all petitioners must demonstrate sufficient severity of the injury by proving that the injured person: 1) suffered the residual effects or complications of the alleged vaccine-related injury for more than 6 months after vaccine's administration; 2) died from administration of the vaccine; or 3) sustained inpatient hospitalization and surgery as a result of the alleged vaccine-related injury. Section 2111(c)(1)(D), PHS Act (42 U.S.C. 300aa–11(c)(1)(D)). In the case of rotavirus vaccine administration and subsequent intussusception, the Secretary does not consider a reduction of intussusception with therapeutic enemas to be "surgical intervention."

Petitions must also be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed with the VICP, set forth in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)), continues to apply. In addition, section 2116(b) of the PHS Act 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 section, individuals who may be eligible to file petitions based on the revised Table may file a petition for compensation not later than two years after the effective date of the revision if the injury or death occurred not more than eight years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)).

III. Comments and Responses

The comment period for this regulation ran for 6 months (July 24, 2013–January 21, 2014) and included two public hearings that were held on January 13, 2014, and April 28, 2014. The Secretary received ten comments as a result of this process. None of the commenters objected to the Secretary's proposal to add intussusception as an injury for rotavirus vaccines to the Table, and the overwhelming majority of commenters expressed their support for the proposal. In addition, commenters raised four additional points. Below is a summary of those points and the Secretary's responses to them.

1. Notice to Potential Petitioners

COMMENT: A commenter suggested that the Secretary make additional efforts to increase public awareness about expanding the Table and to increase the general public awareness about the VICP.

RESPONSE: The Secretary will continue efforts to increase the general public's awareness about the VICP, including revisions to the Table.

2. Demonstrating Severity of Injury

COMMENT: One commenter suggested that the definition of surgical intervention be broadened to include therapeutic enema treatment.

RESPONSE: Defining the term "surgical intervention" is beyond the scope of the Table amendments. While the preamble to both the NPRM and final rule includes the Secretary's view that a reduction of intussusception with an enema is not a "surgical intervention," such language is not included in the regulatory text. Further, the definition of "surgical intervention" is decided by the court.

3. Onset Time Frame

COMMENT: A commenter stated that none of the data for either vaccine supports an association with intussusception for days 8–21 after dose 2 and suggested that the Secretary consider revising the time frame for qualification as a Table injury after dose 2 to 1–7 days.

RESPONSE: The Secretary has considered the approach suggested by the commenter and also the recommendation of the Advisory Commission on Childhood Vaccines (ACCV). The ACCV unanimously recommended the proposed change of 1–21 days for all rotavirus vaccines.

The ACCV's "Guiding Principles for Recommending Changes to the Vaccine Injury Table," consist of two overarching principles: (1) the Table should be scientifically and medically credible; and (2) where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, the change should, whenever possible, be made to the benefit of petitioners. The Guiding Principles were established in 2006 to assist the ACCV in evaluating

proposed Table revisions and determining whether to recommend Table changes to the Secretary. The ACCV followed these Guiding Principles in making its recommendations to the Secretary for revising this Table. Therefore, the Secretary has decided that the 1–21 day timeframe for both vaccines is the best approach to capture any cases related to the vaccine after day 7.

4. Published Studies since the Publication of the NPRM

COMMENT: A commenter identified studies that have been published since the initial NPRM was published.

RESPONSE: The Secretary has reviewed these studies and found that the most recent data have shown a small but statistically significant increased risk of intussusception within 7 days after the first and second doses of the licensed rotavirus vaccines. However, as discussed above, following the Guiding Principles, the ACCV unanimously recommended the proposed change of 1–21 days for all rotavirus vaccines. Therefore, the Secretary has decided that the 1–21 day timeframe for both vaccines is the best approach to capture any cases related to the vaccine after day 7.

IV. Regulatory Impact Analysis

HHS has examined the impact of this rulemaking as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, the Congressional Review Act (5 U.S.C. 804(2)), the Regulatory Flexibility Act (RFA), section 202 of the Unfunded Mandates Reform Act of 1995, section 654(c) of the Treasury and General Government Appropriations Act of 1999, and Executive Order 13132 on Federalism.

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 used prior to the revisions of this final rule. The only purpose of this rule is to lessen 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 rule does not meet the criteria for a major rule as defined by Executive Order 12866, and it would not have a major effect on the economy or federal expenditures. The Secretary has determined that this 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, or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The Secretary finds that the provisions of this rule will not have an adverse effect on family well-being, because this rule does not 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" 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 rule would modify the Table based on legal authority.

Impact of the New Rule

This rule will have the effect of making it easier for future VICP petitioners alleging the injury of intussusception as the result of a rotavirus vaccine that meets the criteria in the 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.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Dated: May 27, 2015.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: June 5, 2015.

Sylvia M. Burwell,

Secretary.

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 part 100 is revised 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. Amend § 100.3 as follows:

■ a. Amend paragraph (a) by revising Item XI in the table.

■ b. Add paragraph (b)(3).

The revision and addition read as follows:

§ 100.3 Vaccine injury table.

(a) * * *

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
* *	* * *	* *
XI. Rotavirus vaccines	A. Intussusception	1–21 days
	B. Any acute complication or *sequela* (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable
* *	* * *	* *

(b) * * *

(3) *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 pre-existing 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).

* * * * *

[FR Doc. 2015–14771 Filed 6–22–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–8385]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Bret Gates, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4133.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register.**

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency

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and Welfare and Advance Notice of Proposed Rulemaking in the **Federal Register** on July 1, 2015. This action provides notice of three updates regarding the public hearing.

DATES: The EPA will hold a public hearing on August 11, 2015 in Washington, DC starting at 10 a.m. local time.

ADDRESSES: The hearing will be held at the Headquarters office of the US EPA, the William Jefferson Clinton East Building, Room 1153, 1201 Constitution Avenue NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Ms. JoNell Iffland, Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, Michigan 48105, telephone number: (734) 214–4454, fax number: (734) 214–4816, email address: *Iffland.jonell@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA published a proposed finding that greenhouse gas emissions from aircraft cause or contribute to air pollution that may reasonably be anticipated to endanger public health and welfare and an advance notice of proposed rulemaking regarding aircraft engine greenhouse gas emissions on July 1, 2015 (80 FR 37758). This action corrects a typographical error in the street address for the public hearing and provides notice of availability of a conference call-in number for the public to listen to the hearing. Additionally, this action provides notice that video recording will be allowed in the hearing room provided that it does not interfere with or interrupt the public hearing.

Updates

The **DATES** section of the proposed finding and advance notice of proposed rulemaking published in the **Federal Register** on July 1, 2015 (78 FR 37758), provided information on the public hearing. This action updates that information.

The EPA will hold a public hearing on August 11, 2015 in Washington, DC, at the William Jefferson Clinton East Building, Room 1153, 1201 Constitution Avenue NW., Washington, DC 20004. The EPA will provide the opportunity for the public to listen to the hearing through the following conference call-in line: 1–866–299–3188, conference code 1433527160. Please note that this conference line will allow the public to listen only; persons listening will not be able to give an oral presentation via the conference line.

Additionally, the proposed finding and advance notice of proposed rulemaking stated that no large signs will be allowed in the building, cameras may only be used outside of the building and demonstrations will not be allowed on federal property for security reasons. This update confirms that video recording will be allowed in the hearing room provided that it does not interfere with or interrupt the public hearing.

Dated: July 21, 2015.

Christopher Grundler,

Director, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2015–18518 Filed 7–28–15; 8:45 am]

BILLING CODE 6560–50–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: Notice of proposed rulemaking (NPRM).

SUMMARY: The Secretary proposes to amend the Vaccine Injury Table (Table) by regulation. These proposed regulations will have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the final regulations become effective. The Secretary is seeking public comment on the proposed revisions to the Table.

DATES: Written comments must be submitted on or before January 25, 2016.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB01 in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only *one* of these ways to minimize the receipt of duplicate submissions.

1. *Federal eRulemaking Portal.* You may submit comments electronically to *http://www.regulations.gov.* Click on the link "Submit electronic comments on HRSA regulations with an open comment period." Submit your comments as an attachment to your message or cover letter. (Attachments should be in Microsoft Word or WordPerfect; however, Microsoft Word is preferred).

2. *By regular, express or overnight mail.* You may mail written comments to the following address only: Health Resources and Services Administration, Department of Health and Human Services, Attention: HRSA Regulations Officer, Parklawn Building, Room 14–101, 5600 Fishers Lane, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *Delivery by hand (in person or by courier).* If you prefer, you may deliver your written comments before the close of the comment period to the same address: Parklawn Building Room 14–101, 5600 Fishers Lane, Rockville, MD 20857. Please call in advance to schedule your arrival with one of our HRSA Regulations Office staff members at telephone number (301) 443–1785. This is not a toll-free number.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, Program cannot accept comments by facsimile (FAX) transmission. In commenting, by any of the above methods, please refer to file code (#HRSA–0906–AB01). All comments received on a timely basis will be available for public inspection without change, including any personal information provided, in Room 14–101 of the Health Resources and Services Administration's offices at 5600 Fishers Lane, Rockville, MD, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (excluding Federal holidays). Phone: (301) 443–1785. This is not a toll-free number.

FOR FURTHER INFORMATION CONTACT: Please visit the National Vaccine Injury Compensation Program's Web site, *http://www.hrsa.gov/vaccinecompensation/*, or contact Dr. Avril Melissa Houston, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857. Phone calls can be directed to (301) 443–6593.

SUPPLEMENTARY INFORMATION: The President encourages Federal agencies through Executive Order 13563 to develop balanced regulations by encouraging broad public participation in the regulatory process and an open exchange of ideas. The Department of Health and Human Services (HHS) accordingly urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any data to support your positions. If you have questions before submitting comments, please see the "For Further Information" box below for the name and contact information of the subject-matter expert involved in this proposal's development. We must consider all written comments received

during the comment period before issuing a final rule.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please contact HRSA's Regulations Officer at Parklawn Building, Room 14–101, 5600 Fishers Lane, Rockville, MD 20857; or by telephone at 301–443–1785, to obtain this information in an accessible format. This is not a toll free telephone number. Please visit *http://www.HHS.gov/regulations* for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the **Federal Register** providing details of this hearing. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

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

In order to receive an award under this Program, a petitioner must establish a vaccine-related injury or death, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what has been 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 sections 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a) of the Act). Currently, cases are often resolved by settlements reached by both parties and approved by the Court.

When Congress first enacted the Act, it mandated reviews by the Institute of Medicine (IOM) of the National Academy of Sciences with the express purpose of providing a better scientific rationale for any presumptions of vaccine causation. Under sections 312 and 313 of Public Law 99–660, Congress mandated that the IOM review the scientific literature and other information on specific adverse consequences of vaccines covered by the Program. Congress enacted a mechanism for modification of the statutory Table, through the promulgation of regulatory changes by the Secretary, after consultation with the Advisory Commission on Childhood Vaccines (ACCV). By statutory directive, the membership of the ACCV reflects a variety of stakeholders with different perspectives (42 U.S.C. 300aa–19).

Efforts by the Secretary to modify the initial statutory Table, and its definitional counterpart, the Qualifications and Aids to Interpretation (QAI) began with publication of the two congressionally mandated IOM reviews in 1991 and 1994, respectively. With a few exceptions, the approach by the Secretary was straightforward: If the IOM concluded that there was evidence that a condition was "causally related," it was added to or left on the Table. However, if there was no proven scientific evidence of an association, it was not added to the Table or it was removed. The entire process, from publication of the IOM reports, to promulgation of final rules in 1995 and 1997 took approximately 3 to 4 years.

The IOM has analyzed numerous possible vaccine injury connections over the years and after conducting a third comprehensive review of the scientific literature on vaccines and adverse events, released a report entitled, *Adverse Effects of Vaccines: Evidence and Causality* (2012). This third IOM report was conducted under the Department's initiative and was not statutorily mandated. 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 (*http://www.iom.edu/reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx*). The members of the review committee are subject to the stringent conflict of interest criteria imposed by the IOM. The committee met eight times over the course of 35 months, surveying more than 11,000 abstracts and reviewing in-depth 1,487 scientific and medical studies. The committee did not perform any original research.

The IOM Committee undertook the task of judging whether, based on available scientific evidence, a causal relationship exists between each adverse event examined and exposure to the following eight vaccines: Measles-mumps-rubella vaccine, varicella virus vaccine, seasonal influenza vaccines (which did not include the H1N1 influenza vaccine distributed in 2009), hepatitis A vaccine, hepatitis B vaccine, human papillomavirus vaccine, diphtheria tetanus toxoid and acellular pertussis-containing vaccines, and meningococcal vaccine. The charge to the Committee involved these eight vaccines because they are the vaccines with the vast majority of alleged adverse events in the claims for compensation filed under the Program. In addition, some of these vaccines had not been reviewed previously by the IOM.

Two types of evidence were utilized by the IOM in determining the strength of a causal association: Epidemiologic evidence from studies of populations and mechanistic evidence derived primarily from biological and clinical studies in animals and humans such as case reports. To determine the weight of the evidence, the IOM used a summary classification scheme that incorporated both the quality and quantity of the individual articles and the consistency of the group of articles in terms of direction of effect. Four weight-of-evidence categories were utilized, with epidemiologic evidence assessed to be high, moderate, limited or insufficient, and mechanistic evidence assessments of strong, intermediate, weak or lacking.

The IOM started each adverse event assessment from a position of neutrality, moving in either direction (*i.e.*, evidence favoring or rejecting causation) only when the epidemiologic and/or mechanistic evidence suggested a more definitive assessment. As with the previous IOM studies, a classification system was used to categorize the IOM's conclusions about the strength of a causal association. These categories are as follows:

1. Evidence convincingly supports a causal relationship;
2. Evidence favors acceptance of a causal relationship;
3. Evidence favors rejection of a causal relationship; or
4. Evidence is inadequate to accept or reject a causal relationship.

The IOM Committee concluded in certain circumstances that the evidence convincingly supports, or favors acceptance of, a causal relationship based only on a mechanistic assessment, even when the epidemiological evidence was inconclusive or absent. The 2012 IOM Report, on pages 17–18 explains that strong mechanistic evidence "always carries sufficient weight for the committee to conclude the evidence convincingly supports a causal relationship. . .This conclusion [attributing the disease to the vaccine and not to other etiologies] can be reached even if the epidemiologic evidence is rated high in the direction of no increased risk or even decreased risk."

The IOM concluded the evidence convincingly supports 14 specific vaccine-adverse event relationships, with all but one based on strong mechanistic evidence, and the epidemiologic evidence rated as either having limited confidence or being insufficient. Four vaccine adverse events judged to have either epidemiologic evidence of moderate certainty or mechanistic evidence of intermediate weight were placed in the "evidence favors acceptance of a causal relationship" category, while five other vaccine adverse events were placed in the "evidence favors rejection" category. A finding against a causal relationship required high or moderate epidemiologic evidence in the direction of no effect or decreased risk along with the absence of strong or intermediate mechanistic evidence supporting a causal relationship. The vast majority (135 vaccine-adverse event combinations) were placed in the "evidence is inadequate to accept or reject a causal relationship" category.

After release of the report, nine HHS workgroups including HRSA and the Centers for Disease Control and Prevention (CDC) medical staff reviewed the IOM conclusions on 158 vaccine-adverse events, as well as any newly published scientific literature not contained in the IOM report, and developed a set of proposed changes to the Table and QAI. The work of the HHS workgroups ended and HRSA continued to monitor the literature.

In 2006, the ACCV established "Guiding Principles for Recommending Changes to the Vaccine Injury Table" (Guiding Principles) to assist the ACCV in evaluating proposed Table revisions and determining whether to recommend changes to the Table to the Secretary. The Guiding Principles consist of two overarching principles: (1) The Table should be scientifically and medically credible; and (2) where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, the change should, whenever possible, be made to the benefit of petitioners. The Guiding Principles also state, among other factors, that "[t]o the extent that the [IOM] has studied the possible association between a vaccine and an adverse effect, the conclusions of the IOM should be considered by the ACCV and deemed credible but those conclusions should not limit the deliberations of the ACCV." Although not binding on the Secretary, the ACCV Guiding Principles were utilized by the nine HHS workgroups in the development of the proposed changes to the Table. In particular, recommendations regarding appropriate time intervals for the onset of a Table injury, or diagnostic criteria in the QAI were influenced by the Guiding Principles. As part of its mandate under the Act, the ACCV considered the proposed changes set forth in this NPRM in its quarterly meetings on March 8, 2012, September 5, 2013, December 5, 2013, June 5, 2014, and September 4, 2014. The ACCV deliberations included scientific and public policy considerations, and were also influenced by the 2006 Guiding Principles. For each proposed change by the Secretary, the ACCV voted for one of three options:

1. ACCV concurs with the proposed change(s) to the Table (and QAI) and would like the Secretary to move forward (with or without comments);
2. ACCV does not concur with the proposed change(s) to the Table (and QAI) and would not like the Secretary to move forward; or
3. ACCV would like to defer a recommendation on the proposed change(s) to the Table (and QAI) pending further review at a future ACCV meeting.

Findings

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 based on the 2012 IOM report, the work of the nine workgroups that reviewed the IOM findings, and after giving due consideration to the ACCV's recommendations.

For the vast majority of the vaccine adverse event pairs that were reviewed by the IOM (135), the IOM determined that the evidence is inadequate to accept or reject a causal relationship. With the exception of seasonal influenza vaccine and Guillain-Barré Syndrome (GBS), unless the IOM findings addressed a condition that was already on the Table, the Secretary makes no additional findings and proposes no change to the Table with regard to the vaccine adverse event pairs in this category. For seasonal influenza vaccines, the Secretary proposes to add the injury of GBS to the Table for the policy reasons discussed in this NPRM. 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.

Applying the remaining IOM conclusions, with the Guiding Principles, the Secretary intends to make certain changes to the Table, and also intends to leave certain items already on the Table unchanged. In so doing, the Secretary makes the following findings:

Findings That Result in Additions or Changes to the Table

1. The scientific evidence convincingly supports a causal relationship between measles-mumps-rubella (MMR) vaccine and measles inclusion body encephalitis.
2. The scientific evidence convincingly supports a causal relationship between varicella vaccine and vaccine disseminated varicella infection (widespread chickenpox rash shortly after vaccination).
3. The scientific evidence convincingly supports a causal relationship between varicella vaccine and disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies.
4. The scientific evidence convincingly supports a causal relationship between varicella vaccine and vaccine strain viral reactivation.
5. The scientific evidence convincingly supports a causal relationship between varicella vaccine and vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis.
6. The scientific evidence convincingly supports a causal relationship between varicella vaccine and anaphylaxis.
7. The scientific evidence convincingly supports a causal

relationship between influenza vaccines and anaphylaxis.

8. The scientific evidence convincingly supports a causal relationship between meningococcal vaccines and anaphylaxis.

9. The scientific evidence favors acceptance of a causal relationship between human papillomavirus vaccines and anaphylaxis.

10. The scientific evidence convincingly supports a causal relationship between an injection-related event and deltoid bursitis. For reasons detailed below, the Secretary proposed adding a more expansive injury of Shoulder Injury Related to Vaccine Administration (SIRVA) to the Table.

11. The scientific evidence convincingly supports a causal relationship between an injection-related event and syncope.

12. The scientific evidence is inadequate to accept or reject a causal relationship between seasonal influenza vaccines and GBS. However, the Secretary proposes a Table change for the reasons discussed in this NPRM.

Findings That Do Not Result in Changes to the Table Because the Injury Is Already on the Table

1. The scientific evidence convincingly supports a causal relationship between MMR vaccine and anaphylaxis.

2. The scientific evidence convincingly supports a causal relationship between Hepatitis B vaccine and anaphylaxis.

3. The scientific evidence convincingly supports a causal relationship between tetanus toxoid vaccine and anaphylaxis.

4. The scientific evidence is inadequate to accept or reject a causal relationship between tetanus toxoid-containing vaccines (including those containing the acellular pertussis component but not the whole cell pertussis component) and encephalopathy and encephalitis.

5. The scientific evidence is inadequate to accept or reject a causal relationship between MMR vaccine and chronic arthritis in women.

6. The scientific evidence is inadequate to accept or reject a causal relationship between MMR vaccine and chronic arthritis in children.

7. The scientific evidence is inadequate to accept or reject a causal relationship between MMR vaccine and encephalopathy or encephalitis.

Findings That Do Not Result in Changes to the Table Because the Injury Is Transient in Nature

1. The scientific evidence convincingly supports a causal relationship between MMR vaccine and febrile seizures.

2. The scientific evidence favors acceptance of a causal relationship between MMR vaccine and transient arthralgia in women.

3. The scientific evidence favors acceptance of a causal relationship between MMR vaccine and transient arthralgia in children.

Findings That Do Not Result in Changes to the Table Because the Evidence Favors Rejection of a Causal Relationship

1. The scientific evidence favors a rejection of a causal relationship between MMR vaccine and autism.

2. The scientific evidence favors a rejection of a causal relationship between MMR vaccine and type 1diabetes.

3. The scientific evidence favors a rejection of a causal relationship between DTaP (tetanus) vaccine and type 1diabetes.

4. The scientific evidence favors a rejection of a causal relationship between inactivated (as opposed to the live intranasal) influenza vaccine and Bell's palsy.

5. The scientific evidence favors a rejection of a causal relationship between inactivated influenza vaccine and exacerbation of asthma or reactive airway disease episodes in children and adults.

Discussion of Proposed Table Changes

The Secretary has examined the recommendations of the ACCV and proposes that the Table set forth at 42 CFR 100.3 be revised as described below. Following each vaccine and adverse event there is a discussion of the IOM conclusion and, where applicable, other relevant conclusions, as well as the Department's proposal. It should be noted that the ACCV concurred with all of the proposals regarding the Table and QAI. Each of the changes proposed by the Department and the rationale for the proposal is described in detail. An important consideration in proposing changes to the Table is the need to make the Table as easy to understand and as clear as possible. With this goal in mind, the Secretary has proposed new language and clarified certain sections of the QAI which must be used by the Special Masters and the parties in understanding when a particular set of symptoms is consistent with a particular Table injury.

As provided in 42 U.S.C. 300aa–14(c)(4), the modified Table will apply only to petitions filed under the Program after the effective date of the final regulation. Petitions must also be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed with the VICP, set forth in 42 U.S.C. 300aa–16(a), continues to apply. In addition, 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 section, 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 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).

Based on the requirements of the Administrative Procedure Act, the Department publishes a Notice of Proposed Rulemaking in the **Federal Register** before a regulation is promulgated. The public is invited to submit comments on the proposed rule. In addition, a public hearing will be held for this proposed rule. After the public comment period has expired, the comments received and the Department's responses to the comments will be addressed in the preamble to the final regulation. The Department will publish the final rule in the **Federal Register**.

In the following sections, background information on different categories of vaccines as well as the Secretary's rationale for any proposed Table change is provided. It should also be noted that the proposed QAIs are designed to define the conditions covered on the Table and to rule out other conditions that are not covered on the Table (and for which there has been no finding of a causal relation to the vaccines). In addition, the QAIs make clear that if certain other circumstances exist that do not, in the Secretary's view, warrant a presumption of causation, the Table presumption will not be apply.

I. Vaccines Containing Tetanus Toxoid

Currently there are four tetanus-diptheria (Td) vaccines licensed in the United States, two of which also contain acellular pertussis vaccines (Tdap and DTap); a diphtheria-tetanus (DT) vaccine for children younger than age 7 years; and one tetanus toxoid vaccine (TT). In addition, there are three combination vaccines approved for use in children, including (DTaP–IPV–HepB), (DTaP–IPV–Hib), and (DTaP–IPV). Immunity to tetanus wanes over time, so booster doses are needed. According to the CDC recommended schedule of immunizations for children, an infant and child should receive four doses of DTaP in the first 18 months of life and a booster dose between 4 to 6 years. Tdap is recommended at age 11 to 12 years.

Since 2005, the Advisory Committee on Immunization Practices (ACIP) and the CDC have recommended a Tdap vaccine booster dose for all adolescents aged 11 through 18 years of age and for adults aged 19 through 64 years who have not received a dose. A Td booster is recommended every 10 years thereafter. As part of wound management care to prevent tetanus, a tetanus toxoid-containing vaccine is recommended for wound management in anyone who has not received a tetanus-containing vaccine for 5 years or more. The CDC recommends that one dose of Tdap be administered to pregnant women during each pregnancy regardless of the interval since the prior Td or Tdap vaccination.

A. Shoulder Injury Related to Vaccination

Shoulder Injury Related to Vaccine Administration (SIRVA) is an adverse event following vaccination thought to be related to the technique of intramuscular percutaneous injection (the procedure where access to a muscle is obtained by using a needle to puncture the skin) into an arm resulting in trauma from the needle and/or the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder. As the proposed definition indicates, SIRVA is an injury related to the intramuscular injection of a vaccine. Consequently, by definition, a Table injury of SIRVA will not result for those vaccines that are not administered by intramuscular injection, including oral polio and rotavirus; subcutaneous MMR, MMRV, varicella, and meningococcal-polysaccharide; intranasal influenza; and intradermal influenza. In addition, a Table injury of SIRVA will not result for those vaccines that are administered via a needleless jet device. Jet injectors are needleless systems for vaccine or medication administration that utilize a high-pressure jet of liquid to penetrate the skin. During administration, the needleless syringe is placed against the injection site and as the medication or vaccine passes through the injector under high pressure it forms a jet of fluid that penetrates the skin. These devices do not penetrate the skin to a degree that would result in SIRVA. Current information regarding routes of administration for various vaccine formulations is available on the Centers for Disease Control and Prevention's Web site: *http://www.cdc.gov/vaccines/recs/vac-admin/default.htm?s_cid=.*

Clinical signs of shoulder pain and restricted motion in the affected shoulder appear shortly after vaccination. Medical review of VICP claims shows more than 30 cases of severe, persistent shoulder pain beginning shortly after vaccination and resulting in prolonged restriction of function. Often these cases were diagnosed as deltoid bursitis. [Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, Shoulder injury related to vaccine administration (SIRVA), *Vaccine* 28(51):8049–8052.]

The IOM reviewed the scientific and medical literature finding evidence that convincingly supports a causal relationship between vaccine injection (with a needle) into an arm and deltoid bursitis. The report noted that the published VICP case series (Atanasoff et al.), as described, were clinically consistent with deltoid bursitis. The VICP case series found that 93 percent of patients had the onset of shoulder pain within 24 hours of vaccine administration and 54 percent had immediate pain following vaccine injection. The VICP case series found several diagnoses, beyond deltoid bursitis, that resulted in shoulder pain following vaccination, including tendonitis, impingement syndrome, frozen shoulder syndrome, and adhesive capsulitis. Another case series reported two cases of shoulder pain, weakness and reduced range of motion following vaccination with onset of symptoms within 48 hours of vaccination. [Bodor M, Montalvo E, Vaccination related shoulder dysfunction, Vaccine 25(2007) 585–587.]

In order to capture the broader array of potential injuries, the Secretary proposes to add SIRVA for all tetanus toxoid-containing vaccines that are administered intramuscularly through percutaneous injection into the upper arm. The interval of onset will be less than or equal to 48 hours.

While the Secretary proposes adding SIRVA to the Table for the MMR and Varicella vaccines, to meet the proposed QAI for SIRVA, the vaccine must be one intended for intramuscular administration in the upper arm. The Secretary acknowledges that currently there are no MMR or Varicella vaccines that are administered by intramuscular injection. However, the Secretary proposes that the Table include SIRVA as an injury for those vaccines, recognizing that, presently, the absence of an intramuscular formulation of the vaccines will prevent petitioners from meeting the Table QAI for SIRVA with respect to those vaccines. The advantage of such proposal is that the Table would not require modification should an intramuscular formulation of those vaccines develop. The disadvantage of this proposal could be confusion about whether a Table injury for SIRVA may be satisfied for those vaccines, despite the QAI's requirement that the associated vaccine be intended for intramuscular administration. Accordingly, the Secretary specifically seeks the public's views on her proposal to include SIRVA as a Table injury for the MMR and varicella vaccines notwithstanding the fact that there currently is not an intramuscular formulation. Consequently, by definition, a Table injury of SIRVA will not result for those vaccines that are not administered by intramuscular injection, including oral polio and rotavirus; subcutaneous MMR, MMRV, varicella, and meningococcal-polysaccharide; intranasal influenza; and intradermal influenza.

B. Vasovagal Syncope

Vasovagal syncope is the loss of consciousness (fainting) caused by a transient decrease in blood flow to the brain. Vasovagal syncope is usually a benign condition but may result in falling and injury. Vaccination is known to be one cause of vasovagal syncope. Both serious and non-serious injuries can occur as a result of syncope. The types of serious injuries that may occur following a syncopal episode include, but are not limited to, skin lacerations, bone fractures, dental injuries, traumatic brain injuries, and death. Other injuries include traumatic injuries sustained from automobile accidents that occurred due to a vaccinee experiencing syncope while driving within a short time period after vaccine receipt.

The IOM reviewed the literature concerning a possible link between the injection of a vaccine and syncope. Although the Committee found the epidemiologic evidence was insufficient or absent to assess an association

between the injection of a vaccine (with a needle) and syncope, the Committee concluded the mechanistic evidence was strong based on 35 cases presenting definitive clinical evidence. In addition, the HHS's Division of Injury Compensation Programs (DICP) has identified eight cases from its database alleging syncope as a vaccine injury (unpublished data). All had six months of residual symptoms as a result of syncope. In all eight cases, DICP found that syncope was directly related to vaccine administration.

The IOM concluded that the evidence convincingly supports a causal relationship between the injection of a vaccine (with a needle) and syncope. It did not limit this conclusion to a particular vaccine and explained that the evidence from one case report it examined as part of the mechanistic evidence it reviewed suggested "that the injection, and not the contents of the vaccine, contributed to the development of syncope."

In order to be eligible for compensation, the Act requires that the residual effects of the alleged vaccine injury must have continued for a period of at least 6 months (unless the injury results in in-patient hospitalization and surgery, or death). The Secretary recognizes that in many instances cases involving syncope will not meet the statutory severity criteria, as the reaction can be short-lived and treated effectively. However, there is a known risk of serious residual injury or of death from syncope.

Although syncope typically has no long term consequences, the Program has found that not infrequently, syncope is associated with residual effects lasting more than 6 months. Therefore, the Secretary proposes to add vasovagal syncope to the Table for all tetanus toxoid containing vaccines that are administered through percutaneous injection to permit an award of compensation in serious cases meeting the severity criteria. The proposed time interval of onset is less than or equal to 1 hour following vaccination. Syncope is an injury related to the injection of a vaccine. Consequently, the Secretary does not propose adding syncope as a Table injury for those vaccines that are not administered by injection, including oral polio and rotavirus vaccine. With respect to other vaccines, such as the intranasal influenza vaccine, while syncope is proposed as an injury for the general category of vaccines (*i.e.*, seasonal influenza vaccines), the specific formulation will not result in a Table injury of syncope by definition because it is not administered by injection. 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; however, it may be plausible for syncope to occur with this route of administration. Therefore, the Secretary seeks the public's views as to whether the Secretary should include syncope as a Table injury for those vaccines that are administered via a needleless jet device. The Secretary also seeks the public's views as to whether syncope should be a Table injury for other categories of vaccines (*e.g.*, rotavirus) notwithstanding the fact that there currently is not a formulation that is administered by injection in order to encompass future formulations that may be administered by injection.

II. Vaccines Containing Extracted or Partial Cell Pertussis Bacteria, or Specific Pertussis Antigen(s)

Diphtheria, tetanus, and whole cell pertussis (DTwP) vaccines were used for much of the 20th century to control pertussis (whooping cough) disease. Concerns about the safety of DTwP (also referred to as DTP) vaccine prompted development of vaccines with an acellular pertussis component. With data showing fewer local, systemic, and more serious adverse events after acellular (DTaP) vaccine when compared to whole cell DTwP vaccine, the FDA licensed diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccines in 1991 for use in children aged 15 months to 6 years, and in 1996 for use in infants and children aged 6 weeks to 6 years. By 2000, DTaP had replaced DTwP and, like the whole cell pertussis vaccine, was subsequently licensed in combination with other vaccines for routine use in children. Further, in 2005, FDA licensed tetanus and diphtheria toxoid (Td) and, acellular pertussis (Tdap) vaccine, for use in persons 10 years of age and older, as this vaccine is thought to decrease the number of pertussis carriers in the population, which would lead to a decrease in the number of pertussis outbreaks.

The Secretary notes that there are significant differences between whole cell and acellular pertussis vaccines. Although both vaccine types were developed for the same purpose (*i.e.*, immunization against pertussis), they have significantly different compositions, and different effects on biological systems (*e.g.*, the immune and nervous systems). DTwP is distinct from DTaP because the former contains many bacterial proteins, including endotoxins (some of which are known neurotoxins) and the latter does not. These neurotoxins are thought to possibly act synergistically to cause adverse neurologic events in susceptible DTwP vaccine recipients. To date, no adequate study has been published that demonstrates a causal relationship between acellular pertussis vaccines and encephalopathy/encephalitis. Furthermore, 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. [Pertussis vaccination: use of acellular pertussis vaccines among infants and young children recommendations of the advisory committee on immunization practices (ACIP), MMWR, 1997; 46(RR–7):1–25.] [Le Saux N, et al. Health Canada Immunization Monitoring Program–Active (IMPACT)] [Decrease in hospital admissions for febrile seizures and reports of hypotonic-hyporesponsive episodes presenting to hospital emergency departments since switching to acellular pertussis vaccine in Canada: A report from IMPACT. Pediatrics. 2003; 112(5):e348.] Pertussis antigen-containing vaccines were included in the original statutory Table.

A. Encephalopathy/Encephalitis

The initial Table and QAI set forth in the 1986 statute reflected Congress' initial legislative determinations on vaccine-related injuries for DTwP vaccine. Further, modifications to the Table and QAI promulgated by the Secretary in 1995 were based on the scientific findings related to DTwP vaccine, the key study being the British National Childhood Encephalopathy Study (NCES), which found some evidence of acute neurologic illness (encephalopathy) 1 to 7 days after vaccination with the whole cell pertussis vaccine. Similarly, a 10 year NCES follow-up found evidence of chronic nervous system effects. However, the evidence from this follow-up study remained insufficient to indicate the presence or absence of a causal relation between DTP and chronic nervous system dysfunction. On the other hand, a more recent epidemiologic study of whole cell pertussis-containing vaccines did not show a relationship with encephalopathy or encephalitis (Ray et al). The IOM conclusions in 1991 and 1994 were mixed regarding the statistically significant findings of encephalopathy in both the original NCES and its 10 year follow-up. [IOM, Adverse Effects of Pertussis and Rubella Vaccines, 1991. IOM, Adverse Events Associated with Childhood Vaccines, 1994.] In the end, the Secretary, with

unanimous support of the ACCV, retained encephalopathy on the Table, but clarified the definition of encephalopathy in the QAI to make it more clinically precise. [Miller D, Wadsworth J, Ross E, Severe neurological illness: Further analysis of the British National Childhood Encephalopathy Study. Tokai J Exp Clin Med. 1988; 13(suppl):145–155; Miller D, Madge N, Diamond J, Wadsworth J, and Ross E, Pertussis Immunization and Serious Acute Neurological Illnesses in Children, BMJ, 1993;307:1171–6; Ray P, Hayward J, Michelson D, Lewis E, Schwalbe J, Black S, Shinefield H, Marcy M, Huff K, Ward J, Mullooly J, Chen R, Davis R, and the Vaccine Safety Datalink Group, Encephalopathy After Whole-Cell Pertussis or Measles Vaccination: Lack of Evidence for a Causal Association in a Retrospective Case-Control Study. Ped Infec Dis J. 2006; 25(9):768–773.]

Acellular pertussis-containing vaccines were developed because of concerns about events due to whole cell pertussis. Toxicologists argue that components in these two types of pertussis vaccines differ greatly and should be treated as separate entities. Animal models have demonstrated that whole cell pertussis constituents have different effects than those with acellular pertussis. In one study, only whole cell pertussis vaccines caused seizure activity in mice. Levels of inflammatory markers were elevated in the whole cell pertussis group but not the acellular pertussis group. In another study, mice that received whole cell pertussis intravenously succumbed while those that received acellular pertussis did not. [Sato Y, Sato H, Comparison of Toxicities of Acellular Pertussis Vaccine with Whole Cell Pertussis Vaccine in Experimental Animals, *Dev Biol Stand*, 1991; 73:251–62; Donnelly S, Loscher CE, Lynch MA, Mills KH, Whole-cell but not Acellular Pertussis Vaccines Induce Convulsive Activity in Mice: evidence of a role for toxin-induced interleukin-1beta in a new murine model for analysis of neuronal side effects of vaccination. Infect Immun. 2001 July; 69(7):4217–4223.]

The 2012 IOM report on adverse events found that the evidence was inadequate to accept or reject a causal association between acellular pertussis-containing vaccines and encephalopathy and encephalitis. As previously stated, there is no credible evidence of a causal relationship between acellular pertussis vaccines and encephalopathy/encephalitis. Clinical studies have demonstrated a significant reduction in the number of common adverse events with acellular pertussis vaccine, as compared to whole cell pertussis vaccine, such as crying and fevers, and less common ones, such as febrile seizures. Although there have been large-scale surveillance studies conducted on the effects of acellular pertussis vaccines in infants and young children, such as those done in Canada and Australia, the study design used passive surveillance and therefore, the evidence is not as definitive as a controlled, well-designed epidemiologic study using a case control or cohort design [Le Saux N, et al. e348] [Lawrence G., Menzies R., Burgess M., McIntyre P., Wood N., Boyd I., Purcell P., Isaacs D. Surveillance of adverse events following immunization: Australia, 2000–2002. *Commun Dis Intell.* 2003; 27(3):307–23]. With regard to adolescents and adults, the Committee included a study by Yih (2009) which found that the number of encephalitis, encephalopathy or meningitis cases within 42 days of Tdap vaccination were less than a historical Td cohort with a relative risk of 0.84. [Yih W. K., Nordin J.D., Kulldorff M., Lewis E., Lieu T.A., Shi P., and Weintraub E. S., 2009, An assessment of the safety of adolescent and adult tetanus-diphtheria-acellular pertussis (Tdap) vaccine, using active surveillance for adverse events in the vaccine safety datalink, *Vaccine* 27(32):4257–4262]

In view of the limited epidemiological data, and as influenced by the Guiding Principles, the Secretary does not propose to make any changes to the Table, leaving intact the Table injury of encephalopathy/encephalitis for vaccines containing pertussis antigens, with an onset less than 72 hours from vaccination. However, the Secretary proposes to re-organize, clarify, and update the QAI for acute and chronic encephalopathy, and to include a new definition for acute encephalitis based on the Brighton Collaboration criteria and several other references. The Brighton Collaboration is an international voluntary collaboration that develops globally accepted and standardized case definitions of adverse events following immunizations. More information can be found at: *https://brightoncollaboration.org/public.*

B. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA for pertussis antigen-containing vaccines. [See I.A.] The interval of onset will be less than or equal to 48 hours.

C. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for pertussis antigen-containing vaccines. [See I.B.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

III. Vaccines Containing Measles, Mumps, and Rubella Vaccine or Any of Its Components

Since the 1960s, measles, mumps, and rubella (MMR), a live, attenuated virus vaccine, has been routinely administered to children in the U.S. In 2005, the tetravalent measles, mumps, rubella, and varicella (MMRV) vaccine was added to the immunization schedule. MMR vaccine was included in the original statutory Table.

A. Vaccine Strain Measles Viral Disease Including Measles Inclusion Body Encephalitis (MIBE)

Severe complications associated with the measles virus or a mutated form of the virus, such as measles inclusion body encephalitis (MIBE), can be broadly categorized as measles viral diseases. The Table currently lists "vaccine-strain measles viral infection in an immunodeficient recipient" as a Table injury for vaccines containing measles virus, with an onset of 6 months. This condition is defined in the QAI as "a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests."

MIBE is a rare, slow encephalitis caused by chronic with the measles virus, and is thus a subset of the condition already listed on the Table. MIBE is confined to immunodeficient individuals and is frequently fatal. MIBE occurs primarily in children and young adults, and typically occurs within 1 year of the initial infection or vaccination. A gradual decline in intellectual abilities and behavioral alterations are followed by progressive myoclonus; muscle spasticity; seizures; dementia; autonomic dysfunction; and ataxia. Death usually occurs 1 to 3 years after disease onset. Pathologic features include perivascular cuffing, eosinophilic cytoplasmic inclusions, neurophagia, and fibrous gliosis.

The IOM concluded that the evidence convincingly supports a causal relationship between MMR vaccine and MIBE in individuals with demonstrated immunodeficiencies. Out of the five case reports the IOM found, two had wild-type measles infection and these did not contribute to the weight of evidence. Only one out of the three

contributing case reports had vaccine-strain measles virus isolated. Because of limitations due to testing and viral properties, in most cases it is difficult to characterize wild-type versus vaccine-strain measles. [Bitnun A., Shannon P., Durward A., Rota P.A., Bellini W.J., Graham C., Wang E., Ford-Jones E.L., Cox P., Becker L., Fearon M., Petric M., and Tellier R.,. 1999. Measles inclusion-body encephalitis caused by the vaccine strain of measles virus. *Clinical Infectious Diseases* 29(4):855–861.] The current Table lists "Vaccine-strain measles viral infection in an immunodeficient recipient" for measles virus-containing vaccines with a time interval of onset of 6 months. Case reports of MIBE cited by the IOM showed a time interval of onset that varied from 8 days to 11 months.

For the reasons discussed above and in keeping with the spirit of the Guiding Principles, the Secretary proposes to change the injury of "vaccine-strain measles viral infection in an immunodeficient recipient" to "vaccine-strain measles viral disease in an immunodeficient recipient." Because MIBE is a type of measles virus-associated disease occurring in immunodeficient individuals, the Secretary proposes a new time interval of onset of up to 12 months from the date of vaccination for those cases in which the typing of vaccine strain was not performed, because most cases of vaccine-strain disease occur within 1 year of vaccination. There is no time interval for onset proposed if the vaccine strain of the virus is identified, as it can be concluded that the vaccine was a contributing cause of the injury. Cases in which wild-type measles strain is isolated will be excluded. Revisions to the Table will distinguish between cases in which the measles vaccine strain is identified versus those cases in which laboratory testing was not done or the results were inconclusive. In addition, the Secretary proposes adding diagnostic criteria to the QAI.

B. Encephalopathy and Encephalitis

The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between MMR vaccine and encephalopathy or encephalitis. Not only is there limited epidemiologic evidence on a possible causal association, the mechanistic evidence is weak, based on current knowledge about natural infection and few case reports. Natural (wild-type) infection (measles, mumps, and/or rubella virus) is thought to cause neurologic illness through damage to the neurons by direct viral invasion. This is thought to be either from direct viral infection and/or viral reactivation (particularly in immunocompromised patients). These same mechanisms may be responsible for vaccine-associated encephalopathy/encephalitis, but evidence linking these mechanisms directly to MMR vaccine strains (detection of viral antigens or antibodies) has not been shown. [Makela A., J. P. Nuorti, and H. Peltola. 2002. Neurologic disorders after measles-mumps-rubella vaccination. *Pediatrics* 110(5):957–963.] [Ray, P., J. Hayward, D. Michelson, E. Lewis, J. Schwalbe, S. Black, H. Shinefield, M. Marcy, K. Huff, J. Ward, J. Mullooly, R. Chen, and R. Davis. 2006. Encephalopathy after whole-cell pertussis or measles vaccination: Lack of evidence for a causal association in a retrospective case-control study. *Pediatric Infectious Disease Journal* 25(9):768–773.]

In view of the limited mechanistic data, and as influenced by the Guiding Principles, the Secretary does not propose to make any changes to the Table, leaving intact the Table injury of encephalopathy/encephalitis for MMR vaccines, with an onset not less than 5 days and no more than 15 days from vaccination. However, the Secretary proposes to re-organize, clarify, and update the QAI for acute and chronic encephalopathy and include a new definition for acute encephalitis based on the Brighton Collaboration criteria and several other references. [Ford-Jones L., MacGregor D., Richardson S., et al. Acute childhood encephalitis and meningoencephalitis: Diagnosis and management. Paediatr Child Health (1988). Jan–Feb;3(1):33–40] [Ball R., Halsey N., Braun M., et al. Development of case definitions for acute encephalopathy, encephalitis, and multiple sclerosis reports to the Vaccine Adverse Event Reporting System. Journal of Clinical Epidemiology (2002). 55:819–824.]

C. Febrile Seizures

Febrile seizures are a common cause of convulsions in young children. Generally viewed as benign and not indicative of brain disease, they occur in two to four percent of children up to age 5 years. Febrile seizures are often seen as the body temperature increases rapidly; but, may develop as the fever is declining. Most events last a minute or two, although some can be as brief as a few seconds. A family history of febrile seizures increases the child's risk of occurrence. Anything that causes fever, such as viral or bacterial infections, can bring on a febrile seizure.

The IOM Committee concluded that the evidence convincingly supports a causal relationship between MMR vaccine and febrile seizures. Based on seven epidemiologic studies, the Committee had a high degree of confidence that there is an increased risk of febrile seizures after receipt of MMR vaccine. The Committee assessed the mechanistic evidence regarding an association between MMR vaccine and febrile seizures as intermediate based on 12 cases presenting clinical evidence. [Farrington, P., S. Pugh, A. Colville, A. Flower, J. Nash, P. Morgan-Capner, M. Rush, and E. Miller. 1995. A new method for active surveillance of adverse events from diphtheria/tetanus/pertussis and measles/mumps/rubella vaccines. *Lancet* 345(8949):567–569.] [Miller, E., N. Andrews, J. Stowe, A. Grant, P. Waight, and B. Taylor. 2007. Risks of convulsion and aseptic meningitis following measles-mumps-rubella vaccination in the United Kingdom. *American Journal of Epidemiology* 165(6):704–709.] [Barlow, W. E., R. L. Davis, J. W. Glasser, P. H. Rhodes, R. S. Thompson, J. P. Mullooly, S. B. Black, H. R. Shinefield, J. I. Ward, S. M. Marcy, F. DeStefano, and R. T. Chen. 2001. The risk of seizures after receipt of whole-cell pertussis or measles, mumps, and rubella vaccine. *New England Journal of Medicine* 345(9):656–661.]

Patients who had post-MMR vaccination febrile seizures had no higher risk of subsequent seizure or neurodevelopmental disability than other children with febrile seizures in the absence of vaccine administration. The long-term rate of epilepsy was not increased in children who had febrile seizures following MMR vaccination compared with children who had febrile seizures of a different etiology [Vestergaard, M., A. Hviid, K. M. Madsen, J. Wohlfahrt, P. Thorsen, D. Schendel, M. Melbye, and J. Olsen. 2004. MMR vaccination and febrile seizures: Evaluation of susceptible subgroups and long-term prognosis. *Journal of the American Medical Association* 292(3):351–357.] [Barlow, W. E., R. L. Davis, J. W. Glasser, P. H. Rhodes, R. S. Thompson, J. P. Mullooly, S. B. Black, H. R. Shinefield, J. I. Ward, S. M. Marcy, F. DeStefano, and R. T. Chen. 2001. The risk of seizures after receipt of whole-cell pertussis or measles, mumps, and rubella vaccine. *New England Journal of Medicine* 345(9):656–661.]

Although febrile seizures can be alarming to parents and other family members, the overwhelming majority of children who have febrile seizures recover quickly and have no lasting effects. Only very rarely can febrile seizures lead to serious injury or disability.

The National Childhood Vaccine Injury Act of 1986 requires the effects of the alleged vaccine injury must have continued for at least 6 months (unless the injury results in in-patient hospitalization *and* surgery, or death). Because the current medical literature supports febrile seizures only very rarely have long term consequences this condition is not being proposed for inclusion on the Table. However, the Program will consider causation-in-fact claims for febrile seizures leading to serious injury or death on a case-by-case basis.

D. Transient Arthralgia in Women and Children

Arthralgia means joint pain without signs of inflammation (*e.g.* erythema, warmth, pallor, edema, or decreased range of movement). Arthritis is arthralgia with signs of inflammation. Arthropathy encompasses arthralgia or arthritis and refers to any joint disease. Unlike arthritis, arthralgia is a symptom and there may be no objective measures for confirmation. The IOM concluded that the evidence favors acceptance of a causal relationship between MMR vaccine (attributable to the rubella component) and transient arthralgia in women and children. The IOM had a moderate degree of confidence in the epidemiologic evidence for women (based on four studies) that consistently reported an increased risk of transient arthralgia after MMR vaccination. Similarly, the mechanistic evidence regarding an association between rubella vaccine and transient arthralgia in women was intermediate based on 13 case reports. Two-thirds of the studies involved post-partum women. [Slater, P. E., T. Ben-Zvi, A. Fogel, M. Ehrenfeld, and S. Ever-Hadani. 1995. Absence of an association between rubella vaccination and arthritis in underimmune postpartum women. *Vaccine* 13(16):1529–1532.] [Ray, P., S. Black, H. Shinefield, A. Dillon, J. Schwalbe, S. Holmes, S. Hadler, R. Chen, S. Cochi, and S. Wassilak. 1997. Risk of chronic arthropathy among women after rubella vaccination. *Journal of the American Medical Association* 278(7):551–556] [Tingle, A. J., L. A. Mitchell, M. Grace, P. Middleton, R. Mathias, L. MacWilliam, and A. Chalmers. 1997. Randomised double-blind placebo-controlled study on adverse effects of rubella immunisation in seronegative women. *Lancet* 349(9061):1277–1281.] [Mitchell, L. A., A. J. Tingle, L. MacWilliam, C. Home, P. Keown, L. K. Gaur, and G. T. Nepom. 1998. HLA–DR class II associations with rubella vaccine-induced joint manifestations. *Journal of Infectious Diseases* 177(1):5–12.]

There were seven epidemiologic studies of children that consistently reported an increased risk of arthralgia after MMR vaccination. The IOM had a moderate degree of confidence in the epidemiologic evidence based on the seven studies with sufficient validity and precision to assess an association between MMR vaccine and transient arthralgia in children. The mechanistic evidence was weak based on knowledge about natural rubella infection. [Peltola, H., and O. P. Heinonen. 1986. Frequency of true adverse reactions to measles-mumps-rubella vaccine. *Lancet* 327(8487):939–942.] [Virtanen, M., H. Peltola, M. Paunio, and O. P. Heinonen. 2000. Day-to-day reactogenicity and the healthy vaccinee effect of measles-mumps-rubella vaccination. *Pediatrics* 106(5):E62.] [Benjamin, C. M., G. C. Chew, and A. J. Silman. 1992. Joint and limb symptoms in children after immunization with measles, mumps, and rubella vaccine. *BMJ* 304(6834):1075–1078.] [Davis, R. L., E. Marcuse, S. Black, H. Shinefield, et al. 1997. MMR2 immunization at 4 to 5 years and 10 to 12 years of age: A comparison of adverse clinical events after immunization in the vaccine safety datalink project. *Pediatrics* 100(5):767–771] [dos Santos, B. A., T. S. Ranieri, M. Bercini, M. T. Schermann, S. Famer, R. Mohrdieck, T. Maraskin, and M. B. Wagner. 2002. An evaluation of the adverse reaction potential of three measles-mumps-rubella combination vaccines. *Revista Panamericana de Salud Publica/Pan American Journal of Public Health* 12(4):240–246.] [LeBaron, C. W., D. Bi, B. J. Sullivan, C. Beck, and P. Gargiullo. 2006. Evaluation of potentially common adverse events associated with the first and second doses of measles-mumps-rubella vaccine. *Pediatrics* 118(4):1422–143] [Heijstek, M. W., G. C. S. Pileggi, E. Zonneveld-Huijssoon, et al. 2007. Safety of measles, mumps and rubella vaccination in juvenile idiopathic arthritis. *Annals of the Rheumatic Diseases* 66(10):1384–1387.]

Because transient arthralgia is a subjective symptom that frequently lacks objective evidence for confirmation and has no long-term effects or consequences, this condition is not being proposed for inclusion on the Table.

E. Chronic Arthropathy in Women and Children and Arthropathy in Men

The IOM concluded that the evidence was inadequate to accept or reject a causal relationship between MMR vaccine and chronic arthropathy in women and children, as well as arthropathy in men. The committee had limited confidence in the epidemiologic evidence for rubella vaccine and chronic arthralgia or arthritis. The epidemiologic evidence was insufficient or absent to assess an association between measles or mumps vaccine and chronic arthralgia or chronic arthritis in women. The IOM assessed the mechanistic evidence regarding rubella vaccine and chronic arthralgia or chronic arthritis in women as low-intermediate; and as lacking between measles or mumps vaccine and chronic arthralgia or chronic arthritis in women. In children, the IOM found the epidemiologic evidence to be insufficient or absent for the association between MMR and chronic arthropathy. The IOM found the mechanistic evidence between rubella vaccine and chronic arthropathy to be weak and they found the evidence to be lacking for measles and mumps vaccines. The IOM had limited confidence in the epidemiologic evidence for an association between MMR vaccine and arthropathy in men. The IOM found the mechanistic evidence regarding the association between rubella vaccine and arthropathy in men to be weak. The IOM found the mechanistic evidence between measles or mumps vaccine and arthropathy in men as lacking. [Ray, P., S. Black, H. Shinefield, A. Dillon, J. Schwalbe, S. Holmes, S. Hadler, R. Chen, S. Cochi, and S. Wassilak. 1997. Risk of chronic arthropathy among women after rubella vaccination. *Journal of the American Medical Association* 278(7):551–556.] [Tingle, A. J., L. A. Mitchell, M. Grace, P. Middleton, R. Mathias, L. MacWilliam, and A. Chalmers. 1997. Randomised double-blind placebo-controlled study on adverse effects of rubella immunization in seronegative women. *Lancet* 349(9061):1277–1281.] Peters, M. E., and S. Horowitz. 1984. Bone changes after rubella vaccination. *American Journal of Roentgenology* 143(1):27–28. Geiger, R., F. M. Fink, B. Solder, M. Sailer, and G. Enders. 1995. Persistent rubella infection after erroneous vaccination in an immunocompromised patient with acute lymphoblastic-leukemia in remission. *Journal of Medical Virology* 47(4):442–444.]

In spite of the limited epidemiological and mechanistic data, based on the Guiding Principles, the Secretary does not propose to make any changes to the Table, leaving intact the Table injury of chronic arthritis for MMR vaccines, with an onset not less than 7 days and no more than 42 days from vaccination. However, the Secretary proposes to

provide a definition for chronic arthritis in the QAI, based on the Brighton Collaboration criteria and several other references.

F. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA to the Table for vaccines containing measles, mumps and/or rubella virus. [See section I.A above.] The interval of onset will be less than or equal to 48 hours. However, the Secretary recognizes that there currently is no intramuscular formulation of this vaccine available and therefore, petitioners alleging an injury of SIRVA associated with this vaccine presently cannot meet the QAI for SIRVA. Please see section I.A., above, for additional discussion on this point.

G. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for vaccines containing measles, mumps and/or rubella virus. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

IV. Vaccines Containing Polio Inactivated Virus

Since 2000, inactivated polio vaccine (IPV) has been the only polio vaccine used in the United States, although live virus oral polio vaccine (OPV) is still used in many parts of the world. The Secretary proposes changes to the Table related only to IPV, as an injected vaccine. OPV was included in the original statutory Table and remains on the regulatory Table.

A. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for vaccines containing polio inactivated virus. [See Section I.A above.] The interval of onset will be less than or equal to 48 hours.

B. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for vaccines containing polio inactivated virus. [See Section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

V. Hepatitis B Vaccines

The recombinant hepatitis B vaccine was first licensed by the FDA in 1986. Produced from cultured and purified yeast cells, it is the current form of vaccine used in the United States. Prior to 1991, the vaccine was recommended only for high risk individuals. However, the recommendation was extended to include all infants, since infected infants and children are at higher risk for developing chronic liver disease with subsequent liver cancer, and approximately one-third of those who acquire hepatitis B infection do not have any identified risk factors, and, therefore, were frequently not immunized. The effective date of coverage for hepatitis B vaccine is August 6, 1997.

A. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for hepatitis B vaccines. [See section I.A above.] The interval of onset will be less than or equal to 48 hours.

B. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for hepatitis B vaccines. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

VI. Haemophilus Influenzae Type B Vaccines

Haemophilus influenzae type b (Hib) conjugate vaccines were first licensed by the FDA in 1987 and have been recommended by the CDC for routine use since 1991. The vaccine is given to infants and children up to the age of school entry. The effective date of coverage for Hib vaccines is August 6, 1997, with no injuries or conditions specified.

In order for a category of vaccines to be covered under the VICP, the category of vaccine must be recommended for routine administration to children by the Centers for Disease Control and Prevention (for example, vaccines that protect against seasonal influenza), subject to an excise tax by Federal law, and added to the Program by the Secretary of Health and Human Services. The Internal Revenue Code defines a "taxable vaccine" as including "[a]ny HIB vaccine". *See* 26 U.S.C. 4132(a)(1)(H). Thus, the Secretary proposes to modify category IX on the Table from "Haemophilus influenzae type b polysaccharide conjugate vaccines" to "Haemophilus influenza type b vaccines," as a technical change in order to be most inclusive.

A. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for Hib vaccines. [See section I.A above.] The interval of onset will be less than or equal to 48 hours.

B. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for Hib vaccines. [See I.B.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

VII. Varicella Vaccines

The varicella (chickenpox) virus vaccine, which was first licensed by the Food and Drug Administration in 1995, contains a live, attenuated strain of the varicella virus. Chickenpox is a highly contagious disease and although usually mild, infants, adolescents, adults, pregnant women, and immunocompromised individuals are at higher risk for serious complications. Since the introduction of the vaccine there has been a significant decrease in the number of cases of the disease with the greatest effect in states with the highest vaccination coverage. Varicella vaccine is listed on the Table, effective August 6, 1997, with no injuries or conditions specified.

A. Disseminated Vaccine-Strain Viral Disease

Disseminated varicella vaccine-strain viral disease is a condition in which the affected individual develops the varicella rash caused by the vaccine strain that spreads beyond the dermatome (an area of skin supplied by the nerve fibers of a single spinal root) involved in the vaccination and/or there is involvement of other organs such as the brain, lungs, and liver. For organs other than the skin, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. In this section, the word "disseminated" is defined by the IOM as the spreading of the rash (or the virus) beyond the dermatome involved in the vaccination.

The IOM reviewed the evidence for vaccine causation of disseminated varicella disease with and without involvement of organs beyond the skin. They found three case reports in which vaccinated individuals developed lesions confined to the skin after immunization, and in whose lesions the vaccine strain of the varicella virus was identified. In addition, the IOM identified 550 cases reported to passive surveillance systems in which an attempt was made to identify the virus from skin lesions in individuals who developed disseminated varicella disease after vaccination without involvement of another organ. The wild-type virus was identified in 210 cases; the vaccine-strain virus was identified in 125 cases; and in the remaining cases either the sample was inadequate, the virus could not be identified, or there

was no virus present. The committee also identified nine cases in which the vaccine strain of the virus was identified in individuals who had meningitis, pneumonia or hepatitis in addition to skin lesions. Cases of disseminated disease, which were reviewed by the IOM in individuals who were thought to be immunocompetent, all occurred within 42 days of immunization. The time of onset was not further specified. In many cases the timeframe from vaccination to onset of disseminated illness, without other organ involvement, was not provided for immunocompromised individuals, but in the cases for which there was data, there was a broad range of onset, spanning from 1 week in one case to "up to 87 days" in another. For four cases, in which onset was reported, the interval following vaccination was 18 days to 6 weeks. For disseminated disease with other organ involvement, onset was 13 days after vaccination in the only immunocompetent patient for whom data was available, and onset was between 10 and 35 days in eight immunocompromised individuals. [Wise, R. P., M. E. Salive, M. M. Braun, G. T. Mootrey, J. F. Seward, L. G. Rider, and P. R. Krause. 2000. Postlicensure safety surveillance for varicella vaccine. *Journal of the American Medical Association* 284(10):1271–1279.] [Goulleret, N., E. Mauvisseau, M. Essevaz-Roulet, M. Quinlivan, and J. Breuer. 2010. Safety profile of live varicella virus vaccine (Oka/Merck): Five-year results of the European varicella zoster virus identification program (EU VZVIP). *Vaccine* 28 (36):5878–5882.]

The IOM found the evidence convincingly supports a causal relationship between varicella vaccine and disseminated varicella disease, both for cases confined to the skin and for cases where the spread involves other organs. However, the IOM limited their finding of causation in cases in which organs beyond the skin were involved to those with demonstrated immunodeficiencies. The Secretary notes that there is a significant overlap in the time-frames involved in the onset of disseminated disease in both immunocompetent and immunocompromised individuals. The Secretary further notes that although the IOM found convincing support for disseminated disease with other organ involvement only in immunocompromised individuals, the Secretary proposes, in accordance with the ACCV Guiding Principles, that the Table injury apply to all individuals, regardless of the status of their immune system, because it is possible that an individual so affected may not have been completely evaluated for an existing immunodeficiency, or suffered from an immunodeficiency that is subtle and beyond our current ability to test.

The Secretary proposes to add disseminated vaccine-strain infection, both with and without other organ involvement, as a Table injury for varicella-containing vaccines. There is no time interval for onset if the vaccine strain of the virus is identified. However, if testing is not done or does not identify the virus, it is proposed that the injury qualify as a Table injury if the onset is 7 to 42 days following vaccination. If the wild-type virus or another non-vaccine-strain virus is identified, there will be no presumption of causation and it will not meet the Table criteria. 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.

B. Varicella Vaccine-Strain Viral Reactivation

Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster (shingles) with or without concurrent disease in another organ. Shingles is a painful, blistering skin rash due to the reactivation of varicella (chickenpox) virus that involves one or more sensory dermatomes. After natural varicella infection, the virus lies dormant in the spinal dorsal root ganglia. Shingles occurs after the virus becomes active again.

There is a significant body of literature showing that the vaccine-strain of the virus can cause shingles without other organ involvement. However, the wild-type chickenpox virus has been identified in many of the cases occurring after vaccination. The Committee reviewed 111 cases in which individuals who received a varicella-containing vaccine developed reactivated varicella disease without other organ involvement and in whom the vaccine-strain of the virus was identified. The IOM found six cases in which individuals who had received varicella vaccine developed reactivated disease in another organ, and in all the cases, the vaccine-strain of the virus was identified in the other organ. In four of those cases, the vaccine-strain of the virus was also identified in the skin. The findings for other organ involvement in these case reports were limited to the meninges and brain. The IOM concluded that the evidence convincingly supports a causal relationship between varicella vaccine and vaccine-strain viral reactivation, with or without involvement of an organ other than the skin. [Chaves, S. S., P. Haber, K. Walton, R. P. Wise, H. S. Izurieta, D. S. Schmid, and J. F. Seward. 2008. Safety of varicella vaccine after licensure in the United States: Experience from reports to the vaccine adverse event reporting system, 1995–2005. *Journal of Infectious Diseases* 197(SUPPL. 2):S170–S177.] [Iyer, S., M. K. Mittal, and R. L. Hodinka. 2009. Herpes zoster and meningitis resulting from reactivation of varicella vaccine virus in an immunocompetent child. *Annals of Emergency Medicine* 53(6):792–795.] [Levin, M. J., R. L. DeBiasi, V. Bostik, and D. S. Schmid. 2008. Herpes zoster with skin lesions and meningitis caused by two different genotypes of the Oka varicella-zoster virus vaccine. *Journal of Infectious Diseases* 198(10):1444–1447.]

The Secretary proposes to add vaccine-strain viral reactivation, both with and without other organ involvement, as a Table injury for varicella-containing vaccines. Although the IOM specified whether they considered immunocompetent or immunocompromised individuals, their causality conclusions for vaccine-strain reactivation, with and without other organ involvement, did not differentiate between these two groups. Because disease caused by varicella virus reactivation can occur many years, or even decades, after the initial disease or vaccination, the Secretary proposes that the QAI require laboratory confirmation of the presence of the vaccine-strain of the virus. With such confirmation, the status of the affected individual's immune system is not relevant. In addition, there is no proposed time interval for this injury, as laboratory confirmation of vaccine-strain virus obviates the need for such a proposal. Since petitioners must demonstrate the presence of vaccine-strain varicella infection, the presumption includes the involvement of skin and other organs.

C. Anaphylaxis

Anaphylaxis is a single discrete event that presents as a severe and potentially life threatening multi-organ reaction, particularly affecting the skin, respiratory tract, cardiovascular system, and the gastrointestinal tract. The diagnosis of anaphylaxis requires the simultaneous involvement of two or more organ systems. In an anaphylactic reaction, an immediate reaction generally occurs within minutes after exposure, and in most cases, the individual develops signs and symptoms within 4 hours after exposure to the antigen. The immediate reaction

leads to a combination of skin rash, mucus membrane swelling, leakage of fluid from the blood into surrounding tissues, tightening of the air passages in the lungs with tissue swelling, and gastrointestinal symptoms that can lead to shock, organ damage, and death if not promptly treated.

Symptoms may include swelling, itching, rash, trouble breathing, chest tightness, and/or dizziness. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema (throat swelling) or bronchospasm and may be associated with cardiovascular collapse.

Other significant clinical signs and symptoms may include the following: cyanosis (bluish coloration in the skin due to low blood oxygen levels), hypotension (low blood pressure), bradycardia (slow heart rate), tachycardia (fast heart rate), arrhythmia (irregular heart rhythm), edema (swelling) of the pharynx and/or larynx (throat or upper airway) with stridor (noisy breathing on inspiration), dyspnea (shortness of breath), diarrhea, vomiting, and abdominal pain. Autopsy findings may include acute emphysema (a type of lung abnormality), which results from lower respiratory tract obstruction, edema (swelling) of the upper airway, and minimal findings of eosinophilia (an excess of a type of white blood cell associated with allergy) in the liver. When death occurs within minutes of exposure without signs of respiratory distress, lack of significant pathologic findings would not exclude a diagnosis of anaphylaxis.

Anaphylaxis may occur following exposure to allergens from a variety of sources including food, aeroallergens, insect venom, drugs, and immunizations. Most treated cases resolve without sequela. Anaphylaxis can be due to an exaggerated acute systemic hypersensitivity reaction, especially involving immunoglobulin E antibodies, as in allergic anaphylaxis, or it could be a non-immunologically mediated reaction leading to similar clinical symptomatology as in non-immune anaphylaxis. Non-immune anaphylaxis cannot be detected by skin tests or in vitro allergy diagnostic procedures. As stated, anaphylaxis is a single discrete event. It is not an initial episode of a chronic condition such as chronic urticaria (hives).

Anaphylaxis following immunization is a rare occurrence with estimates in the range of 1–10 per 1 million doses distributed, depending on the vaccine studied. [The Brighton Collaboration Anaphylaxis Working Group, "Anaphylaxis: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data, Vaccine, Aug. 2007; 5676.] The IOM has reported that the evidence favors acceptance of a causal relationship between certain vaccines and anaphylaxis based on case reports and case series. The IOM has reported that causality could be inferred with reasonable certainty based on one or more case reports because of the unique nature and timing of anaphylaxis following vaccine administration and provided there is an absence of likely alternative causes. [Institute of Medicine (IOM), Immunization Safety Review Vaccination and Sudden Unexpected Death in Infancy, Washington, DC: The National Academies Press, 2003) 55.] The IOM concluded that the scientific evidence convincingly supports a causal relationship between varicella vaccine and anaphylaxis. There are multiple, well-documented reports in the literature that anaphylaxis occurs after receipt of the varicella vaccine. One case series reported 16 cases of anaphylaxis after vaccination against varicella, with nearly all demonstrating anti-gelatin immunoglobulin E (IgE) antibodies. [Sakaguchi, M., T. Nakayama, H. Fujita, M. Toda, and S. Inouye. 2000b. Minimum estimated incidence in Japan of anaphylaxis to live virus vaccines including gelatin. *Vaccine* 19(4–5):431–436.]

There is a long history of including anaphylaxis as a known adverse effect of vaccines, including in the initial Table contained in the Act. The time-frame for the first symptom or manifestation of onset contained in the original statutory Table was shortened from 24 hours to 4 hours in the Table changes promulgated in 1995. Since that time, anaphylaxis has been added as an injury for the Hepatitis B vaccine.

The statute requires that injuries eligible for compensation under the Program be of sufficient seriousness to cause continued effects for more than 6 months, result in death, or result in inpatient hospitalization and surgical intervention. The Secretary continues to recognize that in many instances, cases involving anaphylaxis will not meet the statutory severity criteria, as the reaction can be short-lived and treated effectively. However, because there is a known risk of serious residual injury or death from anaphylaxis, the Secretary continues to recommend that anaphylaxis be included on the Table for other vaccines, and be added for varicella virus vaccines.

The Secretary proposes to add anaphylaxis as a Table injury for varicella virus-containing vaccines, with an onset less than or equal to 4 hours from the administration of the vaccine. In addition, the Secretary proposes to update the definition of anaphylaxis in the QAI. (see proposed regulation text at proposed paragraph (c)(1)).

D. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for varicella virus-containing vaccines. [See section I.A above.] The interval of onset will be less than or equal to 48 hours. However, the Secretary recognizes that there currently is no intramuscular formulation of this vaccine available, and therefore petitioners alleging an injury of SIRVA associated with this vaccine presently cannot meet the QAI for SIRVA. Please see section I.A., above, for additional discussion on this point.

E. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for varicella virus-containing vaccines. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

VIII. Pneumococcal Conjugate Vaccines

Pneumococcal conjugate vaccines were first licensed by FDA in 2000. Over the next decade, the heptavalent (seven serotypes) vaccine dramatically reduced the rate of invasive pneumococcal disease in young infants and nasal carriage of the vaccine serotypes among all age groups, including the immunocompromised and older individuals. A 13-valent pneumococcal conjugate vaccine licensed in 2010 has replaced the 7-valent product in the infant schedule. Pneumococcal conjugate vaccines are included on the Table, with an effective date of coverage of December 19, 1999, with no injuries or conditions specified.

A. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for pneumococcal conjugate vaccines. [See section I.A above.] The interval of onset will be less than or equal to 48 hours.

B. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for pneumococcal conjugate vaccines. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

IX. Hepatitis A Vaccines

Hepatitis A vaccine was first licensed by FDA in 1996 and introduced incrementally, first for children living in

communities with the highest rates of disease and then in 1999 for children living in States/communities with consistently elevated rates of infection. The impact of immunization with hepatitis A vaccine has been a dramatic decline in the rates of disease and a sharp reduction in the groups with the highest risk of infection: Native Americans and Alaskan natives. Rates of hepatitis A infection are now similar in most areas of the United States. As a consequence, hepatitis A vaccine has now been recommended for all children in the United States who are 12–23 months of age. Hepatitis A vaccine is included on the Table, with an effective date of December 1, 2004.

A. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for hepatitis A vaccines. [See section I.A above.] The interval of onset will be less than or equal to 48 hours.

B. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for hepatitis A vaccines. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

X. Seasonal Influenza Vaccines

All seasonal trivalent influenza vaccines have been covered under the VICP since July 1, 2005. At that time, all seasonal influenza vaccines were trivalent. Quadrivalent vaccines for seasonal influenza became available for general use for the 2013–14 influenza season. On June 25, 2013, Public Law 113–15 was enacted, extending the applicable excise tax on trivalent influenza vaccines to also include any other vaccines against seasonal influenza. *See* Public Law 113–15 (amending 26 U.S.C. 4132(a)(1)(N)). The amendment included in Public Law 113–15 ensured that seasonal influenza vaccines are covered under the Program. Seasonal influenza vaccines (other than trivalent influenza vaccines) were added to the Table under the final catch-all category (42 CFR 100.3(c)(8)) with an effective date of November 12, 2013. The Secretary proposes to modify category XIV on the Table from "Trivalent influenza vaccines" to "Seasonal influenza vaccines."

There are currently six types of seasonal influenza vaccines distributed during flu season. The standard dose trivalent inactivated influenza vaccine (IIV3) contains three killed virus strains and is injected. IIV3 is indicated in individuals 6 months of age or older, including healthy people and those with chronic medical conditions (such as asthma, diabetes, or heart disease). High dose trivalent inactivated influenza vaccine (IIV3 High dose) is indicated in individuals who are 65 years of age or older. Trivalent recombinant influenza vaccine (RIV3) is indicated for individuals between the ages of 18 and 49 years. The standard dose quadrivalent inactivated influenza vaccine (IIV4) has the same indications as IIV3. The quadrivalent live attenuated influenza vaccine (LAIV4) is indicated for healthy, non-pregnant persons aged 2–49 years. The cell-culture based inactivated influenza vaccine (ccIIV3) is indicated for individuals who are 18 years of age and older.

The covered injuries proposed for seasonal influenza vaccines are the same as those proposed for trivalent influenza vaccines. The trivalent influenza vaccine and the quadrivalent influenza vaccine, distributed each year during flu season, are types of seasonal influenza vaccines.

A. Anaphylaxis

The Secretary proposes to add anaphylaxis as a Table injury for seasonal influenza vaccines. [See section VII.C above.] The IOM concluded that the scientific evidence convincingly supports a causal relationship between trivalent influenza vaccines and anaphylaxis. Sensitivity to eggs has long been known to cause allergic reactions to influenza vaccination in some individuals. The IOM assessed the mechanistic evidence as strong, including the following: 21 case reports of potential anaphylaxis following influenza vaccine; a strong temporal relationship between vaccine administration and anaphylactic reaction; isolation of anti-gelatin IgE in two cases; positive skin testing as a positive re-challenge in two cases; and repeated symptoms to vaccination against influenza on two occasions. Their conclusion made no distinction between the intranasal live attenuated vaccine and the injected vaccine. [Coop, C.A., S.K. Balanon, K.M. White, B. A. Whisman, and M.M. Rathkopf. 2008. Anaphylaxis from the influenza virus vaccine. *International Archives of Allergy and Immunology* 146(1):85–88.] [Chung, E.Y., L. Huang, and L. Schneider. 2010. Safety of influenza vaccine administration in egg-allergic patients. *Pediatrics* 125(5):e1024–e1030.] [Lasley, M.V. 2007. Anaphylaxis after booster influenza vaccine due to gelatin allergy. *Pediatric Asthma, Allergy and Immunology* 20(3):201–205.]

The Secretary proposes to add anaphylaxis as a Table injury for seasonal influenza vaccines, with an onset of less than or equal to 4 hours from the administration of the vaccine. In addition, the Secretary proposes to update the definition of anaphylaxis in the QAI.

B. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA only for seasonal influenza vaccines that are injected intramuscularly (as detailed in the proposed QAI). As proposed, this injury would not apply to formulations of the live attenuated influenza vaccine (LAIV), as LAIV is not administered intramuscularly with a needle. [See section I.A above.] In addition, this injury would not apply to the formulations of influenza vaccine where the route of administration is intradermal, such as the formulation that delivers 0.1 milliliters of vaccine through a prefilled microinjection system that contains a needle that is only 1.5 millimeters long. This needle is not long enough to enter the deltoid bursa or any other structure in the shoulder related to the development of SIRVA. SIRVA would apply only to formulations of the seasonal influenza vaccine that are administered through intramuscular injection. The interval of onset will be less than or equal to 48 hours.

C. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for injected vaccines only (as detailed in the proposed QAI). As proposed, this injury would apply to the seasonal inactivated influenza vaccine that is injected intramuscularly but not to the LAIV, as LAIV is not administered with a needle, and the syncopal reaction appears to be related to the act of injection. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

D. Guillain-Barré Syndrome (GBS)

GBS is an acute paralysis caused by dysfunction in the peripheral nervous system (*i.e.*, the nervous system outside the brain and spinal cord). GBS may manifest with weakness, abnormal sensations, and/or abnormality in the autonomic (involuntary) nervous system. In the United States, each year approximately 3,000 to 4,000 cases of GBS are reported, and the incidence of GBS increases in older individuals. Senior citizens tend to have a poorer prognosis. Most people fully recover from GBS, but some people can either

develop permanent disability or die due to respiratory difficulties. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system, as occurs with infections, can lead to the formation of autoimmune antibodies and cell-mediated immunity that play a role in its development.

GBS may present as one of several clinicopathological subtypes. The most common type 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 roots. Demyelination refers to a loss or disruption of the myelin sheath, which wraps around the axons of some nerve cells and which is necessary for the normal conduction of nerve impulses in those nerves that contain myelin. Polyneuropathy refers to the involvement of multiple peripheral nerves. Motor nerves affect muscles or glands. Sensory nerves transmit sensations. The axon is a portion of the nerve cell that transmits nerve impulses away from the nerve cell body. Another subtype of GBS, 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 axons of sensory nerves and roots.

The diagnosis of the AIDP, AMAN, and AMSAN subtypes of GBS requires bilateral flaccid (relaxed with decreased muscle tone) limb weakness and decreased or absent deep tendon reflexes in weak limbs, and a monophasic illness pattern with the interval between onset and nadir of weakness between 12 hours and 28 days with a subsequent clinical plateau. The clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without 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. In addition, there must not be a more likely alternative diagnosis for the weakness.

Other factors in all subtypes of GBS that add to diagnostic certainty, but are not required for diagnosis, include electrophysiologic findings consistent with GBS or cytoalbuminologic dissociation (*i.e.,* elevation of cerebral spinal fluid (CSF) protein and a total white cell count in the CSF less than 50 cells per microliter).

The weakness in the AIDP, AMAN, and AMSAN subtypes of GBS is usually, but not always, symmetric and usually has an ascending pattern of progression from legs to arms. However, other patterns of progression may occur. The cranial nerves can be involved. Respiratory failure can occur due to respiratory involvement. Fluctuations in the degree of weakness prior to reaching the point of greatest weakness or during the plateau or improvement phase may occur, especially in response to treatment. These fluctuations occur in the first 9 weeks after onset and are generally followed by eventual improvement.

According to the Brighton Collaboration, 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 GBS may be seen with limb weakness. [James J. Sejvar et. al. Guillain-Barre Syndrome and Fisher Syndrome: Case definitions and guidelines for collection, analysis, and presentation of immunization safety data Vaccine 29(3):599–612]. The diagnosis of FS requires bilateral ophthalmoparesis; bilateral reduced or absent tendon reflexes; ataxia; the absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN); a monophasic illness pattern; an interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms or subsequent improvement without significant relapse); no alteration in consciousness; no corticospinal track signs; and the absence of an identified, more likely, alternative diagnosis. Death may occur without a clinical plateau.

Exclusionary criteria for the diagnosis of GBS include the ultimate diagnosis of any of the following conditions: Chronic inflammatory demyelinating polyneuropathy (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. [Sejvar 599–612].

For all subtypes of GBS (AIDP, AMAN, AMSAN, and FS), the onset of symptoms less than 3 days (72 hours) after exposure excludes that exposure as a cause because the immunologic steps necessary to create symptomatic disease require a minimum of 3 days.

CIDP is clinically and pathologically distinct from GBS. The onset phase of CIDP is generally greater than 8 weeks and the weakness may remit and relapse. CIDP is also not monophasic. [Sejvar 599–612.]

In the past, GBS has been causally associated with certain vaccines. For example, the 1976 influenza A (swine flu) vaccine was found by the IOM to be causally associated with GBS. The risk of developing GBS in the 6 week period after receiving the 1976 swine flu vaccine was 9.2 times higher than the risk for those who were not vaccinated. [Lawrence B. Schonberger, *et al.*, "Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977," American Journal of Epidemiology, 25 Apr. 1979; 118 and IOM, "Immunization Safety Review: Influenza Vaccines and Neurological Complications," (Washington, DC: The National Academies Press, 2004) 25]. Since the 1976 influenza season, numerous studies have been conducted to evaluate whether other influenza vaccines were associated with GBS. In most published studies, no association was found, but one large study published in the *New England Journal of Medicine* evaluated the 1992–93 and 1993–94 influenza seasons and suggested approximately one additional case of GBS out of 1 million persons vaccinated, in the 6 weeks following vaccination, may be attributable to the vaccine formulation used in those years. The background incidence of GBS not associated with a vaccine among adults was documented in the study to be 0.87 cases per million persons for any 6 week period. [Tamar Lasky, et al., "The Guillain-Barré Syndrome and the 1992–1993 and 1993–1994 Influenza Vaccines," The New England Journal of Medicine, Dec. 17, 1998; 1797.]

The IOM published a thorough scientific review of the peer-reviewed literature in 2004 and concluded that people who received the 1976 swine influenza vaccine had an increased risk for developing GBS [IOM, Immunization Safety Review: Influenza Vaccines and Neurological Complications, 25]. Based on its review of the published literature, the IOM also decided that the evidence linking GBS and influenza vaccines in influenza seasons other than 1976 was not clear. This led to the IOM's conclusion that the evidence was inadequate to accept or reject a causal relationship between influenza immunization and GBS for years other than 1976.

In 2012, the IOM published another report that evaluated the association of seasonal influenza vaccine and GBS. Pandemic vaccines, such as the influenza vaccine used in 1976 and the monovalent 2009 H1N1 influenza vaccine, were specifically excluded and not evaluated. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between seasonal influenza vaccine and GBS. (IOM, Adverse Effects of Vaccines 334). It is important to note that monovalent vaccines are usually only given in response to an actual or potential pandemic, while seasonal influenza vaccines are offered annually. The monovalent 2009 H1N1 vaccine, a type of pandemic vaccine, is covered under the Countermeasures Injury Compensation Program. The VICP does not cover pandemic influenza vaccines, such as the 2009 H1N1 Influenza vaccine.

A meta-analysis of the VSD, EIP (Emerging Infections Program—an active population-based surveillance program), and PRISM (Post-Licensure-Rapid Immunization Safety Monitoring—a cohort-based active surveillance network) data was performed and published, together with additional data from safety surveillance studies performed by Medicare, the Department of Defense, and the Department of Veterans Affairs, which, in total, analyzed data from 23 million people who were vaccinated with the influenza A (H1N1) 2009 monovalent vaccine. [Daniel A. Salmon et al., "Association between Guillain-Barré syndrome and influenza A (H1N1) 2009 monovalent inactivated vaccines in the USA: a meta-analysis," Lancet, electronically published March 13, 2013, *http://dx.doi.org/10.1016/S0140-6736(12)62189-8.*] The meta-analysis provides the benefit of additional statistical power. Additional power allows for the analyses of certain hypotheses which were not possible to analyze individually in the six studies that made up the meta-analysis. The meta-analysis found that the 2009 H1N1 inactivated vaccine was associated with a small increased risk of GBS within 6 weeks of vaccination. This excess risk is equivalent to 1.6 excess cases in the 6 weeks after vaccination per million people vaccinated. This increased risk found in the meta-analysis was consistent: (1) Across studies looking at different groups of people; (2) using different definitions of illness; (3) in people who received or did not receive a concurrent seasonal influenza vaccine or had influenza-like symptoms; (4) across various time windows; and (5) in different age categories. This suggests that these five factors did not affect the risk of developing GBS.

Considering the totality of the evidence with the enhanced surveillance studies and meta-analysis performed to monitor the safety of the monovalent 2009 H1N1 vaccine, scientific evidence demonstrates a small increased risk of GBS in the 6 weeks following administration of the monovalent 2009 H1N1 vaccines.

Presently, there is no scientific evidence demonstrating that current formulations of the seasonal influenza vaccine, which contain the H1N1 virus, can cause GBS. However, the degree of surveillance needed to detect an increased risk of one case per million vaccinations, as was seen with the monovalent 2009 H1N1 vaccine, is unlikely to be routinely performed as the strains in the flu vaccines change from year to year. Nonetheless, numerous studies have been conducted in order to determine whether a possible association between seasonal influenza vaccines and GBS exists, and almost all have not shown any causal relationship. The IOM reviewed literature concerning such studies and concluded that the evidence was inadequate to accept or reject a causal association for all versions of seasonal influenza vaccines since 1976.

Using studies demonstrating a causal association between the 2009 H1N1 and 1976 swine flu vaccines and GBS as background, the Secretary proposes to add the injury of GBS to the Table for seasonal influenza vaccines. Although the scientific evidence does not show a causal association for current formulations of seasonal flu vaccines and GBS, the Secretary proposes including the injury of GBS for seasonal influenza vaccines on the Table in accordance with the ACCV Guiding Principles, acknowledging the fact that seasonal influenza vaccine formulations, unlike other vaccines, change from year-to-year and that enhanced surveillance activities may not occur with each virus strain change. This is done even though it appears that any instances of GBS caused by seasonal influenza vaccines, if they exist at all, are very rare. The Secretary proposes adding GBS to the Table for seasonal influenza vaccines and recognizes that this will create a presumption of causation that will result in compensation for numerous instances of GBS that are not vaccine-related.

While there is no evidence demonstrating that current formulations of the seasonal influenza vaccine can cause GBS, the totality of the evidence, particularly the enhanced surveillance studies and meta-analysis performed to monitor the safety of the 2009 H1N1 vaccine, provides compelling evidence of a small increased risk of GBS in the 6 weeks following the administration of the 2009 H1N1 vaccine. Utilizing this scientific data as background, the Secretary proposes an onset interval of 3–42 days for GBS presumed to be caused by the seasonal influenza vaccine to be covered under the proposed Table. Day 3 begins 72 hours after administration of the vaccination and takes into account the time interval needed to show first signs or symptoms after exposure. [Peripheral Neuropathy (Philadelphia, PA: Elsevier Saunders, 2005, 626].

XI. Meningococcal Vaccines

There are two types of meningococcal vaccines administered in the United States. The polysaccharide vaccine was licensed by the FDA in 1978, and is indicated for persons 2 years of age and older; the meningococcal conjugate vaccines were licensed starting in 2005. The conjugate vaccines were developed with the expectation that they would provide more long-lasting immunity, a more rapid immune response upon exposure to Neisseria meningitidis, and the development of "herd immunity" through reduction of the asymptomatic carrier state. The meningococcal polysaccharide and conjugate vaccines were added to the Table with an effective date of February 1, 2007.

A. Anaphylaxis

The Secretary proposes to add anaphylaxis as a Table injury for meningococcal vaccines. [See section VII.C above.] The IOM Committee, following an extensive review of the scientific and medical literature, concluded that the evidence convincingly supported a causal relationship between meningococcal vaccines and anaphylaxis. The Institute of Medicine based their conclusion on a case report of anaphylaxis with onset

30 minutes following vaccination. [Yergeau, A., L. Alain, R. Pless, and Y. Robert. 1996. Adverse events temporally associated with meningococcal vaccines. *Canadian Medical Association Journal* 154(4):503–507.]

The Secretary proposes to add anaphylaxis as a Table injury for meningococcal vaccines, with an onset less than or equal to 4 hours from the administration of the vaccine. In addition, the Secretary proposes to update the definition of anaphylaxis in the QAI.

B. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for meningococcal vaccines. [See section I.A above.] The interval of onset will be less than or equal to 48 hours.

C. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for meningococcal vaccines. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

XII. Human Papillomavirus Vaccines

The first human papillomavirus (HPV) vaccine was licensed by the FDA in June 2006 for females between the ages of 9–26 years. In 2011, one of the two licensed HPV vaccines was given a permissive use recommendation in males by the CDC and other recommending bodies (*i.e.*, the American Academy of Pediatrics and the American Academy of Family Physicians). HPV vaccine was added to the Table with an effective date of February 1, 2007.

A. Anaphylaxis

The Secretary proposes to add anaphylaxis as a Table injury for HPV vaccines. [See VII.C] The IOM Committee concluded that the evidence favors acceptance of a causal relationship between human papillomavirus vaccines and anaphylaxis. They based their conclusion on temporality and clinical symptoms consistent with anaphylaxis in 9 reports from VAERS over 31 months of surveillance. [Slade, B.A., L. Leidel, C. Vellozzi E.J. et al. Post licensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *Journal of the American Medical Association* 2009. 302(7):750–757.]

The Secretary notes that there are limitations to the VAERS passive reporting system. First, there is underreporting; not all adverse events following vaccines are reported to the system. The rates of underreporting have been examined for different disorders and are greatest for adverse events of mild severity. Second, many reports are filed before a complete clinical evaluation has been conducted. Therefore, the presumptive diagnosis that has been provided at the time of the report may not be the correct diagnosis. Third, investigations conducted after the initial report sometimes reveal alternative causes for the adverse event. In many instances, incomplete information is provided in the initial report. Follow-up of the reports by the CDC and FDA may be conducted to collect additional information from the healthcare providers. The primary purpose of VAERS is to look for signals for evidence of unexpected adverse events that would require other investigations to try to determine causal relationships. Although conclusions about causation are not possible for most adverse events reported to VAERS, the IOM found likely causality based on the distinctive nature of anaphylactic reactions and the temporal relationship between the HPV vaccine administration and the event. The Secretary proposes to add anaphylaxis as a Table injury for HPV vaccines, with an onset of less than or equal to 4 hours from the administration of the vaccine. In addition, the Secretary proposes to update the definition of anaphylaxis in the QAI.

B. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA as a Table injury for HPV vaccines. [See section I.A above.] The proposed time interval of onset is less than or equal to 48 hours.

C. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for HPV vaccines. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

XIII. Category for 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

Category XVII of the current Table pertains to any new vaccine recommended by the CDC for routine administration to children, after publication by the Secretary of a notice of coverage. This category pertains to vaccines that are covered under the Program, but with respect to which the Secretary has not yet finalized actions adding the vaccines as separate categories to the Table. Through this rule, the Secretary proposes retaining this category and adding two associated injuries for vaccines covered by this category.

A. Shoulder Injury Related to Vaccination

The Secretary proposes to add SIRVA for the category of vaccines captured under Category XVII of the Table. [See section I.A above.] As detailed in the proposed QAI, this injury would only apply to intramuscular vaccines injected into the upper arm. The interval of onset will less than or equal to 48 hours.

B. Vasovagal Syncope

The Secretary proposes to add vasovagal syncope to the Table for this category of vaccines. As detailed in the proposed QAI, this injury would apply only to injected vaccines as the syncopal reaction appears to be related to the act of injection. [See section I.B above.] The proposed time interval of onset is less than or equal to 1 hour following vaccination.

XIV. Additional Table Changes

The Secretary is proposing a number of organizational and structural changes to the Table and QAI designed to increase clarity and scientific accuracy, including the addition of a glossary of terms used within the Table and the QAI.

Organizational Changes

- To streamline the Table, the Secretary proposes a new paragraph (b), *Provision that applies to all vaccines listed.* This section includes any acute complication or sequela, including death, of the illness, disability, injury, or condition listed, rather than adding this provision to every line of the Table.
- To further streamline the Table, the Secretary proposes the deletion of 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). In addition, complicated language previously included in the definition of encephalopathy, which indicated that idiopathic injuries do not rebut the Table presumption, has been simplified and made generally applicable to all injuries. This has also been included in paragraph (b).
- The QAI (proposed paragraph (c)) contain definitions for those terms that are used in the Table (paragraphs (a) and (b)).

• The newly added glossary (proposed paragraphs (d)) defines terms used in multiple places in the QAI (proposed paragraph (c)). Most of these terms were formerly contained in the QAI, and have been moved to the glossary so that each reference is consistent. These definitions include: chronic encephalopathy, significantly decreased level of consciousness, injected, and seizure.

• The proposed Table and QAI include some changes made by the Final Rule adding Intussusception as an Injury for Rotavirus Vaccines to the Vaccine Injury Table (80 FR 35848, June 23, 2015).

Expansion

• The Secretary proposes to add definitions for new Table injuries, including SIRVA, disseminated varicella-strain virus disease, varicella vaccine-strain viral reactivation disease, GBS, and vasovagal syncope.

• The Secretary proposes to add definitions of terms that had been on the Table or in the QAI, but that previously were undefined, including encephalitis, injected, and immunodeficient recipient.

Harmonization

• The Secretary proposes additional changes to the QAI to address certain changes in scientific nomenclature. Definitions, such as acute encephalopathy and acute encephalitis, both of which lead to chronic encephalopathy, have been harmonized. Definitions for brachial neuritis and SIRVA have also been harmonized.

• The Secretary proposes modification of category XIV on the Table from "Trivalent influenza vaccines" to "Seasonal influenza vaccines".

• The Secretary proposes modification of category IX on the Table from "Haemophilus influenzae type b polysaccharide conjugate vaccines" to "Haemophilus influenzae type b vaccines".

• Minor technical changes resulting from updated medical information have been included in the definitions of anaphylaxis, encephalopathy, chronic arthritis, brachial neuritis, thrombocytopenic purpura, and seizure.

All of the proposed changes were discussed and approved by the ACCV, although the ACCV expressed some reservations regarding the definition of "immunodeficient recipient". The discussion was reviewed, and the Secretary has modified the definition to address the concerns raised by the ACCV.

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, of costs, of benefits, of incentives, of equity, and of 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 proposed 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 proposed 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 proposed 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.

Nor on the basis of family well-being will the provisions of this rule 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" 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 proposed rule would modify the Vaccine Injury Table based on legal authority.

Impact of the New Rule

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

Paperwork Reduction Act of 1995

This proposed rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Dated: June 24, 2015.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: July 10, 2015.

Sylvia M. Burwell,

Secretary.

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

PART 100—VACCINE INJURY COMPENSATION

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

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

■ 2. 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 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.

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
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.
	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) 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 an 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) 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 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/determatomyositis, 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, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. 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, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. 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 nine 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 to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after [EFFECTIVE DATE OF THE FINAL REGULATION.]

(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. 2015–17503 Filed 7–28–15; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–IA–2013–0091; 96300–1671–0000–R4]

RIN 1018–AX84

Endangered and Threatened Wildlife and Plants; Revision of the Section 4(d) Rule for the African Elephant (Loxodonta africana)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are proposing to revise the rule for the African elephant promulgated under section 4(d) of the Endangered Species Act of 1973, as amended (ESA), to increase protection for African elephants in response to the alarming rise in poaching of the species to fuel the growing illegal trade in ivory. The African elephant was listed as threatened under the ESA effective June 11, 1978, and at the same time a rule issued under section 4(d) of the ESA (a "4(d) rule") was promulgated to regulate import and use of specimens of the species in the United States. This proposed rule would update the current 4(d) rule with measures that are appropriate for the current conservation needs of the species. We are proposing measures that are necessary and advisable to provide for the conservation of the African elephant as well as appropriate prohibitions from section 9(a)(1) of the ESA. Among other things, we propose to incorporate into the 4(d) rule certain restrictions on the import and export of African elephant ivory contained in the African Elephant Conservation Act (AfECA) as measures necessary and advisable for the conservation of the African elephant. We are not, however, revising or reconsidering actions taken under the AfECA, including our determinations in 1988 and 1989 to impose moratoria on the import of ivory other than sport-hunted trophies from both range and intermediary countries. We are proposing to take these actions under section 4(d) of the ESA to increase protection and benefit the conservation of African elephants, without unnecessarily restricting activities that have no conservation effect or are strictly regulated under other law.

DATES: In preparing the final decision on this proposed rule, we will consider comments received or postmarked on or before September 28, 2015.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–HQ–IA–2013–0091, which is the docket number for this rulemaking. You may submit a comment by clicking on "Comment Now!"
- *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–IA–2013–0091; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: BPHC; Falls Church, VA 22041.

We will not accept email or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section at the end of **SUPPLEMENTARY INFORMATION** for further information about submitting comments).

FOR FURTHER INFORMATION CONTACT: Craig Hoover, Chief, Wildlife Trade and Conservation Branch, Division of Management Authority; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: IA; Falls Church, VA 22041 (telephone, (703) 358–2093).

SUPPLEMENTARY INFORMATION:

Applicable Laws

In the United States, the African elephant is primarily protected and managed under the Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq.*); the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES or Convention) (27 U.S.T. 1087), as implemented in the United States through the ESA; and the African Elephant Conservation Act (AfECA) (16 U.S.C. 4201 *et seq.*).

Endangered Species Act

Under the ESA, species may be listed either as "threatened" or as "endangered." When a species is listed as endangered under the ESA, certain actions are prohibited under section 9 (16 U.S.C. 1538), as specified at 50 CFR 17.21. These include prohibitions on take within the United States, within the territorial seas of the United States, or upon the high seas; import; export; sale and offer for sale in interstate or foreign commerce; and delivery, receipt, carrying, transport, or shipment in interstate or foreign commerce in the course of a commercial activity.

The ESA does not specify particular prohibitions and exceptions to those

6.3

at the end of the effective period of this temporary deviation.

This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 3, 2015.

David M. Frank,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2015–19377 Filed 8–6–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0624]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs four Multnomah County bridges: the Broadway Bridge, mile 11.7, Burnside Bridge, mile 12.4, Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1, all crossing the Willamette River at Portland, OR. This deviation is necessary to accommodate the annual Portland Providence Bridge Pedal event. This deviation allows the bridges to remain in the closed-to-navigation position to allow safe roadway movement of event participants.

DATES: This deviation is effective from 6 a.m. on August 9, 2015, to 12:30 p.m. on August 9, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0624] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: Multnomah County has requested a temporary deviation from the operating schedule for the Broadway Bridge, mile 11.7, Burnside Bridge, mile 12.4, Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1, all crossing the Willamette River at Portland, OR. The requested deviation is to accommodate the annual Providence Bridge Pedal event. To facilitate this event, the draws of the bridges will be maintained in the closed-to-navigation positions as follows: The Broadway Bridge, mile 11.7, provides a vertical clearance of 90 feet in the closed position; Burnside Bridge, mile 12.4, provides a vertical clearance of 64 feet in the closed position; Morrison Bridge, mile 12.8, provides a vertical clearance of 69 feet in the closed position; and Hawthorne Bridge, mile 13.1, provides a vertical clearance of 49 feet in the closed position; all clearances are referenced to the vertical clearance above Columbia River Datum 0.0. The normal operating schedule for all four bridges is set in 33 CFR 117.897, and states that the bridges need not open from 7 a.m. to 9 a.m., and from 4 p.m. to 6 p.m. Monday through Friday. These four bridges need not open for vessel traffic from 6 a.m. on August 9, 2015, to 12:30 p.m. on August 9, 2015. This deviation period is from 6 a.m. on August 9, 2015, to 12:30 p.m. August 9, 2015. The deviation allows the Broadway Bridge, Burnside Bridge, Morrison Bridge, and the Hawthorne Bridge all crossing the Willamette River, to remain in the closed-to-navigation position and need not open for maritime traffic from 6 a.m. to 12:30 p.m. on August 9, 2015. The four bridges shall operate in accordance to 33 CFR 117.897 at all other times. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation positions may do so at any time. The bridges will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 17, 2015.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2015–19373 Filed 8–6–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 110

RIN 0906–AA79

Countermeasures Injury Compensation Program: Pandemic Influenza Countermeasures Injury Table

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

ACTION: Final rule.

SUMMARY: HHS is establishing the Pandemic Influenza Countermeasures Injury Table as authorized by the Public Readiness and Emergency Preparedness Act (PREP Act). Through this final rule, the Secretary of the U.S. Department of Health and Human Services (Secretary) adds regulations for the purpose of creating Covered Countermeasures Injury Tables. The pandemic influenza countermeasures are identified in Secretarial declarations relating to pandemic influenza, including influenza caused by the 2009 H1N1 pandemic influenza virus (hereafter referred to as the 2009 H1N1 virus) and other potential pandemic strains, such as H5N1 avian influenza.

DATES: This rule is effective September 8, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Avril M. Houston, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857, or by telephone (855) 266–2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION: On March 30, 2014, HHS published the Notice of Proposed Rulemaking (NPRM) in the **Federal Register** to amend the Countermeasures Injury Compensation Program's (CICP or Program) implementing regulation and establish a table of injuries resulting from the administration or use of covered

pandemic influenza countermeasures. The NPRM provided a 60-day comment period resulting in HHS receipt of five sets of comments—one set from a physicians' organization and four sets from individuals. HHS carefully considered these comments when developing this final rule. In "Section III, Comments and Responses" of this final rule, the comments are summarized and HHS provides responses to them.

I. Background

The Public Readiness and Emergency Preparedness Act of 2005 (PREP Act) directs the Secretary to establish, through regulation, a Covered Countermeasures Injury Table (Table) identifying serious physical injuries that are presumed to be directly caused by the administration or use of covered countermeasures identified in PREP Act declarations issued by the Secretary.

The Secretary may only add to a Table injuries that are directly caused by the administration or use of the covered countermeasure based on "compelling, reliable, valid, medical and scientific evidence." [1] This Table informs the public about serious physical injuries known to be directly caused by covered countermeasures through support by compelling, reliable, valid, medical and scientific evidence. In addition, this Table creates a rebuttable presumption of causation for eligible individuals whose injuries are listed on a Table and meet the requirements of a Table.

The PREP Act authorizes both liability protections and compensation based on the terms of the PREP Act declarations, but this final rule concerns only the compensation program, not the liability protections set forth therein.

The Secretary published the interim final rule implementing the Program on October 15, 2010.[2] The final rule, which was published on October 7, 2011, explains the Program's policies, procedures, and requirements. Title 42 of the Code of Federal Regulations (CFR) § 110.20(a) states that individuals must establish that a covered injury occurred in order to be eligible for benefits under the Program. A covered injury is death or a serious injury determined by the Secretary to be: (1) An injury meeting the requirements of a Table, which is presumed to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause; or (2) an injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes a covered countermeasure causing a serious aggravation of a pre-existing condition.[3] In general, only injuries that warranted hospitalization (whether or not the person was actually hospitalized), or injuries that led to a significant loss of function or disability are considered serious injuries.[4]

Individuals with injuries not meeting the requirements listed on the Table may still pursue their claims as non-Table injuries under the Program. In this instance, the requester does not receive the presumption of causation for a Table injury and must demonstrate that the use or administration of the covered countermeasure directly caused the injury. Proof of a causal association for the non-Table injury must be based on compelling, reliable, valid, medical and scientific evidence.

II. Summary of the Final Rule

Through this final rule, the Secretary will be adding subpart K to 42 CFR part 110, which had been reserved for the purpose of creating a Covered Countermeasures Injury Table. The Table established in this final rule is limited to pandemic influenza covered countermeasures. These countermeasures are identified in Secretarial declarations relating to pandemic influenza, including influenza caused by the 2009 H1N1 virus, and other potential pandemic strains, such as H5N1 avian influenza. The Secretary may create and publish Tables in the **Federal Register** through separate amendments to 42 CFR part 110 in the future. Tables may be created for other countermeasures in accordance with the PREP Act. To date, declarations have been issued with respect to countermeasures against pandemic influenza A viruses, anthrax, botulism, smallpox, acute radiation syndrome, and the Ebola virus.

Through the Pandemic Influenza Countermeasures Injury Table Final Rule, the Secretary provides, as authorized by statute, a Table for several covered countermeasures listing serious physical injuries. The serious physical injuries included on the Table are injuries that are supported by compelling, reliable, valid, medical and scientific evidence showing that the administration or use of the covered countermeasures directly causes such injuries. The Table lists the serious injuries directly caused by a specific countermeasure, the time interval within which the first symptom or manifestation of onset of injury must appear, and the definition of the injury. Table definitions are included to further explain each covered injury and the level of severity necessary to qualify as a Table injury.

The injuries, time intervals, definitions, and requirements reflect the Secretary's efforts to identify those serious physical injuries causally related to the covered countermeasures. The causal linkages between the covered countermeasures and these associated injuries are based on compelling, reliable, valid, medical and scientific evidence. The Secretary will stay informed of updates in the scientific and medical field concerning new information about causal associations between injuries and covered countermeasures.

In this final rule, the Secretary has made the following changes to the Qualifications and Aids to Interpretation (QAI) of the Table for purposes of clarity.

a. Changed section (b)(4)(i) by adding an accent over the "e" in Guillain-Barre Syndrome (GBS). The revised section term reads, "Guillain-Barré Syndrome." In the first sentence, added "currently is known to encompass" after "that" and delete "encompasses." The revised sentence states, "GBS is an acute monophasic peripheral neuropathy that currently is known to encompass a spectrum of four clinicopathological subtypes described below." In the fourth sentence, changed "nine" to "9." The revised sentence states, "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."

b. Changed section (b)(4)(iv) by adding "The results of both . . ." to the beginning of the second sentence. The revised sentence states, "The results of both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS."

c. Deleted section (b)(4)(v) which states, "For all types of GBS, the onset of symptoms less than three days (72 hours) after exposure to the influenza vaccine excludes vaccine exposure as a cause" because timeframes for serious physical injuries to be Table injuries are listed in the Table, not in the QAI.

d. Changed section (b)(4)(vi) to (b)(4)(v) since (b)(4)(v) has been deleted as stated above and added to the beginning of the first sentence of section (b)(4)(v), "For GBS to qualify as a Table injury." The revised sentence states, "For GBS to qualify as a Table injury, there must not be a more likely alternative diagnosis for the weakness."

[1] 42 U.S.C. 247d–6e(b)(5)(A).

[2] 42 CFR part 110.

[3] 42 CFR 110.3(g)(2).

[4] 42 CFR 110.3(z).

e. Changed section (b)(5)(i)(A) by adding "or" after "tube;". The revised statement states, "(A) trauma or necrosis from an endotracheal tube; or."

f. Changed section (b)(6)(i) by deleting "Definition -" before "VAP" at the beginning of the first sentence. In the fourth sentence, changed the phrase "radiographic infiltrate in the lungs that is consistent with pneumonia" to "radiographic infiltrate that is in the lungs and consistent with pneumonia."

g. Changed section (b)(7) by adding "To qualify as Table injuries," before "these" to the beginning of the last sentence. The revised sentence states, "To qualify as Table injuries, these manifestations must occur in patients who are being mechanically ventilated at the time of initial manifestation of the VILI." VILI is Ventilator-Induced Lung Injury.

h. Changed section (b)(8) by adding "who are" after "patients" and before "under" to the first sentence. The revised sentence states, "Bleeding events are defined as excessive or abnormal bleeding in patients who are under the pharmacologic effects of anticoagulant therapy provided for extracorporeal membrane oxygenation (ECMO) treatment."

III. Comments and Responses

The NPRM set forth a 60-day public comment period, which ended on May 30, 2014. During this comment period, HHS received five sets of comments—one set from a physicians' organization and four sets from individuals. Below is a summary of the comments and HHS's responses.

1. Anaphylaxis

Comment: A commenter suggested expanding to 12 hours the time frame within which the first symptom or manifestation of anaphylaxis must appear, stating that some cases of anaphylaxis may exhibit a late phase response up to 8–12 hours after exposure, and thus the 0–4 hour time frame is not long enough.

Response: HHS respectfully disagrees with this comment. There is no consensus within the medical and scientific community about the time frame in which the late phase response starts. As stated in the NPRM, anaphylaxis after immunization is serious, but it occurs rarely. After initial treatment and clinical improvement, some patients with allergic reactions may develop a late phase or "biphasic" reaction, which may be more severe than the initial presentation. Little is known of the pathophysiology of biphasic reactions. The variations and the subjective nature of definitions used for determining the incidence of biphasic reactions in various studies are likely a major contributor to differing results, ranging from a 0.5 percent to 20 percent incidence rate. This makes comparisons of data across studies problematic. Previous guidelines have advocated the monitoring of patients post-anaphylaxis, with recommended durations varying between 4 and 24 hours. This is likely a testament to the uncertainty in the literature. Hence there is no compelling, reliable, valid, medical and scientific evidence upon which to base a Table time frame for biphasic anaphylactic reactions. HHS recognizes the occurrence of biphasic anaphylactic reactions in a minority of cases. Therefore, the Program will consider a claim for anaphylaxis occurring after the 4-hour time frame leading to a serious injury or death on a case-by-case basis as a non-Table claim.

2. Pandemic Influenza Intranasal Vaccines

Comment: A commenter asked if a child would be eligible to receive compensation if he/she is injured from the intranasal vaccine, which was administered because the child was advised by his/her doctor to have the intranasal vaccine, even if perhaps, the child would have been more suited for the vaccine injection.

Response: Under the CICP, any person who meets the appropriate declaration's definition of covered population, is administered or used a covered countermeasure in accordance with the terms of that declaration (or in good faith belief of such), and is seriously injured as a direct result of the countermeasure, may be eligible for CICP benefits.

3. Antiviral Usage in Individuals Younger Than 2 Years of Age

Comment: A commenter was concerned that the guidelines for administration of Tamiflu (oseltamivir), Relenza (zanamivir), and peramivir for infants are not uniform. The commenter stated that the Food and Drug Administration has approved Tamiflu for children as young as 2 weeks of age but that the Centers for Disease Control and Prevention (CDC) recommends Tamiflu, through its safety profile, for treatment of both term and preterm infants from birth, as benefits for therapy are likely to outweigh possible risks of treatment. The commenter suggested that this rule establish the minimum age for administration of these countermeasures to children so that children are not denied compensation because of conflicting policy recommendations about the appropriate administration of these antiviral medications.

Response: The CICP is not authorized to establish age ranges for the administration of any drug, and therefore, cannot do so through this rule, as suggested by the commenter. The Program can only provide benefits to the population of individuals set forth in the applicable Secretarial declaration.

4. Incorporation of Children and Infants in Overall Guidelines

Comment: A commenter made the statement that his organization "firmly believes that the Table should better incorporate the needs of children." The commenter wants HHS and HRSA to ensure that children are being considered in all aspects of the proposed countermeasures, as well as in this Table.

Response: As indicated above, Secretarial declarations describe the covered countermeasures and the covered population. Under the CICP, any person who meets the definition of the covered population in the relevant declaration, who receives or uses a covered countermeasure in accordance with the terms of that declaration (or in good faith belief of such), and is seriously injured as a direct result of the countermeasure may be eligible for CICP benefits.

5. Guillain-Barré Syndrome

Comment: One commenter was concerned that the description of Guillain-Barré Syndrome (GBS) is incomplete because it does not address the fact that GBS affects the peripheral nervous system.

Response: HHS respectfully disagrees with this comment. The description of GBS as stated in the NPRM and final rule is complete and explicitly addresses that GBS affects the peripheral nervous system. It is an acute monophasic peripheral neuropathy that currently is known to encompass a spectrum of four clinicopathological subtypes described in the Qualifications and Aids to Interpretation section of the Table. GBS may manifest with weakness, abnormal sensations, and/or abnormality in the autonomic (involuntary) nervous system.

Comment: A commenter was concerned that this allegedly incomplete description of GBS may make it difficult for requesters to prove injuries such as Miller-Fisher Syndrome or other variants of GBS that include attacks that lead to organ damage. Another commenter noted that the variants of GBS should be considered.

Response: HHS respectfully disagrees with the comments that the variants of GBS were not considered. The Table, including its Qualifications and Aids to Interpretation, explicitly addresses how variants of GBS, including Miller-Fisher Syndrome, can meet the Table requirements. GBS may present as one of a spectrum of four clinicopathological subtypes or variants. The most common type 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 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. The axon is a portion of the nerve cell that transmits nerve impulses away from the nerve cell body. 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 axons of sensory nerves and roots.

According to the Brighton Collaboration, 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 GBS may be seen with limb weakness.

GBS is proposed for inclusion on the Table because it is a serious physical injury, and the fact that it may be directly caused by the use of the monovalent 2009 H1N1 influenza vaccine (hereafter 2009 H1N1 vaccine) is supported by compelling, reliable, valid, medical and scientific evidence. Further, GBS is characterized by various degrees of weakness, sensory abnormality and autonomic dysfunction due to damage to peripheral nerves and nerve roots. These variants or subtypes of GBS were addressed fully in the NPRM and are adopted in the final rule.

Furthermore, as explained above, the description of GBS as stated in the NPRM, and adopted in this final rule, is complete. To the extent that one comment suggested that organ damage should be included as a Table injury, HHS respectfully disagrees. Although demyelination of peripheral nerves or axonal damage can lead to disruption of organ function, they do not lead directly to organ damage. At this time, there is no compelling, reliable, valid, medical and scientific evidence to support including organ damage on the Table.

Comment: A commenter was concerned that the 3- to 42-day window of GBS onset is unreasonable because some cases of GBS have been reported to have an onset outside of this interval. The commenter cited the article, "Chart-Confirmed Guillain-Barré Syndrome After 2009 H1N1 Influenza Vaccination Among the Medicare Population, 2009–2010, *American Journal of Epidemiology*, (2014), 179(5): 660."

Response: HHS respectfully disagrees with this comment. The study that was cited by the commenter and published in the *American Journal of Epidemiology* looked at the risk of GBS development within 119 days of vaccination. The researchers found a slightly increased statistically significant risk of GBS only within the 6-week period after 2009 H1N1 vaccination when compared with the post-vaccination control period.

As stated in the NPRM, multiple studies performed to monitor the safety of 2009 H1N1 vaccine provide evidence that demonstrates a small statistically significant increased risk of GBS in the 6 weeks following administration of the 2009 H1N1 vaccine.[5] Additionally, a meta-analysis was performed of the Emerging Infections Program, the Vaccine Safety Datalink, and the Post-Licensure Rapid Immunization Safety Monitoring System data, together with additional data from safety surveillance studies performed by the Centers for Medicare & Medicaid Services, the Department of Defense, and the Department of Veterans Affairs, which analyzed data from 23 million vaccinated people. The meta-analysis found that the 2009 H1N1 inactivated vaccine was associated with a small increased risk of GBS within 6 weeks of vaccination.

The symptoms of GBS do not develop immediately after exposure to the causative agent. The immune system requires a specified time to complete the steps leading to nerve injury and dysfunction and the early symptoms of GBS. A minimum of 3 days would be necessary from the time of exposure and immune system stimulation to the first symptoms of GBS. Therefore, onset of GBS within less than 72 hours or 3 days of immunization would be strong evidence that the vaccine is not the causative agent.[6]

HHS believes that the *American Journal of Epidemiology* study cited by the commenter is consistent with the other studies referenced above in indicating that the window of onset for GBS on the Table is appropriate based on current compelling, reliable, valid medical and scientific evidence.

6. Comparison of CICP Table Injuries to the VICP Table Injuries

Comment: A commenter compared the CICP Table injuries with the National Vaccine Injury Compensation Program (VICP) Table injuries because the 2009 H1N1 strain has been included in the seasonal influenza vaccine since 2010 and questioned why the Tables are different.

Response: The VICP and CICP are different programs authorized by two distinct federal statutes. The VICP covers certain vaccines that are recommended by the CDC for routine administration to children and are subject to an excise tax, whereas the CICP covers certain countermeasures, including pandemic influenza vaccines, as identified in Secretarial declarations. Accordingly, the VICP covers seasonal influenza vaccines, such as the quadravalent influenza vaccine, and the CICP covers pandemic vaccines, such as the 2009 monovalent H1N1 vaccine. Presently, the VICP's Table does not include any associated injuries for seasonal influenza vaccines.

7. West Nile Virus (WNV)

Comment: A commenter stated "I strongly believe it is beneficial to have an injury compensation program implemented for those who have been extremely touched by West Nile and other harmful influenzas . . ." HHS' understanding is that the commenter wants a compensation program established that would cover the adverse effects of the underlying pandemic or epidemic condition itself.

Response: Injuries from the WNV or any influenza infection are not covered by the CICP. As stated in the NPRM, only serious injuries directly caused by the administration or use of the covered countermeasure—not injuries that result from the disease (or health condition or threat to health) itself—are covered injuries. For more information, see 42 CFR 110.20(d).

[5] Lawrence B. Schonberger, *et al.*, "Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977, *American Journal of Epidemiology*, 25 Apr. 1979, 118; IOM, "Immunization Safety Review: Influenza Vaccines and Neurological Complications," (Washington, DC: The National Academies Press, 2004) 25; Sharon K. Greene, *et al.*, "Risk of Confirmed Guillain-Barré Syndrome Following Receipt of Monovalent Inactivated Influenza A (H1N1) and Seasonal Influenza Vaccines in the Vaccine Safety Datalink Project, 2009–2010; and *American Journal of Epidemiology*, Jun. 1, 2012, 1100.

[6] *Peripheral Neuropathy*, 4th edition, 2005; Dyck & Thomas, eds. 626.

8. Notification to Individuals Who Have Been Deemed Ineligible for Compensation

Comment: A commenter suggested that HHS inform all individuals who have previously applied but were deemed ineligible for compensation that they can reapply for compensation.

Response: HHS agrees with the commenter. Previous requesters, who were deemed ineligible for compensation, will be notified of the new Table by its publication in the **Federal Register**. The published final rule also will be posted on the CICP Web site at *www.hrsa.gov/cicp*. Such requesters may have an additional 1-year filing deadline from the effective date of the Table amendment or publication. This additional filing deadline will apply only if the new or amended Table enables a requester, who could not establish a Table injury before the new or amended Table, to establish a covered injury.[7]

IV. Regulatory Impact Analysis

HHS has examined the impact of this rulemaking as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, the Congressional Review Act (5 U.S.C. 804(2)), the Regulatory Flexibility Act (RFA), section 202 of the Unfunded Mandates Reform Act of 1995, section 654(c) of the Treasury and General Government Appropriations Act of 1999, and Executive Order 13132 on Federalism.

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. In 2011, President Obama supplemented and reaffirmed Executive Order 12866. This rulemaking is not being treated as a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the final rule has not been reviewed by the Office of Management and Budget.

Executive Order 13563 provides that, to the extent feasible and permitted by law, the public must be given a meaningful opportunity to comment on any proposed regulations, with at least a 60-day comment period. In addition, to the extent feasible and permitted by law, agencies must provide timely on-line access to both proposed and final rules of the rulemaking docket on Regulations.gov, including relevant scientific and technical findings, in an open format that can be searched and downloaded. Federal agencies must consider approaches to maintain the freedom of choice and flexibility, including disclosure of relevant information to the public. Regulations must be guided by objective scientific evidence, easy to understand, consistent, and written in plain language. Furthermore, Federal agencies must attempt to coordinate, simplify, and harmonize regulations to reduce costs and promote certainty for the public.

In this final rule, the Secretary specifies a Table identifying serious physical injuries that shall be presumed to result from the administration or use of the covered countermeasures, and the time interval in which the onset of the first symptom or manifestation of each such serious physical injury must manifest in order for such presumption to apply. The Secretary is also specifying Table definitions and requirements. This final rule would have the effect of affording certain persons a presumption that particular serious physical injuries were sustained as the result of the administration or use of covered pandemic influenza countermeasures. The Table will establish a presumption of causation and relieve requesters of the burden of demonstrating causation for covered injuries listed on the Table. However, this presumption is rebuttable based on the Secretary's review of the evidence. In addition, this Table may afford some requesters a new filing deadline.

Other than showing that a serious physical injury or death directly resulted from an injury included on the Table, individuals may, in the alternative, be eligible for compensation if they otherwise meet the CICP's requirements and can show a causation-in-fact relationship between an injury or death and a covered countermeasure. This rule is based upon legal authority.

Because any resources required to implement the regulatory requirements imposed by the Program are not required by virtue of the establishment of a Table, and because the Secretary conducted an independent analysis concerning any burdens associated with the implementation of the Program when the Secretary published the companion regulation setting forth the Program's administrative implementation,[8] the Secretary has determined that no resources are required to implement the provisions included in this final rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA) and the Small Business Regulatory Enforcement Fairness 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 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. The Secretary has determined that this 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 or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995. This final rule comports with the 2011 supplemental requirements.

Unfunded Mandates Reform Act of 1995

The Secretary has determined that this final rule will not have effects on State, local, and tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Federalism Impact Statement

The Secretary has also reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." This final rule will not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Impact on Family Well-Being

This final rule will not adversely affect the following elements of family well-being: 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. In fact, this rule may have a positive impact on the disposable

[7] 42 CFR 110.42(f).

[8] 75 FR 64955.

income and poverty elements of family well-being to the extent that injured persons or their families may receive medical, lost employment income, and/or death benefits paid under this part without imposing a corresponding burden on them.

Paperwork Reduction Act of 1995, as Amended

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 110

Anaphylaxis, Anticoagulation, Antiviral, Avian, Benefits, Biologics, Bleeding, Bursitis, Compensation, Countermeasure, Declaration, Deltoid, Diagnostics, Device, Eligibility, Extra-Corporeal Membrane Oxygenation (ECMO), Fisher Syndrome, Guillain-Barré Syndrome, 2009 H1N1, Influenza, Injury Table, Immunization, Oseltamivir, Pandemic, Peramivir, Public Readiness and Emergency Preparedness Act (PREP Act), Radiation syndrome, Respiratory protection, Relenza, Respirator, Respirator support, Tamiflu, Tracheal Stenosis, Vaccine, Vasovagal Syncope, Ventilator, Ventilator-Associated Pneumonia and Tracheobronchitis, Ventilator-Induced Lung Injury, Zanamivir.

Dated: July 24, 2015.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: July 30, 2015.

Sylvia M. Burwell,

Secretary.

Therefore, for the reasons stated, the Department of Health and Human Services amends 42 CFR part 110 as follows:

PART 110—COUNTERMEASURES INJURY COMPENSATION PROGRAM

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 42 U.S.C. 247d–6e.

■ 2. Add § 110.100 to subpart K to read as follows:

§ 110.100 Injury Tables.

(a) *Pandemic influenza countermeasures injury table.*

Covered countermeasures under Secretarial declarations	Serious physical injury (illness, disability, injury, or condition) [1]	Time interval (for first symptom or manifestation of onset of injury after administration or use of covered countermeasure, unless otherwise specified)
I. Pandemic influenza vaccines administered by needle into or through the skin.	A. Anaphylaxis	A. 0–4 hours.
	B. Deltoid Bursitis	B. 0–48 hours.
	C. Vasovagal Syncope	C. 0–1 hour.
II. Pandemic influenza intranasal vaccines	A. Anaphylaxis	A. 0–4 hours.
III. Pandemic influenza 2009 H1N1 vaccine	A. Guillain-Barré Syndrome	A. 3–42 days (not less than 72 hours and not more than 42 days).
IV. Oseltamivir Phosphate (Tamiflu) when administered or used for pandemic influenza.	A. Anaphylaxis	A. 0–4 hours.
V. Zanamivir (Relenza) when administered or used for pandemic influenza.	A. Anaphylaxis	A. 0–4 hours.
VI. Peramivir when administered or used for 2009 H1N1 influenza.	A. Anaphylaxis	A. 0–4 hours.
VII. Pandemic influenza personal respiratory protection devices.	A. No condition covered [2]	A. Not applicable.
VIII. Pandemic influenza respiratory support devices.	A. Postintubation Tracheal Stenosis	A. 2–42 days (not less than 48 hours and not more than 42 days) after extubation (removal of a tracheostomy or endotracheal tube).
	B. Ventilator-Associated Pneumonia and Ventilator-Associated Tracheobronchitis.	B. More than 48 hours after intubation (placement of an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).
	C. Ventilator-Induced Lung Injury	C. Throughout the time of intubation (breathing through an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).
IX. Pandemic influenza respiratory support device: Extra-corporeal membrane oxygenation (ECMO).	A. Bleeding Events	A. Throughout the time of anticoagulation treatment for ECMO therapy, including the time needed to clear the effect of the anticoagulant treatment from the body.
X. Pandemic influenza diagnostic testing devices.	A. No condition covered	A. Not applicable.

[1] Serious physical injury as defined in 42 CFR 110.3(z). Only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability will be considered serious physical injuries.

[2] The use of "No condition covered" in the Table reflects that the Secretary at this time does not find compelling, reliable, valid, medical and scientific evidence to support that any serious injury is presumed to be caused by the associated covered countermeasure. For injuries alleged to be due to covered countermeasures for which there is no associated Table injury, requesters must demonstrate that the injury occurred as the direct result of the administration or use of the covered countermeasure. *See* 42 CFR 110.20(b), (c).

(b) *Qualifications and aids to interpretation (table definitions and requirements).* The following definitions and requirements shall apply to the Table set forth in this subpart and only apply for purposes of this subpart.

(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 *sequelae.* 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) *Deltoid bursitis.* Deltoid bursitis is an inflammation of the bursa that lies beneath the deltoid muscle and between the acromion process and the rotator cuff. Subdeltoid bursitis manifests with pain in the lateral aspect of the shoulder similar to rotator cuff tendonitis. The presence of tenderness on direct palpation beneath the acromion process distinguishes this bursitis from rotator cuff tendonitis. Similar to tendonitis, isolated bursitis will have full passive range of motion. Other causes of bursitis such as trauma (other than from vaccination), metabolic disorders, and systemic diseases such as rheumatoid arthritis, dialysis, and infection will not be considered Table injuries. This list is not exhaustive. The deltoid bursitis must occur in the same shoulder that received the pandemic influenza vaccine.

(3) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and loss of postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected countermeasure. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant *sequelae.* 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. 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; psychiatric conditions; seizures; trauma; and situational as can occur with urination, defecation, or cough. This list is not complete. Episodes of recurrent syncope occurring after the applicable time period are not considered to be *sequelae* of an episode of syncope meeting the Table requirements.

(4) *Guillain-Barré Syndrome (GBS).* (i) GBS is an acute monophasic peripheral neuropathy that currently is known to encompass 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 bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs; a monophasic illness pattern; an interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse); and, the absence of an identified more likely alternative diagnosis. Death may occur without a clinical plateau.

(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 bilateral ophthalmoparesis; bilateral reduced or absent tendon reflexes; ataxia; the absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP); a monophasic illness pattern; an interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse); no alteration in consciousness; no corticospinal track signs; and, the absence of an identified more likely alternative diagnosis. Death may occur without a clinical plateau.

(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. The results of both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) For GBS to qualify as a Table injury there must not be a more likely alternative diagnosis for the weakness. 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.

(5) *Tracheal stenosis.* (i) Postintubation tracheal stenosis means an iatrogenic (caused by medical treatment) and symptomatic stricture of the airway (narrowing of the windpipe) resulting from:

(A) Trauma or necrosis from an endotracheal tube; or

(B) Stomal injury from a tracheostomy; or

(C) A combination of the two.

(ii) Tracheal stenosis or narrowing due to tumors (malignant or benign), infections of the trachea (such as

tuberculosis, fungal diseases), radiotherapy, tracheal surgery, trauma, congenital, and inflammatory or autoimmune diseases will not be considered post-intubation tracheal stenosis. Post-intubation tracheal stenosis requires either tracheostomy with placement of a tracheostomy tube or endotracheal intubation. Diagnosis requires symptoms of upper airway obstruction such as stridor (inspiratory wheeze) or exertional dyspnea (increased shortness of breath with exertion), and positive radiologic studies showing abnormal narrowing of the trachea or bronchoscopic evaluation that demonstrates abnormal narrowing.

(6) *Ventilator-Associated Pneumonia (VAP) and Ventilator-Associated Tracheobronchitis (VAT).* (i) VAP is defined as an iatrogenic pneumonia caused by the medical treatment of mechanical ventilation. Similarly, VAT is an iatrogenic infection of the trachea and/or bronchi caused by mechanical ventilation. The initial manifestation of VAP and VAT must occur more than 48 hours after intubation (placement of the breathing tube) and up to 48 hours after extubation (removal of the breathing tube). VAP will be considered to be present when the patient demonstrates a new or progressive radiographic infiltrate that is in the lungs and consistent with pneumonia, fever, leukocytosis (increased white blood cell count) or leucopenia (decreased white blood cell count), purulent (containing pus) tracheal secretions from a tracheal aspirate, and a positive lower respiratory tract culture. The positive lower respiratory tract culture is a diagnostic requirement only if there has not been a change in antibiotics in the 72 hours prior to collection of the culture. In addition, a tracheal aspirate that does not demonstrate bacteria or inflammatory cells in a patient without a change in antibiotics in the previous 72 hours is unlikely to be VAP and shall not be considered a condition set forth in the Table.

(ii) VAT will be considered to be present when the patient demonstrates fever, leukocytosis or leukopenia, purulent tracheal secretions, and a positive tracheal aspirate culture in the absence of a change of antibiotics within the 72 hours prior to culture. Tracheal colonization with microorganisms is common in intubated patients, but in the absence of clinical findings is not a sign of VAT.

(7) *Ventilator-Induced Lung Injury (VILI).* VILI results from mechanical trauma such as volutrauma leading to rupture of alveoli (air sacs in the lungs where oxygen and carbon dioxide are exchanged with the blood) with subsequent abnormal leakage of air. VILI manifests as iatrogenic pneumothorax (abnormal air from alveolar rupture in the pleural space), pneumomediastinum (abnormal air from alveolar rupture in the mediastinum (middle part of the chest between the lungs)), pulmonary interstitial emphysema (abnormal air in the lung interstitial space between the alveoli), subpleural air cysts (an extreme form of pulmonary emphysema where the abnormal air in the interstitial space has pooled into larger pockets), subcutaneous emphysema (abnormal air from alveolar rupture that has dissected into the skin), pneumopericardium (abnormal air from alveolar rupture that has traveled to the pericardium (covering of the heart)), pneumoperitoneum (abnormal air from alveolar rupture that has moved into the abdominal space), or systemic air embolism (abnormal air from alveolar rupture that has moved into the blood). To qualify as Table injuries, these manifestations must occur in patients who are being mechanically ventilated at the time of initial manifestation of the VILI.

(8) *Bleeding events.* Bleeding events are defined as excessive or abnormal bleeding in patients who are under the pharmacologic effects of anticoagulant therapy provided for extracorporeal membrane oxygenation (ECMO) treatment.

(c) *Covered countermeasures.* The Office of the Secretary publishes Secretarial declarations on the following covered countermeasures in the **Federal Register**:

(1) Pandemic influenza vaccines;
(2) Tamiflu;
(3) Relenza;
(4) Peramivir;
(5) Personal respiratory protection devices;
(6) Respiratory support devices;
(7) Diagnostic testing devices.

[FR Doc. 2015–19228 Filed 8–6–15; 8:45 am]
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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2014–0008; 4500030113]

RIN 1018–BA32

Endangered and Threatened Wildlife and Plants; 4(d) Rule for the Georgetown Salamander

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, finalize a rule under authority of section 4(d) of the Endangered Species Act of 1973, as amended, that provides measures that are necessary and advisable to provide for the conservation of the Georgetown salamander *(Eurycea naufragia)*, a species that occurs in Texas. This final 4(d) rule will provide the Service the opportunity to work cooperatively, in partnership with the local community and State agencies, on conservation of the Georgetown salamander and the ecosystems on which it depends.

This 4(d) rule is necessary and advisable to provide for the conservation of the Georgetown salamander because it strengthens water quality protection measures throughout the species' range, allows for consideration of new information to optimize conservation measures, and furthers conservation partnerships that can be leveraged to improve the status of the Georgetown salamander.

DATES: This rule is effective September 8, 2015.

ADDRESSES: This final rule, the final environmental assessment, and a list of references cited are available on the Internet at *http://www.regulations.gov* under Docket No. FWS–R2–ES–2014–0008, or by mail from the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). Comments and materials we received are available for public inspection at *http://www.regulations.gov*. All of the comments, materials, and documentation that we considered in this rulemaking are available by appointment, during normal business hours at the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Adam Zerrenner, Field Supervisor, U.S. Fish and Wildlife Service, Austin Ecological Services Field Office, 10711 Burnet Rd., Suite 200, Austin, TX 78758; telephone 512–490–0057; facsimile 512–490–0974. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Previous Federal Actions

On August 22, 2012, we published a proposed rule in the **Federal Register** (77 FR 50768) to list the Georgetown salamander (*Eurycea naufragia*), Salado salamander (*Eurycea chisholmensis*), Jollyville Plateau salamander (*Eurycea*

7

7.1

Influenza Activity — United States, 2014–15 Season and Composition of the 2015–16 Influenza Vaccine

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(Author affiliations at end of text)

During the 2014–15 influenza season in the United States, influenza activity* increased through late November and December before peaking in late December. Influenza A (H3N2) viruses predominated, and the prevalence of influenza B viruses increased late in the season. This influenza season, similar to previous influenza A (H3N2)–predominant seasons, was moderately severe with overall high levels of outpatient illness and influenza-associated hospitalization, especially for adults aged ≥65 years. The majority of circulating influenza A (H3N2) viruses were different from the influenza A (H3N2) component of the 2014–15 Northern Hemisphere seasonal vaccines, and the predominance of these drifted viruses resulted in reduced vaccine effectiveness (*1*). This report summarizes influenza activity in the United States during the 2014–15 influenza season (September 28, 2014–May 23, 2015)† and reports the recommendations for the components of the 2015–16 Northern Hemisphere influenza vaccine.

Viral Surveillance

During September 28, 2014–May 23, 2015, World Health Organization (WHO) and National Respiratory and Enteric Virus Surveillance System collaborating laboratories in the United States tested 691,952 specimens for influenza viruses; 125,462 (18.1%) were positive (Figure 1). Of the positive specimens, 104,822 (83.5%) were influenza A viruses, and 20,640 (16.5%) were influenza B viruses. Among the seasonal influenza A viruses, 52,518 (50.1%) were subtyped; 52,299 (99.6%) were influenza A (H3N2) viruses, and 219 (0.2%) were A (H1N1)pdm09 viruses. In addition, three variant influenza A viruses§ (one H3N2v and two H1N1v) were identified.

Through the peak of the 2014–15 season, H3N2 viruses predominated nationally, with lesser numbers of influenza B viruses and influenza A (H1N1)pdm09 viruses also identified. Based on the percentage of specimens testing positive for influenza to determine the peak of influenza activity, the peak occurred during week 52 (the week ending December 27, 2014) nationally; however, differences among U.S. Department of Health and Human Services regions¶ were observed in the timing of influenza activity and relative proportions of circulating viruses. Activity in region 7 peaked earliest, during the week ending December 13, 2014 (week 50), and activity in region 1 peaked latest, during the week ending January 24, 2015 (week 3).

Although H3N2 activity peaked between late December and early January, substantial influenza B activity occurred late in the season. Influenza A viruses predominated until late February, with influenza B viruses predominating from the week ending February 28, 2015 (week 8) through the week ending May 23, 2015 (week 20). The highest proportion of influenza B viruses was observed in Region 4 (19.8%), and the lowest proportion of influenza B viruses was detected in Region 10 (11.1%).

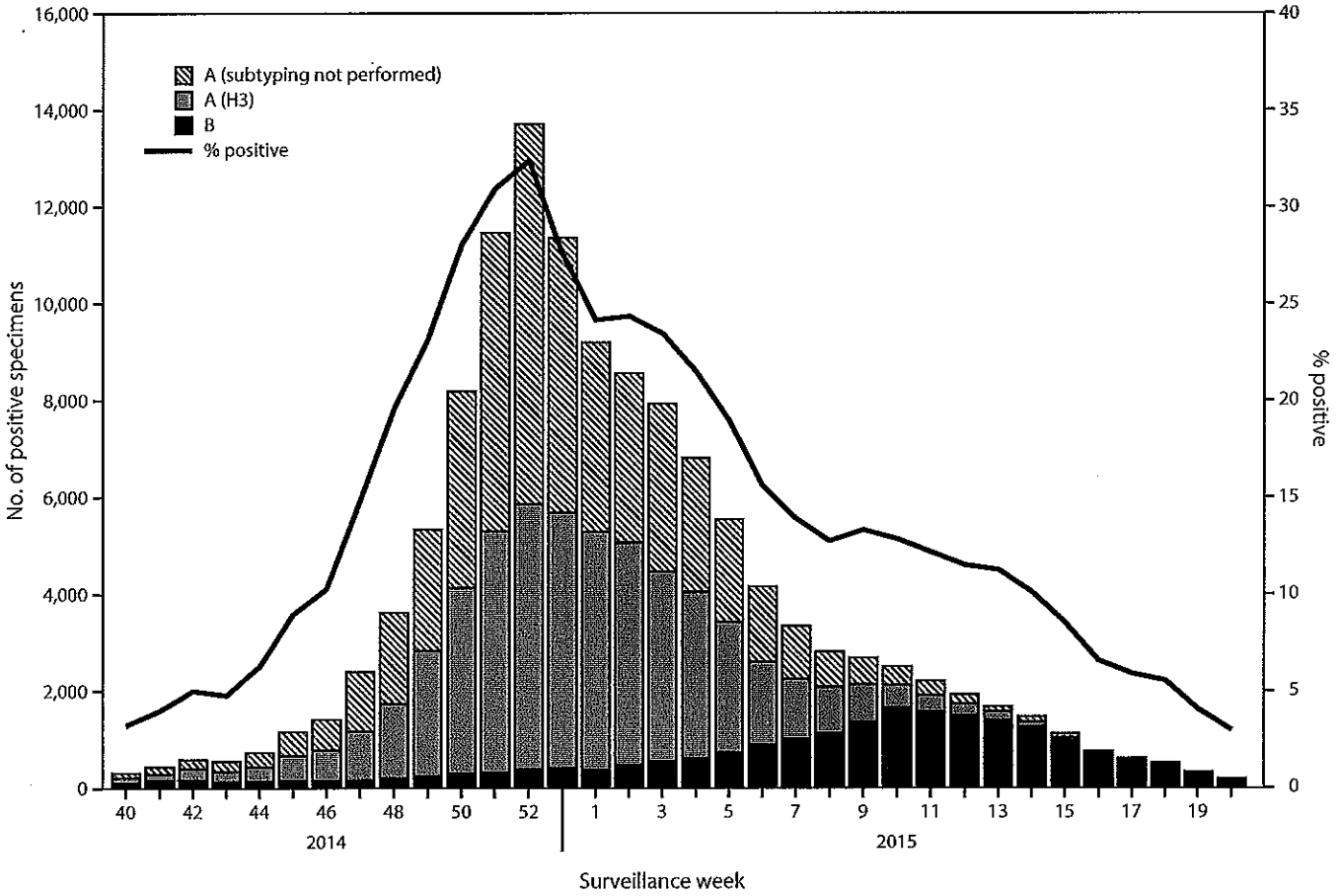
*The CDC influenza surveillance system collects information in five categories from eight data sources: 1) viral surveillance (World Health Organization collaborating laboratories, the National Respiratory and Enteric Virus Surveillance System, and novel influenza A virus case reporting); 2) outpatient illness surveillance (U.S. Outpatient Influenza-Like Illness Surveillance Network); 3) mortality (122 Cities Mortality Reporting System and influenza-associated pediatric mortality reports); 4) hospitalizations (Influenza Hospitalization Surveillance Network [FluSurv-NET], which includes the Emerging Infections Program and surveillance in three additional states); and 5) summary of the geographic spread of influenza (state and territorial epidemiologist reports).

†Data as of May 23, 2015.

§Influenza viruses that normally circulate in pigs are called "variant" viruses when they are found in humans. Influenza A (H3N2) variant viruses ("H3N2v" viruses) with the matrix (M) gene from the 2009 H1N1 pandemic virus were first detected in humans in July 2011. Since then, 352 cases of H3N2v infection have been confirmed in humans, mostly associated with prolonged exposure to pigs at agricultural fairs. Of the other variant viruses, to date, 19 cases of H1N1v and five cases of H1N2v have been detected in humans.

¶*Region 1:* Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. *Region 2:* New Jersey, New York, Puerto Rico, and the U.S. Virgin Islands. *Region 3:* Delaware, the District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. *Region 4:* Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. *Region 5:* Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. *Region 6:* Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. *Region 7:* Iowa, Kansas, Missouri, and Nebraska. *Region 8:* Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. *Region 9:* Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau. *Region 10:* Alaska, Idaho, Oregon, and Washington.

FIGURE 1. Number* and percentage of respiratory specimens testing positive for influenza reported by World Health Organization and National Respiratory and Enteric Virus Surveillance System collaborating laboratories, by type, subtype, and surveillance week — United States, 2014–15 influenza season†



* N = 125,462.
† Data as of May 23, 2015.

Novel Influenza A Viruses

During the 2014–15 influenza season, three cases of human infection with novel influenza A viruses have been reported. One infection with an influenza A (H3N2) variant virus occurred during the week ending October 18, 2014 (week 42) in Wisconsin, and one infection with an influenza A (H1N1) variant (H1N1v) virus was reported to CDC during the week ending January 24, 2015 (week 3) from Minnesota. Both patients had illness onset in October 2014 and reported contact with swine in the week preceding illness. Both patients fully recovered, and no further cases were identified in contacts of either patient, The third case, a fatal infection with an H1N1v virus was reported from Ohio during the week ending April 2, 2015 (week 17). The patient worked at a livestock facility that housed swine, but no direct contact with swine in the week before illness onset was reported. The patient died from complications of the infection, and no ongoing human-to-human transmission was identified.

Antigenic and Genetic Characterization of Influenza Viruses

WHO collaborating laboratories in the United States are requested to submit a subset of their influenza-positive respiratory specimens to CDC for further virus characterization. CDC has antigenically and/or genetically characterized**

** CDC routinely uses hemagglutination inhibition (HI) assays to antigenically characterize influenza viruses year-round to compare how similar currently circulating influenza viruses are to those included in the influenza vaccine, and to monitor for changes in circulating influenza viruses. However, a portion of recent influenza A (H3N2) viruses did not yield sufficient hemagglutination titers for antigenic characterization by HI. For many of these viruses, CDC performed genetic characterization to infer antigenic properties and is also using alternative methods (e.g., focus forming unit reduction) for antigenic characterization.

2,193 influenza viruses collected and submitted by U.S. laboratories since October 1, 2014, including 59 influenza A (H1N1)pdm09 viruses, 1,324 influenza A (H3N2) viruses, and 810 influenza B viruses. Of the 59 influenza A (H1N1)pdm09 viruses tested, all were antigenically similar to A/California/7/2009, the influenza A (H1N1) component of the 2014–15 Northern Hemisphere influenza vaccine.

A total of 246 (18.6%) of the 1,324 H3N2 viruses tested have been characterized as A/Texas/50/2012-like, the influenza A (H3N2) component of the 2014–15 Northern Hemisphere influenza vaccine. A total of 1,078 (81.4%) of the 1,324 viruses tested showed either reduced titers with antiserum produced against A/Texas/50/2012 or belonged to a genetic group that typically shows reduced titers to A/Texas/50/2012. The viruses that showed reduced titers to A/Texas/50/2012 belonged to multiple genetic groups; most but not all were antigenically similar to the influenza A (H3N2) virus selected in September 2014 for the 2015 Southern Hemisphere and in February 2015 for the 2015–16 Northern Hemisphere influenza vaccines, A/Switzerland/9715293/2013. A total of 948 of the 1,324 A (H3N2) viruses were further characterized; 889 (93.7%) were antigenically similar to A/Switzerland/9715293/2013, and fifty-nine (6.2%) showed reduced titers with antiserum produced against A/Switzerland/9715293/2013 virus.

Of the 810 influenza B viruses tested, 582 (71.9%) belonged to the B/Yamagata lineage, and the remaining 228 (28.1%) influenza B viruses tested belonged to the B/Victoria/02/87 lineage. A total of 571 (98.1%) of the 582 B/Yamagata-lineage viruses were characterized as B/Massachusetts/2/2012-like, which was included as an influenza B component of the 2014–15 Northern Hemisphere trivalent and quadrivalent influenza vaccines. Eleven (1.9%) of the B/Yamagata-lineage viruses tested showed reduced titers to B/Massachusetts/2/2012. Among the 582 B/Yamagata lineage viruses characterized, 576 (98.9%) viruses were antigenically similar to B/Phuket/3073/2013 virus, the B/Yamagata lineage virus selected for the 2015 Southern Hemisphere influenza vaccine and 2015–16 Northern Hemisphere influenza vaccine. Six (1.0%) showed reduced titers with antiserum produced against B/Phuket/3073/2013 virus. A total of 223 (97.8%) of the 228 B/Victoria-lineage viruses were characterized as B/Brisbane/60/2008-like, the virus that is included as an influenza B component of the 2014–15 Northern Hemisphere quadrivalent influenza vaccine. Five (2.2%) of the B/Victoria-lineage viruses tested showed reduced titers to B/Brisbane/60/2008.

Antiviral Resistance to Influenza Viruses

Since October 1, 2014, a total of 4,192 influenza virus specimens have been tested for resistance to influenza antiviral medications. All 896 influenza B viruses and 3,232 influenza A (H3N2) viruses tested were sensitive to oseltamivir and zanamivir. All 896 influenza B viruses and 1,723 influenza A (H3N2) viruses tested were sensitive to peramivir. Among 64 pH1N1 viruses tested for resistance, one (1.6%) was found to be resistant to oseltamivir and one (1.6%) to peramivir. All 58 influenza A (H1N1)pdm09 viruses tested for resistance to zanamivir were sensitive. High levels of resistance to the adamantanes (amantadine and rimantadine) persist among influenza A viruses currently circulating globally (the adamantanes are not effective against influenza B viruses).

Composition of the 2015–16 Influenza Vaccine

The Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee has recommended that the 2015–16 influenza trivalent vaccines used in the United States contain an A/California/7/2009 (H1N1)pdm09-like virus, an A/Switzerland/9715293/2013 (H3N2)-like virus, and a B/Phuket/3073/2013-like (B/Yamagata lineage) virus. It is recommended that quadrivalent vaccines, which have two influenza B viruses, contain the viruses recommended for the trivalent vaccines, as well as a B/Brisbane/60/2008-like (B/Victoria lineage) virus (*2*). This represents a change in the influenza A (H3) and influenza B (Yamagata lineage) components compared with the composition of the 2014–15 influenza vaccine. These vaccine recommendations were based on several factors, including global influenza virologic and epidemiologic surveillance, genetic characterization, antigenic characterization, antiviral resistance, and the candidate vaccine viruses that are available for production.

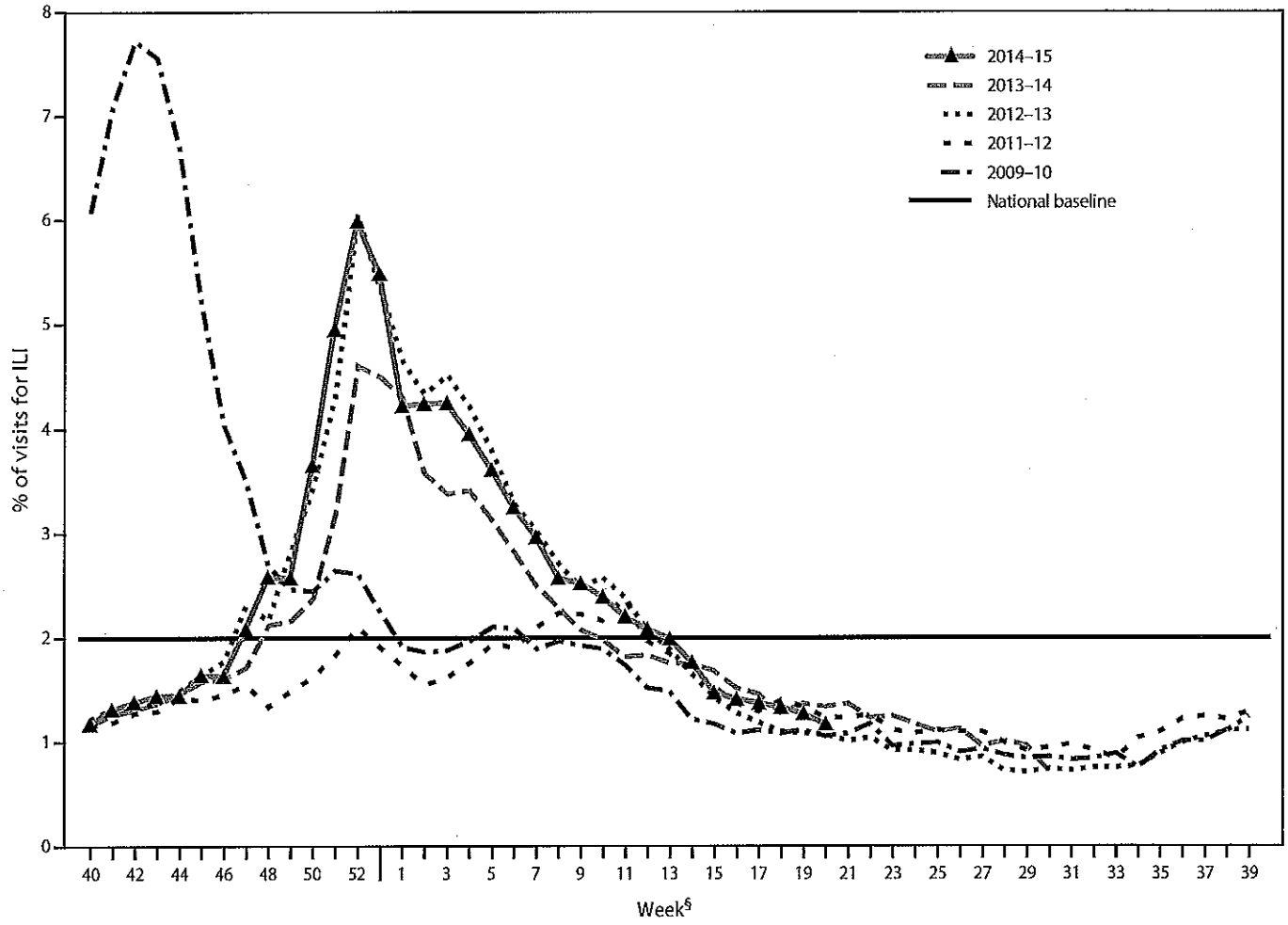
Outpatient Illness Surveillance

Nationally, the weekly percentage of outpatient visits for influenza-like illness (ILI)[††] to health care providers participating in the U.S. Outpatient Influenza-Like Illness Surveillance Network (ILINet) was at or above the national baseline level[§§] of 2.0% for 20 consecutive weeks during the 2014–15 influenza season (Figure 2). The peak percentage of outpatient visits for ILI was 6.0% and occurred in the week ending December 27, 2014 (week 52). During the 2001–02 through 2013–14 seasons, peak weekly percentages of outpatient visits

[††] Defined as a temperature of ≥100.0°F (≥37.8°C), oral or equivalent, and cough or sore throat, in the absence of a known cause other than influenza.

[§§] The national and regional baselines are the mean percentage of visits for ILI during weeks with little or no influenza virus circulation (non-influenza weeks) for the previous three seasons plus two standard deviations. A non-influenza week is defined as periods of ≥2 consecutive weeks in which each week accounted for <2% of the season's total number of specimens that tested positive for influenza. National and regional percentages of patient visits for ILI are weighted on the basis of state population. Use of the national baseline for regional data is not appropriate.

FIGURE 2. Percentage of visits for influenza-like illness (ILI)* reported to CDC, by surveillance week — Outpatient Influenza-Like Illness Surveillance Network, United States, 2014–15 influenza season and selected previous influenza seasons†



* Defined as a fever (≥100.0°F [≥37.8°C]), oral or equivalent, and cough and/or sore throat, without a known cause other than influenza.
† Data as of May 23, 2015.
§ Because there was no week 53 in the previous influenza seasons displayed, the week 53 data point for those seasons is an average of percentages from weeks 52 and 1.

for ILI ranged from 2.4% to 7.7% and remained at or above baseline levels for an average of 13 weeks (range = 1–19 weeks).

ILINet data are used to produce a weekly jurisdiction-level measure of ILI activity[¶¶] ranging from minimal to high. The number of jurisdictions experiencing elevated ILI activity peaked during the weeks ending December 27, 2014 (week 52) and January 24, 2015 (week 3), when a total of 31 states and Puerto Rico experienced high ILI activity. A total of 45 jurisdictions experienced high ILI activity during at least 1 week this season. The peak number of jurisdictions experiencing high ILI activity in a single week during the last five influenza seasons has ranged from four during the 2011–12 season to 44 during the 2009–10 season.

Geographic Spread of Influenza Activity

State and territorial epidemiologists report the geographic distribution of influenza in their jurisdictions through a weekly

¶¶ Activity levels are based on the percentage of outpatient visits in a jurisdiction attributed to ILI and are compared with the average percentage of ILI visits that occur during weeks with little or no influenza virus circulation. Activity levels range from minimal, which would correspond to ILI activity from outpatient clinics being at or below the average, to high, which would correspond to ILI activity from outpatient clinics being much higher than the average. Because the clinical definition of ILI is very nonspecific, not all ILI is caused by influenza; however, when combined with laboratory data, the information on ILI activity provides a clearer picture of influenza activity in the United States.

influenza activity code.*** The geographic distribution of influenza activity was most extensive during the weeks ending January 3, 2015 (week 53) and January 10, 2015 (week 1), when a total of 47 jurisdictions reported influenza activity as widespread. During the previous five seasons, the peak number of jurisdictions reporting widespread activity has ranged from 20 in the 2011–12 season to 49 in the 2010–11 season.

Influenza-Associated Hospitalizations

CDC monitors hospitalizations associated with laboratory-confirmed influenza virus infections using the FluSurv-NET††† surveillance system. Cumulative hospitalization rates (cases per 100,000 population) were calculated by age group based on 17,911 total hospitalizations resulting from influenza during October 1, 2014–April 30, 2015. Among 17,856 cases with influenza type specified, 15,271 (85.5%) were associated with influenza A and 2,473 (13.8%) with influenza B virus and 112 (0.6%) were associated with influenza A and influenza B coinfections; 55 had no virus type information available. Adults aged ≥65 years accounted for approximately 61.0% of reported cases. The cumulative incidence§§§ for all age groups since October 1, 2014, was 65.5 per 100,000 (Figure 3). The cumulative incidence rate (cases per 100,000 population) by age group for this period was 57.2 (0–4 years), 16.5 (5–17 years), 18.9 (18–49 years), 54.8 (50–64 years), and 322.8 (≥65 years). During the past four influenza seasons, age-specific hospitalization rates ranged from 16.0 to 67.0 (0–4 years), 4.0 to 14.6 (5–17 years), 4.2 to 21.5 (18–49 years), 8.1 to 53.7 (50–64 years), and 30.2 to 183.2 (≥65 years).

As of April 30, 2015, among the FluSurv-NET adult patients for whom medical chart data were available, the most frequent underlying conditions were cardiovascular disease (51.0%), metabolic disorders (45.8%) and obesity (33.1%). Among children hospitalized with laboratory-confirmed influenza and for whom medical chart data were available, 43.3% did not have any recorded underlying conditions, and 26.4% had underlying asthma or reactive airway disease. Among the 626 hospitalized women of childbearing age (15–44 years), 200 (31.9%) were pregnant.

Pneumonia and Influenza-Associated Mortality

During the 2014–15 influenza season, the percentage of deaths attributed to pneumonia and influenza (P&I) exceeded the epidemic threshold¶¶¶ for 8 consecutive weeks from January 3 to February 21, 2015 (weeks 53–7). The weekly percentage of deaths attributed to P&I ranged from 5.0% to 9.3% (Figure 4). The peak weekly percentages of deaths attributed to P&I for the previous five seasons ranged from 7.9% during the 2011–12 season to 9.9% during the 2012–13 season.

Influenza-Associated Pediatric Mortality

For the 2014–15 influenza season, as of May 23, 2015, a total of 141 laboratory-confirmed, influenza-associated pediatric deaths had been reported from 40 states and New York City. The deaths occurred in 14 children aged <6 months, 23 aged 6–23 months, 22 aged 2–4 years, 45 aged 5–11 years, and 37 aged 12–17 years; mean and median ages were 7.2 years and 5.9 years, respectively. Among the 141 deaths, 109 were associated with an influenza A virus, 29 were associated with an influenza B virus, two were associated with an influenza virus for which the type was not determined, and one was associated with an influenza A and influenza B virus coinfection.

Since influenza-associated pediatric mortality became a nationally notifiable condition in 2004, the total number of influenza-associated pediatric deaths had previously ranged from 34 to 171 per season; this excludes the 2009 pandemic, when 358 pediatric deaths were reported to CDC during April 15, 2009–October 2, 2010.

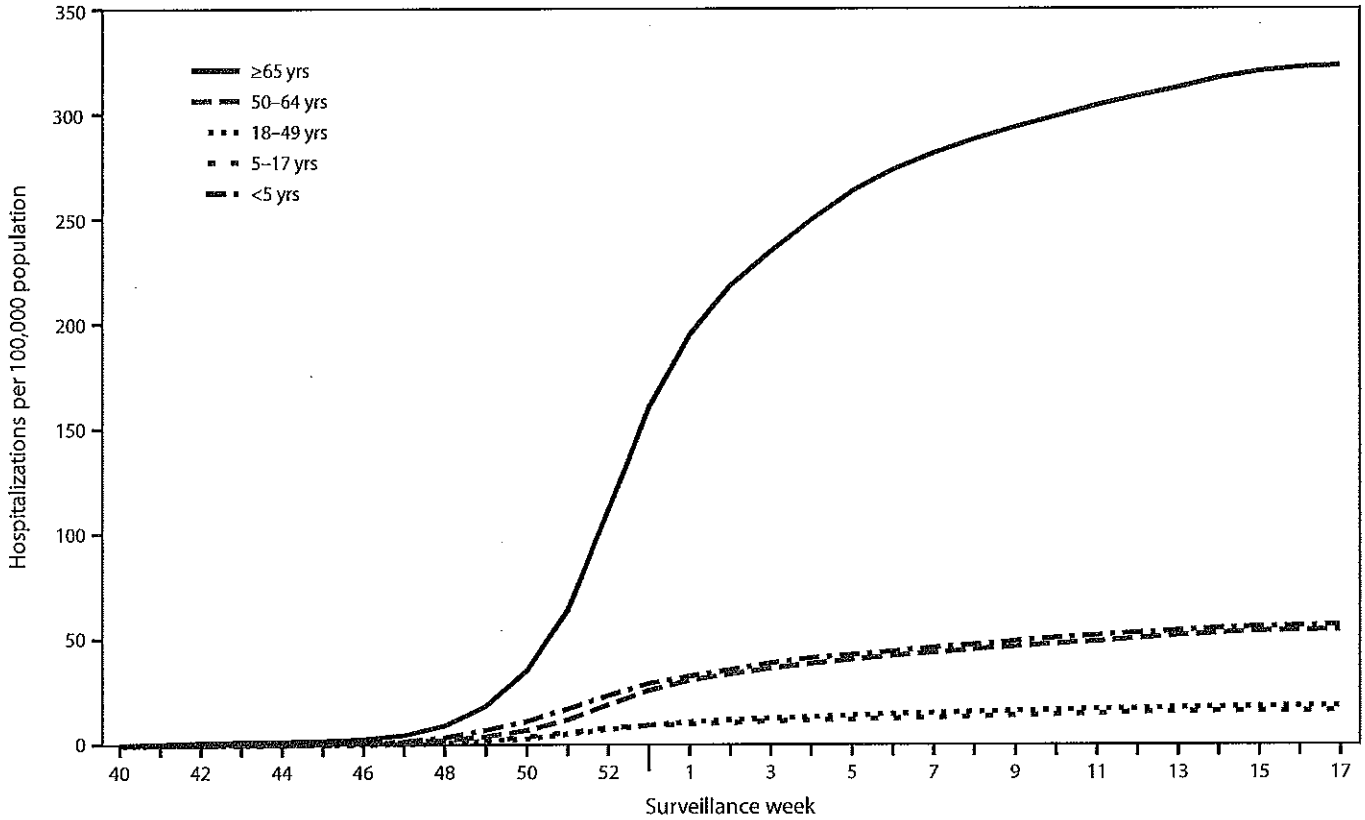
*** Levels of activity are 1) no activity; 2) sporadic: isolated laboratory-confirmed influenza case(s) or a laboratory-confirmed outbreak in one institution, with no increase in activity; 3) local: increased ILI, or at least two institutional outbreaks (ILI or laboratory-confirmed influenza) in one region of the state, with recent laboratory evidence of influenza in that region and virus activity no greater than sporadic in other regions; 4) regional: increased ILI activity or institutional outbreaks (ILI or laboratory-confirmed influenza) in at least two but less than half of the regions in the state with recent laboratory evidence of influenza in those regions; and 5) widespread: increased ILI activity or institutional outbreaks (ILI or laboratory-confirmed influenza) in at least half the regions in the state, with recent laboratory evidence of influenza in the state.

††† FluSurv-NET conducts population-based surveillance for laboratory-confirmed influenza-associated hospitalizations among children aged <18 years (since the 2003–04 influenza season) and adults aged ≥18 years (since the 2005–06 influenza season). FluSurv-NET covers approximately 70 counties in the 10 Emerging Infections Program states (California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee) and additional Influenza Hospitalization Surveillance Project (IHSP) states. IHSP began during the 2009–10 season to enhance surveillance during the 2009 H1N1 pandemic. IHSP sites included Iowa, Idaho, Michigan, Oklahoma, and South Dakota during the 2009–10 season; Idaho, Michigan, Ohio, Oklahoma, Rhode Island, and Utah during the 2010–11 season; Michigan, Ohio, Rhode Island, and Utah during the 2011–12 season; Iowa, Michigan, Ohio, Rhode Island, and Utah during the 2012–13 season; and Michigan, Ohio, and Utah during the 2013–14 and 2014–15 seasons.

§§§ Incidence rates are calculated using CDC's National Center for Health Statistics population estimates for the counties included in the surveillance catchment area. Laboratory confirmation is dependent on clinician-ordered influenza testing, and testing for influenza often is underutilized because of the poor reliability of rapid influenza diagnostic test results and greater reliance on clinical diagnosis for influenza. As a consequence, the number of cases identified as part of influenza hospitalization surveillance likely is an underestimation of the actual number of persons hospitalized with influenza.

¶¶¶ The seasonal baseline proportion of P&I deaths is projected using a robust regression procedure, in which a periodic regression model is applied to the observed percentage of deaths from P&I that were reported by the 122 Cities Mortality Reporting System during the preceding 5 years. The epidemic threshold is set at 1.645 standard deviations above the seasonal baseline.

FIGURE 3. Cumulative rates of hospitalization for laboratory-confirmed influenza, by age group and surveillance week — FluSurv-NET,* United States, 2014–15 influenza season†



* FluSurv-NET conducts population-based surveillance for laboratory-confirmed influenza-associated hospitalizations in children aged <18 years (since the 2003–04 influenza season) and adults aged ≥18 years (since the 2005–06 influenza season). FluSurv-NET covers approximately 80 counties in the 10 Emerging Infections Program states (California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee) and three additional Influenza Hospitalization Surveillance Project states (Michigan, Ohio, and Utah).

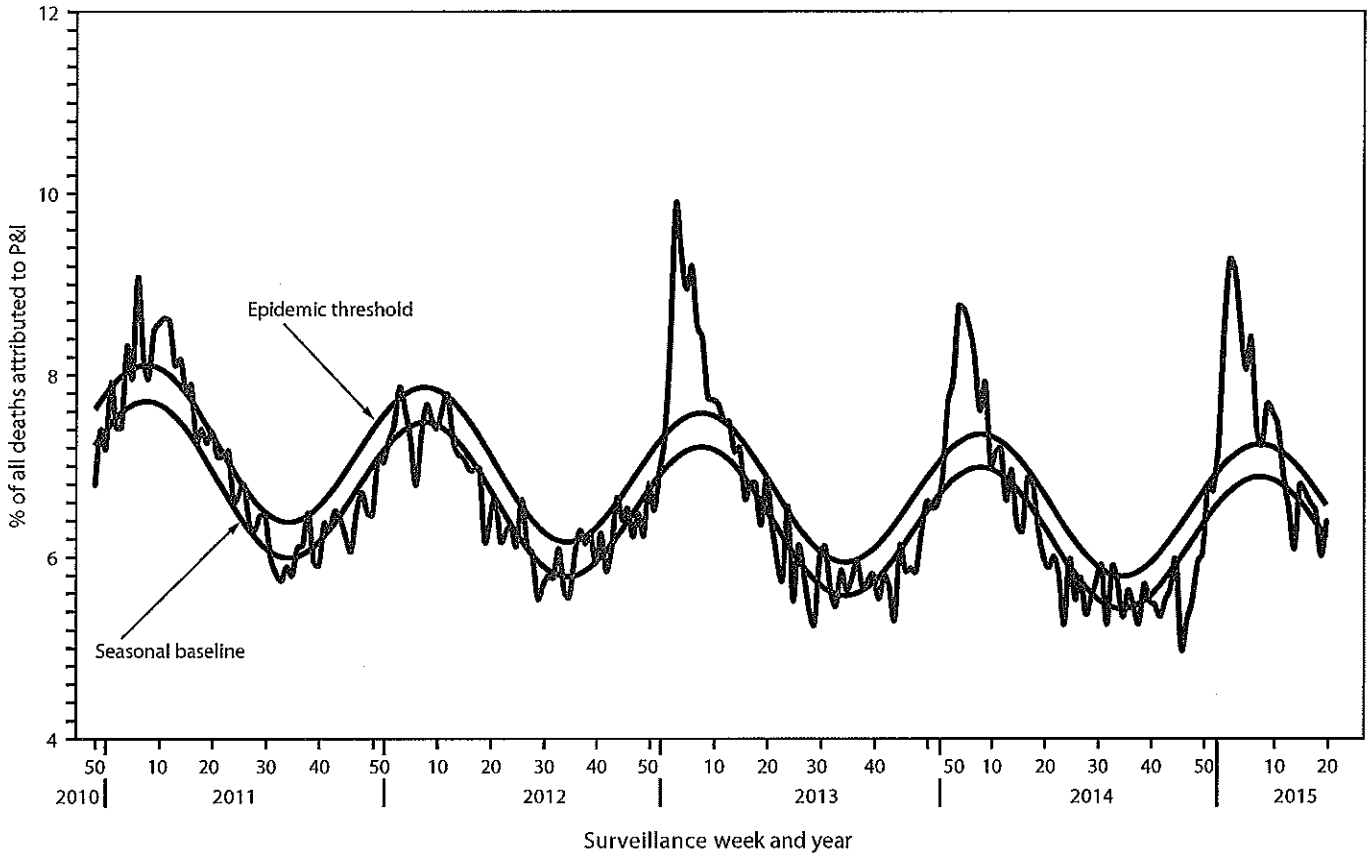
† Data as of May 23, 2015.

Discussion

The 2014–15 influenza season was moderately severe overall and especially severe in adults aged ≥65 years, with predominant circulation of antigenically and genetically drifted influenza A (H3N2) viruses. Influenza activity peaked during late December, with influenza A (H3N2) viruses predominant early in the season through the week ending February 21, 2015 (week 7). Influenza B became the predominant virus starting week 8 (the week ending February 28, 2015). The majority of influenza A (H3N2) viruses sent to CDC for antigenic and/or genetic characterization were different from the influenza A (H3N2) component of the 2014–15 Northern Hemisphere seasonal vaccines (A/Texas/50/2012).

Previous influenza A (H3N2)–predominant seasons have been associated with increased hospitalizations and deaths compared to seasons that were not influenza A (H3N2)–predominant, especially among children aged <5 years and adults aged ≥65 years (*3–6*). Influenza activity this season was similar to the 2012–13 season, which was the most recent influenza A (H3N2)–predominant season, but with higher rates of influenza-associated hospitalizations among adults aged ≥65 years. The cumulative rate of influenza-associated hospitalizations among this age group was 319.2 per 100,000 population, exceeding the cumulative total of 183.2 per 100,000 population for the 2012–13 season, which had previously been the highest recorded rate of laboratory-confirmed, influenza-associated hospitalizations since this type of surveillance began in 2005. Among children aged <5 years, the cumulative hospitalization rate (57.1 per 100,000 population) was slightly less than that observed during the 2012–13 season (66.2 per 100,000 population). Older adults also accounted for the majority of deaths attributed to P&I this season. Approximately 79.0% of the P&I deaths this season have occurred in adults aged ≥65 years, which is similar to what was observed during the 2012–13 influenza season (79.5%).

FIGURE 4. Percentage of all deaths attributable to pneumonia and influenza (P&I), by surveillance week and year* — 122 Cities Mortality Reporting System, United States, 2010–2015



* Data as of May 23, 2015.

However, the peak weekly percentage of deaths attributed to P&I for the current influenza season (9.3%) was lower than the peak observed during the 2012–13 influenza season (9.9%).

Influenza vaccination this season offered reduced protection against the predominant circulating viruses, drifted influenza A (H3N2), compared with previous seasons when most circulating and vaccine strain viruses were well-matched. Data collected during November 10, 2014–January 30, 2015, indicated that the influenza vaccine was 19% (95% confidence interval [CI] = 7%–29%) effective in preventing medical visits against all influenza across all age groups, and was 18% (CI = 6%–29%) and 45% (CI = 14%–65%) effective in preventing medical visits associated with influenza A (H3N2) and influenza B (Yamagata lineage), respectively (*7*). Despite reduced vaccine effectiveness, influenza vaccination was still recommended for all unvaccinated persons aged ≥6 months (*8,9*). Influenza vaccination provided protection against vaccine-like influenza A (H3N2) viruses that had not undergone significant antigenic drift and against influenza B viruses, which predominated later in the season (*1,3,6*). Of note, among the influenza A (H3N2) viruses, most, but not all, were antigenically similar to the influenza A (H3N2) virus selected for the 2015 Southern Hemisphere influenza vaccine (A/Switzerland/9715293/2013) (*1*).

Testing for seasonal influenza viruses and monitoring for novel influenza A virus infections should continue throughout the summer. Although summer influenza activity in the United States is typically low, influenza cases have occurred during the summer months and clinicians should remain vigilant in considering influenza in the differential diagnosis of summer respiratory illnesses. Health care providers also are reminded to consider novel influenza virus infections in persons with ILI, swine or poultry exposure, or with severe acute respiratory infection after travel to areas where avian influenza viruses have been detected. Providers should alert the local public health department if novel influenza virus infection is suspected. Early treatment with influenza antiviral medications is recommended for persons at high risk for influenza-associated complications,

What is already known on this topic?

CDC collects, compiles, and analyzes data on influenza activity year-round in the United States. Substantial influenza activity generally begins in the fall and continues through the winter and spring months; however, the timing and severity of influenza activity varies by geographic location and season.

What is added by this report?

The 2014–15 influenza season was an influenza A (H3N2)-predominant and moderately severe season overall, but was especially severe for adults aged ≥65 years. This age group had the highest laboratory-confirmed influenza hospitalization rates and also accounted for the majority of pneumonia and influenza deaths. Antigenic and genetic characterization showed that most of the circulating influenza A (H3N2) viruses were different from the influenza A (H3N2) component of the 2014–15 Northern Hemisphere vaccines, resulting in reduced vaccine effectiveness.

What are the implications for public health practice?

Influenza vaccination remains the most effective way to prevent influenza illness and its associated complications. Although vaccine effectiveness was reduced this season because of antigenic drift in H3N2 viruses, vaccination was still protective against vaccine-like influenza A (H3N2) viruses and influenza B viruses. Timely influenza surveillance informs vaccine strain selection; the influenza A (H3) and influenza B components of the subsequent 2015–16 season vaccine have been changed to more optimally match circulating viruses. As an adjunct to vaccination, timely empiric antiviral treatment is also recommended for all patients with severe, complicated, or progressive influenza illness and those at higher risk for influenza-associated complications, including adults aged ≥65 years.

as defined by the Advisory Committee on Immunization Practices, or with severe influenza illness. In randomized, controlled trials, antivirals have been shown to shorten the duration of influenza symptoms (*10*). In observational studies, influenza antiviral medications have reduced the risk for severe complications (*10*). Antiviral treatment decisions should not be delayed while awaiting laboratory confirmation of influenza; rather, treatment should be administered as soon as possible for any patient with confirmed or suspected influenza at high risk for influenza-associated complications (*10*).

Influenza surveillance reports for the United States are posted online weekly and are available at http://www.cdc.gov/flu/weekly. Additional information regarding influenza viruses, influenza surveillance, influenza vaccine, influenza antiviral medications, and novel influenza A infections in humans is available at http://www.cdc.gov/flu.

Acknowledgments

State, county, city, and territorial health departments and public health laboratories. U.S. World Health Organization collaborating laboratories. National Respiratory and Enteric Virus Surveillance System collaborating laboratories. U.S. Outpatient Influenza-Like Illness Surveillance Network sites. Influenza Hospitalization Surveillance Network. 122 Cities Mortality Reporting System.

[1]Influenza Division, National Center for Immunization and Respiratory Diseases, CDC.

Corresponding author: Grace D. Appiah, ydg3@cdc.gov, 404-639-3747.

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7.2

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US | Thu Jul 2, 2015 6:56pm EDT

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Washington state reports first U.S. measles death in 12 years

SEATTLE | BY ERIC M. JOHNSON

A previously undetected measles infection was found by an autopsy to be the underlying cause of a Washington state woman's death this spring, marking the first known U.S. fatality from the disease in 12 years, public health officials said on Thursday.

The woman from Clallam County, in northwestern Washington, was most likely exposed to measles at a medical facility during a recent outbreak in the area, the state Health Department said in a statement on its website.

She was there at the same time as another person who turned out to have been contagious with the virus. But the woman never developed some of the common symptoms of measles, such as a rash, so her infection was not discovered until after her death, the agency said.

Her precise immunization status was unknown, and though she had measles anti-bodies, the woman also had several other health conditions and was on medications that suppressed her immune system, Health Department spokesman Donn Moyer said.

The cause of her death was ruled by medical examiners as pneumonia due to measles, according to the agency.

People with compromised immune systems often cannot be vaccinated, and even if they are inoculated, such individuals may lack a strong immune response when exposed to infection, making them especially susceptible to outbreaks.

The agency cited the death to illustrate how vaccines for highly infectious diseases are important not just to protect the individual but to provide "herd" immunity for those most vulnerable among the public.

The last confirmed measles death in the United States was reported in 2003, according to the U.S. Centers for Disease Control and Prevention in Atlanta.

The latest death was reported two days after California Governor Jerry Brown signed a bill into law making it harder for parents in his state to opt out of vaccinating their children for communicable diseases.

That measure, passed by the Legislature in the aftermath of a measles outbreak at Disneyland that was linked to low inoculation rates, makes California the third state to abolish religious and other personal exemptions to vaccinations.

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The bill generated staunch opposition from some parents, many of whom feared a now-debunked link between childhood vaccines and autism and others who objected to what they saw as an intrusion on their religious faith.

State Senator Richard Pan, a Democrat and pediatrician who sponsored the bill, said the Washington death underscored the need to maximize vaccination rates.

He also pointed to a 4-year-old patient in hospice care in Los Altos, California, who he said was suffering complications from a measles infection contracted when the child was 5 months old and too young to be immunized.

(Writing and additional reporting by Steve Gorman from Los Angeles, additional reporting by Sharon Bernstein in Sacramento, California; Editing by Eric Walsh)

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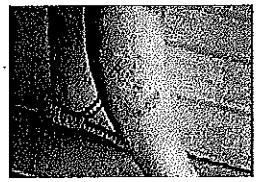

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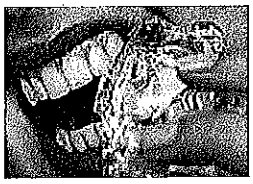

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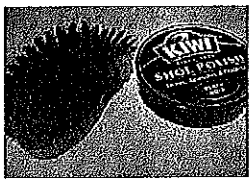

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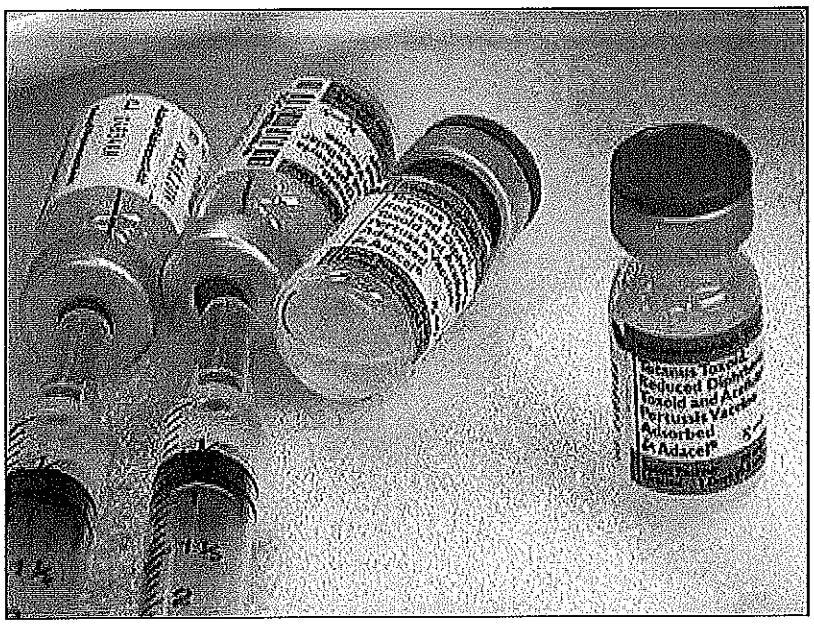
7.3

KOMO News

Whooping cough at 'outbreak levels' in Clark County

By *Mary Loos* | Published: Jul 13, 2015 at 7:39 AM PDT (2015-07-13T14:39:6Z)



Doses of the whooping cough vaccine are seen in a file photo.

VANCOUVER, Wash. – Health officials in Clark County are tracking cases of whooping cough to what they're calling "outbreak levels."

County Public Health Director, Dr. Alan Melnick, says 237 cases have been reported in Clark County so far this year. That's opposed to 21 at this time last year.

Symptoms can start just like a common cold; sneezing, having a runny nose, a mild cough, and a low-grade fever.

Those symptoms can worsen over the next two weeks and become cough fits, followed by a "whooping" noise and difficulty breathing.

Young children, especially infants who've not had all their vaccinations, can be particularly susceptible to the disease. It's easily transferred when someone coughs, sneezes or even talks.

Adults need at least one dose of the Tdap vaccine, especially if they have not had it before. If your child is 18 or under, your health care provider can provide the best course of action to get them protected.

Clark County has more information on free clinics and other places to get the vaccine (http://www.clark.wa.gov/public-health/diseases/whoopingcough.html).

7.4

Sanofi Pasteur Ships First 2015-2016 Seasonal Influenza Vaccine Doses in U.S.

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http://www.infectioncontroltoday.com/
By:
Posted on: 07/14/2015

PRINT

Sanofi Pasteur, the vaccines division of Sanofi, announced today that its first doses of Fluzone® (Influenza Vaccine) for the 2015-2016 influenza season have been released by the Food and Drug Administration (FDA) for shipment. This represents the first of more than 65 million total doses of seasonal influenza vaccine manufactured by Sanofi Pasteur that will be delivered to U.S. healthcare providers and pharmacies beginning in July and continuing throughout the 2015-2016 flu season.

According to the Centers for Disease Control and Prevention (CDC), the single best way to prevent influenza is to get an annual vaccination, which is recommended for everyone six months of age and older, with rare exception. In fact, during the 2013-2014 season, the CDC estimated influenza vaccination prevented 7.2 million influenza-associated illnesses, 3.1 million medically attended illnesses, and 90,000 hospitalizations.

"Influenza is a serious respiratory illness that is easily spread and can lead to severe complications involving the heart, lung, endocrine and other organ systems, potentially leading to death," says David P. Greenberg, MD, vice president of scientific and medical affairs, and chief medical officer, Sanofi Pasteur U.S. "Vaccination is important for high-risk age groups, including children and older adults. For older adults, vaccination is particularly important given their susceptibility to influenza and its complications due to an age-related weakening of the immune system."

Sanofi Pasteur will supply a wide portfolio of Fluzone influenza vaccine options this season to meet the immunization needs of multiple age groups, from children as young as 6 months of age through adults 65 years of age and older:
• Fluzone High-Dose vaccine is specially formulated for adults 65 years of age and older. As people age, the immune system weakens, which can put older adults at risk for influenza-related complications.iv Clinical data demonstrated that Fluzone High-Dose vaccine was 24.2 percent more effective than Fluzone vaccine in preventing laboratory-confirmed influenza caused by any influenza viral type or subtype in association with influenza-like illness, in adults 65 years of age and older.
• Fluzone Intradermal Quadrivalent vaccine, licensed by the FDA in 2014 for adults 18 through 64 years of age, will be available for the first time this influenza season. Fluzone Intradermal Quadrivalent vaccine offers four-strain protection in a microinjection system that is convenient, efficient, and easy to use, allowing for streamlined administration by health care providers. The vaccine is administered directly into the skin through a 90 percent smaller, 1.5 mm microneedle. As the skin has a high concentration of immune cells, an intradermal vaccine is able to use the skin's natural defenses to induce a robust immune response. In addition, the microinjection system is ideal for vaccine administrators, since it has a pre-affixed needle and an integrated needle shield.
• Fluzone Quadrivalent vaccine helps protect against four influenza strains (two A strains and two B strains), in contrast to trivalent influenza vaccines, which help protect against three strains (two A strains and only one B strain). The influenza B strain is associated with high hospitalization and mortality rates, especially in children and young adults. In fact, on average, over multiple recent seasons, 34 percent of influenza-related deaths in children up to 18 years of age were due to influenza B.vi Fluzone Quadrivalent vaccine is licensed for use in people six months of age and older.
• Fluzone vaccine, a trivalent influenza vaccine that protects against three influenza strains, is approved for use in people six months of age and older.

Healthcare providers who placed reservations with Sanofi Pasteur should expect to receive initial shipments by the end of August to support fall immunization campaigns. Healthcare providers wishing to reserve vaccine can do so by visiting www.vaccineshoppe.com or by calling 1-800-VACCINE (1-800-822-

2463). Members of the public seeking a specific vaccine option, such as Fluzone High-Dose vaccine, Fluzone Intradermal Quadrivalent vaccine, or Fluzone Quadrivalent vaccine, can search for local providers at www.Fluzone.com.

Source: Sanofi Pasteur

7.5

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™
Morbidity and Mortality Weekly Report (*MMWR*)

Pertussis and Influenza Vaccination Among Insured Pregnant Women — Wisconsin, 2013–2014

Weekly
July 17, 2015 / 64(27);746-750

Ruth Koepke, MPH1,2; Danielle Kahn, MSPH1; Ashley B. Petit, MPH1; Stephanie L. Schauer, PhD1; Daniel J. Hopfensperger1; James H. Conway, MD2; Jeffrey P. Davis, MD1 (Author affiliations at end of text)

On February 22, 2013, the Advisory Committee on Immunization Practices (ACIP) revised recommendations for vaccination of pregnant women to recommend tetanus-diphtheria-acellular pertussis vaccine (Tdap) during every pregnancy, optimally at 27–36 weeks of gestation, to prevent pertussis among their newborns (*1*). Since 2004, influenza vaccination has been recommended for pregnant women in any trimester to prevent influenza and associated complications for mother and newborn (*2*). To evaluate vaccination of pregnant women in Wisconsin after the 2013 Tdap recommendation, health insurance claims data for approximately 49% of Wisconsin births were analyzed. The percentage of women who received Tdap during pregnancy increased from 13.8% of women delivering during January 2013 (63.1% of whom received Tdap 2–13 weeks before delivery) to 51.0% of women delivering during March 2014 (90.9% of whom received Tdap 2–13 weeks before delivery). Among women delivering during November 2013–March 2014, 49.4% had received influenza vaccine during pregnancy. After the 2013 recommendation, Tdap vaccination among pregnant women increased but plateaued at rates similar to influenza vaccination rates. Prenatal care providers should implement, evaluate, and improve Tdap and influenza vaccination programs, and strongly recommend that pregnant patients receive these vaccines to prevent severe illness and complications among mothers and infants.

Infants too young for vaccination have the greatest risk for severe pertussis morbidity and mortality. Tdap vaccination of pregnant women stimulates production of maternal antipertussis antibodies which are transplacentally transported to the fetus, providing passive protection to newborn infants. Results of studies conducted in the United Kingdom indicate that Tdap vaccination during the third trimester is approximately 90% effective in preventing pertussis among infants aged <2 months (*3,4*). ACIP first recommended Tdap during pregnancy in 2011; women who had previously not received Tdap were recommended to receive it, preferably after 20 weeks of gestation (*5*). After the 2011 recommendation, Tdap vaccination rates among pregnant women were low (*6,7*), and results of antibody persistence studies suggested that Tdap vaccination before pregnancy or during early pregnancy might not provide sufficient levels of maternal antibodies to the fetus (*8*). Therefore, ACIP revised its recommendation to recommend Tdap during every pregnancy. Additionally, because ≥2 weeks are needed after Tdap vaccination for the mother to mount a maximal immune response and antibody transport across the placenta is greatest after 30 weeks of gestation, ACIP recommended Tdap administration to pregnant women at 27–36 weeks of gestation (*1*).

The Wisconsin Health Information Organization Datamart is a deidentified all-payer claims database that contains a rolling 24 months of medical and pharmacy claims data from Wisconsin Medicaid and most private insurance plans in Wisconsin.* Claims data were extracted from Datamart version 12, which included services during April 2012–March 2014. Pregnant women and their delivery dates were identified using *International Classification of Diseases, Ninth Revision* and *Current Procedural Terminology* (CPT) codes that indicate delivery.† Women aged 11–44 years with deliveries during the January 2013–March 2014 study period were included; each woman was included once. Vaccinations received by these women during April 2012–March 2014 were identified using CPT codes (Tdap, 90715; influenza, 90654–90662, 90672, 90673, 90685–90688, and 90724). Vaccination during the 40 weeks before the delivery date was considered vaccination during pregnancy. Because gestational age data were not available, vaccination 2–13 weeks before delivery was used to evaluate Tdap receipt during the recommended time. Percentages of women who received Tdap, influenza, or both vaccines during pregnancy were calculated by month and year of delivery. During delivery months November 2013–March 2014, an interval during influenza season when vaccination rates were stable, vaccination rates were compared by maternal age, county of residence, delivery provider specialty, and insurance type.

The study population included 40,054 women with deliveries during the study period and represented approximately 49% of deliveries in Wisconsin. Median maternal age was 28 years. Residents of the two most populous counties (Milwaukee and Dane) accounted for 33.9% of the women (Table). Most (75.6%) delivery providers were obstetrician/gynecologists; 65.8% of women were insured by Medicaid.

Among the 40,054 women, 14,033 (35.0%) received Tdap during pregnancy. The percentage of women who received Tdap during pregnancy increased from 13.8% among women delivering during January 2013 to 51.0% among women delivering during March 2014 (Figure 1). Among women who received Tdap during pregnancy, the percentage who received Tdap 2–

13 weeks before delivery increased from 63.1% among women delivering during January 2013 to 90.9% among women delivering during March 2014 (Figure 2).

Influenza vaccine was received during pregnancy by 15,501 (38.7%) women. The percentage of women who received influenza vaccine during pregnancy was lowest among women who delivered during July–September 2013 and higher among women who delivered during the 2012–13 and 2013–14 influenza seasons (Figure 1). Among women delivering during November 2013–March 2014, 49.4% received influenza vaccine during pregnancy. Receipt of both Tdap and influenza vaccines during pregnancy increased from 9.3% of women delivering during January 2013 to 34.7% of women delivering during November 2013–March 2014 (Figure 1).

Among 12,089 (30.2%) women delivering during November 2013–March 2014, vaccination rates were highest among women aged 30–34 years and lowest among women aged 11–19 years (Table). Dane County residents had higher vaccination rates than Milwaukee County and other Wisconsin residents. Women delivering to family medicine or general practitioner providers had higher vaccination rates than women delivering to obstetrician/gynecologists or nurse practitioners/midwives. Vaccination rates were higher among women with private insurance than women with Medicaid.

Discussion

After the February 2013 ACIP recommendation, Tdap vaccination of pregnant women in Wisconsin increased steadily but plateaued near 50% during November 2013–March 2014. During this 5-month period coinciding with the 2013–14 influenza season, a similar percentage of pregnant women were reported to have received influenza vaccine during pregnancy. However, only 34.7% received both vaccines during pregnancy. These findings indicate that despite the rapid implementation of Tdap vaccination among pregnant women in Wisconsin, many pregnant women did not receive both recommended vaccines, including women who demonstrated a willingness to receive at least one other vaccine during pregnancy.

To optimize the concentration of antipertussis antibodies transported across the placenta from mother to infant, ACIP recommends Tdap administration at 27–36 weeks of gestation, during the third trimester and ≥2 weeks before delivery. After the 2013 recommendation, the percentage of women vaccinated 2–13 weeks before delivery increased to 90.9% among Tdap-vaccinated pregnant women who delivered during March 2014. This finding indicates that among women vaccinated with Tdap during pregnancy, Tdap was typically received during the time expected to confer the greatest level of protection to the infant.

This study evaluated implementation of ACIP's 2013 Tdap recommendation among publicly and privately insured pregnant women across multiple health care providers. Tdap vaccination rates among women who delivered during January 2013 were similar to rates reported in other U.S. states before the February 2013 recommendation (*6,7*). After the 2013 recommendation, one Massachusetts hospital reported most (81.6%) pregnant patients had received Tdap, but most were vaccinated after 37 weeks of gestation (*9*). Results of a national Internet panel survey demonstrated that among women pregnant anytime during October 2013–January 2014, 34.6% reported receiving influenza vaccine during pregnancy (*10*).

Among characteristics examined in this study, Tdap and influenza vaccination rates during pregnancy were lowest among women who were aged <20 years, resided in Milwaukee County, were insured by Medicaid, and delivered to nurse practitioners or midwives, although nurse practitioners and midwives represented <8% of delivery providers. Previous studies of vaccination rates among pregnant women have identified differences by maternal age, race, poverty level, and prenatal care adequacy (*6,7,9,10*). These differences highlight the importance of public health programs using local data to identify disparities and target interventions to specific populations and health care providers. However, even among women in Wisconsin who delivered to family physicians and general practitioners, less than half had received both Tdap and influenza vaccine, and among those who delivered to obstetricians and gynecologists, only about one third had received both vaccines during November 2013–March 2014.

The findings in this report are subject to at least two limitations. First, only deliveries and vaccinations properly coded, paid by the insurer, and submitted to the Datamart database were included. Therefore, vaccination rates might be underestimated if vaccinations were received but not paid by the insurer, and the findings in this report are not generalizable to uninsured women, women insured by payers not included in the database, or women outside of Wisconsin. Second, because the database did not include gestational age data, neither the exact week of pregnancy during which Tdap was received nor the effect of preterm birth on vaccination during pregnancy could be evaluated.

Health care provider recommendation and offer of vaccination are among the strongest predictors of whether a woman will be vaccinated during pregnancy (*10*). Health care providers are encouraged to strongly recommend and offer Tdap and influenza vaccination during pregnancy and to use materials developed by CDC§ to educate patients regarding the importance of vaccination during pregnancy to prevent illness and severe complications among mothers and infants.

Acknowledgments

Sara Jensen, Wisconsin Health Information Organization, Madison; Karl Pearson, MS, Wisconsin Division of Public Health.

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* Additional information available at http://wisconsinhealthinfo.org/about.

† Additional information available at http://www.ncqa.org/portals/0/Prenatal%20Postpartum%20Care.pdf.

§ Available at http://www.cdc.gov/pertussis/pregnant/index.html and http://www.cdc.gov/pertussis/materials/pregnant.html.

Summary

What is already known on this topic?

Pertussis (whooping cough) incidence is increasing in the United States, including among infants, who are at highest risk for hospitalization and death. To prevent pertussis among newborn infants, pregnant women are recommended to receive tetanus-diphtheria-acellular pertussis vaccine (Tdap) during every pregnancy, a strategy that provides passive protection to the newborn infant. Additionally, pregnant women are recommended to receive influenza vaccine during pregnancy to prevent influenza-associated complications among mothers and infants.

What is added by this report?

After the 2013 Advisory Committee on Immunization Practices guidelines that recommended Tdap vaccination during every pregnancy, Tdap vaccination rates among privately and publicly insured pregnant women in Wisconsin increased quickly but plateaued at rates similar to influenza vaccination rates. Tdap and influenza vaccination rates were lowest among women who were younger, had public insurance, resided in Milwaukee County, and had nurse practitioners or midwives as delivery providers.

What are the implications for public health practice?

Collaboration among public health programs and providers of prenatal care is needed to identify and overcome barriers to improving vaccination rates among pregnant women.

TABLE Percentage of the study population who received Tdap, influenza, or both vaccines during pregnancy, by maternal and health care provider characteristics and delivery period — Wisconsin, January 2013–March 2014

Characteristic	Delivery period					
	January 2013–March 2014		November 2013–March 2014			
	Total	Tdap	Total	Tdap	Influenza	Both

	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Total study population	**40,054**	**(100.0)**	**14,033**	**(35.0)**	**12,089**	**(100.0)**	**5,992**	**(49.6)**	**5,970**	**(49.4)**	**4,194**	**(34.7)**
Maternal age at delivery (yrs)												
11–19	**2,604**	**(6.5)**	737	(28.3)	**849**	**(7.0)**	352	(41.5)	392	(46.2)	247	(29.1)
20–24	**9,818**	**(24.5)**	3,070	(31.3)	**2,979**	**(24.6)**	1,308	(43.9)	1,394	(46.8)	942	(31.6)
25–29	**12,482**	**(31.2)**	4,454	(35.7)	**3,801**	**(31.4)**	1,969	(51.8)	1,865	(49.1)	1,328	(34.9)
30–34	**10,276**	**(25.7)**	3,951	(38.4)	**3,029**	**(25.1)**	1,650	(54.5)	1,594	(52.6)	1,174	(38.8)
35–39	**4,069**	**(10.2)**	1,538	(37.8)	**1,203**	**(10.0)**	600	(49.9)	616	(51.2)	431	(35.8)
40–44	**805**	**(2.0)**	283	(35.2)	**228**	**(1.9)**	113	(49.6)	109	(47.8)	72	(31.6)
Maternal county of residence*												
Dane County	**5,075**	**(12.7)**	2,719	(53.6)	**1,614**	**(13.4)**	1,106	(68.5)	1,036	(64.2)	843	(52.2)
Milwaukee County	**8,477**	**(21.2)**	2,382	(28.1)	**2,423**	**(20.0)**	902	(37.2)	1,017	(42.0)	645	(26.6)
All other Wisconsin counties	**26,502**	**(66.2)**	8,932	(33.7)	**8,052**	**(66.6)**	3,984	(49.5)	3,917	(48.6)	2,706	(33.6)
Specialty of delivery provider†												
Family medicine/General practitioner	**5,417**	**(13.5)**	2,202	(40.6)	**1,604**	**(13.3)**	898	(56.0)	928	(57.9)	686	(42.8)
Nurse practitioner/Midwife	**3,150**	**(7.9)**	1,087	(34.5)	**922**	**(7.6)**	403	(43.7)	418	(45.3)	274	(29.7)
Obstetrician/Gynecologist	**30,299**	**(75.6)**	10,396	(34.3)	**9,182**	**(76.0)**	4,522	(49.2)	4,450	(48.5)	3,128	(34.1)
Type of insurance§												
Private	**13,617**	**(34.0)**	5,960	(43.8)	**4,194**	**(34.7)**	2,588	(61.7)	2,324	(55.4)	1,779	(42.4)
Medicaid	**26,337**	**(65.8)**	8,029	(30.5)	**7,880**	**(65.2)**	3,394	(43.1)	3,637	(46.2)	2,406	(30.5)

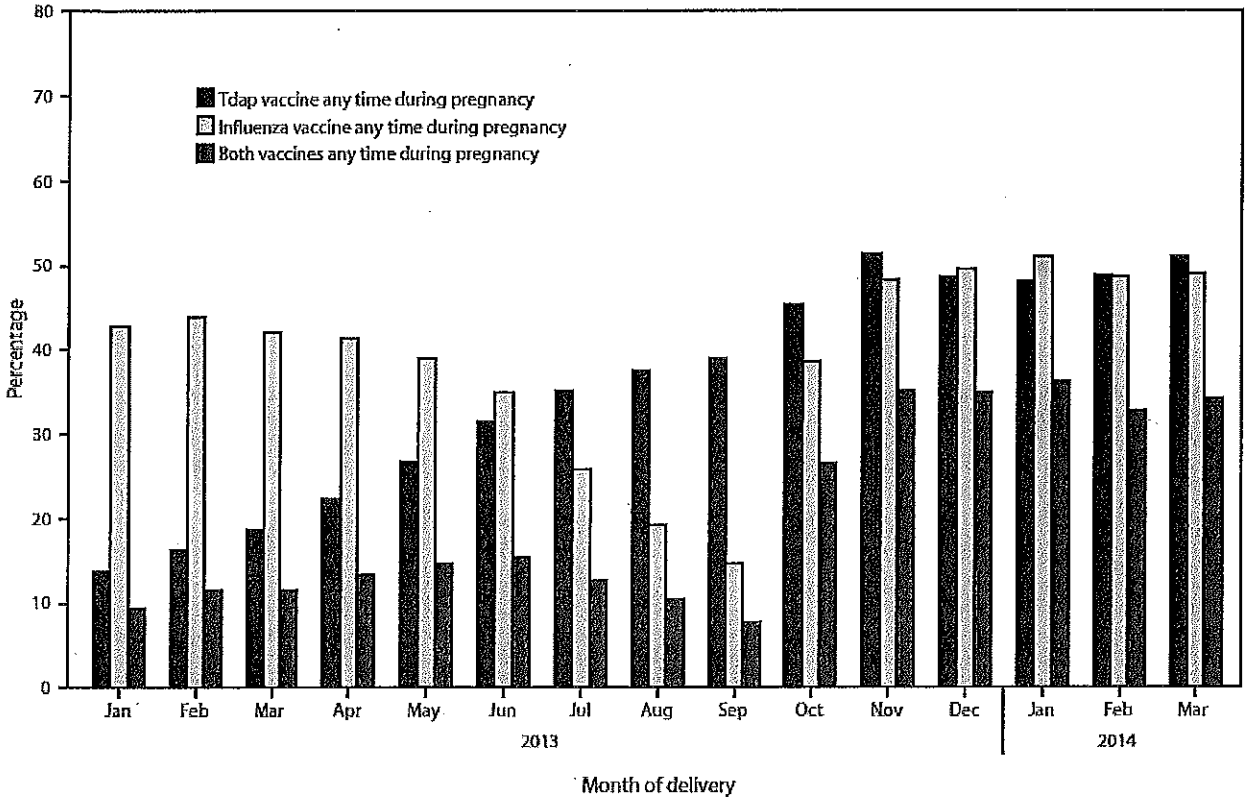
Abbreviation: Tdap = tetanus-diphtheria-acellular pertussis.

* U.S. Census Bureau estimate of percentage of population under federal poverty level during 2009–2013: Dane County, 12.9%; Milwaukee County, 21.6%; and Wisconsin, 13.0%.

† Data not shown for 1,188 deliveries with unknown provider specialty.

§ Data not shown for deliveries paid for by Medicare (four), the Federal Employee Program (47), or unknown type of insurance (49).

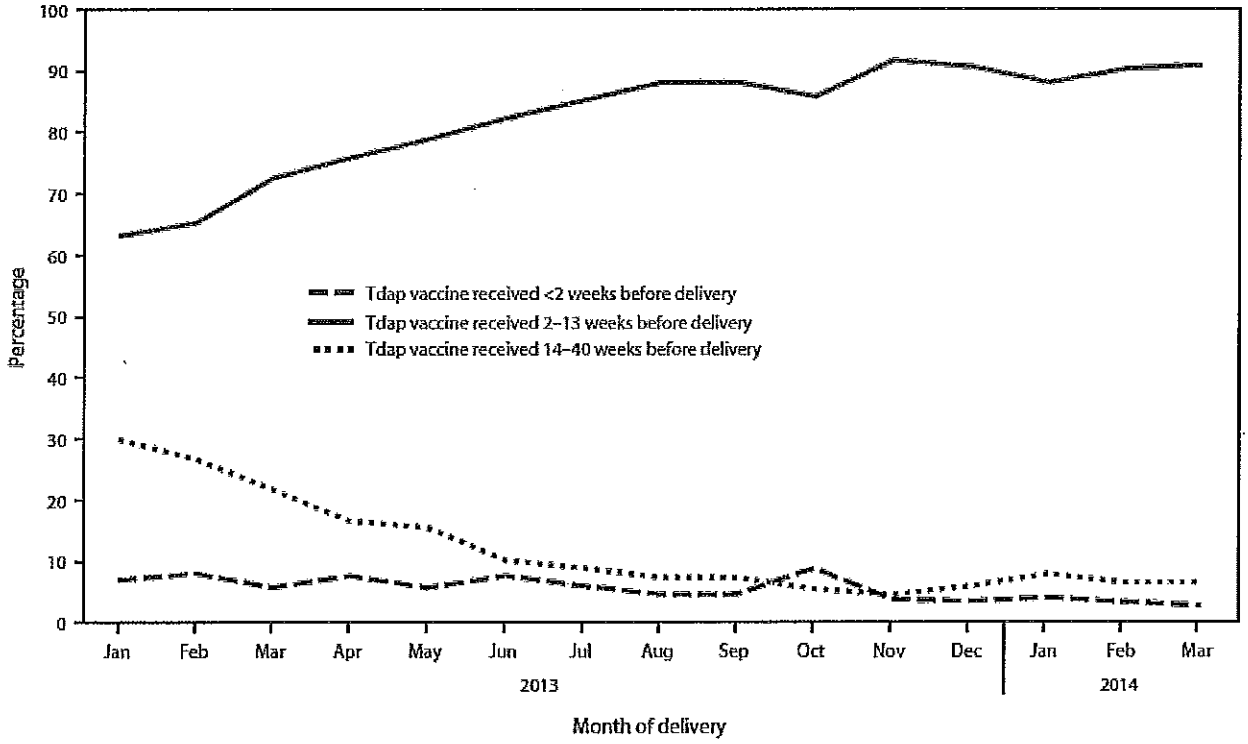
FIGURE 1. Percentage of the study population who received Tdap, influenza, or both vaccines during pregnancy, by month of delivery — Wisconsin, January 2013–March 2014



Abbreviation: Tdap = tetanus-diphtheria-acellular pertussis.

Alternate Text: The figure above is a bar chart showing the percentage of the study population who received Tdap, influenza, or both vaccines during pregnancy, by month of delivery, in Wisconsin during January 2013-March 2014.

FIGURE 2. Timing of Tdap vaccine receipt among women in the study population who received Tdap vaccine during pregnancy, by month of delivery — Wisconsin, January 2013–March 2014



Abbreviation: Tdap = tetanus-diphtheria-acellular pertussis.

Alternate Text: The figure above is a line chart showing the timing of Tdap vaccine receipt among women in the study population who received Tdap vaccine during pregnancy, by month of delivery in Wisconsin during January 2013-March 2014.

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Herzog, Andrea (HRSA)

From: Jean Public <jeanpublic1@yahoo.com>
Sent: Saturday, August 15, 2015 8:00 PM
To: Herzog, Andrea (HRSA); vicepresident@whitehouse.gov; americanvoices@mail.house.gov
Subject: Fw: lic pubcomment on federal register

parent ts should be making decsionos for their own childrens health. they dont need the drug pushers at this agency playng nany to them. adults can make their own decisions, they dont need drug pushers pushing them into deciions that turn their kids into autistic zombies. your vaccine schedule just pushes too many drugs into kids bodies. now you want to do the same to adults. shut down the adult vaccine workgroup. adults have brains to make their own deciisions and dont need drug pusherss ugly as they are to push them into anything. you guys think you are god evidently. i thnk you are the devil. this comment goes to every member. shut down the adult vaccine workgroup. cut the budget for this program by 50%immediately. this agency deeerves a grade of f minus. nobody need you drug purhsers. this commetn is for the publc record pleae receipt. jean publi jeanpublic1@gmail.com

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> Date: Saturday, August 15, 2015, 4:33 PM Federal Register Volume 80,
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> 157 (Friday, August 14, 2015)]
> [Notices]
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> DEPARTMENT OF HEALTH AND HUMAN SERVICES
>
> Health Resources and Services Administration
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>
> Advisory Commission on Childhood Vaccines; Notice of Meeting
>
> In accordance with section 10(a)(2) of the Federal Advisory
> Committee Act (Pub. L. 92-463), notice is hereby given of the
> following
> meeting:
>
> Name: Advisory Commission on Childhood Vaccines (ACCV).
> Date and Time: September 3,

> 2015, 9:00 a.m. to 4:30 p.m. EDT.
> Place: Parklawn Building (and via audio conference call and
> Adobe Connect), 5600 Fishers Lane, Room 10-65, Rockville, MD 20857.
> The ACCV will meet on Thursday,
> September 3, 2015, from 9:00
> a.m. to 4:30 p.m. (EDT). 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, DVIC, Healthcare Systems Bureau (HSB), Health Resources and
> Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane,
> Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Since this
> meeting is going to be held in a federal government building,
> attendees will need to go through a security check to enter the
> building and participate in the meeting. Written notification is
> encouraged so a list of attendees can be provided to Annie Herzog 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
> Mario Lombre at 301-443-3196. The meeting will be held at the
> Parklawn Building, 5600 Fishers Lane, Room 10-65, Rockville, Maryland
> 20857.
> 2. (Audio Portion) The conference Phone Number is 877-917-4913.
> When calling, provide the following information:
> Leaders Name: Dr. A. Melissa Houston.
> Password: ACCV.
> 3. (Visual Portion) Connect to the ACCV Adobe Connect Pro
> meeting using the following URL:
> https://hrsa.connectsolutions.com/accv/ (copy and paste the link into
> your browser if it does not work directly, and enter as a guest).
> Participants should call and connect 15 minutes prior to the meeting
> in order for logistics to be set up. If you have never attended an
> Adobe Connect meeting, please test your connection using the
> following URL:
> https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.
> htm and get a quick overview by following
> URL: http://www.adobe.com/go/connectpro_overview. Call (301)
> 443-6634 or send an email to
> aherzog@hrsa.gov if you are having trouble connecting to the meeting
> site.
> Agenda: The agenda items for the September 2015 meeting will
> include, but are not limited to: updates from ACCV Adult Immunization
> Workgroup, the Division of Injury Compensation Programs (DICP),
> Department of Justice (DOJ), National Vaccine Program Office (NVPO),
> Immunization Safety Office (Centers for Disease Control and
> Prevention), National Institute of Allergy and Infectious Diseases
> (National Institutes of Health), and Center for Biologics, Evaluation
> and Research (Food and Drug Administration). A draft agenda and
> additional meeting materials will be posted on the ACCV Web site

> (http://www.hrsa.gov/vaccinecompensation/accv.htm) prior to the
> meeting. Agenda items are subject to change as priorities dictate.
> Public Comment: Persons interested in providing an oral
> presentation should submit a written request, along with a copy of
> their presentation to: Annie Herzog, DICP, Healthcare Systems Bureau
> (HSB), Health Resources and Services Administration (HRSA), Room
> 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or
> email:
> aherzog@hrsa.gov. Requests should contain the name, address,
> telephone number, email address, and any business or professional
> affiliation of the person desiring to make an oral presentation.
> Groups having similar interests are requested to combine their
> comments and present them through a single representative.
> The
> allocation of time may be adjusted to accommodate the level of
> expressed interest. DICP will notify each presenter by email, mail,
> or telephone of their assigned presentation time. Persons who do not
> file an advance request for a presentation, but desire to make an
> oral statement, may announce it at the time of the public comment
> period. Public participation and ability to comment will be limited
> to space and time as it permits.
> For Further Information Contact: Anyone requiring information
> regarding the ACCV should contact Annie Herzog, DICP, HSB, HRSA, Room
> 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone
> (301) 443-6593, or email: aherzog@hrsa.gov.
>
> Jackie Painter,
> Director, Division of the Executive Secretariat.
> [FR Doc. 2015-20136 Filed 8-13-15; 8:45 am] BILLING CODE 4165-15-P