**ADVISORY COMMISSION ON CHILDHOOD VACCINES**
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**December 4, 2014**

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# *ADVISORY COMMISSION ON CHILDHOOD VACCINES*

## ***Agenda***

**DRAFT** November 24, 2014

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

**Teleconference and Adobe Connect**

December 4, 2014
(10:00 am – 4:15 pm Eastern Daylight Time)
Dial in: 1-877-917-4913
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| Time | Agenda Item | Presenter |
|---|---|---|
| 10:00 AM | Welcome and Chair Report | Dr. Kristen Feemster, Chair |
| 10:10 AM | Approval of September 2014 Minutes | Dr. Kristen Feemster, Chair |
| 10:15 AM | Update on the 27th Annual Judicial Conference | Chief Special Master Denise K. Vowel |
| 10:30 AM | Report from the Division Injury Compensation Programs | Dr. A. Melissa Houston<br>Director, DICP |
| 11:00 AM | Report from the Department of Justice | Mr. Vince Matanoski<br>Deputy Director<br>Torts Branch, DOJ |
| 11:30 AM | Report from the Process Workgroup | Ms. Luisita dela Rosa,<br>ACCV Member |
| 11:45 AM | Report from the Adult Immunization Workgroup | Dr. Sylvia Villarreal,<br>ACCV Member |
| 12:00 PM | Lunch | |
| 1:00 PM | Review of Vaccine Information Statements | Mr. Skip Wolfe,<br>CDC |
| 2:30 PM | Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities | Dr. Tom Shimabukuro<br>CDC |

| Time | Agenda Item | Presenter |
|---|---|---|
| 2:45 PM | Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities | Ms. Barbara Mulach<br>NIAID, NIH |
| 3:00 PM | Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities | LCDR Valerie Marshall<br>CBER, FDA |
| 3:15 PM | Update from the National Vaccine Program Office (NVPO) | Dr. Karin Bok<br>NVPO |
| 3:30 PM | Public Comment (follows the preceding topic and may commence earlier or later the 3:30 pm) | |
| 3:45 PM | Future Agenda Items/New Business | Dr. Kristen Feemster, Chair |
| 4:00 PM | Adjournment of the December ACCV Meeting | Dr. Kristen Feemster, Chair |

# ***Charter***

# 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.

4 – ACCV Charter

Filing Date

July 21, 2014

Approved:

JUL 1 2014

Date

Bahar Niakan
Acting Director, Office of Management

# ***Roster***

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV) ROSTER**
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# ***2014 & 2015 Meeting Dates***

# ADVISORY COMMISSION ON CHILDHOOD VACCINES

## 2014 MEETING DATES

December 4, 2014

## 2015 MEETING DATES

March 5 & 6, 2015
June 4 & 5, 2015
September 10 & 11, 2015
December 3 & 4, 2015

# 2

**Advisory Commission on Childhood Vaccines**

**September 4, 2014**
**93rd Meeting**

**Members Present**

David King, Chair ('14)
Michelle Williams, J.D., Vice Chair ('14) (via telephone)
Charlene Douglas, Ph.D. ('14)
Kirsten Feemster ('14) (via telephone)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('14)
Luisita dela Rosa, Ph.D. ('15)
Sylvia Fernandez Villareal, M.D. ('15)

**Division of Injury Compensation Programs (DICP)**

A. Melissa Houston, MD., Director, DICP
Andrea Herzog, Staff Liaison

**Welcome, Report of the Chair and Approval of Minutes**
**Mr. David King, ACCV Chair**

Mr. King called the meeting to order and invited a roll call of Advisory Commission on Childhood Vaccine (ACCV) members and representatives of federal agencies. He congratulated Dr. Houston on her appointment as permanent director of the DICP. Mr. King noted that several members have reached the end of their terms as commissioners, in particular the chair and vice chair. Therefore it is incumbent on the Commission to select individuals who will serve in those positions for the next term. He added that a number of candidates had been nominated for membership on the Commission, pending Office of White House review and approval.

Mr. King reiterated his longstanding admonition that the Commission's mission is to protect those who are vaccine injured and that recommendations should be developed keeping in mind the importance of protecting their interests. He introduced Ms. Cheryl Dammons, Associate Administrator, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), and invited her comments.

**Welcome by the Associate Administrator, HSB, Ms. Cheryl Dammons.**

Ms. Dammons expressed appreciation on behalf of the agency for the time and effort contributed to the Commission's work. She announced the permanent appointment of Dr. Houston to head newly-named division, the Division of Injury Compensation Programs, which replaces the Division of Vaccine Injury Compensation. The division houses two additional programs, the Countermeasures Injury Compensation Program (CICP) and the Medical Claims

Review Panel. She added that Dr. Houston regularly reports the Commission's activities to her. Also, she assured the commissioners that their recommendations are promptly forwarded to the Secretary of Health and Human Services (Secretary) and that their recent recommendations are under review. Finally, she pointed out how valuable the Commission's help is in reviewing the Vaccine Information Statements (VIS), especially those recently addressed, including hepatitis A and B, tetanus, and diphtheria.

Ms. Dammons invited questions and comments. She was asked about claims that may have been filed under the CICP, and what effect that program might have on the National Vaccine Injury Compensation Program (VICP). Ms. Dammons indicated that the two are different and independent programs. She added that she did not have data on CICP claims. She was asked about the organizational structure of HRSA. Ms. Dammons indicated there was an organization chart on the HRSA web site. HSB is one of five bureaus in the agency and within the HSB there are 11 programs. Three of those programs, all claims related, are under the aegis of Dr. Houston.

Mr. King asked if the Bureau can affect the Commission's interest in having face-to-face meetings. Ms. Dammons stated that the budget is one of the many considerations that influence decisions about whether or not such face-to-face meetings are scheduled. There have been across the board reductions in travel, which directly affects the scheduling of meetings.

Before continuing to the next agenda item, Mr. King mentioned the ethics review that might impact members on an individual basis. He stated that questions could be directed to Laura Ridder who agreed to respond to general questions. There being no other questions, Mr. King moved to the next agenda item.

**Public Comment on Agenda**

Mr. King invited public comment specifically related to the agenda. There were no comments.

**Approval of June 2014 ACCV Meeting Minutes**

Mr. King invited approval of the minutes of the June 2014 Commission meeting. Ms. Pron commented that there had been a number of discussions at the meeting and at previous meetings about whether the term "healthcare provider" should be used rather than simply "doctor," since there are a number of patient contacts in the health care environment – nurse practitioner, pharmacist, etc. She stated that there had been an agreement to consider changing the language in the VIS to broaden the term. Mr. King recalled that discussion and Ms. Herzog stated that the revision would be made.

On motion duly made and seconded, the minutes of the June 2014 meeting minutes, including the revision as described in the preceding discussion, were unanimously approved.

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

Dr. Houston commented that the VICP is co-administered by three federal agencies – the Department of Health and Human Services (HHS), the Department of Justice (DOJ) and the U.S. Court of Federal Claims (CFC). Noting that Mr. Vince Matanoski would make a formal presentation later in the meeting, Dr. Houston introduced Chief Special Master of the CFC, Denise Vowel, who would be participating in the meeting. She introduced the new Chief Medical Officer, Dr. Narayan Nair, who would also be present for the meeting.

Dr. Houston previewed meeting highlights agenda, which included a discussion of proposed changes to the Vaccine Injury Table, an update from the DOJ, a report from the ACCV Process Workgroup, a briefing on the proposed VAERS Form 2.0 that will eventually replace the current hard copy reporting form, safety presentations on pneumococcal vaccine (Pneumovax23) and zoster (singles) vaccine, as well as reports from the ex officio members.

Concerning the activities of the DICP since the last ACCV meeting, Dr. Houston announced that 451 claims had been filed as of August 1, which projected that approximately 541claims would be filed for the year, slightly up from the previous fiscal year. There had been 375 claims adjudicated and 349 non-autism claims adjudicated. It was projected that 450 claims would be adjudicated by the end of FY 2014 which would be slightly down from the same time last fiscal year and 418 non-autism claims would be processed for this fiscal year which would be about the same as FY 2013. Awards of $177 million have been made as of August 1 to petitioners, and petitioner attorneys have received $17.4 million. The Vaccine Injury Compensation Trust Fund (Trust Fund) stands at $3.4 billion, with revenues of $127 million from excise taxes and $45 million from interest earned on investments.

Dr. Houston stated that two significant meeting were held since the last ACCV meeting. The National Vaccine Advisor Committee (NVAC) met on June 10-11 and the Advisory Committee on Immunization Practices (ACIP) met on June 25-26. She added that the division had been responding to inquiries from the General Accountability Office (GAO) concerning the Trust Fund, outreach, claims processing data, and the process for making changes to the Vaccine Injury Table. The GAO has indicated that a draft report should be provided to DICP to review in mid-September.

Dr. Houston provided contact information for the division – Annie Herzog, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857, at telephone number 301-443-6634, and by e-mail at aherzog@hrsa.gov.

**Clarification of Proposed Changes to the Vaccine Injury Table, Dr. A. Melissa Houston, Director, DICP**

Mr. King explained that the next section was affected by the ethics regulation of HHS and that Ms. Pron would limit her participation to asking clarifying questions and would recuse herself from any decisions made as a result of the discussion. There was a review of ethics practices that resulted in a decision by the HHS to impose certain restrictions on participation in

discussions by individual commission members based on reviews of each member's financial disclosure statements. The division may request a waiver of that restriction but it would not be approved until the next ACCV meeting.

Dr. Houston stated that the DICP is currently updating the Vaccine Injury Table (Table) and that the Commission approved proposed revisions to the table in March 2012 and in June 2014. The VICP has also revised some of the language previously approved by the ACCV in the Qualifications and Aids to Interpretation (QAIs). The last formal revision to the table was made in 1997 after which nine vaccines were added to the table although no specific injuries were identified for any of the vaccines. Those nine vaccines were: haemophilus influenza type B polysaccharide conjugate, pneumococcal conjugate, hepatitis A and B, varicella, meningococcal, human papillomavirus, trivalent influenza, and rotavirus vaccines.

The HHS commissioned an Institute of Medicine (IOM) expert committee to review certain vaccines and related adverse events and the results of that study were, in turn, reviewed by a HHS task force. As a result, it was recommended that several vaccine-associated injuries be addedto the Table.

The IOM found that measles inclusion body encephalitis (MIBE), a rare encephalitis caused by chronic infection with the measles virus, mainly in immune deficient individuals, was associated with the measles, mumps, and rubella (MMR) vaccine. MIBE was added as an injury to the Table. Injuries listed on the Table usually include a time frame within which symptoms following inoculation must occur. The timeframe for MIBE was 4 to 9 months. However, there would be no time limitation if MIBE was confirmed by lab tests.

The IOM also confirmed there was a causal association between the varicella vaccine and disseminated vaccine viral disease on the skin and in other organs. The proposal was to add the disorder if the vaccine was confirmed by lab testing or within 7 to 42 days if lab testing was not performed or was inconclusive. The IOM also stated that there was convincing evidence of a casual association between varicella vaccine and vaccine strain virus reactivation, which is the appearance of the rash months to years after vaccination, with or without infection in other organs. The brain and meninges could also be involved in vaccine strain reactivation, usually in immune compromised individuals, but the proposal did not limit the involvement to those two organs. That was in keeping with the second overarching ACCV Guiding Principles which states 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.

These proposals associated with multiple vaccines were approved in March 2012. Any acute complication or sequela was deleted from the individual vaccines and placed in a separate paragraph. The IOM concluded there was a causal relationship between any injected vaccine and deltoid bursitis, not related to the specific vaccine. It could also affect other similar injuries. Therefore the program proposed that injury of Shoulder Injury Related to Vaccine Injury (SIRVA) be added to the table, to include more than only deltoid bursitis, if they occurred within 48 hours. The IOM also found a causal relationship between vaccine injection and syncope,

usually within 15 minutes. In keeping with the ACCV Guiding Principles, the DICP recommended a timeframe of one hour.

The IOM found a causal relationship between the vaccine for trivalent influenza, meningococcal, human papilloma and varicella vaccines with episodes of anaphylaxis. Usually the onset was less than an hour and the DICP recommended adding the injury to the Table with an onset of four hours.

The QAIs were expanded from 9 to 13 to provide definitions for the additional adverse events. There was also a revision to the paragraph on brachial neuritis to harmonize with the new language for SIRVA, since the conditions are similar. The proposed definition for disseminated varicella vaccine strain virus disease clarified the requirement for laboratory testing and time frames, defined the illness as one that involved the skin beyond the dermatome where the immunization was administered, and stated that clear evidence of disease in an organ must be present.

The QAI language regarding varicella strain reactivated disease states that there is no applicable time frame associated with this condition. With regard to syncope, the QAI states that loss of consciousness clearly related to causes other than an injection would not be considered a table injury. With regard to anaphylaxis, minor changes were made that eliminates the description of autopsy results since autopsy findings do not confirm a diagnosis of anaphylaxis.

The QAI section on vaccine strain measles viral disease was expanded to provide more detail with regard to the definition, the involvement of skin and other organs, testing and exclusions. With regard to encephalopathy and encephalitis, the IOM rejected a causal relationship with acellular pertussis-containing or MMR vaccines. The definition of encephalopathy was revised and a definition was developed for encephalitis. For clarity, a revised definition of chronic arthritis was proposed, although it was no revision to that condition was proposed. The definition of thrombocytopenic purpura was expanded to make it compatible with medical diagnostic language, instead of just the laboratory test result definition.

Finally, Dr. Houston stated that the glossary was revised to include the definition of "chronic encephalopathy", the technical definition of "injection" and the definition of an "immune deficient recipient". Two definitions previously described in other sections of the table were moved unchanged to the glossary – the definitions of "significantly decreased level of consciousness," "seizure" and "sequela".

During discussion, Dr. Tom Shimabukuro, Immunization Safety Office, Centers for Disease Control and Prevention, commented that, in the glossary, concerning injection, there is an intradermal injection now in use. Also there has been a device recently approved for a non-needle injection, an intramuscular subcutaneous "diffusion" that does not involve a needle stick.

Mr. King commented that the preceding review addressed ACCV action taken in March 2012. Dr. Houston discussed recommendations approved by the Commission at its June 2014 meeting. She noted that all seasonal trivalent flu vaccines were covered under the program in July 2005. Quadrivalent vaccines became available during the 2013-2014 flu season and are

covered by the program as of November 12, 2013. Congress passed Public Law 113-15 on June 25, 2013 that authorized an excise tax on all flu vaccines changing the previous vaccine category known as "trivalent influenza vaccines" to "seasonal influenza vaccines".

Haemophilus influenza polysaccharide type B conjugate vaccines were first licensed in 1987 and have been recommended by the CDC for routine use in children since 1991. The category was changed to haemophilus influenza type B vaccine as a technical change to harmonize with the terminology in the excise tax law.

Mr. King invited discussion. Hearing none, he invited Dr. Houston to discuss proposed changes to the QAI language previously approved in March 2012. After the discussion, Dr. Houston indicated that the Commission would be requested to either approve or not approve the revisions. Mr. King commented that Dr. Pron would continue to be limited in her participation in the discussion.

Dr. Houston stated that the first change would make the definition of encephalopathy less restrictive, such that if it could be shown that the exclusions were related to the vaccine, the presumption of causation would continue to apply. She added that a reference in the original recommendation requiring evaluation of the entire medical record was deleted because it is in the statute, which would make the language unnecessary. That is, there is an assumption that the evaluation takes place in all circumstances.

Mr. Kraus commented that, when the 2012 changes were approved, most of the commission members were relatively new to the Commission, and the consideration of the changes was felt to be very important and somewhat urgent. He conceded that staff made clear presentations justifying the changes and the Commission approved them. Then there was no discussion until the December 2013 meeting, when the Commission approved adding Guillain-Barrè Syndrome (GBS) following flu vaccination to the table. Then in June 2014 the Commission approved changes to the 2012 recommendations, most of which were clarifying revisions. Mr. Kraus commented that the entire process prompted him to review the original 2012 recommendations, which in turn raised some issues in his mind that he proposed discussing – that is, it would re-open the discussion of the 2012 recommendations, and not just the subsequent changes that were approved since that original Commission action.

Asked for specifics, Mr. Kraus commented that he had concerns about the recommendation regarding the definition of encephalopathy in the QAI. He explained that the wording in the 2012 version seemed to place the onus of proof on the petitioner to show that the conditions listed were unrelated to the vaccine or were underlying conditions of a systemic disease. Secondly, Mr. Kraus expressed concern that the definition of anaphylaxis had been expanded to require simultaneous involvement of two or more organ system, making it more restrictive. Dr. Houston assured the Commission that the medical definition of anaphylaxis required the involvement of two or more organ systems. Mr. Kraus summarized his concern that the revisions seem to require the petitioner to take on more of the burden of proof than existed before the revisions were approved.

There was a brief discussion concerning the responsibility for substantiating a claim that is filed as a table injury. Dr. Houston noted that the table prior to 2012 had exclusions, which are similar to those in the 2012 recommended language. There was agreement that the initial burden rests with the petitioner, but once established as a table injury, it would become the HHS's obligation to disprove the assumption. Mr. Kraus made a motion to reconsider the 2012 recommendation concerning encephalitis. The motion failed because of a lack of a second to that motion.

Resuming the discussion of QAI revisions, Dr. Houston commented that the QAI was revised from encephalopathy "symptoms within six months of vaccination" to "at least six months from first symptoms or manifestation of onset or of significant aggravation of acute encephalopathy or encephalitis."

Another proposed revision would change the definition of thrombocytopenic purpura making the definition less restrictive – if culture or serologic testing was performed and the viral illness was attributed to the vaccine strain measles virus then the presumption of causation would remain in effect. Finally, in the case of SIRVA injury, the wording was refined to clarify that the injection referred to in the QAI was presumed to be intramuscular, which involves a longer needle than the subcutaneous injections, which are far less likely to cause a SIRVA-type injury.

Mr. King noted that the Commission would address the disposition of the recommendations – that is, to concur with the recommendations or not to concur with the recommendations. He suggested addressing each recommendation individually, as had been done at the March 2012 meeting. Asked about the Commission's options in terms of the charge to issue a decision with regard to the proposed revisions, Dr. Houston explained that the Commission is allowed 90 days to review the revisions and arrive at a decision to concur or not concur. The Commission could also not make any recommendations.

The first revision related to the new wording for the encephalopathy definition in the QAI, and on motion duly made and seconded, the Commission approved the revision, six in favor, one abstention, and one member recused and did not vote.

The second revision related to the new wording for the thrombocytopenic purpura definition in the QAI, and on motion duly made and seconded, the Commission approved the revision, six in favor, one abstention, and one member recused and did not vote.

The third revision related to the new wording for the chronic encephalopathy definition in the QAI, and on motion duly made and seconded, the Commission approved the revision, seven in favor and one member recused and did not vote.

The fourth revision related to the new wording for the SIRVA definition in the QAI, and on motion duly made and seconded, the Commission approved the revision, seven in favor and one member recused and did not vote.

**Report from the Department of Justice. Mr. Vince Matanoski, Deputy Director, Torts Branch**

Mr. Matanoski referenced the Department of Justice PowerPoint materials (DOJ PP), dated September 4, 2014, as part of his presentation. Mr. Matanoski reported that 168 petitions were filed since the last report to the Commission (DOJ PP at 2), which extrapolates to over 500 for the fiscal year. The number of claims is increasing each year. Nearly 80 percent of the claims were filed by adults. The number of cases filed is mainly a function of the number of seasonal influenza vaccinations. Those vaccinations also account for the increase in GBS and SIRVA claims. Some of the increase in claims could be the result of a more active petitioner's bar, which makes information about the program more available to the public.

Mr. Matanoski stated that adjudications this reporting period, which totaled 152, slightly lagged behind petitions filed (168), a trend that would be concerning if it continues because it could forecast an increasing backlog of pending claims (DOJ PP at 3). The numbers suggest that adjudications could exceed 600 for the fiscal year, which is a significant increase over past years. About two-thirds of the adjudicated cases were compensated through settlement. Mr. Matanoski added that nine cases were voluntarily dismissed (DOJ PP at 4).

Regarding appeals, the U.S. Supreme Court dismissed petitioner's *writ of certiorari* on June 30, 2013, in *Tembenis v. Sebelius* (DOJ PP at 5). *Tembenis* has been discussed at prior meetings and involved a claim for compensation to a deceased child's estate for unearned wages. Three cases were decided during this reporting period by the U.S. Court of Appeals for the Federal Circuit (CAFC). Petitioners' appeals in *Graves v. HHS* and *Price v. HHS* were denied because they were filed outside the statute of limitations (DOJ PP at 6). In *Dobrydnev v. HHS*, an appeal by respondent, the Court reversed the holding of the CFC, finding that the judge erroneously substituted her factual findings for those of special master's, which is only permitted if the special master made a legal error (DOJ PP at 6). The petitioner has moved for *en banc* review. The other listed cases currently pending before the CAFC were discussed at the last Commission meeting, and no new cases were added to that docket (DOJ PP at 7).

Turning to the CFC, two cases were decided this reporting quarter (DOJ PP at 8). In *Bast v. HHS*, the CFC affirmed the special master's decision that respondent's expert witness was more reliable than petitioner's expert witness. In *Scanlon v. HHS*, the CFC vacated the special master's denial of attorneys' fees and costs and remanded the claim to the special master for an award even though the underlying petition for compensation alleged an injury from a vaccine (shingles vaccine) that is not covered by the National Childhood Vaccine Injury Act of 1986, as amended, (Vaccine Act). Several appeals are pending before the CFC with four new appeals filed by petitioners during the reporting period (DOJ PP at 9). *Castaldi v. HHS* involved statute of limitations and entitlement issues. In *Mosley v. HHS*, the special master found that the appearance of transverse myelitis occurred too soon after the tetanus toxoid vaccination (the day following the vaccination). In *Godfrey v. HHS*, petitioner alleged that human papillomavirus (HPV) vaccine and meningococcal conjugate vaccines caused juvenile rheumatoid arthritis. The special master found respondent's experts more reliable in a battle of the experts on causation. In *Harris v. HHS*, the special master found that petitioner failed to satisfy prong one of *Althen* in

that there was no reliable evidence that the HPV vaccine could cause lupus, and, further, there was evidence that petitioner's symptoms of lupus began prior to vaccination.

Turning to settlements, Mr. Matanoski discussed the compilation of settlements adjudicated during the preceding quarter (DOJ PP at 11-19). There were 90 settlements finalized in the quarter, which is impressive in a three-month period. Of those, Mr. Matanoski noted that 40% of cases were settled within the first year of the date they were filed. An additional 33% were adjudicated in the second year and an additional 11% in the third year. In all, 88% of cases reported were settled in three years or less. That number has been relatively stable for the last several reporting periods. In the more distant past, significantly lower percentages were settled within three years of filing. Mr. Matanoski explained that the office is becoming more efficient, learning to adjudicate similar cases more quickly, and the Office of Special Masters has supported efforts to expedite the settlement process.

He was asked the ratio of on-table injury adjudications versus off-table injury adjudications. Mr. Matanoski responded that a majority of the adjudications were off-table claims, but that trend might change if injuries such as GBS and SIRVA are added to the Table. He was asked about DOJ's approach to processing cases meeting the criteria for proposed Table changes, Mr. Matanoski acknowledged that accommodations are being made such as identifying cases for "fast-track" that have been and are continuing to be implemented. Finally, when asked about the current caseload, Mr. Matanoski indicated there were about a 1,000 cases on the docket. He warned that although there have been impressive improvements in efficiency, case processing is subject to the limited resources available.

Mr. Matanoski expressed appreciation for being able to update the Commission.

**VICP Outreach Plan, CAPT Narayan Nair, M.D., DICP**

Dr. Nair began by discussing the background related to outreach efforts. He explained that the Vaccine Act stated that the public should be informed about the program. In the past, there were two groups involved in outreach: the ACCV Outreach Workgroup and the Communications Liaison Outreach Group who was concerned mainly with participation in professional meetings. The VICP contracted with Banyan Communications to develop a marketing and communications plan, which was presented to the ACCV in 2010.

Dr. Nair then discussed the objectives and strategy related to outreach. He noted that the present objectives of the outreach program are to increase awareness in the public arena about the VICP, how the program works, and to develop partnerships with organizations that can support the outreach effort. These organizations could include HRSA grantees such as community health centers; Healthy Start Programs; and maternal, infant, and early childhood home visit programs. Partnerships can also be developed with other HHS agencies and professional organizations.

Dr. Nair concluded by discussing current and future outreach efforts. Currently, a toll-free number is maintained to answer questions about the program and written inquiries are

promptly answered. In the future, the VICP web site will be significantly improved to enable easier navigation and make it more user-friendly. The printed material will be improved and made more available and partners will be recruited to distribute VICP information materials.

Ms. Williams noted that a former Commission member, Sara Hoiberg, had indicated an interest to support the outreach process.

**Public Comment**

Theresa Wrangham, representing the National Vaccine Information Center (NVIC), endorsed the face-to-face meeting format. In addition, she stated that there was a report from an outside group, the Banyan Communications that revealed some deficits in the outreach process. This report mentioned the value of television and radio public service announcements. Also, the report recommended a satisfaction survey of petitioners for which response was limited, perhaps because of timing of the survey. Such a survey should be made on a timely basis when memories are fresh.

Concerning the discussion about encephalopathy, the discussion was thoughtful, but changes have been made in the table that may not be fully responsive to changes made outside the recommendations of the IOM. She stated that the NVIC is opposed to the changes made with regard to encephalopathy. Because the provision in the table is too narrow and restrictive to potential claims related to encephalopathy.

**Adjournment**

Mr. King recessed the meeting until 9:00 a.m. the following day.

**Advisory Commission on Childhood Vaccines**

**September 5, 2014**
**93rd Meeting**

**Members Present**

David King, Chair ('14)
Michelle Williams, J.D., Vice Chair ('14)
Charlene Douglas, Ph.D. ('14)
Kirsten Feemster ('14)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('14)
Luisita dela Rosa, Ph.D. ('15)
Jason Smith, J.D. ('15) (via telephone)
Sylvia Fernandez Villareal, M.D. ('15)

**Division Injury Compensation Programs (DICP)**

A. Melissa Houston, MD., Director, DICP
Andrea Herzog, Staff Liaison

**Welcome, Report of the Chair and Approval of Minutes, Mr. David King, ACCV Chair**

Mr. King called the meeting to order. After introductions, he noted that Kristen Feemster was en route to the meeting and that Theresa Wrangham, in her capacity as director of the National Vaccine Information Center (NVIC), submitted a letter from the NVIC requesting that it be included in the official record of the Advisory Commission on Childhood Vaccines (ACCV) meeting. He indicated the letter was relatively long and would require some review before specific action could be taken with regard to including it in the minutes.

**Report from the Process Workgroup, Ms. Luisita dela Rosa, ACCV Member**

Ms. dela Rosa reported that the Workgroup met by telephone on May 8 and discussed a statistical table provided by Ms. Theresa Wrangham of the NVIC that included historical data on vaccine injury cases filed with the National Vaccine Injury Compensation Program (VICP) over the past few years. The Workgroup discussed how the information was different from that made available on the VICP web site. Ms. Wrangham described how the DICP could prepare a similar presentation that would respond to the needs of parents about the kinds of claims being filed. She also reminded the Workgroup of the U.S. Court of Federal Claims' requirement to submit an annual report on vaccine cases.

Ms. dela Rosa reported that the DICP staff had reviewed the information and stated that creating such a table would require additional staff support since much of the information

required is not located within DICP. The information would have to be gleaned from other sources. It was noted that determining why cases were or were not filed, why filed cases may have been dismissed, or reasons for compensating, or not compensating a claim, requires review of individual cases, which is a labor intensive process. The Workgroup agreed that it was important for such information to be made available and for the DICP to respond to non-governmental advocacy groups such as the NVIC. The Workgroup requested that Dr. Houston follow up on the feasibility of creating the table.

At the Workgroup's September 4th meeting Dr. Houston reported that the program had reviewed the statutory and regulatory reporting requirements and that DICP was comfortable that the published information adequately describes program operations. Information about individual cases is provided on the U.S. Court of Federal Claims (Court) web site as well. Some information, such as reported injuries after vaccination, is provided by the Centers for Disease Control and Prevention (CDC).

The Workgroup also discussed the possibility that the ACCV might invite individuals to testify about personal experiences with the statute of limitations when that part of the law might have presented an impediment to timely filing of a claim. In addition, the Vaccine Injury Petitioners Bar could be invited to provide information. The Workgroup agreed that such information might be just as well collected through a survey process. However, there is a lengthy process involving U.S. Office of Management and Budget (OMB) approval when such surveys are undertaken. The Workgroup asked Dr. Houston to provide information about what the approval process entails.

Finally, the Workgroup asked for an update on the appointment of new commissioners since the nominations have apparently been submitted to the Office of the White House for review and approval. Ms. dela Rosa concluded her report.

During discussion there was a question about whether the Commission had received certain information pertaining to cases that the Court had handled, and it was noted that there was information provided in a report related to cases from 2012 and 2013. Chief Special Master Vowell commented that information under Tab 3 was taken from annual reports to Congress and that information was not under her control. The Commission was interested in exploring that area of the report further and the Clerk of the Court should be contacted. Mr. King noted that the information received at the meeting was not identified by tabs, and Chief Special Master Vowell stated that it was submitted in that format and if the information was re-sent it should be organized in tabular format. Mr. King stated that unless the issue is clarified the information received will not be disseminated to the public. There was a brief discussion that clarified that information sent to the Commission or any of its subcommittees would be available through a formal Freedom of Information Act (FOIA) request.

Mr. King noted that Dr. Feemster had joined the meeting.

**Election of Succeeding Chair and Vice Chair**

Mr. King noted that with all of the commissioners present the issue of electing the next chair and vice chair would be addressed. He stated that a number of commissioners were at the end of their tenure, including the present officers and Ms. Pron, and that it would probably be necessary to extend the terms of the next group of commissioners, including Dr. Feemster, Mr. Smith, and Ms. Douglas (the second 2014 cohort).

Mr. Kraus nominated Dr. Feemster to be chair, seconded by Ms. Williams. Mr. King, noting that there were no other nominations, called for the election to occur. There was unanimous approval of the nomination.

Calling for nominations for vice chair, there were nominations for Ms. Douglas and Mr. Smith. A secret ballot was taken and Mr. Smith was elected by a vote of five versus four votes for Ms. Douglas.

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

Dr. Shimabukuro outlined his report stating that he would provide a follow-up on the 2010-2011 febrile seizure signal for trivalent inactivated influenza (TIV) and pneumococcal 13-valent conjugate vaccines (PCV13) and discuss the June 2014 ACIP meeting.

Dr. Shimabukuro reported that there was a Vaccine Adverse Event Reporting System (VAERS) data mining signal during the 2010-2011 flu season for febrile seizure following Fluzone, a TIV that is approved for children six months and older. At the same time there was a Vaccine Safety Datalink (VSD) rapid cycle analysis signal for febrile seizures in infants 6-59 months of age following TIV administration. A follow-on VSD study found that there was increased risk for febrile seizure primarily when TIV and PCV13 were administered during the same healthcare visit. The risk peaked at about 16 months of age with an additional 45 cases per 100,000 children vaccinated. In a Clinical Immunization Safety Assessment (CISA) Project study, children aged 6-23 months who received the vaccines at the same time were about three times as likely to have fever on day 0 or day 1 post vaccination. Fever precedes a febrile seizure. CDC posted information on its web site communicating these findings and stating that no changes in the childhood immunization schedule were necessary. Information was also added to the Vaccine Information Statement (VIS) regarding the risks.

In addition, Dr. Shimabukuro described the VSD and a Post-licensure Rapid Immunization Safety Monitoring System (PRISM) studies that looked at multiple vaccines. The results were that when looking at independent risk for febrile seizures when TIV is given alone there was of no evidence of increased risk of febrile seizure. The updated VSD analysis for 2010-11 season suggests that the relative risk increased about three-fold when TIV was given with PCV and/or DTaP compared with unexposed periods, with similar result for prior seasons from 2006 to 2009. The Food and Drug Administration (FDA) PRISM study looked at one flu season, 2010-2011, same day versus separate day vaccinations of TIV and PCV13 and found no increased risk in either circumstance.

In summary, Dr. Shimabukuro stated that the VSD analysis over several flu seasons showed that the risk of febrile seizure is not increased when TIV is given alone, but when TIV is given with PCV and/or DTaP that risk is increased, and the highest risk occurs when all three vaccines are administered together at age 15 months. That risk is about 38 additional febrile seizures per 100,000 vaccinations, which is similar to the risk seen in measles-mumps-rubella vaccine. Simultaneous administration of TIV with PCV and/or DTAP appears to increase risk of febrile seizure, but the risk is transient (same day or following day), and although seizures can be alarming to parents they typically do not have lasting effects.

During discussion, Dr. Shimabukuro assured the commissioners that febrile seizures, of which 3-5% of children experience, do not increase the risk of developing epilepsy or similar seizure disorders. He deferred a question about non-physical effects to the pediatricians on the Commission. Dr. Villareal commented that when parents experience a child's febrile seizure, it can cause a lasting impact in terms of increased anxiety when a child gets fever or when a child is scheduled to receive a further vaccination. Dr. Pron added that parents often become opposed to any further vaccinations for their children and can become advocates opposing mandatory vaccinations. Mr. King was concerned the words "lasting effect" might not be accurate in that instance. Dr. Shimabukuro assured the commission that although a child may be more or less likely to have additional similar seizures related to fever, the child's risk of developing a seizure disorder after a febrile seizure is not increased because of the initial event.

Turning to his report on the June 24 Advisory Committee on Immunization Practices (ACIP) meeting, Dr. Shimabukuro reported that there was an influenza session that reviewed the 2013-2014 flu season that confirmed there were no new safety concerns and the formulation for the 2014-2015 season would remain the same. He described safety monitoring activities, including an enhanced surveillance of children with incidents of asthma or wheezing after live attenuated influenza vaccine quadrivalent (LAIV4) since the vaccine may be administered to younger children. The specific recommendation is to give children live attenuated influenza vaccine (LAIV) preferentially, if available, but give inactivated influenza vaccine (IIV) if LAIV is not available.

Mr. Smith interjected a comment that his company, Pfizer, markets Prevnar, a PCV13 vaccine and is also developing a meningococcal serogroup B vaccine and for that reason, for the record, he recused himself from the discussion.

Dr. Shimabukuro commented that the ACIP discussed adding a dose of PCV13 following the currently recommended dose of pneumococcal polysaccharide vaccine (PPSV23) at age 65 and up. The Committee also discussed replacing a dose of PPSV23 with a dose of PCV13 at age 65 and up. Concerning the meningococcal vaccines, the Committee discussed publication of interim guidance for the use of a serogroup B meningococcal vaccine under a CDC-sponsored expanded access investigational new drug (IND). Updates to CDC's comprehensive meningococcal disease outbreak guidelines will be published once the vaccines are licensed in the United States.

Dr. Shimabukuro mentioned several recent publications. Nordin et al. found no acute safety signals within six weeks of vaccination in a large cohort of pregnant women who received

monovalent 2009 H1N1 (pandemic) inactivated influenza vaccine. Stokley et al. reported in the Morbidity and Mortality Weekly Report (MMWR) that post licensure monitoring of Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) recombinant vaccine (HPV4) vaccine continued to confirm safety with a commentary that appropriate practice patterns for physicians should include consistent encouragement for patients to take advantage of the human papillomavirus (HPV) vaccine. Grohskopf et al., also in MMWR, updated the recommendations for seasonal influenza vaccines. Also in the MMWR, Markowitz et al. described HPV vaccine recommendations. Dr. Shimabukuro concluded his report.

During discussion, Mr. Kraus expressed concern, notwithstanding the CDC recommendation that administering vaccines on the same visit may have significant advantages, that parents should be given full information about the increased risks of febrile seizure when vaccines are administered simultaneously.

**Discussion of Proposed Revisions to VAERS Form 2.0**

Dr. Shimabukuro explained that VAERS receives about 30,000 reports annually. Anyone can submit an adverse event (AE) report to VAERS – health care workers, public health personnel, individuals including parents, relatives and others. He noted that manufacturers are required by law to submit AEs to VAERS that come to their attention. VAERS is administered jointly by the CDC and FDA and is authorized by the National Childhood Vaccine Injury Act of 1986. VAERS is national in scope and can rapidly detect potential safety problems and rare AEs. The reports are accepted without judging clinical importance or causality. VAERS provides for rapid signal detection, contains information concerning the vaccine and adverse event as well as information about the individual vaccinated. The data, with personal identifiers removed, is posted on the VAERS web site and is available to the public. Limitations of VAERS include reporting bias, varying data quality and completeness, and a general inability to determine cause and effect. Reporting for pregnant women is inconsistent. Rates of AE occurrence cannot be calculated using VAERS data and therefore, relative risk cannot be estimated, nor can vaccination coverage.

The current method for submitting a non-online VAERS report is manual. The report form (VAERS-1) can be downloaded from the VAERS web site, printed and filled in by the person making the report, then mailed or faxed to the VAERS contractor who manually processes reports and conducts data entry and coding. A report may be made verbally to a VAERS customer service representative who fills in the form with the information provided on the phone. The process is resource and labor intensive.

The objective for the proposed VAERS 2.0 reporting form is to provide a fillable/savable electronic form that can be completed on a computer and submitted through an electronic upload process. Secondary objectives include adding new information fields that will improve surveillance and eliminating fields that are no longer relevant or useful, updating and clarifying language, giving the form a more modern easy to use appearance, and insuring that data entered on the new form is compatible with historical data so that historical comparisons are possible. The electronic format facilitates consistency in the entries (e.g., dates and phone number formats), allows pop-up reminders if a field is left blank, and eliminates human errors, such as

illegible handwriting, illogical answers and other errors. However, Dr. Shimabukuro assured the Commission that incomplete forms and even forms with errors in some fields could be submitted. The electronic format should eliminate a large amount of the manual processes for the VAERS contractor.

The proposed VAERS 2.0 form partially addresses the problem of getting "timed out" on the online reporting tool. The fillable/savable VAERS 2.0 would allow the form to be saved and completed in stages, by multiple persons, if necessary. The form can be partially filled out and saved for later completion, then uploaded to the VAERS contractor via the VAERS web site. The contractor would transfer the reported data to the VAERS database. As before, for those not comfortable with computers or otherwise not able to report via computer, there is a third option to make a phone call to the VAERS customer service representative and dictate a verbal report. Finally, Dr. Shimabukuro reviewed the specific changes in the new form as listed on the presentation. He noted that there have been several levels of review, including interviews with potential reporters and testing of this process will continue as the form is finalized.

Dr. Shimabukuro discussed next steps. The "smart form" with electronic smart features will be created and tested. The proposed VAERS 2.0 will also be presented to the NVAC and ACIP at the next scheduled meetings. The VAERS 2.0 form will be published in the Federal Register inviting public comment and final revisions will be made to the form based on those comments and the ongoing computer testing of the form. The final platform that will enable acceptance of the electronic VAERS Form 2.0 and online reporting tool will updated to reflect the new data elements.

During discussion, Dr. Shimabukuro stated that there are no capabilities for reporting in other languages at this time. He added that the English language version has been made as simple as possible while still insuring that the data needed can be collected. Asked about who submits reports, Dr. Shimabukuro commented that about 25% of the reports come from parents and patients, about 30% from providers, but there is an "Other" category that may contain some parents and some providers. There was a question about how long it takes to fill out the form and Dr. Shimabukuro stated that it depends on the individual submitting the report and the adverse event, but that the amount of data required is about the same in the current VAERS-1 form.

Asked about the roll-out of the new form, Dr. Shimabukuro stated that there would probably be an initial period when a report could be submitted either the current manual method or by electronic reporting.

**Pneumococcal Polysaccharide (Pneumovax 23) Vaccine Safety Presentation, Ms. Elaine Miller, R.N., MPH, CDC**

Ms. Miller provided background about the disease burden of pneumococcal infections that annually cause 3,000 to 6,000 cases of meningitis, 50,000 cases of bacteremia and as many as half a million cases of pneumonia in the U.S. Deaths from meningitis may exceed 30% in younger victims and up to 80% in the elderly. The fatality rate for bacteremia is about 20% (up

to 60% in the elderly) and pneumonia claims up to 7% of individuals with the infection, more in the elderly. The pneumococcal polysaccharide vaccine, Pneumovax 23, is effective in preventing disease caused by the 23 serotypes contained in the vaccine and is recommended for adults 50 years of age and older, and for children ages 2 years and up who are at increased risk for pneumococcal disease. Those children may have chronic conditions (such as heart disease or diabetes mellitus), lack of a functioning spleen, or congenital or acquired immunodeficiency (e.g., HIV, chronic renal failure, or similar conditions). Children under two do not develop an effective immune response. The 23 serotypes in the vaccine cause approximately 88% of bacteremic pneumococcal disease. Pneumovax 23 is an inactivated vaccine and cannot cause the disease.

Pneumovax 23 was licensed in 1983 and is now the only pneumococcal polysaccharide vaccine on the market in the US. There have been several ACIP recommendations over the years, which will now be harmonized into a single set of recommendations. The ACIP recommendation for adults is the same as for children, except that all over age 65 should receive the vaccine regardless of prior history. Ms. Miller noted that certain adverse events were common though non-serious, mainly localized reactions at the injection site (pain, swelling, erythema) and systemic reactions like headache, fatigue, and myalgia.

A VAERS review was completed. The strengths and weaknesses of VAERS were outlined in the previous discussion by Dr. Shimabukuro. The VAERS reports for pneumococcal polysaccharide vaccines received from 1990-2013 were summarized, not including those of Pnu-Immune, a vaccine used from 1983 until 2002 comprising about 10% of VAERS reports. Another analysis known as empirical Bayesian data mining was conducted, which detects disproportional reporting for a vaccine and an adverse event. It does not necessarily demonstrate that a vaccine has an increased risk for an adverse event. Data mining findings may indicate the need for further analysis. There were over 25,000 AE reports. Slightly over 2,000 were considered serious. The majority of reports came from health care providers (10,462), mainly concerning individuals in the 19-64 age group (11,040), followed by reports about those 65 and older (10,546). There were 66 deaths reported, four of which occurred in children.

Ms. Miller reported that 144.2 million Pneumovax doses were distributed in the U.S. from January 1991 to December 2013 (no way to tell how many were actually administered to individuals). That works out to 17.7 VAERS reports per 100,000 doses distributed. Mr. King observed that since fewer doses are actually given than distributed the percentages related to actual AEs would be higher than the number of reports. He was asked about whether Pneumovax can be stored over a long period of time and therefore, should have a higher actual use rate than vaccines with relatively short expiration date. Dr. Shimabukuro stated his belief that the vaccine probably does have a longer shelf life than some others that expire and must be destroyed. Nonetheless there is no data on actual number of doses administered. He added that when a vaccine is first introduced there may be a higher level of reporting of adverse events than after the vaccine has been in use for a period of time. The same thing occurs when a vaccine is substantially changed and the new version is put on the market.

Ms. Miller provided statistics about co-administered vaccines in children included in the VAERS reports. Pneumovax alone was administered in 45% of the reports, and flu vaccine

(TIV) was mentioned in an additional 28%. In adults the numbers were similar. Ms. Miller also briefly discussed the reported deaths in children (4) and in adults (61), which did not appear to be causally related to the vaccine.

In summary, Ms. Miller stated that from 1990-2013, VAERS received 25,168 Pneumovax reports, 92% of which were non-serious. Fever was the most commonly reported adverse event (47%) in children followed by injection site issues. Death reports among children were very rare and cause of death did not suggest any causative relationship to the vaccine. In adults the most commonly reported adverse event was injection site erythema and pain (57%) and fever (24%). No concerning patterns were detected through VAERS for Pneumovax 23 for children or adults. A 2008 World Health Organization (WHO) position paper confirmed most of the findings discussed.

**Zoster (Shingles) Vaccine Safety Presentation, Ms. Elaine Miller, R.N., MPH, CDC**

Noting that the presentation for the herpes zoster vaccine parallels the previous Pneumovax presentation, Ms. Miller commented that she would focus on the information that has not been presented the Commission. An individual with a history of the varicella zoster virus (chicken pox) could have a reactivation of the virus. Those individuals, usually the elderly and those immunosuppressed, experience herpes zoster, also known as shingles. Also at risk are persons who had varicella at less than 18 months of age and those who had intrauterine exposure to varicella zoster virus. Symptoms occur in a specific area related to a sensory nerve and complications include post-herpetic neuralgia (persistent pain after the rash disappears), vision loss if the shingles occur near an eye, and other neurologic problems. In the U.S., up to a million individuals experience the condition annually and the lifetime exposure risk is about 32%.

The zoster vaccine, Zostavax, is a live attenuated vaccine given in a single dose and currently licensed for individuals 50 years of age and older. The ACIP limited its recommendation to individuals 60 and older partly because the condition mainly affects older individuals and partly in consideration of the possibility of a limited vaccine supply. Since it is a live, although weakened virus vaccine, it is contraindicated for those who are immune suppressed and women who are pregnant. Also, it should not be given to individuals who have had an anaphylactic reaction to any component in the vaccine.

The vaccine reduced the risk of developing shingles by approximately 51%, which is a lower rate than most vaccines, but the efficacy is higher in preventing post-herpetic neuralgia at 62% and increases to approximately 73% in preventing episodes of post-herpetic neuralgia lasting 182 days or more. In prelicensure studies, the most common adverse event was injection site reaction occurring in 48% of recipients. Far behind were headaches affecting 1.4% of the recipients. A prelicensure safety study showed that Zostavax recipients experienced a higher number of cardiovascular events (20 or 0.6%) than those receiving placebo (12 or 0.4%).

The VAERS surveillance system was discussed during the Pneumovax presentation as was the empirical Bayesian data mining study procedure. The results for the VAERS Zostavax data received May 2006 to February 2014 revealed that 15,930 reports were received 723 of

which (5%) were considered serious adverse events. Women were the subject of 11,500 (72%) reports. As in the Pneumovax VAERS data manufacturers and healthcare providers accounted for the majority of reports, amounting to 73% of the total reports filed.

Most of the reports were for older adults, 60 years of age and up (12,486 or 78%), with an additional 1,541 (10%) filed for individuals 50 to 59 years of age. There were 638 reports for individuals under age 50 (4%) for whom the vaccine is not recommended and most were medication errors. Finally, there were 51 deaths reported (0.3%) none of which were in children or younger adults.

Between 2006 and 2013, 18.4 million doses of Zostavax were distributed in the U.S. The rate for all reports was 82.6 per 100,000 doses distributed and only 3.9 serious reports per 100,000 doses distributed. By MedDRA-codes, the most common symptoms among non-serious reports were injection site erythema, injection site swelling, and development of herpes zoster (shingles). Among serious reports, the most common symptoms based on MedDRA codes were shingles, pain and rash. Zostavax was the only vaccine mentioned in 90% of the reports, followed by three vaccines also mentioned— TIV (5%), pneumococcal polysaccharide (3%) and Tdap (2%). There were only 15 reports related to pregnant women, of which seven were pregnant vaccine administrators (usually a vaccine spill on the body of the vaccine recipient), and eight involved pregnant vaccines.

Ms. Miller outlined the conclusion of her report. From 2006 to 2013, VAERS received 15,930 reports, 95% of which were non-serious. In the 50-59 age group, the most commonly reported symptoms were injection site erythema (36%), injection site swelling (23%), generalized erythema (17%), and injection site warmth (16%). In the 60 and older age group, the most commonly reported symptoms were injection site erythema (25%), shingles (17%), injection site swelling (15%), and rash (14%). Death reports were rare and did not suggest a causal relationship with the vaccine. No concerning patterns were detected in VAERS for Zostavax.

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

Ms. Schuster stated that NIAID is responsible for responding to emerging infectious disease threats, among which the recent Ebola outbreak is of especially urgent concern. NIAID supports Ebola research, including the development of vaccine candidates to protect against the disease. Currently there is a Phase I clinical trial taking place on the NIH campus in Bethesda, Maryland, to assess an investigational vaccine co-developed by NIAID and GlaxoSmithKline. The study is assessing the vaccine's safety and ability to stimulate an immune response in healthy volunteers. There is an experimental vaccine developed in Canada that will also be tested in healthy controls in a separate trial. NIAID is also collaborating with partners in the United Kingdom to test an Ebola vaccine candidate in West Africa.

Another emerging threat is chikungunya virus which is spread through the bites of infected mosquitos, resulting in high fever, joint and muscle aches, and headaches. Although

rarely fatal, the disease can cause long-term chronic pain. It has been reported in a number of Asian countries and arrived in the Western Hemisphere last year. As of August 29, 2014, there were more than 659,000 cases reported in the Americas, 696 cases in the continental U.S. including six cases in Florida that are thought to have been locally acquired. Therapy has not been developed and the best prevention is to avoid mosquito bites.

In August, NIAID reported on an experimental chikungunya vaccine that appeared to elicit a robust immune response in 25 healthy volunteers who participated in an early clinical trial conducted by NIAID. The antibodies persisted in the volunteers, even those who received the lowest dose, for up to nine months suggesting that the vaccine could provide protection against the disease.

NIAID recently established the NIAID Centers of Excellence for Translational Research to support early research, testing, licensure, and use of diagnostics, new therapies, and vaccines for emerging and re-emerging infectious diseases. There are 14 multi-project centers across the United States. Five of the centers are engaged in Ebola-related research.

Finally, Ms. Schuster mentioned several meetings of interest. NIAID and FDA co-sponsored a meeting on the development of new antibacterial products on July 30-31. A meeting will be held on September 22-23 entitled "Overcoming Bottlenecks in Antibacterial Product Development." Also on September 23-24, the "Coordinated Development of Diagnostics and Therapeutics Workshop" will be held at NIH.

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

LCDR Marshall reported that in July 2014, the FDA approved a supplement to the biologics license application for diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed and inactivated poliovirus vaccine. The brand name is Kinrix and the marketing will include revised package insert to include safety and immunogenicity data to support co-administration of Kinrix with varicella virus vaccine, and to update the pharmacovigilance plan.

In July 2014, the FDA approved a supplement to the biologics license application for human papillomavirus bivalent (types 16 and 18) vaccine, recombinant (Cervarix) to include efficacy and immunogenicity data from an end-of-study analysis in the package insert and to update the pharmacovigilance plan.

In July 2014, the FDA approved supplements to the biologics license application for licensed influenza vaccines to include 2014-2015 United States formulations. Influenza vaccine lots that have been released by FDA are available for distribution by the manufacturers.

In July 2014, the FDA (CBER, CDER, CDRH) released draft guidance intended to provide information for institutional review boards, clinical investigators, and study sponsors about FDA's informed consent regulations.

In August 2014, the FDA approved a supplement to the biologics license application (BLA) for influenza vaccine, Afluria, to include data in the labeling for the use of Afluria with the PharmaJet Stratis Needle-Free Injection System for use in persons 18 through 64 years of age.

The FDA received biologic license applications from Pfizer and Novartis for vaccines to protect against meningococcal B disease.

Finally, a conference will be held on September 22-23, cosponsored by NIAID, entitled "Translational and Laboratory Science of Polio Vaccines and Antivirals." The purpose is to bring together stakeholders to identify gaps in scientific knowledge on developing and introducing new vaccines and antivirals against polio virus.

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

Dr. Bok reported that NVPO completed a study, which they funded through Agency for Healthcare Research and Quality (AHRQ), in which the Rand Corporation reviewed the published literature on the safety of vaccines currently recommended in the U.S. for both children and adults including pregnant women. This study was meant to be a follow-up to the Institute of Medicine (IOM) study. A manuscript detailing the results of the study in children was published in the Journal of Pediatrics. Dr. Bok mentioned adverse events associated with certain vaccines including hepatitis A (minor reports of purpura), influenza (TIV, febrile seizures), PCV 13 (also febrile seizures), and rotavirus vaccine, which has a very low risk of intussusception.

NVPO is investing in vaccine safety research including a new collaboration with CISA following infants born to mothers who received the Tdap vaccination while pregnant. There will also be a pilot program announced in early 2015 to fund vaccine safety studies focusing on pregnant women.

**Public Comment**

Mr. King invited members of the public to comment. There were no comments.

**Future Agenda Items/New Business**

Mr. King invited recommendations for future agenda items or submission of items that could be considered new business. Dr. Houston noted that in the past there had been comments about whether or not adult vaccines should be considered for addition to the program, which could be a potential agenda item for the next meeting. Tamara Overby, Acting Deputy Director, DICP commented that the presentations on Pneumovax and Zostavax, the latter of which is not recommended for children, were included in the meeting agenda to give the Commission an opportunity to consider adult vaccines. Incoming Chair, Kristen Feemster, suggested either referring the topic to a work group or adding it to the agenda for the next meeting.

Dr. Shimabukuro commented on the distinction between vaccines that are recommended for routine use in children which, when given to adults (like the influenza vaccines), may cause injury. Those injuries are covered by the program for adult recipients, versus vaccines that are routinely recommended for adults but not children, which are not covered when an adult is injured.

Dr. Feemster recommended establishing a working group to consider these issues. Mr. King agreed, noting that recruitment to the workgroup could be deferred. Ms. Williams commented that the Commission could also recommend that legislation be pursued to include adults in the program whether or not the vaccines are routinely recommended for children.

**Adjournment**

Mr. King and Ms. Williams both expressed appreciation for the opportunity to serve as chair and co-chair, and for the support the members had shown during their tenures. Mr. King invited a motion to adjourn and, on motion duly made and seconded, adjournment was unanimously approved.

# 3

Vaccine Injury Compensation Trust Fund

**Balance as of September 30, 2014**

$3,515,428,504.10

**Figures for October 1, 2013 – September 30, 2014**

Excise Tax Revenue: $243,333,090
Interest on Investments: $61,253,807
Net Income: $304,586,897
Interest as a Percentage of Net Income: 20%

*Source: U.S. Treasury, Bureau of Public Debt*
*November 4, 2014*

# 4

# 4.1

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

# National Vaccine Injury Compensation Program Statistics Report For November 2014

## 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 | 216 |
| FY 2002 | 957 |
| FY 2003 | 2,592 |
| FY 2004 | 1,214 |
| FY 2005 | 735 |
| FY 2006 | 325 |
| FY 2007 | 410 |
| FY 2008 | 418 |
| FY 2009 | 397 |
| FY 2010 | 449 |
| FY 2011 | 386 |
| FY 2012 | 400 |
| FY 2013 | 503 |
| FY 2014 | 632 |
| FY 2015 | 73 |
| **Total** | **15,588** |

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

# Adjudications[1]

| 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 | 233 | 295 |
| FY 2005 | 60 | 121 | 181 |
| FY 2006 | 69 | 191 | 260 |
| FY 2007 | 82 | 121 | 203 |
| FY 2008 | 147 | 134 | 281 |
| FY 2009 | 134 | 231 | 365 |
| FY 2010 | 180 | 293 | 473 |
| FY 2011 | 265 | 1,370 | 1,635 |
| FY 2012 | 261 | 2,439 | 2,700 |
| FY 2013 | 367 | 627 | 994 |
| FY 2014 | 347 | 167 | 514 |
| FY 2015 | 12 | 7 | 19 |
| **Totals** | **3,813** | **9,841** | **13,654** |

[1]Generally, petitions/claims are not adjudicated in the same fiscal year as filed. On average, it takes 2-3 years to adjudicate a petition/claim after it is filed.

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

# Awards Paid[1]

| Fiscal Year | Compensated[2] | | | Dismissed | | Interim Fees | | Total Outlays |
|---|---|---|---|---|---|---|---|---|
| | # of Awards | Petitioners' Award Amount | Attorneys' Fees/ Cost Payments | # of Payments to Attorneys | Attorneys' Fees/ Costs Payments | # of Payments to Attorneys | Attorneys' Fees/ Costs Payments | |
| 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 |

# Awards Paid[1]

| Fiscal Year | Compensated[2] | | | Dismissed | | Interim Fees | | Total Outlays |
|---|---|---|---|---|---|---|---|---|
| | # of Awards | Petitioners' Award Amount | Attorneys' Fees/ Cost Payments | # of Payments to Attorneys | Attorneys' Fees/ Costs Payments | # of Payments to Attorneys | Attorneys' Fees/ Costs Payments | |
| 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 | $202,303,447.68 | $12,001,875.82 | 505 | $6,856,345.79 | 38 | $2,493,460.73 | $223,655,130.02 |
| FY 2015 | 48 | $17,544,844.93 | $1,507,769.13 | 17 | $394,943.13 | 9 | $381,313.82 | $19,828,871.01 |
| **Total** | **3812** | **$2,819,735,611.02** | **$118,697,427.28** | **4897** | **$64,557,977.86** | **214** | **$18,089,086.93** | **$3,021,080,103.09** |

[1]"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 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.

[2]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.

# 4.2

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

# National Vaccine Injury Compensation Program (VICP) Adjudication Categories by Vaccine for Claims Filed Calendar Year 2006 to Present[1]

| Vaccine Alleged by Petitioner[2] | No. of Doses Distributed US CY 2006 - CY 2013 (Source: CDC)[3] | Compensable | | | Compensable Total | Dismissed/ Non-Compensable Total | Grand Total |
|---|---|---|---|---|---|---|---|
| | | Concession | Court Decision | Settlement | | | |
| DT | 652,327 | 1 | | 3 | 4 | 4 | 8 |
| DTaP | 75,888,233 | 12 | 19 | 74 | 105 | 73 | 178 |
| DTaP-Hep B-IPV | 43,929,797 | 4 | 7 | 18 | 29 | 37 | 66 |
| DTaP-HIB | 1,135,474 | | | | | 1 | 1 |
| DTaP-IPV-HIB | 39,590,896 | | | 6 | 6 | 11 | 17 |
| DTP | 0[4] | | 1 | 2 | 3 | 2 | 5 |
| DTP-HIB | 0[4] | | | | | 1 | 1 |
| Hep A-Hep B | 11,662,755 | | | 8 | 8 | 2 | 10 |
| Hep B-HIB | 4,796,583 | 1 | 1 | 1 | 3 | 1 | 4 |
| Hepatitis A (Hep A) | 124,212,280 | 4 | 2 | 21 | 27 | 19 | 46 |
| Hepatitis B (Hep B) | 129,820,136 | 2 | 10 | 39 | 51 | 34 | 85 |
| HIB | 83,517,849 | | 1 | 4 | 5 | 4 | 9 |
| HPV | 67,250,524 | 10 | 1 | 63 | 72 | 80 | 152 |
| Influenza[5] | 944,000,000 | 46 | 81 | 779 | 906 | 174 | 1,080 |
| IPV | 58,019,052 | | | 4 | 4 | 2 | 6 |
| Measles | 135,660 | | | 1 | 1 | | 1 |
| Meningococcal | 58,412,363 | 1 | 2 | 22 | 25 | 3 | 29 |
| MMR | 73,441,556 | 16 | 14 | 56 | 86 | 73 | 159 |
| MMR-Varicella | 11,028,270 | 8 | | 8 | 16 | 8 | 24 |
| Nonqualified[6] | N/A | | | 1 | 1 | 22 | 23 |
| OPV | 0 | 1 | | | 1 | 3 | 4 |

# National Vaccine Injury Compensation Program (VICP) Adjudication Categories by Vaccine for Claims Filed Calendar Year 2006 to Present[1]

| Vaccine Alleged by Petitioner[2] | No. of Doses Distributed US CY 2006 - CY 2013 (Source: CDC)[3] | Compensable | | | Compensable Total | Dismissed/ Non-Compensable Total | Grand Total |
|---|---|---|---|---|---|---|---|
| | | Concession | Court Decision | Settlement | | | |
| Pneumococcal Conjugate | 132,932,107 | | 1 | 5 | 6 | 13 | 19 |
| Rotavirus | 70,719,103 | 1 | 3 | 15 | 19 | 6 | 25 |
| Rubella | 422,548 | | 1 | | 1 | | 1 |
| Td | 55,742,830 | 4 | 6 | 50 | 60 | 16 | 76 |
| Tdap | 155,106,848 | 14 | 7 | 81 | 102 | 12 | 114 |
| TETANUS | 3,836,052 | 3 | | 17 | 20 | 11 | 31 |
| Unspecified[7] | N/A | 1 | | 2 | 3 | 545 | 548 |
| Varicella | 90,425,492 | 3 | 6 | 22 | 31 | 10 | 41 |
| **Grand Total** | **2,236,678,735** | **132** | **163** | **1,302** | **1,595** | **1,167** | **2,763** |

**DEFINITIONS:**

• Compensable – The injured person who filed a claim was paid money by the VICP. Compensation can be achieved through a concession by the Department of Health and Human Services (HHS), a decision on the merits of the claim by a special master or a judge of the United States 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:

- The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or

- 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:
    - 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).
    - 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).
    - The injured person voluntarily withdrew his or her claim.

[1]The date range for this table was selected to reflect the status of the current Program since the inclusion of influenza in July 2005, which now constitutes the majority of all VICP claims.

[2]This is the first vaccine listed by the petitioner in the claim, and other vaccines may be alleged or may form the basis of compensation.

[3]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.

[4]Whole cell pertussis vaccines were not distributed during this time period.

[5]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.

[6]Claims filed for vaccines which are not covered under the VICP.

[7]Insufficient information submitted by petitioner 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.

# 5

# 5.1

# The National Vaccine Injury Compensation Program (VICP)

## Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines
December 4, 2014
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

- Report from the Office of the Special Masters on the 27th Annual Judicial Conference
- Update from the Department of Justice Vaccine Litigation Office
- Report from the ACCV Process Workgroup
- Report from the ACCV Adult Immunization Workgroup
- Review of Vaccine Information Statements
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH, NVPO

## Number of Petitions Filed as of November 3, 2014

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

| Fiscal Year | Total |
|---|---|
| FY 2010 | 449 |
| FY 2011 | 386 |
| FY 2012 | 400 |
| FY 2013 | 503 |
| FY 2014 | 632 |
| FY 2015 | 73 |



## Number of Adjudications as of November 3, 2014

| Fiscal Year | Compensable | Dismissed | Total |
|---|---|---|---|
| FY 2010 | 180 | 293 | 473 |
| FY 2011 | 265 | 1,370 | 1,635 |
| FY 2012 | 261 | 2,439 | 2,700 |
| FY 2013 | 367 | 627 | 994 |
| FY 2014 | 347 | 167 | 514 |
| FY 2015 | 12 | 7 | 19 |

## Adjudication Categories for Non-Autism Claims FY 2013 – FY 2015 as of November 4, 2014

| Adjudication Category | FY 2013 | FY 2014 | FY 2015 |
|---|---|---|---|
| Compensable | 367 (100%) | 347 (100%) | 12 (100%) |
| ❖Concession | 21 (6%) | 32 (9%) | 3 (25%) |
| ❖Court Decision (includes proffers) | 21 (6%) | 36 (10%) | 1 (8%) |
| ❖Settlement | 325 (88%) | 279 (81%) | 8 (67%) |
| Not Compensable | 88 | 123 | 5 |
| Adjudication Total | 455 | 470 | 17 |



## Award Amounts Paid as of November 3, 2014

| Fiscal Year | Petitioners' Award | Attorneys' Fees & Costs |
|---|---|---|
| FY 2010 | $179,387,341 | $9,826,788 |
| FY 2011 | $216,319,428 | $17,163,231 |
| FY 2012 | $163,511,999 | $23,145,929 |
| FY 2013 | $254,666,326 | $21,758,310 |
| FY 2014 | $202,303,448 | $21,351,682 |
| FY 2015 | $17,544,845 | $2,284,026 |

## Vaccine Injury Compensation Trust Fund

- Balance as of September 30, 2014
  - $3,515,428,504.10

- Activity from October 1, 2013 to September 30, 2014
  - Excise Tax Revenue: $243,3333,090
  - Interest on Investments: $61,253,807
  - Net Income: $304,586,897
  - Interest as a Percentage of Net Income: 20%

Source: U.S. Treasury, Bureau of Public Debt (November 4, 2014)



## Significant Activities

- Status of VICP Regulations
- GAO Study Update
- National Vaccine Advisory Committee
  - September 9 & 10, 2014
- Advisory Committee on Immunization Practices
  - October 29 & 30, 2014
- Vaccine Safety Datalink (VSD)
- Information on ACCV meetings, presentations and minutes can be found at http://www.hrsa.gov/vaccinecompensation/commissionchildvaccines.html

# The Health Insurance Marketplace

**The next open enrollment period is November 15, 2014- February 15, 2015**

**www.healthcare.gov**



## 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

# 5.2


**Report from the Department of Justice**

**December 4, 2014**

**Vincent J. Matanoski**
*Deputy Director, Torts Branch*

1

# Statistics

**Reporting Period: 8/16/14 – 11/15/14**

**I. Total Petitions Filed in the United States Court of Federal Claims this reporting period: 249**

A. Minors: 42

B. Adults: 207

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# Statistics

**Reporting Period: 8/16/14 – 11/15/14**

**II. Total Petitions Adjudicated this reporting period: 180**

A. Compensated: 134

i. Cases conceded by HHS: 29

1. Decision awarding damages: 0
2. Decision adopting Proffer: 25
3. Decision adopting Settlement: 4

ii. Cases not conceded by HHS: 105

1. Decision awarding damages: 0
2. Decision adopting Proffer: 3
3. Decision adopting Settlement: 102

B. Not Compensated/Dismissed: 46

i. Decision dismissing Non-OAP: 39

ii. Decision dismissing OAP: 7

3

# Statistics

**Reporting Period: 8/16/14 – 11/15/14**

**III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 3**

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

### Recently Decided Cases

**Appeals by Petitioner:**

- *Graves v. HHS*: Affirmed; petition for panel rehearing denied

*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:**

- *Griffin v. HHS** (Entitlement)
- *Crutchfield v. HHS** (Entitlement)
- *Stillwell v. HHS** (Entitlement)
- *Simanski v. HHS* (Entitlement)
- *Flores v. HHS* (Entitlement)
- *Koehn v. HHS* (Entitlement)

**Appeals by Respondent:**

- *Paluck 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:**

- *Harris v. HHS*: Affirmed (Entitlement)
- *Somosot v. HHS*: Affirmed (Statute of Limitations)
- *Griffin v. HHS*: Affirmed (Entitlement)
- *Crutchfield v. HHS*: Affirmed (Entitlement)
- *Stillwell v. HHS*: Affirmed (Entitlement)

*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:**

- *Spahn v. HHS** (Entitlement)
- *Guerrero v. HHS** (Attorneys' Fees and Costs)
- *Hirmiz v. HHS** (Entitlement)
- *Moriarty v. HHS** (Entitlement)
- *Lerwick v. HHS** (Damages)
- *Castaldi v. HHS* (Statute of Limitations, Entitlement)
- *Mosley v. HHS* (Entitlement)
- *Godfrey v. HHS* (Entitlement)
- *D'Angiolini 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:

- Flores v. HHS: December 4, 2014

U.S. Court of Federal Claims:

- Lerwick v. HHS: January 28, 2014

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# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Tdap | Bilateral peripheral neuropathy | 1 year, 1 month |
| Flu | Acute disseminated encephalomyelitis, transverse myelitis, death | 2 years, 8 months |
| Flu | Guillain-Barré Syndrome | 9 months |
| Flu | Guillain-Barré Syndrome | 2 years, 10 months |
| Hep B | Shoulder injury related to vaccine administration | 1 year, 10 months |
| Flu | Shingles (herpes zoster) | 1 year, 6 months |
| Flu | Neuropathic demyelination and/or myelitis | 1 year, 5 months |
| Flu | Guillain-Barré Syndrome | 1 year, 1 month |
| Tdap | Shoulder injury related to vaccine administration | 11 months |
| Flu | Guillain-Barré Syndrome | 8 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )*

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# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Hep B | Transverse myelitis | 2 years, 3 months |
| Flu | Guillain-Barré Syndrome | 1 year, 7 months |
| MMR, Varicella, Hep A, PCV, DTaP, Hib | Thrombocytopenic purpura | 1 year, 4 months |
| Flu | Guillain-Barré Syndrome | 1 year, 1 month |
| Flu | Guillain-Barré Syndrome | 1 year |
| Flu | Guillain-Barré Syndrome | 1 year |
| Flu | Guillain-Barré Syndrome | 10 months |
| Flu, Tdap | Bilateral shoulder pain | 5 months |
| HPV | Systemic lupus erythematosus | 2 years, 8 months |
| Flu | Shoulder injury related to vaccine administration | 10 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )* 11

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Flu | Illness involving progressive respiratory distress resulting in death | 2 years |
| Flu | Guillain-Barré Syndrome | 1 year, 9 months |
| Flu | Transverse myelitis and/or neuromyelitis optica | 1 year, 9 months |
| MMR | Anaphylaxis and chronic cross-reactive allergies | 1 year |
| Flu | Weakness and numbness in arms, legs, feet, hands and overall weakness; severe headaches, postural tachycardia, palpitations, blurred vision, dizziness, fatigue, tinnitus, weight loss and chest pain; Guillain-Barré Syndrome; and/or acute complication or [sequela] of an illness, disability, injury, or condition; and/or autonomic dysfunction and/or autonomic syndrome | 4 years, 9 months |
| MMR, DTaP, Varicella, IPV | Optic neuritis | 2 years, 10 months |
| Flu | Chronic inflammatory demyelinating polyneuropathy | 2 years, 8 months |
| Flu | Seizures secondary to acute demyelinating encephalomyelitis | 2 years |
| Flu | Guillain-Barré Syndrome | 1 year, 10 months |
| Flu | Guillain-Barré Syndrome | 1 year, 6 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )* 12

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Flu | Guillain-Barré Syndrome | 1 year, 2 months |
| Flu | Peripheral neuropathy | 1 year, 11 months |
| Flu | Guillain-Barré Syndrome | 1 year, 4 months |
| Flu | Guillain-Barré Syndrome, or in the alternative transverse myelitis | 7 months |
| Flu, Td | Anaphylaxis or anaphylactic shock, injuries to respiratory tract and esophagus, and/or brachial neuritis | 3 years, 11 months |
| MMR | Transverse myelitis | 3 years, 2 months |
| Flu | Guillain-Barré Syndrome | 2 years, 11 months |
| Flu | Guillain-Barré Syndrome | 1 year, 9 months |
| Flu | Chronic inflammatory demyelinating polyneuropathy | 1 year, 8 months |
| Flu | Transverse myelitis | 11 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )*



# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Flu | Guillain-Barré Syndrome and steroid myopathy | 11 months |
| DTaP, Hep B, IPV, PCV | Encephalopathy or encephalitis, death | 9 months |
| Flu | Guillain-Barré Syndrome | 2 years, 5 months |
| Hep B | Myasthenia gravis, fatigue, muscle weakness, eyelid drooping, and fatigue-induced diplopia | 2 years, 3 months |
| Flu | Guillain-Barré Syndrome | 1 year, 9 months |
| Flu | Guillain-Barré Syndrome | 1 year, 1 month |
| Tdap | Guillain-Barré Syndrome | 9 months |
| Flu | Guillain-Barré Syndrome | 1 year, 6 months |
| Varicella | Guillain-Barré Syndrome | 1 year, 6 months |
| Hep B | Severe asthma and chronic sinus disease | 1 year, 4 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )*

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Tdap, Flu | Deltoid bursitis | 1 year, 1 month |
| Flu | Guillain-Barré Syndrome | 1 year |
| Tdap | Chronic inflammatory demyelinating polyradiculoneuropathy | 11 months |
| Flu | Acute disseminated encephalomyelitis | 11 months |
| Flu | Guillain-Barré Syndrome | 10 months |
| Flu | Brachial plexopathy | 10 months |
| Flu | Guillain-Barré Syndrome | 8 months |
| Flu | Guillain-Barré Syndrome | 4 years, 3 months |
| DTaP, Hib, PCV, MMR | Streptococcal A infection, Streptococcal toxic shock syndrome, and multi-organ system failure | 3 years, 8 months |
| Flu | Myelitis | 2 years, 8 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . .)* 15

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Flu | Shoulder injury related to vaccine administration | 11 months |
| Flu | Guillain-Barré Syndrome | 1 year, 7 months |
| Tdap | Guillain-Barré Syndrome | 1 year, 6 months |
| Flu | Guillain-Barré Syndrome | 11 months |
| Flu | Guillain-Barré Syndrome | 2 years, 9 months |
| DTaP, PCV | Tic disorder, seizures, and other injuries | 1 year, 7 months |
| Flu | Guillain-Barré Syndrome | 1 year, 2 months |
| Flu | Progressive multifocal motor neuropathy, death | 1 year, 2 months |
| Flu | Transverse myelitis | 3 years, 10 months |
| Flu | Shoulder injury related to vaccine administration | 1 year |

*Terms of settlement are memorialized by Stipulation

*(continued . . .)* 16

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Flu | Guillain-Barré Syndrome | 8 months |
| Flu | Neuromuscular symptoms and/or fibromyalgia | 3 years, 1 month |
| Flu | Permanent myalgia, arthralgia, and/or fibromyalgia | 3 years |
| Flu | Guillain-Barré Syndrome | 1 year, 7 months |
| Tdap, MMR | Demyelinating polyneuropathy | 1 year |
| Flu | Guillain-Barré Syndrome | 1 year |
| MMR, Hib, Varicella | Chronic inflammatory demyelinating polyneuropathy and/or Guillain-Barré Syndrome | 2 years, 6 months |
| Flu | Guillain-Barré Syndrome and brachial neuritis | 9 months |
| Flu | Guillain-Barré Syndrome | 2 years, 3 months |
| Flu | Guillain-Barré Syndrome | 1 year, 11 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )* 17

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| MMR | Sensorineural hearing loss | 11 months |
| Flu | Guillain-Barré Syndrome | 1 year, 8 months |
| Flu | Guillain-Barré Syndrome | 1 year |
| Flu | Rheumatoid arthritis | 11 months |
| Flu | Transverse myelitis | 1 year, 9 months |
| Flu | Optic neuritis | 1 year, 5 months |
| Flu | Injuries to right arm and shoulder | 1 year |
| Flu | Transverse myelitis | 11 months |
| Tdap | Acute disseminated encephalomyelitis | 2 years, 1 month |
| Flu | Shoulder injury | 1 year, 9 months |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )* 18

# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Flu | Guillain-Barré Syndrome and/or chronic inflammatory demyelinating polyneuropathy | 1 year, 3 months |
| Tdap | Myelitis | 9 months |
| Flu | Guillain-Barré Syndrome | 1 year, 6 months |
| Flu | Optic neuritis | 1 year, 3 months |
| Flu | Adverse reaction, including chronic regional pain syndrome | 1 year, 3 months |
| Flu | Guillain-Barré Syndrome | 3 years, 6 months |
| Flu | Guillain-Barré Syndrome | 2 years, 7 months |
| Flu | Guillain-Barré Syndrome | 1 year, 7 months |
| Tdap | Left shoulder injuries, to include: a rotator cuff tear, tendinitis, impingement syndrome, and/or bursitis | 6 months |
| Flu | Cervical transverse myelitis | 2 years, 1 month |

*Terms of settlement are memorialized by Stipulation

*(continued . . . )*

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# Adjudicated Settlements*

**Reporting Period: 8/16/14 – 11/15/14**

| Vaccine(s) | Alleged Injury(ies) | Petition Filing to Settlement Filing |
|---|---|---|
| Tdap, MCV, IPV, Hep A, Hep B, MMR, Flu | Brachial neuritis and related sequelae | 1 year, 10 months |
| Flu | Transverse myelitis | 1 year, 7 months |
| Flu | Bell's palsy and Guillain-Barré Syndrome | 10 months |
| MMR | Shoulder injury related to vaccine administration | 2 years, 5 months |
| Flu | Severe sensory motor polyneuropathy | 1 year, 9 months |
| Flu | Guillain-Barré Syndrome | 11 months |

***Total Number of Judgments Adopting Settlement this reporting period: 106***

*Terms of settlement are memorialized by Stipulation

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# 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.

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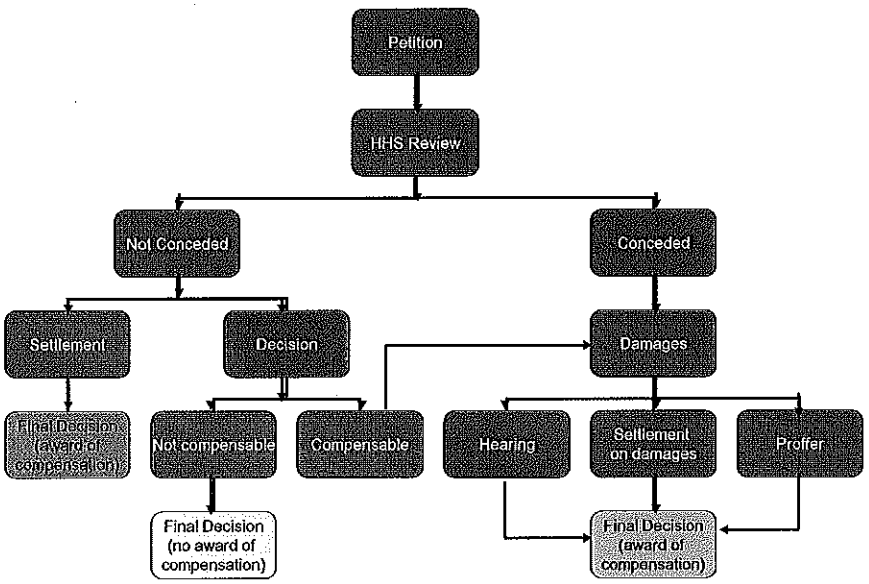
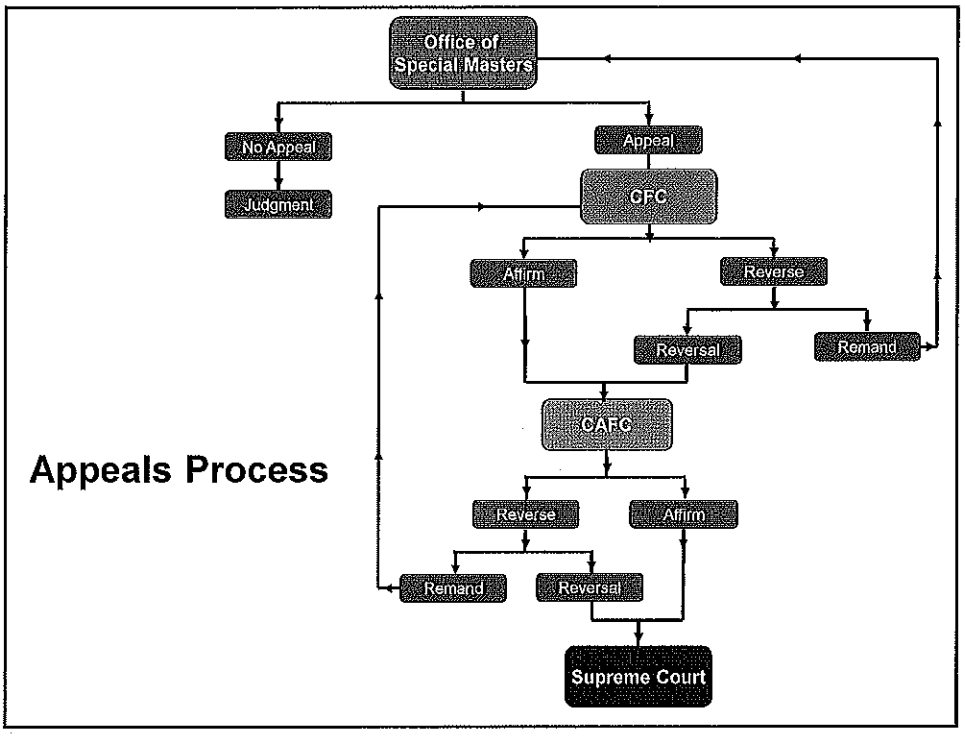
## Petition Processing in the Office of Special Masters




25

## Levels of Appeal in Vaccine Act Cases


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

**Updated for the December 2014 ACCV Meeting**
**Prepared by the U.S. Department of Justice (DOJ)**
**U.S. Court of Appeals for the Federal Circuit (CAFC) / U.S. Supreme Court**

## Entitlement

| CASE NAME<br>CITATION | HOLDING |
|---|---|
| STONE<br>and<br>HAMMITT<br>676 F.3d 1373<br>(Fed. Cir. 2012) | In a consolidated appeal, the CAFC reiterated prior precedent and held that the special master was not precluded from considering respondent's evidence of a genetic mutation as part of examining the record as a whole to determine whether or not petitioners met their burden of proof in establishing a prima facie case merely because that evidence was also relevant as to whether or not respondent had satisfied her burden of showing an alternate cause. Because the special master found that the genetic mutation was the sole cause of the children's condition, there was no need to analyze the question of superseding causes. The CAFC also found that the special master was not arbitrary or capricious in his fact finding and that petitioners failed to show that the DTaP vaccine was the more likely cause of the children's seizure disorder. |
| ROTOLI<br>and<br>PORTER<br>663 F.3d 1242<br>(Fed. Cir. 2011) | The CAFC found that the Claims Court judge incorrectly read Andreu to prohibit a special master from using credibility determinations to reject a petitioner's theory of causation. Rather, in Moberly, Broekelschen, and Doe 11, the CAFC had "unambiguously explained" that special masters are expected to consider credibility of expert witnesses in evaluating vaccine claims. Further, the Claims Court's blanket approach of setting aside the special master's findings of fact without ever determining whether the findings were arbitrary and capricious was legal error. Because the special master's decision contained a thorough and careful evaluation of all of the evidence, including records, tests, reports, medical literature, and expert's opinions and their credibility, the CAFC found that the special master's decision was not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. The CAFC reversed the findings of the Claims Court and remanded with instructions that a decision be entered affirming the special master's denial of compensation. |

| | |
|---|---|
| CEDILLO<br>617 F.3d 1328<br>(Fed. Cir. 2010) | The CAFC affirmed the Court of Federal Claims' decision sustaining the special master's determination that thimerosal containing vaccines combined with the measles-mumps-rubella (MMR) vaccine do not cause autism. In this appeal, appellants argued that the special master improperly based his decision on evidence derived from litigation in the United Kingdom that should have been excluded, and disregarded other evidence that should have been considered. The CAFC disagreed and found that the special master committed no legal error, properly considered all relevant and reliable evidence, and appropriately exercised his discretion in weighing that evidence. Of particular note, the CAFC held that the special master's use of Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), was an appropriate tool to assess the reliability of the parties' evidence, particularly the expert testimony. |
| HAZLEHURST<br>604 F.3d 1343<br>(Fed. Cir. 2010) | The CAFC found that the special master acted consistent with principles of fundamental fairness by admitting and considering respondent's expert's testimony and reports criticizing petitioners' evidence and offered petitioners ample time and opportunity to rebut respondent's evidence. Further, the special master did not commit legal error by according little weight to petitioners' evidence from a research facility, which the special master found to be unpublished, preliminary, and incomplete. The special master further committed no error in discounting testimony by petitioners' expert regarding causation because that opinion was based on studies that were unreliable. |
| DOE 11<br>601 F.3d 1349<br>(Fed. Cir. 2010) | The CAFC found that the special master correctly considered "the record as a whole" in determining whether compensation is warranted, and that the Government is not restricted by proving a "factor unrelated" as the burden never shifted from petitioner to establish a prima facie case. The Government may present evidence of an alternate cause and the special master is not limited or precluded from considering such evidence when deciding whether petitioner has established a prima facie case. Petitioners' failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternate cause. |
| MOBERLY<br>592 F.3d 1315<br>(Fed. Cir. 2010) | The CAFC found that the special master correctly interpreted and applied the traditional tort "preponderance" standard applicable in Vaccine Act cases, and that the petitioners' argument for a more relaxed standard was not consistent with the Act. The Court also held that a close temporal association and the lack of an identifiable alternative cause, standing alone, are insufficient to prove causation. The Court further held that when evaluating an expert's medical theory, a special master is expected to evaluate both the reliability and credibility of the expert's testimony. |

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|---|---|
| ANDREU<br>569 F.3d 1367<br>(Fed. Cir. 2009) | The CAFC found that if a petitioner satisfies the first and third prongs of Althen, the second prong (whether there exists a logical sequence of cause and effect between the vaccination and the injury alleged) can be met through the testimony of a treating physician. The CAFC further found that the special master's determinations regarding the credibility of witnesses are distinct from determinations of the reliability of scientific evidence, and the special master must clearly differentiate between these determinations to allow appropriate review on appeal. |
| DE BAZAN<br>539 F.3d 1347<br>(Fed. Cir. 2008) | The CAFC found that as part of petitioner's evidence in establishing a prima facie case of actual causation, petitioner has the burden of proving a medically appropriate time frame between vaccination and the onset of injury. The Government, like any defendant, may offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief, and a special master is obliged to consider all evidence when deciding whether or not petitioner has met his burden of proof. |
| WALTHER<br>485 F.3d 1146<br>(Fed. Cir. 2007) | The CAFC found that the Vaccine Act does not require petitioners to bear the burden of eliminating alternative causes where the other evidence on causation-in-fact is sufficient to establish a prima facie case. |
| PAFFORD<br>451 F.3d 1352<br>(Fed. Cir. 2006) | The CAFC found that petitioners must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury, when petitioners' other evidence of causation-in-fact is insufficient to establish a prima facie case. |
| CAPIZZANO<br>440 F.3d 1317<br>(Fed. Cir. 2006) | The CAFC found that a claimant could satisfy prongs one and two of the three-prong Althen test but fail to satisfy prong two when medical records and medical opinions do not suggest that the vaccine caused the injury or where the evidence shows that the probability of coincidence or another cause prevents petitioner from establishing causation by a preponderance of the evidence. The CAFC found that statements in the medical records by treating physicians are relevant and should be afforded significant evidentiary weight. |
| ALTHEN<br>418 F.3d 1274<br>(Fed. Cir. 2005) | The CAFC found that in order to prove causation-in-fact, a petitioner must prove by a preponderance of the evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. Lack of peer reviewed literature does not, in and of itself, preclude a finding of causation-in-fact. |

## Statute of Limitations

| CASE NAME CITATION | HOLDING |
|---|---|
| CLOER<br>654 F.3d 1322<br>(Fed. Cir. 2011) | On August 5, 2011, the CAFC, in an 8-4 en banc decision, held that the Vaccine Act does not contain a discovery rule, nor can a discovery rule be read by implication into the Act. Rather, the statute of limitations begins to run on a specific statutory date: the date of the occurrence of the first symptom or manifestation of onset of the injury for which a claimant seeks compensation. In addition, the Court overruled its prior precedent and further held that equitable tolling applies to the Vaccine Act, although it determined that the statute of limitations is not tolled due to unawareness of a causal link between an injury and administration of a vaccine. |
| WILKERSON<br>593 F.3d 1343<br>(Fed. Cir. 2010) | The CAFC found that, consistent with its holding in Markovich, the 36 month statute of limitations period under 42 U.S.C. § 300aa-16(a)(2) begins to run with ***either*** the occurrence of the first symptom of or the manifestation of onset of an alleged vaccine-related injury, whichever is first. The Court held that the Act's time for filing runs from "the date of the occurrence of the first symptom or manifestation of onset," not the date the medical profession recognizes that a symptom is related to an alleged vaccine-related injury, and the Court held that an expert's determination of the first symptom or manifestation of onset may be made in "hindsight," i.e., a medical professional need not have appreciated the significance of the symptom at the time it occurred. |
| MARKOVICH<br>477 F.3d 1353<br>(Fed. Cir. 2007) | The CAFC found that the determination of when the 36 month statute of limitations period under 42 U.S.C. § 16(a)(2) begins to run is made by an objective standard, that is, even if the petitioner reasonably would not have known at the time that the vaccine had caused injury. |

## Death Benefits/Survivorship

| CASE NAME CITATION | HOLDING |
|---|---|
| ZATUCHNI (SNYDER)<br>516 F.3d 1312<br>(Fed. Cir. 2008) | The CAFC found that a petitioner who establishes vaccine-related injuries and a vaccine-caused death is entitled to recover the compensation for vaccine-related injuries and vaccine-related death benefits under 42 U.S.C. § 300aa-15(a)(1)(B), (a)(3), (a)(4), and the death benefit provided under Section 15(a)(2). This applies where petitioner filed a claim for vaccine-related injuries, received a favorable ruling that the injuries were vaccine-related, and then died before receiving compensation for those injuries. |

## Attorneys' Fees and Costs/Interim Fees Requests

| CASE NAME CITATION | HOLDING |
|---|---|
| CLOER<br>133 S. Ct. 1886 (2013) | The U.S. Supreme Court affirmed the judgment of the CAFC, finding that a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs. |
| RODRIGUEZ<br>632 F.3d 1381 (Fed. Cir. 2011) | The CAFC affirmed the special master's decision rejecting the Laffey matrix as prima facie evidence of a forum rate for petitioners' counsel. The issue was whether the reasonable hourly rate for attorneys handling Vaccine Act cases should be determined by applying the Laffey matrix, a schedule of rates maintained by DOJ to compensate attorneys prevailing in "complex federal litigation," or whether the rate should be determined by considering a variety of factors, which may or may not include the Laffey matrix. The CAFC held that Vaccine Act litigation, while potentially involving complicated medical issues and requiring highly skilled counsel, is not analogous to "complex federal litigation" as described in Laffey, so as to justify use of the matrix. Distinguishing between the type of litigation the Laffey matrix is designed to compensate, the CAFC stated that a party need not prevail under the Vaccine Act in order to receive an attorneys' fees award, that attorneys are practically assured of compensation in every case without regard to whether they win or lose and the skill with which they presented their clients' cases, and that the attorneys' fees provisions under the Act "were not designed as a form of economic relief to improve the financial lot of lawyers." Further, the CAFC noted that Vaccine Act proceedings are an alternative to the traditional civil forum, apply relaxed legal standards of causation, have eased procedural rules compared to other federal civil litigation, do not have formal discovery and thus avoid discovery disputes, do not apply the rules of evidence, and are tried in informal, streamlined proceedings before special masters well-versed in the issues commonly repeated in Vaccine Act cases. |

| | |
|---|---|
| RIGGINS<br>406 Fed. App'x. 479 (Fed. Cir. 2011) | The CAFC found that the special master appropriately reduced the amount of attorneys' fees and costs sought by petitioner's counsel for the general development of Hepatitis B vaccine cases from the requested sum of $204,619.18 to an award of $79,782.81. In doing so, the CAFC affirmed the special master's decision to reduce the $97,443.43 in fees and costs associated with the consulting work of two experts to $10,000.00. Among other things, the CAFC agreed with the special master's finding that a hypothetical client would not pay for costly travel by petitioner's counsel and his consultants to France for personal consultation with foreign experts and lawyers, or for time and expenses related to the consultants' attendance at a professional conference in Italy. |
| KAY<br>298 Fed. App'x. 985 (Fed. Cir. 2008) per curiam, affirmance, Nov. 10, 2008 | The CAFC denied an award of attorneys' fees and costs where the petition was found to be time-barred under Markovich and dismissed for lack of jurisdiction, precluding an award of attorneys' fees in a case that was untimely filed. |
| AVERA<br>515 F.3d 1343 (Fed. Cir. 2008) | The CAFC affirmed that, in general, the forum rule should be used to calculate reasonable hourly rates for petitioners' attorneys in claims brought under the Vaccine Act, and found that Washington, DC is the forum for vaccine cases because it is where the CFC, which has exclusive jurisdiction over vaccine cases, is physically located. In applying the forum rule, the CAFC recognized and applied an exception derived from Davis v. U.S. E.P.A., 169 F.3d 755 (D.C. Cir. 1999). Applying Davis, the CAFC found that an exception to the forum rule applies where 1) the bulk of the work was done outside DC and 2) there is a very significant difference between the DC rates and the attorneys' hometown rates. The CAFC found that the appellants' vaccine attorneys hailing from Cheyenne, Wyoming were not entitled to forum rates in this case. The CAFC also held that interim attorneys' fees are permitted under the Vaccine Act. The CAFC considered an award of interim fees particularly appropriate when cases are protracted and costly experts must be retained. The CAFC found that there was no basis for an award of interim fees here because the petitioners only sought an award of interim fees pending an appeal; made no showing of undue hardship; the amount of fees was not substantial; no experts had been employed; and there was only a short delay in the award pending the appeal. |

# 5.3

# 5.4

# 5.5

Vaccine Information Statement

# Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know 2015-16

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

## 1. Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every winter, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose



Flu can also lead to pneumonia, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Young children, people 65 and older, pregnant women, and people with health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

**Flu vaccine** can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

## 2. Inactivated and recombinant flu vaccines

You should get a dose of flu vaccine every year. Some children through 8 years of age need two doses during their first or second year.

You are getting an **"inactivated" or "recombinant"** flu vaccine, or "flu shot." It does not contain any live influenza virus, and is given by injection.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts up to a year.

A different, **live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have shown that thimerosal in vaccines is not harmful, but flu vaccines that do not contain a preservative are available.

Inactivated flu vaccine does not contain live flu virus, so you **cannot get the flu from this vaccine.**

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three of four viruses that are likely to cause disease that year. Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

But flu vaccine that matches the circulating viruses is our best protection from influenza.



**3. Some people should not get this vaccine**

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**
  If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.

- **If you ever had Guillain-Barré Syndrome** (also called GBS).
  Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.

- **If you are not feeling well.**
  It is usually okay to get flu vaccine when you have a mild illness, but you might be advised to come back when you feel better.

**4. Risks of a vaccine reaction**

A vaccine, like any medicine, can cause side effects. These are usually mild and go away on their own.

**Mild problems** following inactivated flu vaccine:

- soreness, redness, or swelling where the shot was given

- hoarseness
- sore, red or itchy eyes
- cough
- fever
- aches
- headache
- itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

**Moderate problems** following inactivated flu vaccine:

Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

**Problems that could happen after any vaccine:**



- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely, and is temporary.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

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

**5. What if there is a serious reaction?**

**What should I look for?**

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

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

**What should I do?**

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

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

*VAERS does not give medical advice.*

**6. The National Vaccine Injury Compensation Program**

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

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



**7. How can I learn more?**

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

Vaccine Information Statement
Inactivated Influenza Vaccine
[Date]
42 U.S.C. § 300aa-26

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

Office Use Only
[Barcode]

Vaccine Information Statement

**Influenza (Flu) Vaccine (Live, Intranasal): What you need to know**
**2015-16**

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

## 1. Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every winter, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.



Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Young children, people 65 and older, pregnant women, and people with health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

**Flu vaccine** can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

## 2. Live, attenuated flu vaccine – LAIV, Nasal Spray

You should get a dose of flu vaccine every year. Some children up through 8 years of age need two doses during their first or second year.

You are getting a **live, attenuated influenza vaccine** (called LAIV), which is sprayed into the nose. "Attenuated" means weakened. The viruses in the vaccine have been weakened so they won't give you the flu.

LAIV may be given to people **2 through 49 years of age.** It may safely be given at the same time as other vaccines.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts up to a year.

LAIV does not contain thimerosal or other preservatives. It is made from weakened flu virus and **does not cause flu.**

There are other flu vaccines that do not contain live virus. These "flu shots" are given by injection. *Injectable flu vaccines are described in a separate Vaccine Information Statement.*

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three of four viruses that are likely to cause disease that year. LAIV contains four flu viruses. Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

But flu vaccine that matches the circulating viruses is our best protection from influenza.



**3. Some people should not get this vaccine**

Tell the person who gives you the vaccine:

- **If you have any severe, life-threatening allergies.**
  If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. LAIV contains egg protein.

- **If you ever had Guillain-Barré Syndrome** (also called GBS).
  Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.

- **If you have long-term health problems.**
  If you have health problems such as certain heart, breathing, kidney, liver, or nervous system problems, your doctor can help you decide if you should get LAIV.

- **If you have gotten any other vaccines in the past 4 weeks.**
  You should wait at least 4 weeks after getting another *live* vaccine before getting LAIV, because getting live vaccines too close together might make them less effective.

- **If you are not feeling well.**
  It is usually okay to get flu vaccine when you have a mild illness, but you might be advised to come back when you feel better

**You should get the flu shot instead of the nasal spray if you:**

- are pregnant
- have a weakened immune system
- are allergic to eggs
- are a young child with asthma or wheezing problems
- are a child or adolescent on long-term aspirin therapy
- will provide care for, or visit someone, within the next 7 days who needs special care for an extremely weakened immune system (ask your health care provider)
- have taken influenza antiviral medications in the past 48 hours

The person giving you the vaccine can give you more information.



**4. Risks of a vaccine reaction**

A vaccine, like any medicine, can cause side effects. These are usually mild and go away on their own.

**Mild problems** that have been reported following LAIV:

*Children and adolescents 2-17 years of age:*

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

*Adults 18-49 years of age:*

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

**Problems that could happen after any vaccine:**

- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would usually be within a few minutes to a few hours after the vaccination.

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

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

**5. What if there is a serious reaction?**

**What should I look for?**

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

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

**What should I do?**

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

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

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**8. How can I learn more?**

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

[Date]
42 U.S.C. § 300aa-26

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

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# 5.6

# 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)
December 4, 2014



# Topics

- October 2014 Advisory Committee on Immunization Practices (ACIP) meeting highlights
- Clinical Immunization Safety Assessment (CISA) Project research studies
- Selected publications

# October 2014 ACIP meeting update

- Vaccine safety
  - Proposed changes to the VAERS reporting form (VAERS 2.0) – previously briefed to ACCV in September 2014
  - Next steps
    - Public comment solicitation through Federal Register
    - Final revisions
    - Develop the platform to accept electronic VAERS 2.0 submissions and update the online reporting tool to reflect new data elements
    - Implement the VAERS 2.0 form
    - Evaluate completeness and quality of VAERS data (pre-post comparison)

http://www.cdc.gov/vaccines/acip/meetings/slides-2014-10.html 3

# October 2014 ACIP meeting update, cont.

- Influenza (influenza vaccine effectiveness [VE])
  - Summary US Flu Vaccine Effectiveness Network
    - 2011-12 and 2012-13: relative effectiveness favored LAIV vs. IIV in young children (though not statistically significant)
    - 2013-14: relative effectiveness favored IIV vs. LAIV in young children
    - H1N1pdm09 was predominant virus in 2013-14
  - Summary of observational data for 2013-14
    - 3 studies reported low VE for LAIV4 against H1N1pdm09 in 2013-14
    - MedImmune post-licensure study reported significant VE for LAIV4 (similar to IIV) against B-Yamagata, but not H1N1pmd09
    - Additional work to evaluate these finding is ongoing

http://www.cdc.gov/vaccines/acip/meetings/slides-2014-10.html 4

## October 2014 ACIP meeting update, cont.

- **PharmaJet Stratis Needle-Free Injection System approved by FDA for use with Afluria in August 2014**
  - Clinical study demonstrated that Afluria TIV influenza vaccine delivered by PJ Stratis needle-free jet injector generates immune responses that are non-inferior to needle and syringe (NS)
  - Local injection-site reactions (mild) more frequent in PJ Stratis injector group
  - Systemic AEs comparable between Afluria given with NS and with jet injector
  - Post-marketing surveys support patient and healthcare provider satisfaction with needle-free flu immunization

http://www.cdc.gov/vaccines/acip/meetings/slides-2014-10.html 5

## October 2014 ACIP meeting update, cont.

- **Meningococcal Serogroup B Vaccines**
  - Bexsero, 4cMenB (Novartis)
    - Biologics License Application (BLA) submitted for persons 10-25 years old, accelerate pathway
    - 2 dose series
    - IND protocol used to control 2 recent US outbreaks
  - Trumenba, rLP2086 (Pfizer)
    - Approved by FDA on 10/29/14 (accelerated approval)
    - Approved for ages 10-25 years old
    - 3 dose series
  - Upcoming ACIP meetings will discuss policy decisions

http://www.cdc.gov/vaccines/acip/meetings/slides-2014-10.html 6

## October 2014 ACIP meeting update, cont.

- HPV vaccines
  - Summary of 9-valent HPV vaccine clinical trial data
    - Generally well tolerated in young men and young woman (similar to that of HPV4)
    - Switching to a 9-valent girls and boys programs is likely cost-effective and cost saving; vaccinating girls with 9-valent provides the great majority of benefits of a 9-valent girls and boys program
    - Expect approval in 2015

http://www.cdc.gov/vaccines/acip/meetings/slides-2014-10.html

7

## Clinical Immunization Safety Assessment (CISA) Project studies registered at ClinicalTrials.gov

- A study to assess the effect of prophylactic antipyretics on immune responses and rates of fever after the 2014-2015 inactivated influenza vaccine (IIV) in young children (*NCT 02212990*)
- Pilot study to assess the effect of prophylactic antipyretics on immune responses and rates of fever after the 2013-2014 inactivated influenza vaccine (IIV) in young children (*NCT01946594*)
- Assessing the feasibility of monitoring influenza vaccine safety in pregnant women using text messaging (*NCT01974050*)
- Immune response to influenza vaccination and effect on reproductive hormones (*NCT01978262*)
- Clinical study of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis vaccine (Tdap) safety in pregnant women (*NCT 02209623*)
- Assessing fever rates in children ages 24 to 59 months after live attenuated influenza vaccine (LAIV) or inactivated influenza vaccines (IIV) using text messaging for U.S. influenza vaccines in 2012–13 & 2013-2014 (*NCT01764269*)
- Pilot study to assess flares of illness following receipt of inactivated influenza vaccine in youth with systemic lupus erythematosus (SLE) (*NCT02006784*)

8

# Selected publications

- Haber et al. Post-licensure surveillance of trivalent live attenuated influenza vaccine in adults, United States, Vaccine Adverse Event Reporting System (VAERS), July 2005-June 2013. Vaccine. 2014 Sep 22. [Epub ahead of print]
  - Review of VAERS reports are reassuring, the only unexpected safety concern for LAIV3 identified was a higher than expected number of GBS reports in the DoD population, which is being investigated. Reports of administration of expired LAIV3 represent administration errors and indicate the need for education, training and screening regarding the approved indications
- Haber et al. Notes from the field: reports of expired live attenuated influenza vaccine being administered--United States, 2007-2014. MMWR Morb Mortal Wkly Rep. 2014 Sep 5;63(35):773.

9

# Selected publications

- Kharbanda et al. Evaluation of the association of maternal pertussis vaccination with obstetric events and birth outcomes. JAMA. 2014 Nov 12;312(18):1897-904.
  - In the study cohort of women with singleton pregnancies that ended in live birth, receipt of Tdap during pregnancy was not associated with increased risk of hypertensive disorders of pregnancy or preterm or small for gestational age birth, although a small but statistically significant increased risk of chorioamnionitis diagnosis was observed.
- Duffy et al. Narcolepsy and influenza A(H1N1) pandemic 2009 vaccination in the United States. Neurology. 2014 Nov 11;83(20):1823-30.
  - Influenza vaccines containing the A(H1N1)pdm09 virus strain used in the United States were not associated with an increased risk of narcolepsy. Vaccination with the influenza A(H1N1)pdm09 vaccine viral antigens does not appear to be sufficient by itself to increase the incidence of narcolepsy in a population

10

# Selected publications

- Tartof et al. Inpatient admission for febrile seizure and subsequent outcomes do not differ in children with vaccine-associated versus non-vaccine associated febrile seizures. Vaccine. 2014 Oct 5. [Epub ahead of print]
  - The risk of hospitalization for index febrile seizure (FS) or select subsequent FS outcomes did not differ between vaccine-associated FS or nonvaccine-associated FS
  - This suggests that the follow-up care of children with vaccine-associated FS does not warrant attention beyond that for nonvaccine-associated FS
- Kharbanda et al. Receipt of pertussis vaccine during pregnancy across 7 Vaccine Safety Datalink sites. Prev Med. 2014 Oct;67:316-9.
  - Authors observed substantial increases in Tdap coverage during pregnancy following California Department of Public Health and ACIP recommendations

11


## Centers for Disease Control and Prevention
### Atlanta, GA

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

12

# Thank You

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



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

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# 5.7

# Vaccine Activities Update

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

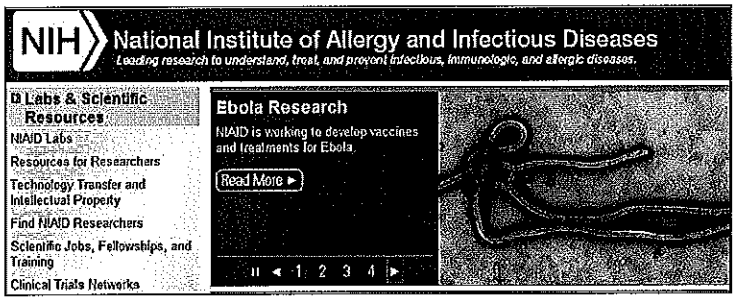
Claire Schuster, MPH
Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS

December 2014

National Institute of Allergy and Infectious Diseases

1

# Ebola Research

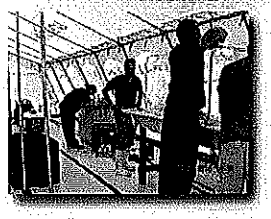


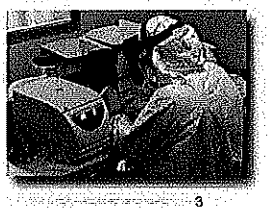

www.niaid.nih.gov/topics/ebolaMarburg/research/Pages/default.aspx

2

## NIH Engagement

- Diagnostic lab support and training in Liberia and Mali
- Provision of equipment and supplies
- Field preparation for clinical trials
- Participation in WHO and UN policy meetings
- Collaboration with pharmaceutical companies and vaccine manufacturers
- Commissioned Corps assignment for clinical care and support
- Provision of expert advice to Government Officials
- Interaction with Congress and the US public





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## Phase I Trial of NIAID/GSK Candidate Ebola Vaccine Fully Enrolled

Credit: NIAID

**20/20 participants have received the investigational NIAID/GSK Ebola vaccine; initial safety and immunogenicity data expected by the end of 2014**

4

AS Fauci/NIAID

## NewLink Genetics VSV Vaccine Phase I Trial Begins

Associated Press

October 13, 2014

### Canadian Ebola Vaccine Begins Testing

TORONTO — Human testing of an experimental Canadian-made Ebola vaccine began Monday, with federal officials saying the [vaccine] could be shipped to West Africa within months if it proves successful.

5

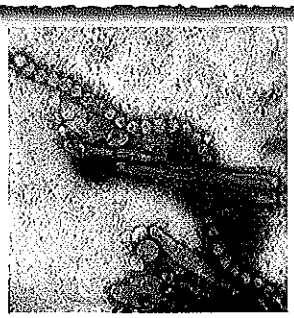
AS Fauci/NIAID

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

National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov
Tuesday, October 7, 2014

## Candidate H7N9 Avian Flu Vaccine Works Better with Adjuvant



Influenza A H7N9 Credit: CDC

6

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

National Institute of Allergy and Infectious Diseases (NIAID)

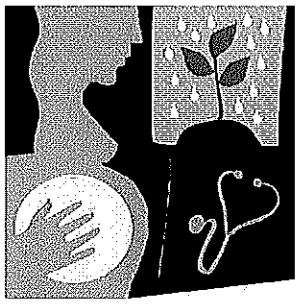
http://www.niaid.nih.gov
Monday, Sept. 29, 2014

## NIH Awards Seven New Vaccine Adjuvant Discovery Contracts

7

## Meetings

Conference on Clinical Research in Pregnant Women: Knowledge, Gaps, and Opportunities
(September 29-30, 2014)



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# 5.8

## ACCV UPDATE

### FOOD AND DRUG ADMINISTRATION

- In September 2014, the package insert for Menactra (Meningococcal Groups (A, C, Y, and W-135 Polysaccharide Diphtheria Toxoid Conjugate Vaccine) was revised to include safety and immunogenicity data to support Menactra revaccination at 15 years through 55 years of age in adolescents and adults at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose

- In October 2014, the Food and Drug Administration approved, Trumenba, the first vaccine licensed in the United States to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age.

- On December 12, 2014, the Food and Drug Administration (FDA), the National Institutes of Allergy and Infectious Diseases (NIAID), the Department of Defense (DoD), the Centers for Disease Control and Prevention (CDC), and the Biomedical Advanced Research and Development Authority (BARDA) will hold a public workshop, entitled "Immunology of Protection from Ebola Virus Infection." The purpose of this workshop is to discuss important aspects of Ebola virus and vaccine immunology in order to inform future clinical, scientific and regulatory decision-making related to vaccines against Ebola.

- On March 4, 2015, the Vaccines and Related Biological Products Committee will meet in an open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2015-2016 influenza season.

# 5.9

# National Vaccine Program Office Update

## ACCV, December 2014

Dr. Karin Bok

National Vaccine Program Office

1

## National Adult Immunization Plan

- NVPO is working with the Adult Immunization Task Force (AITF) under the direction of the Assistant Secretary for Health to develop a comprehensive plan to improve all aspects of immunizations for adults
- The new plan, Adult Immunization Plan, is currently going through clearance
- The plan is expected to be launched late 2014/early 2015

National Vaccine Program Office

2

## NVPO SUPPORTING NVAC MATERNAL IMMUNIZATION ACTIVITIES

- The September 2014 NVAC meeting featured an entire session about maternal immunization. From safety issues to barrier to develop new vaccines to be administered to pregnant women
- NVAC has created a new Maternal Immunization Working Group that will identify barriers to and opportunities for developing vaccines for pregnant women and make recommendations to overcome these barriers

National Vaccine Program Office

3

## THANK YOU

National Vaccine Program Office

4

# 6

# 6.1

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 63 / No. 34
August 29, 2014

# National, State, and Selected Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2013

Laurie D. Elam-Evans, PhD[1], David Yankey, MS[1], James A. Singleton, PhD[1], Maureen Kolasa, MPH[1] (Author affiliations at end of text)

In the United States, among children born during 1994–2013, vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths during their lifetimes (*1*). Since 1994, the National Immunization Survey (NIS) has monitored vaccination coverage among children aged 19–35 months in the United States. This report describes national, regional, state, and selected local area vaccination coverage estimates for children born January 2010–May 2012, based on results from the 2013 NIS. In 2013, vaccination coverage achieved the 90% national *Healthy People 2020* target* for ≥1 dose of measles, mumps, and rubella vaccine (MMR) (91.9%); ≥3 doses of hepatitis B vaccine (HepB) (90.8%); ≥3 doses of poliovirus vaccine (92.7%); and ≥1 dose of varicella vaccine (91.2%). Coverage was below the *Healthy People 2020* targets for ≥4 doses of diphtheria, tetanus, and pertussis vaccine (DTaP) (83.1%; target 90%); ≥4 doses of pneumococcal conjugate vaccine (PCV) (82.0%; target 90%); the full series of *Haemophilus influenzae* type b vaccine (Hib) (82.0%; target 90%); ≥2 doses of hepatitis A vaccine (HepA) (54.7%; target 85%); rotavirus vaccine (72.6%; target 80%); and the HepB birth dose (74.2%; target 85%).† Coverage remained stable relative to 2012 for all of the vaccinations with *Healthy People 2020* objectives except for increases in the HepB birth dose (by 2.6 percentage points) and rotavirus vaccination (by 4.0 percentage points). The percentage of children who received no vaccinations remained below 1.0% (0.7%). Children living below the federal poverty level had lower vaccination coverage compared with children living at or above the poverty level for many vaccines, with the largest disparities for ≥4 doses of DTaP (by 8.2 percentage points), full series of Hib (by 9.5 percentage points), ≥4 doses of PCV (by 11.6 percentage points), and rotavirus (by 12.6 percentage points). MMR coverage was below 90% for 17 states. Reaching and maintaining high coverage across states and socioeconomic groups is needed to prevent resurgence of vaccine-preventable diseases.

NIS is a random-digit–dialed cellular[§] and landline telephone survey of households with children aged 19–35 months

*Additional information is available on *Healthy People 2020* at http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=23.

†The *Healthy People 2020* target for the birth dose (day 0–3) of HepB is 85%, measured by annual birth cohort. In the three most recent completed birth cohorts measured by NIS, coverage with the birth dose of HepB was 65% for children born in 2008, 70.6% for children born in 2009, and 74.5% for children born in 2010.

§All identified cell telephone households were eligible for interview. Sampling weights were adjusted to correct for dual-frame (landline and cell telephone) sampling, nonresponse, noncoverage, and overlapping samples of mixed (landline and cellular) telephone users. A description of NIS dual-frame survey methodology and its effect on reported vaccination estimates is available at http://www.cdc.gov/vaccines/imz-managers/coverage/nis/child/dual-frame-sampling.html.

INSIDE



**Continuing Education** examination available at http://www.cdc.gov/mmwr/cme/conted_info.html#weekly.

**U.S. Department of Health and Human Services**
Centers for Disease Control and Prevention

in the 50 states, the District of Columbia, selected local areas, Guam, and the U.S. Virgin Islands (USVI).[¶] These household interviews are followed by a survey mailed to the child's vaccination providers (with consent of the respondent) to obtain provider-confirmed vaccination histories. Data are weighted to be representative of the population of children aged 19–35 months, and are adjusted for multiple phone lines, mixed telephone use (i.e. landline and cellular), household nonresponse, and the exclusion of phoneless households. Details regarding NIS methodology, including methods for synthesizing provider-reported immunization histories and weighting, have been described previously.[**] The sample size of children with adequate provider data used for national estimates was 13,611, with an additional 449 children from USVI and Guam.[††] For completed interviews (excluding Guam and USVI), 3,152 by landline (63.5%) and 10,459 by cell phone (59.8%) had adequate vaccination data. The national Council of American Survey Research Organization (CASRO) response rates were 62.3% for landline and 30.5% for cell phone frames.[§§] Coverage estimates for Hib[¶¶] and rotavirus[***] vaccines take into account the type of vaccine used because the number of

¶ The local areas separately sampled for the 2013 NIS included areas that receive federal Section 317 immunization funds and are included in the NIS sample every year (Chicago, Illinois; New York, New York; Philadelphia County, Pennsylvania; Bexar County, Texas; and Houston, Texas) and one additional sampled area (El Paso County, Texas). The 2013 NIS was also conducted in USVI and Guam, but these areas were excluded from national coverage estimates.

** A description of the statistical methodology of the NIS is available at ftp://ftp.cdc.gov/pub/health_statistics/nchs/dataset_documentation/nis/nispuf12_dug.pdf.

†† Children from USVI (n = 201) and Guam (n = 248) were excluded from the national estimates. For completed interviews, for Guam, 63 by landline (64.3%) and 185 by cell phone (63.6%) had adequate provider data. For completed interviews, for USVI, 55 by landline (55.9%) and 146 by cell phone (49.8%) had adequate provider data.

§§ The CASRO household response rate, calculated as the product of the resolution rate (percentage of the total telephone numbers called that were classified as nonworking, nonresidential, or residential), screening completion rate (percentage of known households that were successfully screened for the presence of age-eligible children), and the interview completion rate (percentage of households with one or more age-eligible children that completed the household survey). For USVI, the landline and cell phone sample CASRO rates were 72.8% and 37.2%, respectively. For Guam, the landline and cell phone sample CASRO rates were 54.6% and 29.7%, respectively. Additional information is available at http://www.casro.org. The CASRO response rate is equivalent to the American Association for Public Opinion Research (AAPOR) type 3 response rate. Information about AAPOR response rates is available at http://www.aapor.org/am/template.cfm?section=standard_definitions1&template+/cm/contentdisplay.cfm&contented=1814.

¶¶ Coverage for primary Hib series was based on receipt of ≥2 or ≥3 doses, depending on product type received. The PRP-OMB Hib products require a 2-dose primary series with doses at ages 2 months and 4 months. All other Hib products require 3-dose primary series with doses at ages 2, 4, and 6 months. Coverage for the full series, which includes the primary series and a booster dose, was based on receipt of ≥3 or ≥4 doses, depending on product type received. All Hib products require a booster dose at age 12–15 months.

*** Coverage for rotavirus vaccine was based on ≥2 or ≥3 doses, depending on product type received (≥2 doses for Rotarix [RV1], licensed in April 2008, and ≥3 doses for RotaTeq [RV5], licensed in February 2006). ACIP does not recommend using the two rotavirus vaccines interchangeably, but in the event that using more than one product cannot be avoided because of nonavailability of vaccine used to initiate series, then a total of 3 doses are required if RV5 is one of the vaccine doses (e.g., acceptable mixed series could be RV1-RV5-RV5/RV1-RV5-RV1/RV5-RV1-RV1/RV5-RV1-RV5/RV5-RV5-RV1). Additional information at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm.

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doses required depends on the manufacturer. Logistic regression was used to examine differences among racial and ethnic populations, controlling for poverty status. Statistical analyses were conducted using t-tests, based on weighted data and accounting for the complex survey design. A p-value of <0.05 was considered statistically significant.

## National Vaccination Coverage

In 2013, national vaccination coverage among children aged 19–35 months was 83.1% for ≥4 DTaP doses, 92.7% for ≥3 poliovirus doses, 91.9% for ≥1 MMR dose, 82.0% for the full series of Hib, 90.8% for ≥3 HepB doses, 91.2% for ≥1 varicella dose, and 82.0% for ≥4 PCV doses (Table 1). Coverage remained stable for these vaccinations relative to 2012. Coverage with the combined vaccine series††† of these vaccines was 70.4%, similar to coverage in 2012. Coverage increased from 2012 to 2013 for HepB (birth dose) (from 71.6% to 74.2%), for rotavirus vaccine (from 68.6% to

††† The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP/diphtheria and tetanus toxoids vaccine/diphtheria, tetanus toxoids, and pertussis vaccine, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, ≥3 or ≥4 doses of Hib (depending on product type of vaccine), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.

**TABLE 1. Estimated vaccination coverage among children aged 19–35 months, by selected vaccines and dosages — National Immunization Survey, United States, 2009–2013***

| | 2009 | | 2010 | | 2011 | | 2012 | | 2013 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Vaccine and dosage | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) |
| **DTaP** | | | | | | | | | | |
| ≥3 doses | 95.0 | (±0.6) | 95.0 | (±0.6) | 95.5 | (±0.5) | 94.3 | (±0.7) | 94.1 | (±0.9) |
| ≥4 doses | 83.9 | (±1.0) | 84.4 | (±1.0) | 84.6 | (±1.0) | 82.5 | (±1.2) | 83.1 | (±1.3) |
| **Poliovirus (≥3 doses)** | 92.8 | (±0.7) | 93.3 | (±0.7) | 93.9 | (±0.6) | 92.8 | (±0.7) | 92.7 | (±1.0) |
| **MMR (≥1 dose)** | 90.0 | (±0.8) | 91.5 | (±0.7) | 91.6 | (±0.8) | 90.8 | (±0.8) | 91.9 | (±0.9) |
| **Hib†** | | | | | | | | | | |
| Primary series | 92.1 | (±0.8) | 92.2 | (±0.8) | 94.2 | (±0.6) | 93.3 | (±0.7) | 93.7 | (±0.9) |
| Full series | 54.8 | (±1.4) | 66.8 | (±1.3) | 80.4 | (±1.1) | 80.9 | (±1.2) | 82.0 | (±1.3) |
| **HepB** | | | | | | | | | | |
| ≥3 doses | 92.4 | (±0.7) | 91.8 | (±0.7) | 91.1 | (±0.7) | 89.7 | (±0.9) | 90.8 | (±1.0) |
| 1 dose by 3 days (birth)§ | 60.8 | (±1.3) | 64.1 | (±1.3) | 68.6 | (±1.3) | 71.6 | (±1.4) | 74.2 | (±1.4)¶ |
| **Varicella (≥1 dose)** | 89.6 | (±0.8) | 90.4 | (±0.8) | 90.8 | (±0.7) | 90.2 | (±0.8) | 91.2 | (±0.9) |
| **PCV** | | | | | | | | | | |
| ≥3 doses | 92.6 | (±0.7) | 92.6 | (±0.8) | 93.6 | (±0.6) | 92.3 | (±0.8) | 92.4 | (±1.0) |
| ≥4 doses | 80.4 | (±1.2) | 83.3 | (±1.0) | 84.4 | (±1.0) | 81.9 | (±1.1) | 82.0 | (±1.3) |
| **HepA** | | | | | | | | | | |
| ≥1 dose | 75.0 | (±1.1) | 78.3 | (±1.1) | 81.2 | (±1.0) | 81.5 | (±1.1) | 83.1 | (±1.2)¶ |
| ≥2 doses | 46.6 | (±1.4) | 49.7 | (±1.4) | 52.2 | (±1.4) | 53.0 | (±1.5) | 54.7 | (±1.6) |
| **Rotavirus**** | 43.9 | (±1.4) | 59.2 | (±1.4) | 67.3 | (±1.3) | 68.6 | (±1.4) | 72.6 | (±1.5)¶ |
| **Combined series††** | 44.3 | (±1.4) | 56.6 | (±1.3) | 68.5 | (±1.3) | 68.4 | (±1.4) | 70.4 | (±1.5) |
| **Children who received no vaccinations** | 0.6 | (±0.1) | 0.7 | (±0.2) | 0.8 | (±0.2) | 0.8 | (±0.1) | 0.7 | (±0.3) |

**Abbreviations:** CI = confidence interval; DTaP = diphtheria, tetanus toxoids, and acellular pertussis vaccine (includes children who might have been vaccinated with diphtheria and tetanus toxoids vaccine, or diphtheria, tetanus toxoids, and pertussis vaccine); MMR = measles, mumps, and rubella vaccine; Hib = *Haemophilus influenzae* type b vaccine; HepB = hepatitis B vaccine; PCV = pneumococcal conjugate vaccine; HepA = hepatitis A vaccine.

* For 2009, includes children born January 2006–July 2008; for 2010, children born January 2007–July 2009; for 2011, children born January 2008–May 2010; for 2012, children born January 2009–May 2011; and for 2013, children born January 2010–May 2012.

† Hib primary series: receipt of ≥2 or ≥3 doses, depending on product type received. Full series: receipt of ≥3 or ≥4 doses, depending on product type received (primary series and booster dose). Hib coverage for primary or full series not available until 2009.

§ HepB administered from birth through age 3 days.

¶ Statistically significant change in coverage compared with 2012 (p<0.05).

** Rotavirus vaccine includes ≥2 or ≥3 doses, depending on the product type received (≥2 doses for Rotarix [RV1] or ≥3 doses for RotaTeq [RV5]).

†† The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, full series of Hib vaccine (≥3 or ≥4 doses, depending on product type), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.

72.6%), and for ≥1 dose of HepA (from 81.5% to 83.1%). No change was observed in the percentage of children who received no vaccinations.

## Vaccination Coverage by Selected Demographic Characteristics

Children living below the poverty level[§§§] had lower coverage than children living at or above the poverty level for several vaccines, including ≥3 and ≥4 DTaP doses, ≥3 poliovirus doses, Hib (full series), ≥3 HepB doses, ≥3 and ≥4 PCV doses, rotavirus, and the combined vaccine series (Table 2). However, children living below the poverty level had higher coverage than children living at or above the poverty level for HepB (birth dose).

In 2013, black children[¶¶¶] had lower coverage compared with white children for ≥3 and ≥4 DTaP doses, Hib (full series), ≥4 PCV doses, rotavirus, and the combined vaccine series (Table 2). After adjustment for poverty status, these disparities were reduced but remained statistically significant, except for the combined vaccine series. Conversely, other groups had higher coverage for various vaccines compared with white children. American Indian/Alaska Native (AI/AN) and Asian children had higher coverage than white children for ≥1 MMR dose and ≥1 varicella dose. AI/AN children also had higher coverage than white children for ≥3 HepB doses, and Asian children had higher coverage than white children for ≥2 HepA doses. Black and Hispanic children had higher coverage than white children for HepB (birth dose).

## Vaccination Coverage by State

In 2013, wide geographic variation in vaccination coverage was observed among the states (Table 3). Coverage for ≥1 MMR dose ranged from 86.0% (Colorado, Ohio, and West Virginia) to 96.3% (New Hampshire). Coverage ranged from 74.3% (Arkansas) to 93.3% (Massachusetts) for ≥4 DTaP doses, from 44.8% (Vermont) to 88.0% (Kentucky) for HepB (birth dose), from 33.6% (Wyoming) to 72.1% (Connecticut) for ≥2 HepA doses, from 56.0% (Arkansas) to 84.4% (Rhode Island) for rotavirus, and from 57.1% (Arkansas) to 82.1% (Rhode Island) for the combined vaccine series.

[§§§] Poverty level uses income and family size to categorize households into 1) at or above the poverty level and 2) below the poverty level. Poverty level was based on 2011 U.S. Census poverty thresholds, available at http://www.census.gov/hhes/www/poverty/data/threshld.

[¶¶¶] Child's race/ethnicity was reported by their parent or guardian. Children categorized in this report as white, black, Asian, American Indian/Alaska Native, or multiracial were identified as non-Hispanic by their parent or guardian. Children identified as multiracial had more than one race category selected. Persons identified as Hispanic might be of any race.

## Discussion

The results of the 2013 NIS indicate that vaccination coverage among children aged 19–35 months increased relative to 2012 NIS estimates for some vaccines (rotavirus, HepB birth dose, and ≥1 HepA dose) and remained stable for the others, and less than 1% of children had not received any vaccinations. The national *Healthy People 2020* targets were met in 2013 for four vaccines (≥1 MMR, ≥3 HepB, ≥3 poliovirus, and ≥1 varicella doses). Additionally, four vaccines were within eight percentage points of their *Healthy People 2020* targets (≥4 DTaP doses, the full series of Hib, ≥4 PCV doses, and rotavirus), but coverage increased from 2012 to 2013 only for rotavirus vaccination. Further, disparities in coverage by poverty level were larger for these four vaccines compared with vaccines meeting their *Healthy People 2020* targets. Although coverage with ≥2 HepA doses was 30 percentage points below the 85% 2020 target and did not increase from 2012 to 2013, ≥1 HepA dose coverage increased slightly and reached 83% in 2013.

In 2012 and 2013, coverage for DTaP, PCV, and the full series of Hib remained at similar levels (81%–83%). These vaccines require a booster dose during the second year of life, when the opportunities for catch-up doses with these vaccines are fewer because of declining frequency of well-child visits. CDC recommends the use of clinician and system-based interventions to increase opportunities for vaccination, including use of immunization information systems (IIS), clinician assessment and feedback, clinician reminders, and standing orders (*2*).

DTaP, PCV, and Hib coverage were 8 to 12 percentage points lower for children living below the poverty level compared with children living at or above the poverty level. Parents and caregivers of children living below poverty might face additional challenges in maintaining well-child visits and thus be more likely to fall behind on booster doses. Children living below poverty also had rotavirus coverage that was 13 percentage points lower than that of children living at or above the poverty level. The first dose of rotavirus vaccine should be given before age 14 weeks and 6 days, and the final dose should be given by 8 months (*3*). Children living below poverty might be more likely to miss these milestones and thus not able to start or complete the series. The Vaccines for Children program likely has been successful in reducing differences in vaccination coverage between children living at or above poverty level compared with those below the poverty level for these vaccines and in removing poverty differences for vaccines such as MMR and varicella (*1*). To further reduce disparities, clinician and system-based interventions should be targeted to communities with a high proportion of the population living below the poverty level. Interventions to improve parental knowledge

**TABLE 2. Estimated vaccination coverage among children aged 19–35 months, by selected vaccines and dosages, race/ethnicity,* and poverty level† — National Immunization Survey, United States, 2013§**

| | Race/Ethnicity | | | | | | | Poverty level | |
|---|---|---|---|---|---|---|---|---|---|
| Vaccine and dosage | White, non-Hispanic % (95% CI) | Black, non-Hispanic % (95% CI) | Hispanic % (95% CI) | American Indian/Alaska Native only, non-Hispanic % (95% CI) | Asian, non-Hispanic % (95% CI) | Native Hawaiian or other Pacific Islander, non-Hispanic % (95% CI) | Multiracial, non-Hispanic % (95% CI) | At or Above % (95% CI) | Below % (95% CI) |
| DTaP | | | | | | | | | |
| ≥3 doses | 95.1 (±0.9) | 92.4 (±2.3)¶ | 93.4 (±2.4) | 92.4 (±6.4) | 96.0 (±4.6) | NA (±NA) | 92.4 (±3.6) | 95.6 (±0.8) | 91.2 (±2.1)** |
| ≥4 doses | 85.3 (±1.4) | 74.7 (±4.2)¶ | 82.3 (±3.2) | 78.1 (±8.8) | 89.0 (±5.2) | NA (±NA) | 83.1 (±4.5) | 86.0 (±1.3) | 77.8 (±2.7)** |
| Poliovirus (≥3 doses) | 93.7 (±1.0) | 91.2 (±2.6) | 91.6 (±2.7) | 92.2 (±6.4) | 95.5 (±4.7) | NA (±NA) | 90.8 (±3.7) | 94.4 (±0.8) | 89.2 (±2.4)** |
| MMR (≥1 dose) | 91.5 (±1.1) | 90.9 (±2.5) | 92.1 (±2.5) | 96.3 (±2.8)¶ | 96.7 (±1.7)¶ | 90.4 (±9.7) | 91.5 (±3.1) | 92.5 (±0.9) | 90.5 (±2.1) |
| Hib†† | | | | | | | | | |
| ≥3 doses | 93.7 (±1.0) | 90.7 (±2.5)¶ | 92.7 (±2.5) | 89.5 (±6.8) | 92.9 (±4.9) | 90.5 (±9.6) | 91.4 (±3.7) | 94.6 (±0.8) | 89.6 (±2.2)** |
| Primary series | 94.6 (±0.8) | 91.4 (±2.4)¶ | 93.3 (±2.4) | 94.3 (±6.1) | 93.8 (±4.8) | 90.5 (±9.6) | 92.3 (±3.6) | 95.1 (±0.8) | 91.0 (±2.0)** |
| Full series | 84.2 (±1.4) | 74.9 (±4.2)¶ | 80.9 (±3.3) | 82.9 (±7.8) | 82.0 (±6.2) | NA (±NA) | 84.9 (±4.1) | 85.3 (±1.4) | 75.8 (±2.8)** |
| HepB | | | | | | | | | |
| ≥3 doses | 91.0 (±1.0) | 91.1 (±2.4) | 89.7 (±2.6) | 96.1 (±4.3)¶ | 92.0 (±5.1) | 94.9 (±5.6) | 90.7 (±3.5) | 92.0 (±0.9) | 88.3 (±2.2)** |
| 1 dose by 3 days (birth)§§ | 71.9 (±1.8) | 76.7 (±3.7)¶ | 77.8 (±3.5)¶ | NA (±NA) | 73.7 (±6.5) | NA (±NA) | 72.3 (±5.9) | 72.1 (±1.7) | 78.3 (±2.7)** |
| Varicella (≥1 dose) | 90.0 (±1.2) | 92.1 (±2.2) | 92.0 (±2.5) | 95.4 (±3.1)¶ | 96.0 (±2.0)¶ | 88.7 (±9.2) | 91.0 (±3.0) | 91.6 (±0.9) | 90.3 (±2.1) |
| PCV | | | | | | | | | |
| ≥3 doses | 93.1 (±1.0) | 90.8 (±2.6) | 92.2 (±2.5) | 92.3 (±6.1) | 92.0 (±4.9) | 90.9 (±8.6) | 91.5 (±3.6) | 94.2 (±0.8) | 88.8 (±2.3)** |
| ≥4 doses | 84.1 (±1.5) | 76.1 (±3.8)¶ | 80.4 (±3.4) | 79.0 (±8.3) | 85.6 (±5.4) | NA (±NA) | 83.0 (±4.4) | 86.1 (±1.4) | 74.5 (±2.7)** |
| HepA (≥2 doses) | 53.4 (±1.9) | 49.1 (±4.3) | 56.6 (±4.0) | NA (±NA) | 67.3 (±6.8)¶ | NA (±NA) | 57.8 (±6.0) | 56.1 (±1.9) | 53.5 (±2.9) |
| Rotavirus¶¶ | 74.8 (±1.7) | 62.1 (±4.3)¶ | 73.7 (±3.5) | NA (±NA) | 74.9 (±6.7) | NA (±NA) | 72.8 (±5.3) | 76.9 (±1.6) | 64.3 (±2.9)** |
| Combined series*** | 72.1 (±1.8) | 65.0 (±4.4)¶ | 69.3 (±3.8) | 70.1 (±9.2) | 72.7 (±6.6) | NA (±NA) | 71.8 (±5.2) | 73.8 (±1.7) | 64.4 (±3.0)** |

**Abbreviations:** CI = confidence interval; DTaP = diphtheria, tetanus toxoids, and acellular pertussis vaccine (includes children who might have been vaccinated with diphtheria and tetanus toxoids vaccine, or diphtheria, tetanus toxoids, and pertussis vaccine); NA = not available (estimate not available if the unweighted sample size for the denominator was <30 or 95% CI half width / estimate >0.588 or 95% CI half width was ≥10); MMR = measles, mumps, and rubella vaccine; Hib = *Haemophilus influenzae* type b vaccine; HepB = hepatitis B vaccine; PCV = pneumococcal conjugate vaccine; HepA = hepatitis A vaccine.

* Children's race/ethnicity was reported by parent or guardian. Children identified in this report as white, black, Asian, American Indian/Alaska Native, Native Hawaiian or other Pacific Islander, or multiracial were reported by the parent or guardian as non-Hispanic. Children identified as multiracial had more than one race category selected. Children identified as Hispanic might be of any race.

† Children were classified as below poverty if their total family income was less than the poverty threshold specified for the applicable family size and number of children aged <18 years. Children with total family income at or above the poverty threshold specified for the applicable family size and number of children aged <18 years were classified as at or above poverty. A total of 535 children with adequate provider data and missing data on income were excluded from the analysis. Poverty thresholds reflect yearly changes in the Consumer Price Index. Additional information available at http://www.census.gov/hhes/www/poverty.html.

§ Children in the 2013 National Immunization Survey were born January 2010–May 2012.

¶ Statistically significant difference ($p<0.05$) in estimated vaccination coverage by race/ethnicity. Children identified as non-Hispanic white were the reference group.

** Statistically significant difference ($p<0.05$) in estimated vaccination coverage by poverty level. Children living at or above poverty were the reference group.

†† Hib primary series: receipt of ≥2 or ≥3 doses, depending on product type received; full series: primary series and booster dose includes receipt of ≥3 or ≥4 doses, depending on product type received.

§§ HepB administered from birth through age 3 days.

¶¶ Includes ≥2 or ≥3 doses, depending on product type received (≥2 doses for Rotarix [RV1] or ≥3 doses for RotaTeq [RV5]).

*** The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, full series of Hib vaccine (≥3 or ≥4 doses, depending on type), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.

about vaccines and to further facilitate access to vaccinations can also help to reduce disparities in coverage.

Despite a national MMR vaccination coverage level of 91.9%, one child in 12 in the United States is not receiving their first dose of MMR vaccine on time, underscoring considerable measles susceptibility across the country. Vaccination coverage continued to vary by state. In 2013, there were 10 states with ≥1 MMR dose coverage levels ≥95%, and 17 states with ≥1 MMR dose coverage below the *Healthy People 2020* target of 90%. Through August 8, 2014, a total of 593 measles cases had been reported from 21 states, the highest number reported in the United States since measles was declared eliminated in the United States in 2000; most cases have occurred in persons who were unvaccinated or had unknown vaccination status; updated provisional case counts are available at http://www.cdc.gov/measles/index.html. Given the large number of cases this year and the continuing risk for importation, clinicians should have a heightened awareness of the potential for measles in their communities and the importance of vaccination to prevent measles. Communities with lower MMR coverage

**TABLE 3. Estimated vaccination coverage with selected individual vaccines and a combined vaccine series* among children aged 19–35 months, by U.S. Department of Health and Human Services (HHS) region and state and local area — National Immunization Survey, United States, 2013†**

| HHS region, state and local area | MMR (≥1 dose) | | DTaP (≥4 doses) | | Hep B (birth)§ | | HepA (≥2 doses) | | Rotavirus¶ | | Combined vaccine series* | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) |
| **United States overall** | **91.9** | **(±0.9)** | **83.1** | **(±1.3)** | **74.2** | **(±1.4)**** | **54.7** | **(±1.6)** | **72.6** | **(±1.5)**** | **70.4** | **(±1.5)** |
| **HHS Region I** | **94.2** | **(±2.2)** | **90.9** | **(±2.5)** | **74.6** | **(±3.7)** | **63.2** | **(±4.4)** | **81.4** | **(±3.5)** | **77.1** | **(±3.7)** |
| Connecticut | 91.4 | (±5.4) | 88.0 | (±5.9) | 75.2 | (±7.5) | 72.1 | (±7.5) | 81.1 | (±6.3) | 78.2 | (±6.8) |
| Maine | 91.0 | (±4.5) | 87.9 | (±5.7) | 68.9 | (±7.4) | 57.4 | (±7.7) | 72.0 | (±7.1) | 68.0 | (±7.5) |
| Massachusetts | 95.8 | (±3.6) | 93.3 | (±4.0) | 78.0 | (±6.4) | 62.7 | (±8.0) | 84.0 | (±6.3) | 78.5 | (±6.6) |
| New Hampshire | 96.3 | (±2.6) | 91.3 | (±3.9) | 74.1 | (±6.5) | 53.3 | (±7.7) | 78.2 | (±6.7) | 74.9 | (±6.8) |
| Rhode Island | 95.6 | (±3.3) | 91.6 | (±4.9) | 72.7 | (±7.0) | 60.9 | (±8.2) | 84.4 | (±6.2) | 82.1 | (±6.7)** |
| Vermont | 91.2 | (±4.0) | 85.8 | (±5.1) | 44.8 | (±6.8) | 48.5 | (±6.8)** | 73.4 | (±6.1)** | 66.9 | (±6.6) |
| **HHS Region II** | **95.5** | **(±1.9)**** | **86.5** | **(±3.1)** | **62.5** | **(±4.2)** | **49.3** | **(±4.4)** | **72.3** | **(±4.0)**** | **72.4** | **(±4.1)**** |
| New Jersey | 95.6 | (±3.3) | 86.4 | (±5.3) | 59.8 | (±7.2) | 51.2 | (±7.4) | 69.0 | (±6.9) | 72.9 | (±6.8) |
| New York | 95.5 | (±2.3)** | 86.6 | (±3.8) | 63.7 | (±5.2) | 48.4 | (±5.5) | 73.8 | (±4.8)** | 72.2 | (±5.0)** |
| City of New York | 96.8 | (±2.5)** | 86.0 | (±5.3) | 61.2 | (±7.1) | 49.4 | (±7.3) | 67.0 | (±7.1)** | 69.8 | (±6.9) |
| Rest of state | 94.2 | (±3.9) | 87.2 | (±5.5) | 66.3 | (±7.6) | 47.3 | (±8.2) | 80.7 | (±6.4) | 74.6 | (±7.4)** |
| **HHS Region III** | **92.1** | **(±2.6)** | **85.2** | **(±3.4)** | **77.9** | **(±3.8)** | **55.1** | **(±4.3)** | **77.8** | **(±3.7)**** | **73.1** | **(±4.0)** |
| Delaware | 94.8 | (±3.4) | 87.9 | (±5.0) | 83.6 | (±5.3)** | 64.2 | (±7.0) | 83.9 | (±5.6) | 71.8 | (±6.6) |
| District of Columbia | 96.2 | (±3.1) | 86.2 | (±5.8) | 78.3 | (±6.9) | 66.2 | (±8.4) | 68.4 | (±8.1)** | 76.9 | (±7.2) |
| Maryland | 95.3 | (±4.4) | 87.4 | (±6.5) | 75.4 | (±7.7) | 55.6 | (±9.2) | 83.7 | (±6.6)** | 75.8 | (±8.0) |
| Pennsylvania | 93.3 | (±3.2)** | 88.7 | (±3.9)** | 83.3 | (±4.3) | 58.3 | (±5.8) | 77.2 | (±5.3) | 75.5 | (±5.2) |
| Philadelphia | 95.9 | (±2.7) | 88.7 | (±4.5) | 77.9 | (±5.9) | 59.5 | (±7.2) | 73.4 | (±6.4) | 76.7 | (±6.4) |
| Rest of state | 92.8 | (±3.8)** | 88.7 | (±4.5)** | 84.4 | (±5.0) | 58.1 | (±6.7) | 78.0 | (±6.2) | 75.3 | (±6.1) |
| Virginia | 88.6 | (±7.0) | 78.8 | (±9.3) | 72.3 | (±10.2) | 48.0 | (±10.8) | 76.2 | (±9.2) | 69.2 | (±10.0) |
| West Virginia | 86.0 | (±5.8) | 83.4 | (±6.2) | 73.9 | (±7.9) | 57.5 | (±8.4) | 68.4 | (±7.8) | 65.5 | (±7.9) |
| **HHS Region IV** | **93.0** | **(±1.7)** | **82.8** | **(±3.0)** | **73.5** | **(±3.3)** | **51.3** | **(±3.4)** | **68.9** | **(±3.4)** | **70.8** | **(±3.5)** |
| Alabama | 89.7 | (±5.8) | 84.0 | (±7.3) | 81.7 | (±7.1) | 59.2 | (±8.9) | 74.8 | (±7.8) | 77.0 | (±7.8) |
| Florida | 93.4 | (±4.0) | 80.3 | (±7.7) | 58.0 | (±8.3) | 48.7 | (±8.0) | 66.0 | (±8.1) | 70.0 | (±8.7) |
| Georgia | 93.9 | (±4.1) | 83.5 | (±7.9) | 76.4 | (±8.8)** | 58.0 | (±10.1) | 64.6 | (±10.2) | 69.8 | (±9.8) |
| Kentucky | 89.5 | (±5.1) | 84.1 | (±6.4) | 88.0 | (±5.6) | 41.4 | (±8.6) | 66.4 | (±8.5) | 72.7 | (±8.0) |
| Mississippi | 95.2 | (±3.0) | 87.4 | (±5.4) | 79.2 | (±7.1) | 39.1 | (±8.8) | 63.2 | (±8.6) | 74.6 | (±7.7) |
| North Carolina | 96.0 | (±3.3)** | 87.5 | (±5.3) | 82.1 | (±6.1) | 51.6 | (±7.7) | 75.4 | (±7.2) | 72.0 | (±7.5) |
| South Carolina | 89.2 | (±5.3) | 77.3 | (±7.5) | 76.1 | (±7.4) | 52.5 | (±8.8) | 69.9 | (±8.2) | 66.5 | (±8.3) |
| Tennessee | 92.3 | (±4.4) | 81.1 | (±6.0) | 76.6 | (±5.8) | 52.6 | (±7.1) | 73.3 | (±7.2) | 68.5 | (±6.8) |
| **HHS Region V** | **90.1** | **(±1.9)** | **81.6** | **(±2.5)** | **76.5** | **(±2.6)** | **53.0** | **(±3.0)** | **70.9** | **(±2.8)** | **68.0** | **(±2.9)** |
| Illinois | 91.4 | (±3.1) | 82.7 | (±4.5) | 71.4 | (±5.1) | 48.4 | (±5.5) | 72.6 | (±5.0) | 66.8 | (±5.3) |
| City of Chicago | 90.0 | (±5.2) | 82.0 | (±7.3) | 78.9 | (±8.2) | 43.6 | (±9.3) | 76.1 | (±7.7) | 64.4 | (±8.5) |
| Rest of state | 91.9 | (±3.8) | 83.0 | (±5.5) | 68.7 | (±6.2) | 50.1 | (±6.7) | 71.4 | (±6.2) | 67.7 | (±6.5) |
| Indiana | 92.0 | (±3.6) | 82.1 | (±5.3) | 82.8 | (±5.7) | 61.0 | (±6.9)** | 65.7 | (±7.1) | 68.5 | (±6.7) |
| Michigan | 89.2 | (±5.1) | 79.6 | (±6.6) | 82.5 | (±6.1) | 51.2 | (±7.9) | 70.1 | (±7.2) | 70.0 | (±7.4) |
| Minnesota | 90.8 | (±5.5) | 90.5 | (±5.0) | 63.8 | (±8.6) | 54.3 | (±9.1) | 80.3 | (±6.9) | 74.1 | (±7.8) |
| Ohio | 86.0 | (±5.2) | 75.8 | (±7.0) | 78.1 | (±6.4) | 49.2 | (±7.6) | 66.5 | (±7.5) | 61.7 | (±7.5) |
| Wisconsin | 93.2 | (±4.2) | 84.0 | (±6.1) | 80.5 | (±6.0) | 63.2 | (±7.5) | 73.6 | (±6.9) | 72.8 | (±7.1) |

See table footnotes on page 747.

are more vulnerable to measles transmission. Outbreaks of measles most commonly occur in communities with pockets of persons who were unvaccinated because of philosophic or religious beliefs (*4*). Pockets of unvaccinated persons also occur in states with high vaccination coverage, highlighting the importance of state health departments assessing measles susceptibility at the local level.

State and local health departments can identify communities with lower MMR and other vaccination rates among children using IIS (*5*). Based on 2012 reports from 54 of 56 state and local immunization awardees, 86% of U.S. children aged <6 years participated in IIS (*5*), which are effective in increasing vaccination rates through their capabilities for 1) generating patient reminder and recall notifications, enabling clinician assessment and feedback, and providing clinician reminders; 2) determining patient vaccination status for decisions made by clinicians, health departments, and schools; 3) guiding public health responses to outbreaks of vaccine-preventable disease; 4) informing assessments of vaccination coverage by examining missed vaccination opportunities and disparities in vaccination coverage; and 5) facilitating vaccine management and accountability (*2*). The full potential of IIS can be achieved by meeting or exceeding new functional standards for IIS developed by CDC for 2013–2017 and fully utilizing IIS for program planning, implementation, and evaluation (*5*). In addition to IIS, other sources of information on local

**TABLE 3. (*Continued*) Estimated vaccination coverage with selected individual vaccines and a combined vaccine series* among children aged 19–35 months, by U.S. Department of Health and Human Services (HHS) region and state and local area — National Immunization Survey, United States, 2013†**

| HHS region, state and local area | MMR (≥1 dose) | | DTaP (≥4 doses) | | Hep B (birth)§ | | HepA (≥2 doses) | | Rotavirus¶ | | Combined vaccine series* | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) | % | (95% CI) |
| **HHS Region VI** | **91.5** | **(±2.1)** | **80.4** | **(±3.2)** | **80.5** | **(±2.8)**** | **58.9** | **(±3.8)** | **70.5** | **(±3.8)** | **69.8** | **(±3.6)** |
| Arkansas | 88.3 | (±5.9) | 74.3 | (±8.3) | 79.7 | (±7.3) | 35.8 | (±7.9) | 56.0 | (±9.0) | 57.1 | (±8.9) |
| Louisiana | 88.1 | (±5.1) | 78.5 | (±6.4) | 81.6 | (±5.7) | 50.4 | (±7.7) | 69.6 | (±7.3) | 69.1 | (±7.5) |
| New Mexico | 89.1 | (±4.6) | 79.8 | (±6.4) | 67.5 | (±7.0) | 49.3 | (±7.5) | 68.7 | (±7.0)** | 65.7 | (±7.2) |
| Oklahoma | 89.8 | (±3.8) | 79.2 | (±5.4) | 76.7 | (±5.4)** | 51.8 | (±6.5) | 58.8 | (±6.4) | 62.7 | (±6.3) |
| Texas | 92.7 | (±2.8) | 81.5 | (±4.5) | 81.8 | (±3.9)** | 64.2 | (±5.3)** | 73.8 | (±5.2) | 72.5 | (±5.0)** |
| Bexar County | 93.0 | (±3.7) | 79.4 | (±6.5) | 73.0 | (±6.9) | 64.3 | (±7.2) | 67.2 | (±7.5) | 70.6 | (±7.1) |
| City of Houston | 92.4 | (±4.5) | 85.0 | (±6.3) | 83.2 | (±7.9) | 65.8 | (±9.0) | 80.8 | (±7.6) | 77.6 | (±7.4) |
| El Paso County | 93.7 | (±3.3)** | 76.7 | (±6.1) | 74.5 | (±6.2) | 64.8 | (±6.8) | 70.6 | (±6.7) | 69.7 | (±6.6) |
| Rest of state | 92.7 | (±3.5) | 81.4 | (±5.7) | 82.7 | (±4.8)** | 63.9 | (±6.7) | 73.5 | (±6.6)** | 72.0 | (±6.3)** |
| **HHS Region VII** | **91.1** | **(±2.7)** | **84.5** | **(±3.3)** | **79.1** | **(±3.5)** | **54.9** | **(±4.5)** | **73.5** | **(±4.0)** | **71.9** | **(±4.0)** |
| Iowa | 94.5 | (±3.9) | 89.6 | (±4.4) | 79.5 | (±7.2)** | 57.5 | (±8.6) | 74.7 | (±8.2) | 78.3 | (±6.7) |
| Kansas | 89.4 | (±4.7) | 81.6 | (±6.1) | 77.2 | (±6.5) | 60.2 | (±7.6) | 72.6 | (±6.9)** | 68.7 | (±7.1) |
| Missouri | 89.8 | (±5.3) | 82.1 | (±6.6) | 79.2 | (±6.3) | 45.9 | (±8.5) | 72.4 | (±7.5) | 67.9 | (±7.7) |
| Nebraska | 92.5 | (±4.1) | 88.3 | (±4.7) | 81.3 | (±5.3) | 69.5 | (±6.5) | 76.2 | (±6.2) | 79.0 | (±5.9) |
| **HHS Region VIII** | **89.2** | **(±2.7)** | **84.2** | **(±3.0)** | **70.4** | **(±3.7)** | **54.5** | **(±4.0)** | **74.1** | **(±3.5)** | **71.4** | **(±3.7)** |
| Colorado | 86.0 | (±5.5) | 81.2 | (±6.0) | 60.2 | (±7.3) | 47.6 | (±7.4) | 73.8 | (±6.6) | 69.2 | (±6.9) |
| Montana | 87.3 | (±5.2) | 79.0 | (±6.4) | 73.9 | (±6.8) | 46.4 | (±8.5) | 65.5 | (±8.2) | 65.4 | (±8.1) |
| North Dakota | 91.4 | (±3.8) | 78.6 | (±5.9) | 82.0 | (±5.9) | 59.5 | (±6.8) | 78.4 | (±5.4) | 72.0 | (±6.2) |
| South Dakota | 93.1 | (±4.4) | 86.5 | (±5.8) | 70.9 | (±7.8) | 55.4 | (±8.3) | 68.7 | (±7.8) | 73.8 | (±7.7)** |
| Utah | 92.6 | (±3.6) | 90.3 | (±4.1)** | 81.2 | (±5.5) | 67.6 | (±6.8)** | 78.3 | (±5.8) | 75.2 | (±6.1) |
| Wyoming | 89.0 | (±5.4) | 80.9 | (±6.6) | 67.0 | (±8.0) | 33.6 | (±7.6) | 65.7 | (±8.0) | 70.0 | (±7.7) |
| **HHS Region IX** | **90.8** | **(±4.2)** | **82.1** | **(±5.1)** | **71.9** | **(±6.1)** | **56.8** | **(±6.7)** | **75.1** | **(±5.7)** | **68.2** | **(±6.2)** |
| Arizona | 91.4 | (±3.7) | 76.6 | (±6.6) | 79.1 | (±5.8) | 55.4 | (±8.1) | 70.9 | (±7.5) | 65.1 | (±7.7) |
| California | 90.7 | (±5.3) | 83.1 | (±6.4) | 70.3 | (±7.7) | 56.8 | (±8.4) | 76.8 | (±7.2) | 69.3 | (±7.8) |
| Hawaii | 92.8 | (±3.8) | 83.7 | (±6.1) | 77.3 | (±6.7) | 54.2 | (±8.0) | 73.3 | (±6.9) | 66.5 | (±8.2)** |
| Nevada | 90.4 | (±3.5) | 81.1 | (±5.0) | 75.4 | (±5.6) | 61.1 | (±6.4) | 62.1 | (±6.5) | 60.6 | (±6.4) |
| **HHS Region X** | **91.9** | **(±2.5)**** | **81.2** | **(±4.1)** | **71.6** | **(±4.3)** | **56.2** | **(±5.0)** | **72.1** | **(±4.4)** | **69.2** | **(±4.6)** |
| Alaska | 90.5 | (±3.6) | 75.5 | (±6.1) | 59.4 | (±7.0) | 52.5 | (±7.2) | 64.2 | (±6.8) | 63.9 | (±6.8) |
| Idaho | 91.1 | (±4.3) | 84.2 | (±5.3) | 72.7 | (±6.5) | 60.7 | (±7.3) | 74.6 | (±6.4) | 70.2 | (±6.9) |
| Oregon | 89.4 | (±4.4) | 83.8 | (±5.2) | 66.8 | (±6.3) | 55.9 | (±6.7) | 64.3 | (±6.7) | 66.6 | (±6.5) |
| Washington | 93.5 | (±3.9)** | 79.8 | (±7.0) | 75.0 | (±7.1) | 55.7 | (±8.4) | 76.3 | (±7.3) | 70.8 | (±7.8) |
| *Range* | *(86.0–96.3)* | | *(74.3–93.3)* | | *(44.8–88.0)* | | *(33.6–72.1)* | | *(56.0–84.4)* | | *(57.1 – 82.1)* | |
| **Territories** | | | | | | | | | | | | |
| Guam | 84.9 | (±5.5) | 71.5 | (±7.2) | 87.7 | (±4.7) | 45.8 | (±7.5) | 8.0 | (±3.8) | 50.3 | (±7.8) |
| U.S. Virgin Islands | 59.0 | (±8.7) | 51.1 | (±8.8) | 78.5 | (±6.6) | 18.6 | (±6.5) | 23.7 | (±7.8) | 39.8 | (±8.5) |

**Abbreviations:** MMR = measles, mumps, and rubella vaccine; DTaP = diphtheria, tetanus toxoids, and acellular pertussis vaccine (includes children who might have been vaccinated with, diphtheria and tetanus toxoids vaccine, or diphtheria, tetanus toxoids, and pertussis vaccine; HepB = hepatitis B vaccine; HepA = hepatitis A vaccine; CI = confidence interval; Hib = *Haemophilus influenzae* type b vaccine; PCV = pneumococcal conjugate vaccine.

* The combined (4:3:1:3*:3:1:4) vaccine series includes ≥4 doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 dose of measles-containing vaccine, full series of Hib vaccine (≥3 or ≥4 doses, depending on product type), ≥3 doses of HepB, ≥1 dose of varicella vaccine, and ≥4 doses of PCV.

† Children in the 2013 National Immunization Survey were born January 2010–May 2012.

§ HepB administered from birth through age 3 days.

¶ Either ≥2 or ≥3 doses of rotavirus vaccine, depending on product type received (≥2 doses for Rotarix [RV1] or ≥3 doses for RotaTeq [RV5]).

** Statistically significant increase in coverage compared with 2012 estimates from the National Immunization Survey ($p<0.05$).

coverage that might be available include school or community level data from monitoring school vaccination requirements (*6*) and county level estimates from NIS (*7*). Taken together, local coverage estimates from IIS and other sources can provide critical data to inform programs and interventions at the county level that might subsequently further increase vaccination coverage.

The findings in this report are subject to at least three limitations. First, the household response rates for landline and cell phone samples were 62.3% and 30.5%, respectively. Furthermore, only 63.5% of landline and 59.8% of cell phone completed interviews had adequate vaccination data. Thus, estimates might have been biased, even after sample weights were adjusted to combine landline and cell samples and adjusted to correct for nonresponse, exclusion of households without telephones, and overlapping samples of mixed (landline and cell) telephone users. Results are weighted to key population controls. Although weighting does not guarantee against

**What is already known on this topic?**

*Healthy People 2020* has set childhood vaccination targets of 90% for ≥1 dose measles, mumps, and rubella vaccine, ≥3 doses of hepatitis B vaccine, ≥3 doses of poliovirus vaccine, ≥1 dose of varicella vaccine, ≥4 doses of diphtheria, tetanus, and pertussis vaccine, ≥4 doses of pneumococcal conjugate vaccine, and the full series of *Haemophilus influenzae* type b vaccine. For these and other vaccines, the National Immunization Survey estimates coverage among U.S. children aged 19–35 months.

**What is added by this report?**

In 2013, childhood vaccination coverage remains near or above national target levels for ≥1 dose of measles, mumps, and rubella vaccine (91.9%), ≥3 doses of hepatitis B vaccine (90.8%), ≥3 doses of poliovirus vaccine (92.7%), and ≥1 dose of varicella vaccine (91.2%); however, coverage varied by state, and differences in coverage by income persist.

**What are the implications for public health practice?**

To sustain high coverage and improve coverage for more recently recommended vaccines and those that require booster doses after age 12 months, efforts are needed by parents, clinicians, health systems, and local and state health departments to implement interventions recommended by the *Guide to Community Preventive Services*. Further development and use of immunization information systems by state and local health departments can further identify local pockets of undervaccinated children to ensure that all children remain adequately protected.

bias, it does mitigate and minimize the bias. Second, although response rates are within 1–3 percentage points of previous year and weights have been adjusted to reflect the increasing prevalence of cell-only households over time, nonresponse bias might have changed over time, which could affect interpretation of comparisons across data years. Analyses of total survey error for the NIS for 2010,**** 2011 and 2012 (through June) indicated bias in estimates attributable to incomplete sample frame and selection bias was low, on the order of less than two percentage points (*8*). Future analyses will quantify the amount of bias that might be occurring in later years of NIS data. Third, NIS estimates of ≥2 HepA doses might underestimate coverage of children before age 3 years. The first dose of HepA is recommended during age 12–23 months, and the second dose is recommended at 6–18 months after the first dose (*3*). Children's vaccination status in NIS is determined up to age 19–35 months, so some children might have received their second dose, or be due to receive their second dose, after the survey was conducted.

**** Additional information available at http://www.amstat.org/meetings/jsm/2012/onlineprogram/abstractdetails.cfm?abstractid=304324.

Coverage for many childhood vaccinations during 1994–2013 at, near, or above 90% has contributed to low levels of most vaccine-preventable diseases and estimated net savings of $1.38 trillion in total societal costs over the lifetimes of children born during that period (*1*). Results of the 2013 NIS indicate sustained high vaccination coverage and low proportion of children aged 19–35 months who have not received any vaccinations. Established in 1994 and reaching its 20th year in 2013, the NIS will continue to monitor coverage levels overall and in subpopulations (e.g., by poverty status, race/ethnicity, state, and selected local areas) to identify gaps in vaccination coverage. Further development and use of IIS by state and local health departments can further identify local pockets of undervaccinated children to ensure that all children remain adequately protected. To sustain high coverage and improve coverage for more recently recommended vaccines and those that require booster doses after age 12 months, efforts are needed by parents, clinicians, health systems, and local and state health departments to implement the interventions recommended by the *Guide to Community Preventive Services* (*2*). In addition to use of IIS, these interventions are aimed at increasing community demand for vaccination, enhancing access to health services, and implementing provider- and system-based interventions.

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# 6.2

# Vaccination, Early Flu Treatment Critical for Pregnant Women

Troy Brown, RN | October 09, 2014

Pregnant women who developed 2009 H1N1 influenza were sicker and their infants had worse outcomes, according to data from the 2009 H1N1 influenza pandemic and the 2013-2014 influenza season.

In April 2009, a new influenza A virus, now known as influenza A(H1N1)pdm09, began circulating in California. By June 2011, the World Health Organization had raised the global pandemic level to its highest level, 6. In the 5 years that have passed since then, influenza experts have learned much about how the virus affects pregnant women and their unborn babies.

In a perspective piece published in the October 9 issue of the *New England Journal of Medicine*, Sonja A. Rasmussen, MD, and Denise J. Jamieson, MD, MPH, both from the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, present current recommendations for vaccinating and treating pregnant women at risk for influenza.

"[B]y implementing the current antiviral treatment recommendations, clinicians can prevent complications in women with influenza," the authors write. "We need to ensure that the information about influenza and pregnancy that has been gained in the 5 years since the 2009 H1N1 pandemic is translated into reductions in the number of illnesses, hospitalizations, and deaths that occur in future influenza seasons."

During the 2013 to 2014 influenza season, when 2009 H1N1 was again the primary circulating influenza virus in the United States, cases of serious illness, hospitalizations, and deaths were reported among young and middle-aged adults and pregnant women.

"Although data were available before the 2009 pandemic suggesting that pregnant women were at increased risk for influenza-associated complications, the pandemic provided solid data on this vulnerability," the authors write. "Pregnant women with 2009 H1N1 influenza were at substantially higher risk for hospitalization than the general population, and they accounted for approximately 5% of deaths from 2009 H1N1 influenza that were reported to the [CDC], even though pregnant women make up only about 1% of the population."

Infants born to mothers who had been severely ill with influenza also were at increased risk for poor outcomes, including preterm birth and small size for gestational age.

**Prompt Treatment Critical**

Before 2009, pregnant women with influenza were only treated if they had other high-risk medical conditions or severe illness. In 2009, in a significant change in antiviral treatment guidance, the CDC recommended that pregnant women suspected of having 2009 H1N1 influenza "receive prompt antiviral therapy regardless of risk factors, severity of illness, history, or the results of diagnostic testing," the authors write. "During the pandemic, we learned that treating pregnant women with such a medication makes a difference."

"It's very important for physicians' offices to effectively communicate with their patients about what the woman should do if the woman feels that she has influenza-like symptoms. It's very important for her to call her physician's office, rather than show up for a scheduled appointment," James Byrne, MD, chair, Department of Ob-Gyn, Santa Clara Valley Medical Center, San Jose, and affiliated clinical professor, Stanford University School of Medicine, California, told *Medscape Medical News*.

"She could get more rapid care by actually calling and having a prescription for anti-flu medication ordered for her via telephone," Dr Byrne added. He also noted that by handling such cases over the telephone, clinicians can avoid exposing other pregnant women in their waiting rooms to the virus.

A recent systematic review and meta-analysis that studied the effects of antiviral medications on mortality from 2009 H1N1 influenza among hospitalized pregnant women found that those who were given a neuraminidase inhibitor within the first 2 days after becoming ill were about one fifth as likely to die as those who received treatment later or not at all.

Other studies showed that treatment was still clinically beneficial when started after the first 48 hours of illness. Despite these findings, not all pregnant women with influenza signs and symptoms receive treatment with antiviral drugs, the authors write.

Clinicians should educate their pregnant patients about the need for prompt medical care as well as prevention. However, women should receive antiviral treatment if they develop influenza symptoms, regardless of vaccination status because the vaccine is only about 60% effective.

**Vaccination Reduces Risk for Mother, Baby**

"Receiving an influenza vaccine reduces the risk of influenza not only for the pregnant woman but also for her infant during the first 6 months of life," the authors write. Research has also shed light on factors that prevent and encourage influenza vaccination of pregnant women.

In September 2014, the American College of Obstetricians and Gynecologists released an updated committee opinion recommending the influenza vaccine for all pregnant women.

"The flu virus is highly infectious and can be particularly dangerous to pregnant women, as it can cause pneumonia, premature labor, and other complications, " Laura Riley, MD, chair of the college's Immunization Expert Work Group, which developed the opinion in conjunction with the college's Committee on Obstetric Practice, said in a news release about the committee opinion. "Vaccination every year, early in the season and regardless of the stage of pregnancy, is the best line of defense."

"Many women are not aware of how dangerous influenza can be when they're pregnant; it's dangerous for both the mother and her child. The influenza vaccine is extremely effective with reducing the risk, but even with the heightened awareness, more than half of pregnant women fail to be vaccinated each year," Dr Byrne explained.

Vaccination coverage increased substantially during the pandemic but has remained at less than 50% since the 2010 to 2011 influenza season.

*The authors and Dr Byrne have disclosed no relevant financial relationships.*

*N Engl J Med.* 2014;371:1373-1375. Abstract



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# 6.3

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MMWR
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# Vaccination Coverage Among Children in Kindergarten — United States, 2013–14 School Year

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State and local vaccination requirements for school entry are implemented to maintain high vaccination coverage and protect schoolchildren from vaccine-preventable diseases (*1*). Each year, to assess state and national vaccination coverage and exemption levels among kindergartners, CDC analyzes school vaccination data collected by federally funded state, local, and territorial immunization programs. This report describes vaccination coverage in 49 states and the District of Columbia (DC) and vaccination exemption rates in 46 states and DC for children enrolled in kindergarten during the 2013–14 school year. Median vaccination coverage was 94.7% for 2 doses of measles, mumps, and rubella (MMR) vaccine; 95.0% for varying local requirements for diphtheria, tetanus toxoid, and acellular pertussis (DTaP) vaccine; and 93.3% for 2 doses of varicella vaccine among those states with a 2-dose requirement. The median total exemption rate was 1.8%. High exemption levels and suboptimal vaccination coverage leave children vulnerable to vaccine-preventable diseases. Although vaccination coverage among kindergartners for the majority of reporting states was at or near the 95% national *Healthy People 2020* targets for 4 doses of DTaP, 2 doses of MMR, and 2 doses of varicella vaccine (*2*), low vaccination coverage and high exemption levels can cluster within communities.* Immunization programs might have access to school vaccination coverage and exemption rates at a local level for counties, school districts, or schools that can identify areas where children are more vulnerable to vaccine-preventable diseases. Health promotion efforts in these local areas can be used to help parents understand the risks for vaccine-preventable diseases and the protection that vaccinations provide to their children.

Federally funded immunization programs assess vaccination coverage among children entering kindergarten each school year. Health departments, school nurses, or school personnel assess the vaccination and exemption status, as defined by state and local school requirements, of a census or sample of kindergartners enrolled in public and private schools. Among the 49 states and DC reporting vaccination coverage data, 42 used their immunization information system (IIS) as at least one source of data for their school assessment. The type of school survey varied among the

* *Healthy People 2020* objective IID-10.1 is based on 4 doses of DTaP vaccine. This report describes compliance with state regulations of 3, 4, or 5 doses of DTaP vaccine. Of the 49 states and DC, only Nebraska, New York, and Pennsylvania report <4 doses of DTaP vaccine. IID-10.2 sets a target of 95% of kindergartners receiving ≥2 doses of MMR vaccine. IID-10.5 sets a target of 95% of kindergartners receiving ≥2 doses of varicella vaccine.

## INSIDE



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49 states and DC reporting either vaccination coverage or exemption: 38 reported using a census of kindergartners; nine a sample of schools, kindergartners, or both; one a voluntary response of schools; and two a mix of methods. Two states used a sample to collect vaccination coverage data and a census to collect exemption data. Four states changed their type of survey from the previous school year.[†] Data from the public and private school vaccination assessments were aggregated by state and DC immunization programs and sent to CDC.[§] Vaccination coverage data were provided for 4,252,368 kindergartners included in reports from 49 states and DC, and exemption data were provided for 3,902,571 kindergartners included in reports from 46 states and DC.

All estimates of coverage and exemption rates were adjusted based on the type of survey conducted and response rates, using data aggregated at school or county level as appropriate and available, unless otherwise noted.[¶] Vaccination requirements for school entry, as reported to CDC by the federally funded immunization programs, varied.[**] Kindergartners were considered up-to-date for any single vaccine if they had received all of the doses of that vaccine required for school entry in their jurisdiction. Nine states considered kindergartners up-to-date only if they had received all of the doses for all vaccines required for school entry in their jurisdiction.[††] Of the 49 states and DC reporting vaccination coverage, 13 met CDC standards for school assessment methods in 2013–14.[§§]

Among the 49 states and DC that reported 2013–14 school vaccination coverage, median 2-dose MMR vaccination coverage was 94.7% (range = 81.7% in Colorado to ≥99.7% in Mississippi); 23 reported coverage ≥95% (Table 1), and eight reported coverage <90% (Table 1, Figure). Median local requirement for DTaP vaccination coverage was 95.0% (range = 80.9% in Colorado to ≥99.7% in Mississippi);

[†] Alaska, Georgia, Missouri, and North Dakota.

[§] Data from one local area (Houston) were reported separately and included in the data for the state of Texas. Oregon estimates included vaccination coverage and exemption data for children enrolled in public online homeschools. Pennsylvania included homeschool students in their public school data.

[¶] Most of the programs that used complex sample surveys provided CDC with data aggregated at the school or county level for weighted analysis. Coverage and exemption data based on a reported census were adjusted for nonresponse using the inverse of the response rate, stratified by school type. For data collected using a complex sample design and with sufficient data provided, weights were calculated to account for sample design and adjusted for nonresponse. Where sufficient data were not available to account for the use of a stratified two-stage cluster sample design, data were analyzed as a stratified simple random sample (Delaware, Houston, Virginia, and Puerto Rico).

[**] Among the 49 reporting states and DC, all programs required 2 doses of a measles-containing vaccine, of which MMR is the only one available in the United States. For local requirements for DTaP vaccine, two required 3 doses, 27 required 4 doses, 20 required 5 doses, and one state did not require pertussis. For varicella vaccine, 13 required 1 dose, 36 required 2 doses, and 1 did not require varicella vaccination.

[††] States reporting estimates based on receiving all doses of all vaccines required for school entry might have actual antigen-specific coverage estimates at least as high as the coverage for all required vaccines.

[§§] CDC standards include use of a census or random sample of public and private schools or students, assessment using number of doses recommended by the Advisory Committee on Immunization Practices, assessment of vaccination status before December 31, collection of data by health department personnel or school nurses, validation if data are collected by school administrative staff, and documentation of vaccination from a health-care provider.

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**TABLE 1. Estimated vaccination coverage,* by state/area and vaccination among children enrolled in kindergarten — United States, 2013–14 school year**

| State/Area | Kindergarten population† | Total surveyed | Proportion surveyed (%) | Type of survey conducted§ | MMR¶ (%) | DTaP** (%) | Varicella 1 dose (%) | Varicella 2 doses (%) |
|---|---|---|---|---|---|---|---|---|
| Alabama†† | 76,927 | 76,927 | 100.0 | Census | ≥92.0 | ≥92.0 | ≥92.0 | NReq |
| Alaska§§ | 10,222 | 946 | 9.3 | Stratified 2-stage cluster sample | 94.4 | 96.0 | | 92.5 |
| Arizona | 89,606 | 85,861 | 95.8 | Census | 93.9 | 94.3 | 96.4 | NReq |
| Arkansas | 42,649 | 41,068 | 96.3 | Census | 86.5 | 83.3 | | 85.4 |
| California¶¶ | 548,606 | 533,680 | 97.3 | Census | 92.3 | 92.2 | 95.3 | NReq |
| Colorado | 69,904 | 350 | 0.5 | Random sample | 81.7 | 80.9 | | 81.7 |
| Connecticut†† | 40,978 | 40,978 | 100.0 | Census | 96.9 | 97.0 | | 96.7 |
| Delaware | 11,997 | 1458 | 12.2 | Stratified 2-stage cluster sample | ≥96.4 | ≥96.4 | | ≥96.4 |
| District of Columbia†† | 7,856 | 7,856 | 100.0 | Census | 89.0 | 88.7 | | 88.8 |
| Florida†††*** | 233,797 | 233,797 | 100.0 | Census | ≥93.2 | ≥93.2 | | ≥93.2 |
| Georgia†† | 143,988 | 143,988 | 100.0 | Census | ≥94.0 | ≥94.0 | | ≥94.0 |
| Hawaii | 20,056 | 1,074 | 5.4 | Stratified 2-stage cluster sample | 98.7 | 99.0 | 99.2 | NReq |
| Idaho†† | 23,934 | 23,934 | 100.0 | Census | 88.2 | 88.0 | | 86.5 |
| Illinois†† | 163,316 | 163,316 | 100.0 | Census | 94.7 | 95.0 | 96.6 | NReq |
| Indiana†† | 87,193 | 61,336 | 70.3 | Census | 92.9 | 81.8 | | 90.2 |
| Iowa | 43,728 | 41,349 | 94.6 | Census | ≥91.0 | ≥91.0 | | ≥91.0 |
| Kansas§§¶¶ | 41,107 | 11,931 | 29.0 | Stratified 1-stage sample (Public), Census (Private) | 86.9 | 87.6 | | 85.5 |
| Kentucky†† | 57,857 | 57,857 | 100.0 | Census | 92.6 | 93.9 | | 91.9 |
| Louisiana†† | 63,976 | 63,976 | 100.0 | Census | 96.8 | 98.3 | | 96.1 |
| Maine | 15,441 | 12,716 | 82.4 | Census | 89.9 | 94.4 | 93.8 | NReq |
| Maryland¶¶ | 75,659 | 73,349 | 96.9 | Census | 97.6 | 99.0 | 99.0 | NReq |
| Massachusetts | 79,894 | 78,188 | 97.9 | Census | 95.1 | 93.0 | | 93.9 |
| Michigan†† | 120,297 | 120,297 | 100.0 | Census | 97.5 | 94.8 | | 93.0 |
| Minnesota¶¶ | 72,087 | 70,972 | 98.5 | Census | 93.4 | 96.6 | | 92.6 |
| Mississippi†† | 45,719 | 45,719 | 100.0 | Census | ≥99.7 | ≥99.7 | | ≥99.7 |
| Missouri†† | 78,140 | 78,140 | 100.0 | Census | 95.5 | 96.0 | | 94.6 |
| Montana | 12,855 | 12,259 | 95.4 | Census | 93.7 | 94.8 | | NReq |
| Nebraska¶¶ | 27,000 | 26,282 | 97.3 | Census | 96.6 | 96.8 | | 94.9 |
| Nevada | 35,782 | 1,114 | 3.1 | Stratified 2-stage cluster sample | 95.6 | 94.4 | | 93.6 |
| New Hampshire†† | 13,240 | 13,240 | 100.0 | Census | ≥94.7 | ≥94.7 | | ≥94.7 |
| New Jersey | 123,085 | 117,477 | 95.4 | Census | ≥96.8 | ≥96.8 | ≥96.8 | NReq |
| New Mexico¶¶ | 30,725 | 830 | 2.7 | Stratified 2-stage cluster sample | 95.9 | 97.4 | | 93.4 |
| New York¶¶ | 240,318 | 240,318 | 100.0 | Census | 96.8 | 98.1 | 98.2 | NReq |
| North Carolina | 126,084 | 123,192 | 97.7 | Census | 98.8 | 98.7 | 99.7 | NReq |
| North Dakota | 9,780 | 9,397 | 96.1 | Census (public) Stratified 2-stage cluster sample (private) | 90.0 | 90.2 | | 89.4 |
| Ohio | 150,000 | 138,820 | 92.5 | Census | 96.2 | 96.1 | | 95.7 |
| Oklahoma | 57,377 | 40,929 | 71.3 | Voluntary response | 96.4 | 96.1 | | 98.0 |
| Oregon†† | 47,649 | 47,649 | 100.0 | Census | 93.2 | 93.3 | 94.3 | NReq |
| Pennsylvania†††¶¶ | 151,253 | 151,253 | 100.0 | Census | 85.3 | NReq††† | | 84.0 |
| Rhode Island | 11,521 | 11,421 | 99.1 | Census | 95.1 | 96.0 | | 94.7 |
| South Carolina | 61,661 | 6,771 | 11.0 | 1-stage stratified sample | 96.8 | 97.3 | 94.4 | NReq |
| South Dakota†† | 12,566 | 12,566 | 100.0 | Census | 96.6 | 96.7 | | 95.3 |
| Tennessee | 80,212 | 80,079 | 99.8 | Census | ≥94.9 | ≥94.9 | | ≥94.9 |
| Texas§§ (including Houston) | 409,255 | 397,262 | 97.1 | Census | 97.5 | 97.2 | | 97.2 |
| Houston, Texas | 36,254 | 1,856 | 5.1 | 2-stage cluster sample, nonrandom schools selection | 91.9 | 90.4 | | 90.4 |

See table footnotes on page 916.

25 reported coverage ≥95%. Median 2-dose varicella vaccination coverage among the 36 states and DC requiring and reporting 2 doses was 93.3% (range = 81.7% in Colorado to ≥99.7% in Mississippi); nine reported coverage ≥95%.

Among the 46 states plus DC reporting 2013–14 school vaccination exemption data, the percentage of kindergartners with an exemption was <1% for eight states and ≥4% for 11 states (range = <0.1% in Mississippi to 7.1% in Oregon), with a median of 1.8% (Figure; Table 2). Two states reported increases over the previous school year of ≥1.0 percentage point: Kansas (1.5 percentage points) and Maine (1.2 percentage points). One state reported a decrease of ≥1.0 percentage points: West Virginia (1.0 percentage point). Where reported separately, the median rate of medical exemptions was 0.2%

**TABLE 1. (*Continued*) Estimated vaccination coverage,* by state/area and vaccination among children enrolled in kindergarten — United States, 2013–14 school year**

| State/Area | Kindergarten population† | Total surveyed | Proportion surveyed (%) | Type of survey conducted§ | MMR¶ (%) | DTaP** (%) | Varicella 1 dose (%) | Varicella 2 doses (%) |
|---|---|---|---|---|---|---|---|---|
| Utah†† | 54,779 | 54,779 | 100.0 | Census | 98.5 | 98.1 | 99.6 | NReq |
| Vermont†† | 6,771 | 6,771 | 100.0 | Census | 91.2 | 92.0 | | 89.4 |
| Virginia | 105,692 | 4,287 | 4.1 | 2-stage cluster sample | 93.1 | 98.3 | | 91.3 |
| Washington | 89,165 | 78,924 | 88.5 | Census | 89.7 | 90.3 | | 88.4 |
| West Virginia | 22,814 | 19,313 | 84.7 | Census | 96.1 | 96.5 | | 95.5 |
| Wisconsin¶¶ | 71,363 | 1,990 | 2.8 | Stratified 2-stage cluster sample | 92.6 | 96.3 | | 91.2 |
| Wyoming | NA | NA | NA | Not conducted | | | | |
| *Median§§§* | | | | | *94.7* | *95.0* | *96.6* | *93.3* |
| American Samoa | NA | NA | NA | Not conducted | | | | |
| Guam | 2,935 | 1,235 | 42.1 | Stratified 2-stage cluster sample | 88.4 | 92.8 | | NReq |
| Marshall Islands | NA | NA | NA | Not conducted | | | | |
| Micronesia | NA | NA | NA | Not conducted | | | | |
| N. Mariana Islands | 725 | 725 | 100.0 | Census | 96.0 | 94.3 | | 92.3 |
| Palau | 402 | NA | NA | Not conducted | | | | NReq |
| Puerto Rico | 39,170 | 6,789 | 17.3 | Stratified 2-stage cluster sample | 94.3 | 91.3 | | 91.4 |
| U.S. Virgin Islands | 1,612 | 731 | 45.3 | Stratified 2-stage cluster sample | 90.5 | 91.0 | | 87.9 |

**Abbreviations:** MMR = measles, mumps, and rubella vaccine; DTaP = diphtheria and tetanus toxoids and acellular pertussis vaccine; NA = not available; NReq = not required for school entry.

* Estimates are adjusted for nonresponse and weighted for sampling where appropriate, except where complete data were unavailable. Percentages for Delaware, Houston, Virginia, and Puerto Rico are approximations. Estimates based on a completed vaccine series (i.e., not antigen-specific) are designated by use of the ≥ symbol.

† The kindergarten population is an approximation provided by each state/area.

§ Sample designs varied by state/area: census = all schools (public and private) and all children within schools were included in the assessment; simple random = a simple random sample design was used; mixed design = a census was conducted among public schools, and a random sample of children within the schools were selected; 1-stage or 2-stage cluster sample = schools were randomly selected, and all children in the selected schools were assessed (1-stage) or a random sample of children within the schools were selected (2-stage); voluntary response = a census among those schools that submitted assessment data.

¶ Most states require 2 doses; Alaska, California, New York, and Oregon require 2 doses of measles, 1 dose of mumps, and 1 dose of rubella vaccine.

** Pertussis vaccination coverage might include some DTP (diphtheria and tetanus toxoids and pertussis vaccine) vaccinations if administered in another country or if a vaccination provider continued to use DTP after 2000. Most states require 4 doses of DTaP vaccine; 5 doses are required for school entry in Colorado, District of Columbia, Hawaii, Idaho, Indiana, Iowa, Kansas, Massachusetts, Minnesota, New Jersey, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Utah, Vermont, Washington, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands; 3 doses are required by Nebraska and New York. Pertussis vaccine is not required in Pennsylvania.

†† The proportion surveyed is probably <100%, but is shown as 100% based on incomplete information about the actual current enrollment.

§§ Kindergarten coverage data were collected from a sample, and exemption data were collected from a census of kindergartners.

¶¶ Counts the vaccine doses received regardless of Advisory Committee on Immunization Practices recommended age and time interval; vaccination coverage rates shown might be higher than those for valid doses.

*** Does not include nondistrict-specific, virtual, and college laboratory schools, or private schools with fewer than 10 students.

††† Pertussis is not required in Pennsylvania; coverage for diphtheria and tetanus was 88.3%.

§§§ The median is the center of the estimates in the distribution. The median does not include Houston, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

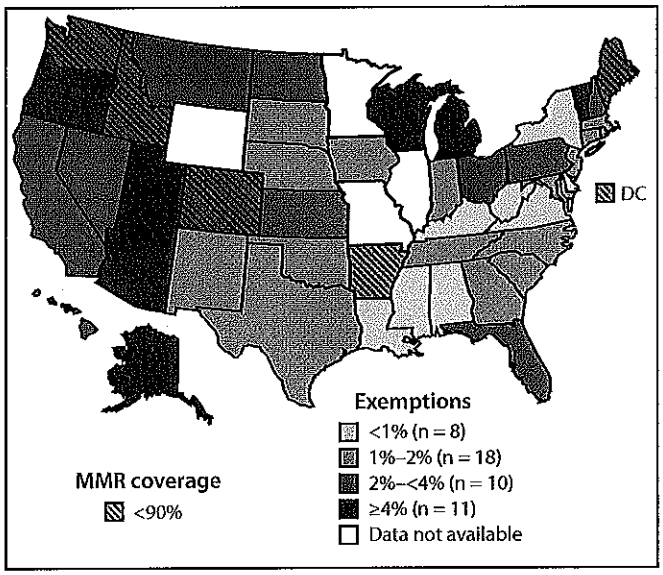
(range = <0.1% in eight states [Alabama, Arkansas, Colorado, Delaware, Georgia, Hawaii, Mississippi, and Nevada] to 1.2% [Alaska and Washington]). Where allowed and reported separately, the median rate of nonmedical exemptions was 1.7% (range = 0.4% in Virginia and DC to 7.0% in Oregon).

## Discussion

Most federally funded immunization programs continued to report high vaccination coverage and stable exemption rates among kindergartners during the 2013–14 school year compared with the 2012–13 school year, although 26 states and DC did not report meeting the *Healthy People 2020* target of 95% coverage for 2 doses of MMR vaccine. Although high levels of vaccination coverage by state are reassuring, vaccination exemptions have been shown to cluster geographically (*3,4*), so vaccine-preventable disease outbreaks can still occur where unvaccinated persons cluster in schools and communities (*5*).

School vaccination coverage assessment is used to assess state or local-level school vaccination requirements. Eighteen states provide local-level data online, helping to strengthen immunization programs, guide vaccination policies, and inform the public.¶¶ Local-level school vaccination and exemption data can be used by health departments and schools to focus vaccine-specific interventions and health communication efforts in a school or local area with documented low vaccination coverage or high exemption rates. Where expanded health communication strategies or other interventions are implemented, continued assessment and reporting can be used to facilitate program improvement.

**FIGURE. Estimated percentage of children enrolled in kindergarten who have been exempted from receiving one or more vaccines* and with <90% coverage with 2 doses of measles, mumps, and rubella (MMR) vaccine — United States, 2013–14 school year**




* Exemptions might not reflect a child's vaccination status. Children with an exemption who did not receive any vaccines are indistinguishable from those who have an exemption but are up-to-date for one or more vaccines.

To be most effective, accurate and reliable estimates of vaccination coverage and exemptions are needed. Use of appropriate sampling and survey methods can improve the usefulness of data for local use and comparability of estimates across school, local area, state, and national levels to accurately assess vaccination coverage and track progress toward *Healthy People 2020* targets.

School vaccination coverage reporting can be labor intensive, involving education systems at the start of the school year, when they are busiest. School vaccination assessment systems can be linked to an IIS, allowing schools to review the vaccination status of individual children. During the 2013–14 school year, 36 of the 50 states and DC reported that they allowed schools to obtain provider-reported vaccination data from their IIS, and 14 reported using an IIS algorithm to determine vaccination status for at least some of the students in their school vaccination assessment. An example of how an IIS can be used to simplify school vaccination assessment is Tennessee's Immunization Certificate Validation Tool, which compares a child's record in the state IIS against Tennessee vaccination requirements for pre-school or school attendance, allowing vaccination providers and school nurses to quickly assess a schoolchild's vaccination status. It produces an official Tennessee Immunization Certificate or a detailed failure report. Tools linking school vaccination assessment systems to IIS data provide access to provider-reported information, reduce the documentation burden on parents and vaccination providers, and lessen the workload required by the assessment process on schools and health departments.

The findings in this report are subject to at least six limitations. First, not every state reported vaccination and exemption data.

**What is already known on this topic?**

To protect school children from vaccine-preventable disease, annual school vaccination assessments indicate vaccination coverage and exemptions from state vaccination requirements. Although state vaccination coverage is high and exemptions are low, undervaccination and exemptions cluster at a local level, where vaccine-preventable diseases might be easily transmitted.

**What is added by this report?**

In 49 states and the District of Columbia (DC), median vaccination coverage for three vaccines was 94.7% for the measles, mumps, and rubella vaccine, 95.0% for varying local requirements for the diphtheria, tetanus toxoid, and acellular pertussis vaccine, and 93.3% for varicella vaccine among states with a 2-dose requirement. Of the 49 states and DC reporting vaccination coverage estimates, 27 did not report meeting the *Healthy People 2020* target of 95% coverage for 2 doses of measles, mumps, and rubella vaccine. Median exemption levels continue to be low overall (1.8%).

**What are the implications for public health practice?**

Local data are essential to controlling the spread of vaccine-preventable disease. Accurate and reliable school vaccination assessments can provide a unique opportunity for school and health departments to identify local areas of undervaccination, even at a school or classroom level, where the potential for disease transmission is higher. Health departments can use these data to identify schools and communities at higher risk for outbreaks and provide health communication interventions to protect school children and the community at large against vaccine-preventable diseases.

¶¶ Information available, by state, at the following websites: Alabama, http://www.adph.org/immunization/index.asp?id=761; Arizona, http://www.azdhs.gov/phs/immunization/statistics-reports.htm; California, http://www.cdph.ca.gov/programs/immunize/pages/immunizationlevels.aspx; Florida, http://www.floridahealth.gov/reports-and-data/immunization-coverage-surveys-reports/state-surveys.html; Illinois, http://www.isbe.state.il.us/research/htmls/immunization.htm#immu; Iowa, http://www.idph.state.ia.us/immtb/immunization.aspx?prog=imm&pg=audits; Kansas, http://www.kdheks.gov/immunize/kindergarten_coverage.htm; Kentucky, http://chfs.ky.gov/dph/epi/annual+immunization+school+and+childcare+survey.htm; Michigan, http://www.michigan.gov/mdch/0,4612,7-132-2942_4911_4914_68361-321114--,00.html; Minnesota, http://www.health.state.mn.us/divs/idepc/immunize/stats/school/index.html; New Jersey, http://www.state.nj.us/health/cd/stats.shtml; North Dakota, www.ndhealth.gov/immunize/rates; Oregon, http://public.health.oregon.gov/preventionwellness/vaccinesimmunization/gettingimmunized/pages/schresources.aspx; Texas, https://www.dshs.state.tx.us/immunize/coverage/default.shtm; Utah, http://www.immunize-utah.org/statistics/utah%20statistics/immunization%20coverage%20levels/index.html; Vermont, http://www.healthvermont.gov/hc/imm/immsurv.aspx; Virginia, http://www.vdh.state.va.us/epidemiology/immunization/datamanagement/sisreports.htm; Washington, http://www.doh.wa.gov/dataandstatisticalreports/schoolimmunization/datareports.aspx.

**TABLE 2. Estimated number and percentage* of children enrolled in kindergarten with exemption(s) from vaccination, by state/area and type of exemption — United States, 2013–14 school year**

| State/Area | Medical exemptions† | | Nonmedical exemptions† | | | | Total exemptions† | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No. | % | No. of religious exemptions | No. of philosophic exemptions | Total no. | % | Total no. | 2013–14 (%) | 2012–13 (%) | Percentage point difference |
| Alabama | 70 | <0.1 | 447 | § | 447 | 0.6 | 517 | 0.7 | 0.7 | 0.0 |
| Alaska | 119 | 1.2 | 421 | § | 421 | 4.1 | 539 | 5.3 | 5.6 | -0.3 |
| Arizona | 175 | 0.2 | ¶ | 4,195 | 4,195 | 4.7 | 4,370 | 4.9 | 4.2 | 0.7 |
| Arkansas | 24 | <0.1 | 135 | 333 | 468 | 1.1 | 493 | 1.2 | 1.1 | 0.1 |
| California | 1017 | 0.2 | †† | 17,253 | 17,253 | 3.1 | 18,270 | 3.3 | 3.0 | 0.3 |
| Colorado | 0 | <0.1 | 195 | 3,097 | 3,292 | 4.6 | 3,291 | 4.6 | 4.3 | 0.3 |
| Connecticut | 128 | 0.3 | 670 | § | 670 | 1.6 | 725 | 1.9 | 1.7 | 0.2 |
| Delaware | 9 | <0.1 | 83 | § | 83 | 0.7 | 92 | 0.8 | 0.7 | 0.1 |
| District of Columbia | 85 | 1.1 | 33 | § | 33 | 0.4 | 118 | 1.5 | 1.6 | -0.1 |
| Florida | 772 | 0.3 | 3,991 | § | 3,991 | 1.7 | 4,763 | 2.0 | 1.8 | 0.2 |
| Georgia | 143 | <0.1 | 2,420 | § | 2,420 | 1.7 | 2,563 | 1.8 | 2.3 | -0.5 |
| Hawaii | 0 | <0.1 | 634 | § | 634 | 3.2 | 634 | 3.2 | 2.5 | 0.7 |
| Idaho | 89 | 0.4 | 147 | 1,304 | 1,451 | 6.1 | 1,540 | 6.4 | 5.9 | 0.5 |
| Illinois** | NA | | | | NA | | NA | NA | 6.1 | NA |
| Indiana | 348 | 0.4 | 727 | § | 727 | 0.8 | 1,075 | 1.2 | 1.3 | -0.1 |
| Iowa | 205 | 0.5 | 521 | § | 521 | 1.2 | 726 | 1.7 | 1.7 | 0.0 |
| Kansas | 213 | 0.8 | 527 | § | 527 | 1.9 | 739 | 2.6 | 1.1 | 1.5 |
| Kentucky | 148 | 0.3 | 357 | § | 357 | 0.6 | 505 | 0.9 | 0.7 | 0.2 |
| Louisiana | 83 | 0.1 | 28 | 394 | 422 | 0.7 | 505 | 0.8 | 0.7 | 0.1 |
| Maine | 56 | 0.4 | 30 | 766 | 796 | 5.2 | 852 | 5.5 | 4.3 | 1.2 |
| Maryland | 244 | 0.3 | 513 | § | 513 | 0.7 | 758 | 1.0 | 1.0 | 0.0 |
| Massachusetts | 332 | 0.4 | 860 | § | 860 | 1.1 | 1,192 | 1.5 | 1.5 | 0.0 |
| Michigan | 573 | 0.5 | 1,250 | 5,226 | 6,476 | 5.4 | 7,049 | 5.9 | 5.9 | 0.0 |
| Minnesota** | NA | | | | NA | | NA | NA | 1.6 | NA |
| Mississippi | 17 | <0.1 | ¶ | § | NA | | 17 | <0.1 | <0.1 | 0.0 |
| Missouri** | NA | | | | NA | | NA | NA | 1.8 | NA |
| Montana | 36 | 0.3 | 426 | § | 426 | 3.3 | 463 | 3.6 | 3.5 | 0.1 |
| Nebraska | 158 | 0.6 | 307 | § | 307 | 1.1 | 465 | 1.7 | 1.7 | 0.0 |
| Nevada | 7 | <0.1 | 724 | § | 724 | 2.0 | 731 | 2.0 | 2.5 | -0.5 |
| New Hampshire | 49 | 0.4 | 328 | § | 328 | 2.5 | 377 | 2.8 | 2.5 | 0.3 |
| New Jersey | 262 | 0.2 | 1,741 | § | 1,741 | 1.4 | 2,003 | 1.6 | 1.4 | 0.2 |
| New Mexico | 72 | 0.2 | 277 | § | 277 | 0.9 | 349 | 1.1 | 0.4 | 0.7 |
| New York | 302 | 0.1 | 1,547 | § | 1,547 | 0.6 | 1,849 | 0.8 | 0.7 | 0.1 |
| North Carolina | 161 | 0.1 | 1,105 | § | 1,105 | 0.9 | 1,266 | 1.0 | 0.8 | 0.2 |
| North Dakota | 32 | 0.3 | 45 | 185 | 230 | 2.3 | 262 | 2.7 | 1.8 | 0.9 |
| Ohio | 369 | 0.2 | †† | †† | 2,681 | 1.8 | 3,050 | 2.0 | 2.0 | 0.0 |
| Oklahoma | 73 | 0.1 | 221 | 586 | 808 | 1.4 | 880 | 1.5 | 1.3 | 0.2 |
| Oregon | 62 | 0.1 | 3,331 | †† | 3,331 | 7.0 | 3,393 | 7.1 | 6.5 | 0.6 |
| Pennsylvania | 510 | 0.3 | 1,133 | 1,419 | 2,552 | 1.7 | 3,062 | 2.0 | 2.0 | 0.0 |
| Rhode Island | 33 | 0.3 | 81 | § | 81 | 0.7 | 114 | 1.0 | 1.1 | -0.1 |
| South Carolina§§ | 83 | 0.1 | 772 | § | 772 | 1.2 | 855 | 1.4 | NA | NA |
| South Dakota§§ | 21 | 0.2 | 199 | § | 199 | 1.6 | 220 | 1.8 | 1.8 | 0.0 |
| Tennessee | 132 | 0.2 | 773 | § | 773 | 1.0 | 906 | 1.1 | 1.2 | -0.1 |
| Texas (Including Houston) | 2,266 | 0.6 | †† | †† | 5,536 | 1.4 | 7,803 | 1.9 | 1.7 | 0.2 |
| Houston | 979 | 0.3 | NA | NA | NA | | 979 | 0.3 | 0.9 | -0.6 |

See table footnotes on page 919.

Second, vaccination and exemption status reflected the child's status at the time of assessment. Reports might not be updated when parents submit amended school vaccination records after the required vaccines are received or an exemption is claimed. Third, a child with an exemption is not necessarily unvaccinated. More than 99% of the 2008–2009 birth cohorts who became kindergartners in 2013–14 received at least one vaccine in early childhood (*6*). An exemption might be provided for all vaccines even if a child missed a single vaccine dose or vaccine, or different exemptions might be provided for different vaccinations. A parent or guardian might choose to complete the required exemption paperwork if that is more convenient than having a child vaccinated or documenting a kindergartner's vaccination history at school enrollment, which might be the reason for up to 25% of nonmedical exemptions (*7–9*).*** Fourth, methodology varied by

*** Tools are available to help parents manage vaccination records for their family; additional information available at http://www.cdc.gov/vaccines/parents/record-reqs/immuniz-records-child.html.

**TABLE 2. (*Continued*) Estimated number and percentage* of children enrolled in kindergarten with exemption(s) from vaccination, by state/area and type of exemption — United States, 2013–14 school year**

| State/Area | Medical exemptions† | | Nonmedical exemptions† | | | | Total exemptions† | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No. | % | No. of religious exemptions | No. of philosophic exemptions | Total no. | % | Total no. | 2013–14 (%) | 2012–13 (%) | Percentage point difference |
| Utah | 94 | 0.2 | 16 | 2,296 | 2,312 | 4.2 | 2,406 | 4.4 | 3.8 | 0.6 |
| Vermont | 11 | 0.2 | 13 | 399 | 412 | 6.1 | 423 | 6.2 | 6.1 | 0.1 |
| Virginia | 173 | 0.2 | 446 | § | 446 | 0.4 | 619 | 0.6 | 0.5 | -0.5 |
| Washington§§ | 1,035 | 1.2 | 311 | 2,866 | 3,177 | 3.6 | 4,212 | 4.7 | 4.6 | 0.1 |
| West Virginia | 35 | 0.2 | ¶ | § | | | 35 | 0.2 | 1.2 | -1.0 |
| Wisconsin | 103 | 0.1 | 373 | 3,042 | 3,415 | 4.8 | 3,519 | 4.9 | 4.5 | 0.4 |
| Wyoming | NA | | | | NA | | NA | NA | 2.3 | NA |
| *Median¶¶* | | *0.2* | | | | *1.7* | | *1.8* | *1.8* | *0.0* |
| American Samoa | NA | | | | NA | | NA | NA | NA | NA |
| Guam | 0 | <0.1 | 1 | § | 1 | <0.1 | 1 | <0.1 | <0.1 | 0.0 |
| Marshall Islands | NA | | | | NA | | NA | NA | NA | NA |
| Micronesia | NA | | | | NA | | NA | NA | NA | NA |
| N. Mariana Islands | 0 | 0.0 | 0 | 0 | 0 | 0.0 | 0 | 0.0 | 0.1 | -0.1 |
| Palau | NA | | | | NA | | NA | NA | 0.6 | NA |
| Puerto Rico | 0 | <0.1 | 0 | § | 0 | <0.1 | 0 | <0.1 | <0.1 | 0.0 |
| U.S. Virgin Islands | 0 | 0.0 | 17 | § | 17 | 1.1 | 17 | 1.1 | 0.6 | 0.5 |

**Abbreviation:** NA = not available (i.e., not collected or reported to CDC).

* Estimates are adjusted for nonresponse and sampling design where appropriate, except where complete data were unavailable. Percentages for Delaware, Houston, Virginia, and Puerto Rico are approximations.

† Medical and nonmedical exemptions might not be mutually exclusive. Some children might have both medical and nonmedical exemptions. Total exemptions is the number of children with an exemption. Temporary exemptions are included in the total for South Carolina, South Dakota, and Washington.

§ Exemptions because of philosophic reasons are not allowed.

¶ Exemptions because of religious reasons are not allowed.

** Lower bounds of the percentage of children with any exemptions, estimated using the individual vaccines with the highest number of exemptions are, for Illinois, 0.3% with medical exemptions, 1.0% with religious exemptions, and 1.3% for total exemptions, and for Missouri, 0.2% with medical exemptions, 1.6% with religious exemptions, and 1.8% for total exemptions. For Minnesota, the lower bounds of the percentage of children with any exemptions, estimated using the number of children exempt for all vaccines, are <0.1% with medical exemptions, 1.7% with religious exemptions, and 1.7% for total exemptions.

†† Religious and philosophic exemptions are not reported separately.

§§ Includes both temporary and permanent medical exemptions.

¶¶ The median is the center of the estimates in the distribution. The median does not include Houston, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

reporting program or between school years for the same program. Methods and times for data collection differed, as did requirements for vaccinations and exemptions. Fifth, some programs (Delaware, Houston, Virginia, and Puerto Rico) were unable to provide detailed information needed to weight and analyze their data in the most statistically appropriate way, limiting the validity of their reported estimates. Finally, in adjusting data collected using school or student census methods to account for nonresponse, it was assumed that nonresponders and responders of the same school type had similar vaccination coverage and exemption rates.

State and local school vaccination assessments might detect local areas of undervaccination where disease transmission is more likely to occur. These data are most useful when the assessment is accurate and reliable. Use of statistically appropriate sampling methods and access to provider-reported vaccination data in an IIS can streamline the data collection process while providing accurate local-level data, allowing health departments to appropriately direct vaccination efforts during outbreaks of vaccine-preventable disease and identify schools and communities potentially at higher risk for vaccine-preventable disease transmission. Accurate local-level data can also be used by health departments and schools to focus health communication and other interventions that protect children and the community at large against vaccine-preventable diseases.

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# 6.4

The New York Times | http://nyti.ms/103LsTS

BUSINESS DAY

# F.D.A. Approves Pfizer's Trumenba, a Vaccine for a Rare Meningitis

By KATIE THOMAS OCT. 29, 2014

The Food and Drug Administration said on Wednesday that it had approved a vaccine for a dangerous strain of meningitis that caused outbreaks last year at Princeton and the University of California, Santa Barbara.

The vaccine, which is made by Pfizer and is to be called Trumenba, is aimed at preventing a variety of bacterial meningitis known as serogroup B. Because the bacteria spread through close physical contact like coughing, kissing and sharing eating utensils, outbreaks — though rare — have occurred on college campuses and other places where people live in close quarters.

"Pfizer is proud to have developed the first and only F.D.A.-approved vaccine that addresses an existing and urgent need in the efforts to help prevent this uncommon but life-threatening and devastating disease in the U.S.," Emilio A. Emini, senior vice president for vaccine research and development at Pfizer, said in a statement.

Pfizer had been in a race with the Swiss drug maker Novartis to win approval in the United States of a vaccine for serogroup B meningitis. Novartis's competing vaccine, Bexsero, has been approved in Canada, Europe and Australia, where the strain is more common. Last year, the F.D.A. authorized Novartis to provide 30,000 doses of Bexsero to students and staff at the two colleges as an emergency measure.

Dr. Karen Midthun, director of the Center for Biologics Evaluation and Research at the F.D.A., described the consequences of infection with serogroup B meningitis as often "devastating," saying in a conference call with reporters that the infection kills 10 to 15 percent of those who contract it. An additional 10 to 20

percent suffer permanent complications like brain damage and limb loss, she said. In 2013, a college student had to have both feet amputated because the infection had disrupted circulation in his legs.

Because of the seriousness of the disease, the agency approved Trumenba on an accelerated schedule. The vaccine's approval was based on results showing an immune response to four different strains of serogroup B, which are representative of strains prevalent in the United States. But Pfizer said its effectiveness against other strains in the serogroup had not been confirmed and that the company was conducting additional studies.

Of the approximately 500 cases of meningitis reported in the United States in 2012, about 160 were caused by serogroup B, according to the Centers for Disease Control and Prevention. Until now, bacterial meningitis vaccines have covered the other four main serogroups — A, C, Y and W.

Trumenba is approved for people between the ages of 10 and 25 and will be administered in a three-dose series. Whether school-age students will someday be required to be vaccinated against serogroup B meningitis has not yet been decided. The C.D.C., not the F.D.A., is charged with making recommendations about vaccine use.

A version of this article appears in print on October 30, 2014, on page B2 of the New York edition with the headline: F.D.A. Approves Vaccine for Rare Meningitis.

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# 6.5

Pharmacy Times

# Meningococcal Vaccine Gets FDA Nod for Booster Immunization

Author: Katie Eder, Senior Editor

The FDA has approved the use of Sanofi's Menactra vaccine as a booster immunization against meningococcal disease in patients at continued risk.

Although meningococcal disease is rare, the condition can result in permanent disabilities and death. As a result, the US Centers for Disease Control and Prevention (CDC) currently recommends that adolescents receive 1 dose of meningococcal conjugate vaccine at age 11 or 12, followed by a booster vaccination at age 16. With its expanded approval, Menactra can now fulfill both of those guidelines.

"The FDA's approval of the Menactra booster vaccination gives health care providers the option to use a meningococcal conjugate vaccine that is approved for both primary and booster immunization, which aligns with the CDC's recommendations for preventing cases of meningococcal meningitis," said David P. Greenberg, MD, Vice President of US Scientific and Medical Affairs at Sanofi Pasteur, in a statement. "With this approval, we hope health care providers are reminded to talk to their teen patients and their parents about the CDC's recommendations, ultimately helping to improve booster immunization rates for teens across the country."

The FDA originally approved Menactra in January 2005 as an active immunization against meningococcal disease caused by the A, C, Y, and W-135 serogroups. According to Sanofi, the vaccine's expanded approval as a booster immunization in patients aged 15 to 55 years was based on an open-label trial that evaluated the safety and immunogenicity of a booster dose among individuals who received Menactra 4 to 6 years earlier.

Following the booster dose, the most common adverse events reported in the study were injection-site pain and myalgia.