**ADVISORY COMMISSION ON CHILDHOOD VACCINES**
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**September 05, 2013**

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# *ADVISORY COMMISSION ON CHILDHOOD VACCINES*

## ***Agenda***

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

**Teleconference and Adobe Connect**

Thursday, September 05, 2013

(10:00 am – 4:00 pm Eastern Daylight Time)

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| Time | Agenda Item | Presenter |
|---|---|---|
| 10:00 AM | Welcome and Chair Report | Mr. David King, Chair |
| 10:10 AM | Public Comment on Agenda Items | |
| 10:15 AM | Approval of June 2013 Minutes | Mr. David King, Chair |
| 10:20 AM | Report from the Division of Vaccine Injury Compensation | Dr. Vito Caserta<br>Acting Director, DVIC |
| 10:50 AM | Report from the Department of Justice | Mr. Vince Matanoski<br>Deputy Director<br>Torts Branch, DOJ |
| 11:20 AM | Adding GBS to the Vaccine Injury Table | Dr. Ahmed Calvo<br>Medical Officer, DVIC |
| 12:00 PM | Lunch | |
| 1:00 PM | Report from the Process Workgroup | Ms. Luisita dela Rosa<br>ACCV Member |
| 1:20 PM | Report from the Maternal Immunization Workgroups | Dr. Kristen Feemster<br>ACCV Member |
| 1:40 PM | Vaccine Information Statements | Skip Wolfe<br>CDC |
| 2:20 PM | Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities | Dr. Tom Shimabukuro<br>CDC |
| 2:35 PM | Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities | Ms. Claire Schuster<br>NIAID, NIH |

| Time | Agenda Item | Presenter |
|---|---|---|
| 2:50 PM | Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities | LT. Valerie Marshall<br>CBER, FDA |
| 3:05 PM | Update from the National Vaccine Program Office (NVPO) | Dr. Steve Bende<br>NVPO |
| 3:20 PM | Public Comment (follows the preceding topic and may commence earlier or later than 3:20 pm) | |
| 3:35 PM | Future Agenda Items/New Business | Mr. David King, Chair |
| 4:00 PM | Adjournment of the ACCV September Quarterly Meeting | Mr. David King, Chair |

# ***Charter***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

# CHARTER

## ADVISORY COMMISSION ON CHILDHOOD VACCINES

### Authority

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

### Objectives and Scope of Activities

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

### Description of Duties

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

### Agency or Official to Whom the Commission Reports

The Commission on Childhood Vaccines 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 $84,685. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $257,582.

Designated Federal Officer

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

Estimated Number and Frequency of Meetings

The Commission shall meet no less than 4 times per year and at the call of the DFO. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

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. Members may serve after the expiration of their term until their successors have taken office.

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 nonvoting 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 committee, formally and informally established subcommittees, or other subgroups of the committee, 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, 2012

Approved:

July 17, 2012
Date

for Jennifer Rizzle
Wendy Ponton
Director, Office of Management

# ***Roster***

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV) ROSTER**
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# ***2013& 2014 Meeting Dates***

## Advisory Commission on Childhood Vaccines

### 2013 Meeting Dates

September 5, 2013
December 5 & 6, 2013

### 2014 Meeting Dates

March 6 & 7, 2014
June 5 & 6, 2014
September 4 & 5, 2014
December 4 & 5, 2014

# 2

**Advisory Commission on Childhood Vaccines**

**June 7, 2013**

**88th Meeting**

**Teleconference Minutes**

**Members Present**

David King, Chair
Charlene Douglas, Ph.D.
Kristen Feemster, M.D.
Edward Kraus, J.D.
Ann Linguiti Pron, DPN, CPNP, RN
Luisita dela Rosa
Jason Smith, J.D.
Sylvia Fernandez Villareal, M.D.

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

Noting a quorum present, Mr. King called the meeting to order and, after introductions, noted that this virtual meeting included an expanded interactive capability. He commented that verbatim transcripts are no longer prepared for the regular meetings of the Commission, but that each meeting is recorded and that the recordings will be available on the National Vaccine Injury Compensation Program (VICP) web site. He also announced that there are two opportunities for public comment on the agenda, the first exclusively for comments concerning the meeting agenda, and the second, at the end of the meeting, for any comments that members of the public would like to offer. If an individual is not able to attend the meeting and make a comment, or desires to offer an expanded comment, such comments may be submitted to the Commission at any time before or after the meeting.

Mr. King explained that there was interest at the last meeting in establishing a workgroup to collect and consider various data that might become available. However, there was no Commission member who was willing to assume the responsibility of chairing that workgroup, which makes it impractical to establish the workgroup. He invited any member amenable to considering that task to contact Ms. Herzog.

**Public Comment on Agenda Items**

There were no individuals who requested time to make a comment.

**Approval of March 2013 Minutes**

On motion duly made by Mr. Kraus and seconded by Dr. Douglas, the minutes of the March 17, 2013 meeting were unanimously approved.

**Report from the Division of Vaccine Injury Compensation**
**Dr. Vito Caserta, Acting Director**

Dr. Caserta briefly reviewed the agenda for the teleconference. He provided some data on the number of claims filed to date, which appear to be in line with the numbers for the previous year, and the adjudications, which are also comparable to the past few years. He noted that, in the past few years, settlements have become the predominant route to adjudication, at an annual rate of about 80%. He

expressed the opinion that a settlement is a good mechanism that allows both parties to negotiate an acceptable agreement.

Dr. Caserta commented that the annual level of total compensation has been steadily increasing, and should reach over $200 million in the current fiscal year. He added that compensation to date already exceeds the total compensation for 2012. The Trust Fund stands at $3.4 billion, annual income to date is $86 million, $56 million from excise tax revenues levied on vaccine doses sold, and $30 million from interest on the corpus of the trust fund.

Concerning significant activities and events, Dr. Caserta mentioned an article in Judicial Watch that was written based on information derived from a FOIA request. The article contended that HPV vaccine appeared to be unsafe based on the number of concessions and the amount of compensation awarded. The article resulted in a challenge to the Canadian Immunization Committee from a private ethicist in Canada. The challenge indicated that Canada should not allow the use of HPV vaccine. That Committee has requested information from DVIC, which will be provided shortly. The Global Vaccine Initiative Alliance (GAVI), an international public-private funding group dedicated to the promotion of vaccine availability in Third World Countries, has also requested information from DVIC. Dr. Caserta explained that basing such a claim on this data from the Program is misleading to assess risk because, most adjudications are by settlement, and in settlements DVIC maintains its position that there was no vaccine causation of the alleged injuries.

Dr. Caserta noted that there is a chart on the DVIC web site that provides data on compensated claims, the number of vaccine injuries and deaths related to those claims, and the compensation awarded. Since that limited data has the same limitations as the data discussed in the Judicial Watch article, that is, lack of a valid analysis of the risks related to the claims, his office has designed a new data table that includes more complete data – numbers of concessions, settlements and court decisions, and the total number of vaccines distributed, which allows a comparison between the number of claims and the number of vaccines made available. Dr. Caserta added that the new data table includes detailed definitions of compensable cases, conceded cases, settlements, and non-compensable/dismissed cases and will be posted on the VICP web site. There was a brief discussion about whether the total number of vaccines distributed was less helpful than total number of vaccines administered. Several points were made including the fact that collecting reliable data from the thousands of distribution points (doctor's offices, public health facilities, storefronts, etc.) was a daunting challenge, whereas reporting doses distributed by manufacturers was more manageable. It was also observed that the economic imperative to avoid waste was motivation to use as many of the doses distributed as possible. There was a comment that, although not perfect, the doses distributed offered a reasonable estimate of consumption.

Noting that the Notice of Proposed Rulemaking (NPRM) for the rotavirus vaccine is pending final approval, Dr. Caserta commented that the Department is awaiting a response from OMB for a waiver to OMB review. If granted the approval process would be considerably shortened.

He added that the NPRM which proposed changes to the Vaccine Injury Table based on the findings of the 2012 Institute of Medicine (IOM) report and was approved by the Commission in March 2012 is still under HRSA review. He stated that the NPRM would be submitted to the Department before the next ACCV meeting.

To provide a better understanding of the process by which an NPRM becomes a Final Rule, Dr. Caserta briefly outlined the process by which a new NPRM winds its way through the system to become a Final Rule published in the Federal Register. After the NPRM is initially developed, it is reviewed by the ACCV and then reviewed and approved by HRSA, working with the Office of the General Counsel (OGC). The NPRM is sent on to the DHHS Executive Secretary, which makes it available to other interested agencies within DHHS for review and comment. Any comments are considered by the Secretary and, if the proposed rule is approved it is sent on to the Office of Management and Budget (OMB), which similarly makes it available to interested federal agencies outside DHHS. OMB review can take up to 90 days.

When all comments are considered and addressed, the NPRM published in the Federal Register and it is open for public comment for 180 days. If comments from the public are received they are reviewed by DVIC, working with OGC, and the Final Rule is written, including an explanation of why any public comments were accepted or rejected. After final HRSA, DHHS and OMB review, , the Final Rule is published in the Federal Register. Dr. Caserta added that the process is lengthy and may take from 18 to 24 months to complete.

**Report from the Department of Justice (DOJ)**
**Vincent J. Matanoski, J.D.**
**Deputy Director, Torts Branch, Civil Division**

Mr. Matanoski referenced the DOJ Power Point materials (DOJ PP), dated June 7, 2013, as part of his presentation.

Mr. Matanoski began with DOJ's statistical report for the time period of February 16, 2013 – May 15, 2013 (DOJ PP at 2-4). During this reporting period, 96 new petitions were filed. No petitions for autism were filed. Of those, 66 were filed on behalf of adults and 30 for minors, with the majority of petitions alleging injuries from seasonal influenza vaccinations. He predicted that the number of filings appears on track with the previous year, and should reach about 400 new petitions for the fiscal year. For this quarter, 338 petitions were adjudicated with 84 compensated and 254 not compensated/dismissed. Of the 84 claims compensated, five were conceded by HHS (all five were by decision adopting a proffer). Of the 79 cases compensated but not conceded by HHS, one was by decision awarding damages and 78 were by decision adopting a stipulation. There were three claims voluntarily withdrawn; all three were non-autism claims.

Mr. Matanoski identified the glossary of terms (DOJ PP at 5-7) together with the wire diagram depicting case processing (DOJ PP at 8) and the appeals chart (DOJ PP at 9-10). These have been presented at past meetings. Turning to appellate activity in at the U.S. Supreme Court, Mr. Matanoski noted that the Court issued its decision in *Sebelius (HHS) v. Cloer* on May 20, 2013. (DOJ PP at 11). The Court affirmed the *en banc* decision issued by the U.S. Court of Appeals for the Federal Circuit (CAFC) awarding attorneys' fees and costs in time-barred cases provided that the petition was filed in good faith with a reasonable basis. This decision could have significant impact on the Program since there are approximately 1,000 pending "time-barred" petitions in the Omnibus Autism Proceeding that could seek fees. Working with the Court, Mr. Matanoski and petitioners' counsel are considering a process to streamline eligibility for fees in those cases. He predicted that adjudication of attorneys' fees will likely involve significant DOJ resources given the fact-specific nature of determining reasonable basis in time-barred claims. Turning to appellate activity at the CAFC, Mr. Matanoski discussed three recently decided cases in appeals brought by petitioners. (DOJ PP at 12). *Shapiro v. HHS*, involved a fact-based dispute about whether or not the alleged injury occurred before the vaccination or shortly afterwards. The CAFC affirmed the special master's dismissal based on evaluation of the expert testimony, finding no legal error. In a 2-1 decision, the CAFC in *Figueroa v. HHS*, reversed the special master's decision dismissing the case (which had been affirmed by the U.S. Court of Federal Claims (CFC)), and remanded the case to the special master for further proceedings. In *Figueroa,* the CAFC found that the personal representative of the estate had standing to file a petition seeking compensation for personal injuries to the decedent, while he was alive, after the decedent's death, even though the death was not caused by the vaccine or alleged vaccine-related injuries. According to the CAFC, petitioner's alleged vaccine-injury claim survived his death even though the death was not vaccine-related. Mr. Matanoski predicted that this case could impact the Program as cases brought by an estate where the death was not vaccine-related will involve litigation as to the cause of a decedent's alleged vaccine-related injuries. Finally, the CAFC affirmed the dismissal of *Hrieche v. HHS*, as time-barred. There were four new appeals to the CAFC, two filed by petitioners and two by the DOJ. (DOJ PP at 13). *Lalonde v. HHS*, was filed by petitioner seeking review of the CFC's affirmance of the special master's decision denying entitlement based on evaluation of expert testimony. Petitioners also sought review in *Issac v. HHS*. There, the CFC affirmed the special master's decision denying entitlement based on expert testimony involving the concept of molecular mimicry,

together with evaluation of a thirty-year-old case report, and evidence from the IOM. The government appealed the CFC's reversal of the special master's dismissals in the cases of *Snyder v. HHS* and *Harris v. HHS*. Both cases involved claims related to the genetic mutation, SCN1A/Dravet's Syndrome, which the special master found caused the alleged seizure disorder in both cases.
Turning to appellate activity at the CFC, Mr. Mantanoski noted that four cases were recently decided. (DOJ PP at 14). In *Barnette v. HHS*, the CFC affirmed the special master's decision denying entitlement where the special master found that the vaccine did not significantly aggravate an underlying genetic condition, SCN1A/Dravet's Syndrome. *LaLonde v. HHS*, was discussed above. *Eisler v. HHS*, involved a redaction issue. In *Graves v. HHS*, the CFC reversed a decision by the special master awarding $60,000 in pain and suffering for petitioners' daughter, who experienced seizures prior to her death. In so doing, the CFC set aside the special master's findings as inconsistent with the Act, and determined that petitioners were entitled to the maximum $250,000 damages cap. Notwithstanding past award calculations, the CFC found that the special master erroneously based his award amount on comparisons with other similar cases, as opposed to determining an amount for pain and suffering, and then reducing that award to $250,000, if it exceeded the cap. Here, the CFC determined that an award of pain and suffering would exceed $250,000, thus the maximum amount of the damages cap was appropriate. Mr. Mantanoski predicted that this decision could impact the Program in terms of seeing higher pain and suffering demands seeking the maximum $250,000 damages cap. Mr. Matanoski expressed that the Act does not mandate a fixed amount for pain and suffering; rather, there should be latitude in arriving at an appropriate award relative to the alleged injuries. No new appeals were filed in the CFC. (DOJ PP at 15). There are no oral arguments scheduled this quarter. (DOJ PP at 16)

Turning to the slides entitled Adjudicated Settlements (DOJ PP at 17-25), Mr. Matanoski noted that 78 cases were settled during the current reporting period. At the Commission's request from the past meeting asking for an apportionment of settlements between adults and minors (under age 18 years), Mr. Matanoski reported that of the 78 settlements this quarter, it appeared that 66 were for adults and 12 for minors. Because the information derives from the petition, he cautioned that it is subject to the caveat that pleadings can be re-captioned during the pendency of the claim if a child reaches the age of majority. He observed that most of the settlements involved injuries allegedly caused by the seasonal flu vaccine. Approximately 65% of the petitions filed identified seasonal flu alone and/or in conjunction with other vaccines. Guillain-Barré Syndrome continued to be the predominant alleged injury. Most of the cases, 88%, were resolved within three years. Broken down, 27% resolved within a year; 38% within two years; and 23% within three years. There were five petitions that took between 5-13 years. The length of time was attributed to administrative issues such as obtaining medical records and/or having the case in an omnibus proceeding, as opposed to delay by the parties. Mr. Matanoski recalled that DOJ started providing this information in response to a prior Commission's request to review case processing time. Mr. Matanoski concluded his remarks by addressing the issue of "data mining" from settlements, in response to a specific request from the Process Working Group. Mr. Matanoski began by reiterating that the process is like a crucible. Releasing further information from individual settlements raises confidentiality issues, and does not lend itself to reliable safety evaluation. Counseling against attempts to gain vaccine safety information from individual settlements, Mr. Matanoski reiterated that there are innumerable reasons that parties settle a case - many of which are unrelated to science - making the value of such data highly suspect, if not completely useless. The settlement process is legal, not scientific, based on a preponderance of evidence and how a court might determine the outcome of a case. There is no reliable correlation between that process and vaccine safety. There is also an increasing trend for claimants to demand privacy and confidentiality with regard to details in the court record and in the settlements, which is required by the Vaccine Act. This is an important privacy protection for individual claimants. Mr. Matanoski reiterated that the quarterly stipulation breakdown discloses as much information as is permissible without breaching confidentiality provisions of the Act about individual settlements. The data provided identifies the vaccine or vaccines involved in a claim, the alleged injury or injuries, and case duration from filing to settlement.

During discussion, Mr. Kraus acknowledged the confidentiality issues while reiterating his position that with 90% of adjudications being achieved by settlement, the unavailability of information about the details of the settled claims and the process of arriving at settlement is a continuing concern in terms of providing valuable information to the public. He added that it should not be prejudicial to petitioners to

reveal settlement amounts in each case since that information is in the public record. Mr. Matanoski responded that the amount of an individual settlement has no relevance to safety issues and that aggregate data on settlement amounts is readily available. Further, he reminded the Commission of the Act's established mechanism to evaluate vaccine safety using medical and scientific bodies such as the IOM to conduct research.

During further discussion related to Congressional intent behind the pain and suffering cap, Mr. Matanoski commented that Congress was aware of the import of the relatively high $250,000 maximum pain and suffering provision and wanted to make the Program attractive to injured individuals who at the time still had the option to sue the vaccine manufacturer.

**Review of Vaccine Information Statements,**
**Mr. Skip Wolf and Ms. Jenifer Hamborski, Centers for Disease Control and Prevention (CDC)**

Mr. Wolf explained there was only one VIS to review, for the Tdap vaccine, which had been previously reviewed and revised. This review was prompted by new recommendations regarding pregnancy. He noted that the format had been revised to reflect the standard format for all VISs. Mr. Wolf invited comment section by section, noting that under the second section, Tdap Vaccine, the new recommendation for pregnant women called for a Tdap vaccination during every pregnancy. There was an observation that the requirement for a Td booster every ten years could be modified if an individual receives a Tdap vaccination during a pregnancy, essentially allowing the clock to start again.

Mr. Wolf commented that at the last ACCV meeting a recommendation was accepted to change the title of the section in all VISs from "Precautions" to "Some people should not get this vaccine." Asked about the lack of a contraindication warning if an individual has severe autoimmune disease, Dr. Caserta stated that there was no such contraindication recommended for Tdap vaccine. In fact studies have shown that the vaccine in individuals with severe autoimmune disease is protective and clearly beneficial. Mr. Wolf noted that the text of the section was unchanged from the earlier Td/Tdap VIS wording. In addition, under the Risks of Vaccine Reaction section, there is no evidence that there is any difference in the risks for either of the two vaccines. Dr. Caserta suggested that there should be some indication of the time frame for adverse reactions relative to the administration of the vaccine. Mr. Wolf recalled that he and Dr. Shimabukuro were tasked at the last meeting to develop wording about the risks of shoulder pain or injury (SIRVA), a task that should be completed before the next ACCV meeting. The wording would be added to all VISs.

Mr. Wolf concluded the discussion noting that there were no changes in sections 5, 6 and 7.

**Report from the Process Workgroup,**
**Luisita dela Rosa, Chair**

Ms. dela Rosa reported that a recommendation had been approved at the last meeting to extend the statute of limitations for filing claims. After that meeting it was noted that there was no effective date in the resolution, and at a subsequent meeting the Workgroup agreed that the proposed recommendation should be revised to reflect an effective date, which would coincide with the date of enactment of the resolution.

At the same meeting the Workgroup considered increased benefits cap for pain and suffering, and for death, and agreed that the cap for both should be tied to the consumer price index for urban consumers (CPI-U). When enacted the cap provisions should apply to all pending cases and all claims filed on or after the enactment date. The cap would go into effect in the year that the decision is made regarding pain and suffering, and the year of death for the death benefit. On motion duly made by Mr. Kraus, and seconded by Ms. Pron, the motion to that effect was unanimously approved.

**Report on the ACCV and NVAC Maternal Immunization Workgroups,**
**Dr. Kristen Feemster, Commission Member**

*Background*

Ms. Anna Jacobs, OGC, provided background for the presentations related to maternal immunization injury claims. As with other injuries pursued under the VCIP, the claimant must prove eligibility, that a covered vaccine or any other vaccine was administered to the individual in an appropriate time frame, and that the alleged injury is either covered under the Vaccine Injury Table, or provide evidence that the vaccine caused the injury alleged. The claim may be for an alleged injury to the mother or for an alleged injury to the unborn fetus as a direct result of the mother's inoculation. However, in the latter case, the special masters who hear cases have not reached a consensus. In general the federal government has not accepted the premise that a claim can be made for a second party, the fetus. Petitioners have contended that the statute does cover such circumstances. Resolution of this issue will rely on case law that develops through decisions and appeals. To date no appeals have reached the Federal Circuit. In addition, the issue is complicated when new vaccines are developed that may be recommended for pregnant women but not for routine administration in children.

Finally, the issue must be considered in light of the CICP, under which regulations have been established that provide compensation protection to a child who survives birth with an injury that can be shown to have been caused by a vaccine received by the mother during pregnancy. Ms. Jacobs stated that the Secretary has asked that ACCV and NVAC consider the issue related to maternal immunization.

*Report of ACCV Maternal Immunization Workgroup*

Dr. Feemster explained that recommendations for immunizing women during pregnancy are expanding. The Advisory Commission on Immunization Practices (ACIP) currently recommends that all pregnant women at 20 weeks or greater gestational age receive Tdap during each pregnancy and that all pregnant women receive inactivated influenza vaccine. New vaccines against respiratory syncytial virus (RSV) and Group B *Streptococcus* are currently under development and, if approved, would likely be exclusively recommended for pregnant women. These current and potential future recommendations address the increased risk of morbidity and mortality associated with influenza in pregnant women and also protects young infants by preventing transmission of pertussis, influenza, RSV, Group B *Streptococcus* and tetanus. Studies have shown that maternal immunization is effective in preventing many of these diseases. Young infants are especially at risk for poor outcomes associated with these diseases and are too young to be vaccinated. Maternal immunization can decrease the risk of exposure by preventing disease in mothers and also provide protection to the young infant through the passage of maternal antibodies. Current studies show that maternal immunization benefits the mother and the infant, and have not identified any vaccine-related adverse events specific to vaccinated pregnant women and their infants. There is evidence that vaccines do not increase risk for specific adverse outcomes, including teratogenicity, growth or functional impairment, spontaneous abortion or preterm birth, small for gestational age or birth defects. Although there is a theoretical possibility of risk if live vaccines are administered, and they are contraindicated for pregnant women, there is no evidence of fetal infection or malformations in births from women who were inadvertently vaccinated with a live vaccine.

Successful implementation of recommendations for maternal immunization will require that women and health care providers have confidence in vaccines, know that the healthcare community will continually monitor the safety and efficacy of vaccines, and be aware that the VICP is available when a vaccine is administered during pregnancy.

Dr. Feemster reviewed the history of the workgroup, which was convened in June 2012 to consider a response to four charges from the Commission for vaccines administered during pregnancy. The workgroup met at least every two months, developed a working relationship with the NVAC Maternal Immunization Working Group, and arrived at the proposed recommendations which would be discussed at this meeting. The four charges addressed by the workgroup focused upon the following areas:

- Charge 1: Eligibility for compensation for injuries from vaccines not currently covered by the vaccine injury compensation program. This would include vaccines recommended for pregnant women but not recommended for routine administration to children. Under the statute, such

vaccines would not be covered by the program. There are no currently recommended vaccines that fit this condition. However, it is likely that both an RSV and Group B Streptococcus vaccine will be licensed for exclusive administration to pregnant women in the future.

- Charge 2: Eligibility for compensation for injuries sustained by a live-born infant from covered vaccines received by the mother while the infant was in utero. This would include covered vaccines currently recommended for administration during pregnancy as well as covered vaccines that are not routinely recommended but may be sometimes given during pregnancy. While the mother is the recipient of such vaccines, the group also considered eligibility of the infant.
- Charge 3: Review the current vaccine safety monitoring infrastructure in light of expanding recommendations for maternal immunization.
- Charge 4: Review ACCV membership guidelines and consider inclusion of individuals who provide care to pregnant women to reflect changes in VICP.

Dr. Feemster discussed the recommendations that the workgroup developed.

- ***The Secretary should pursue expanded coverage under the VICP to include vaccines that are recommended for categories other than children (e.g., pregnant women) and are not recommended for routine administration in children.***

The Secretary could pursue a legislative amendment to effect the provisions of the recommendation, which would be a specific, definitive action, but one that could take significant time, would be influenced by the political process, and which in the end might fail. The Secretary could turn to administrative rule-making to adopt a broader interpretation of the present statute (e.g., to interpret the statute such that an infant could be considered the beneficiary of maternal immunization through the maternal antibodies that would be created by the vaccines). This is an expeditious and flexible approach to policy change, but may have unanticipated consequences since other vaccines recommended for individuals other than children could affect significant VICP changes and increase expenditure of resources. This approach also requires acceptance of a broad interpretation by the Secretary that the approach is legally permissible and in consonance with the intent of the legislation.

- ***The Secretary should support eligibility to pursue compensation for injuries sustained by a live-born infant whose mother receives a vaccine while the infant is in utero. The Secretary may consider support of a statutory amendment, administrative rulemaking (both discussed above) or support for a litigation strategy (e.g., pursue a policy to develop case law that supports the recommendation).***

It was noted that the Department of Justice actually determines legislative strategies, so the recommendation is for the Secretary to *support, not initiate, legislative* strategies. The considerations that apply to pursuing either amendment or rulemaking are the same as those discussed in the first recommendation. In addition, rulemaking is a public process that may reassure the public of the benefits of the changes but, since the court has the final word in the matter of claims, the final rule may not be binding.

- ***The Secretary should continue to support the various systems in place to monitor safety during pregnancy, including the Vaccine Adverse Event Reporting System (VAERS), pregnancy registries maintained by vaccine manufacturers, the more controlled surveillance through the Vaccine Safety Datalink, and the new Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) recently established to conduct prospective, case-controlled surveillance of vaccine exposure and outcomes during pregnancy.***

- ***The Secretary should consider having a health professional with expertise in obstetrics as one of the health professionals required to be a member of the Commission under the ACCV charter.***

That charter states that the ACCV should be composed of nine members, including three health professionals not employed by the federal government, two of whom should be pediatricians. The health professionals must have expertise in pediatric health care, and the epidemiology and etiology of childhood diseases, including adverse events related to vaccines.

**Presentation by National Vaccine Advisory Committee (NVAC), Dr. Catherine Torres**

Dr. Torres explained that there are several illnesses that can be prevented by vaccines that affect pregnant women and their neonates – tetanus (very high rate in developing countries, very low rate in the U.S.); influenza (high morbidity/mortality rates from pandemics and seasonal flu, which can be significantly reduced by immunizing expectant mothers); and pertussis, which is a threat to infants less than three months of age, when they are too young to be immunized. Dr. Torres commented that Healthy People 2020 included goals to reduce pertussis in children under a year of age, and increase the percentage of pregnant women who receive flu vaccine (53% of pregnant women receive flu vaccine). ACIP recommended flu vaccine for pregnant women in 1995, and in early 2013 recommended that pregnant women receive a Tdap booster in the third trimester of each pregnancy.

Dr. Torres briefly described the NVAC, formed in 1987, that makes recommendations to the Director of the National Vaccine Program Office (the Assistant Secretary of Health). In August 2012 NVAC established a Maternal Immunization Working Group (MIWG) to review maternal immunization, identify barriers to optimize maternal immunization, and to make recommendations on those issues. NVAC is addressing uncertainties about vaccine liabilities that may discourage health care providers from recommending/providing vaccines to pregnant women, and may impact progress is development of new vaccines. NVAC's goals include:

- Improve communications about safety and efficacy of recommended vaccines;
- Maximize the likelihood that maternal health care providers will recommend appropriate maternal immunizations;
- Improve financing for immunization services during and after pregnancy;
- Increase use of electronic health records to strengthen surveillance efforts; and
- Address issues related to current vaccine liability to overcome barriers that would inhibit maternal immunization.

The MIWG focuses its recommendations on three of five National Vaccine Plan goals – to enhance vaccine safety; to enhance informed vaccine decision-making; to support efforts to maintain a stable supply of vaccines, and improve access and better use of recommended vaccines in that supply. Next steps for the MIWG will be to submit draft recommendations to the NVAC in June, complete a final draft after comments from NVAC and submit a recommendation report in September. The last step in the fall of 2013 will be to begin looking at barriers to developing new vaccines specifically for pregnant women.

**Discussion**

Asked about specific recommendations for the new vaccines, it was noted that the vaccines are not yet fully developed and recommendations would follow final formulation. It was also noted that it is important to include the new vaccines under the VICP in order to successfully complete the development process. Manufacturers are not enthusiastic about pursuing vaccine development unless there is high confidence that they will be covered.

The Commission commented on each charge/recommendation in order.

There was a brief discussion about the possibility that Recommendation 1, concerning expanding coverage to a number of vaccines being recommended for categories other than children, could create additional burdens on the VICP, both in terms of adding new vaccines to the Vaccine Injury Table, the concomitant administrative costs, burdens on the courts, and increased liability from recommended

vaccines not yet added to the Table. There was also a suggestion that the recommendation be narrowed to include only pregnant women and the following wording was recommended:

> ***Recommendation 1. The Secretary should pursue expanded coverage under the VICP to include vaccines that are recommended for routine administration to pregnant women, and are not recommended for routine administration in children.***

On motion duly made and seconded, the Commission unanimously approved Recommendation 1 by a vote of 8 for and none opposed.

The Commission agreed that the second recommendation should be revised to specify that compensation could be sought for injuries to an infant whose mother received a covered vaccine.

> ***Recommendation 2. The Secretary should support eligibility to pursue compensation for injuries sustained by a live-born infant whose mother receives a covered vaccine while the infant is in utero.***

The word "covered" was added to the wording put forth during the earlier discussion of recommendations.

On motion duly made and seconded, the Commission unanimously approved Recommendation 2 by a vote of 8 for and none opposed.

The Commission agreed that the third charge referred mainly to information collected during the surveillance process, and there was no recommendation proposed.

The recommendation coming from the fourth charge was a straightforward recommendation that a health care professional specializing in health care of children (specifically an obstetrician) be included in the membership of the Commission. There was a brief discussion of the specific descriptions of Commission membership found in the charter, including the requirement for two "pediatricians." There was agreement that the interpretation of "pediatrician" could include pediatric specialties that include other areas of expertise, such as internal medicine.

> ***Recommendation 3. The Secretary should consider mandating that an obstetrician with maternal-fetal expertise be designated as one of the health professionals required to be a member of the Commission under the ACCV charter.***

On motion duly made and seconded, the Commission unanimously approved Recommendation 3 (a response to Charge 4) by a vote of 8 for and none opposed.

Mr. King noted that the discussion regarding the recommendations from the Maternal Immunization Workgroup was concluded.

**Update from the Immunization Safety Office (ISO),**
**Dr. Tom Shimabukuro, CDC**

Dr. Shimabukuro noted that the ACIP meeting would occur later in June and an update of that meeting would be presented at the next ACCV meeting. At the ACIP meeting there will be presentations related to safety and immunogenicity of Japanese encephalitis vaccine in children; a report from the General Recommendations on Immunization Working Group; an update on human papillomavirus (HPV) vaccine, including a discussion of the Merck Pregnancy Registry for quadrivalent HPV vaccine; and an influenza update, including a vaccine safety update for the 2012-2013 influenza season. Finally, there will be a major session devoted to rotavirus vaccines that will include review of data from the Vaccine Safety Datalink, VAERS, the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system, a review of the Australian surveillance experience, and a summary of risks and benefits of rotavirus vaccination in the U.S.

Dr. Shimabukuro commented that the recent outbreak of avian influenza A (H7N9) in China has been in the news and CDC has responded by activating the CDC Emergency Operations Center on April 8, 2013 to support response to the outbreak. A website page is up that provides answers to frequently asked questions (http://www.cdc.gov/flu/avianflu/h7n9-faq.htm) and the Department is coordinating steps to develop H7N9 candidate vaccine viruses for use in vaccine manufacturing. One or more of those candidate vaccine viruses could be used by manufacturers if needed.

There have been several recent publications since the last ACCV meeting. DeStefano et al. concluded that increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines during the first 2 years of life was not related to risk of autism spectrum disorders.

Tseng et al. looked at post licensure surveillance of 13-valent pneumococcal conjugate vaccines, which replaced the 7-valent formulation, and found that compared to the 7-valent pneumococcal conjugate vaccine, no significant increased risk of pre-specified adverse events was identified. There was a non-statistically significant increase in risk for Kawasaki disease that may deserve further investigation.

McNeil et al. analyzed the likelihood of reporting vaccine adverse events to VAERS by primary care providers, a knowledge-attitude-behavior study, and concluded that primary practice area and the practitioners' familiarity with adverse reporting were significantly associated with likelihood of healthcare provider reporting to VAERS.

Irving et al. concluded that there was no statistically significant increase in risk of spontaneous abortion within the four weeks after seasonal inactivated influenza vaccine administration.

Finally, Haber et al. reported that clustering of reported intussusception 3-6 days after initial dose of Rotateq vaccine could suggest a small increased risk of intussusception, which is outweighed by the benefits of rotavirus vaccination. Dr. Shimabukuro added that two additional papers on intussusception would be discussed at the upcoming ACIP meeting in June.

Asked about mandatory reporting to VAERS, Dr. Shimabukuro explained that manufacturers are required to report adverse events in accordance with regulatory requirements, and health care providers are mandated to report adverse event listed on the VAERS table of reportable events, but there is no regulatory requirement for reporting by individuals.

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

Ms. Schuster commented that NIAID is working with other federal agencies to assess and address the threat of H7N9 influenza, supporting basic research, generating vaccine seed strains that could be used in vaccine manufacture, and planning clinical trials. She noted a paper by Kanekiyo et al published in Nature on May 22, 2013 about an experimental vaccine based on the action of a protein, ferritin, fused with hemagglutinin (HA), that resulted in an enhanced immune response in mice and ferrets. It could be a step towards a universal flu vaccine.

Another breakthrough came from a team led by Philip Dormitzer when the team of international collaborators successfully generated flu vaccine seeds in less than 5 days, by using synthetic genomics technology.

Finally, Ms. Schuster described a clinical trial of a vaccine, ROTAVAC, developed through a public/private collaboration with the government of India, Bharat Biotech International, Ltd, Program for Appropriate Technology in Health (PATH), NIAID, and other partners. The vaccine reduced severe rotavirus diarrhea by more than half during the first year of life, with protection extending into the second year of life.

Ms. Schuster stated that at the same time the ACCV teleconference was in progress, NIAID was sponsoring in Rockville, Maryland a workshop on *Staphylococcus aureus* vaccines that will address the current state of the science, and invite discussion on future research.

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

LCDR Marshall reported that FDA had approved a supplement for Japanese Encephalitis Vaccine, Inactivated, Adsorbed to extend the age range to include children 2 months to <17 years of age. There are no reports of JEV infection occurring in North America, so the risk to residents of the U.S. occurs from travel to endemic regions.

She announced that on May 2 and 3, FDA and NIH co-sponsored a workshop to exchange information with the medical and scientific community about the regulatory and scientific issues associated with fecal microbiota for transplantation (FMT). FMT is used to treat patients suffering from *Clostridium difficile* infection, ulcerative colitis, and other related infections. Clinical studies to evaluate the safety and efficacy of FMT are regulated by FDA.

Finally, CBER participated in a briefing for the Assistant Secretary for Health on the pertussis workshop held on March 6 on the state of the science for pertussis prevention and therapy. CBER discussed clinical development of pertussis vaccines and presented its baboon animal model that was developed to address some of the scientific gaps in knowledge regarding pertussis.

While the risk to people in the United States from H7N9 continues to be low, because of the pandemic potential posed by the virus, FDA with CDC, NIH, and other public health agencies are taking proactive steps in the event that virus becomes transmissible between people. FDA is developing clinical protocols, and is actively engaged with vaccine manufacturers.

**Update on the National Vaccine Program Office (NVPO), Dr. Steve Bende, NVPO**

Dr. Bende discussed the policy of the Assistant Secretary for Health, Dr. Howard Koh, to promote an increased participation in immunization by adults. After the 2009 flu pandemic the Department actively promoted immunization successfully in children, pregnant women and for the purpose of reducing disparities – but the response of the adult population was disappointing. A task force was established to focus on adult immunization, made up of federal and non-federal stakeholders, with Dr. Koh as chair. The task force and the Department is also focused on the increasing emergence of pertussis as a health issue. Finally, Dr. Bende mentioned that the Affordable Care Act has a provision that health plans must cover ACIP-recommended vaccines without co-pays or cost-sharing and the issues related to that transition are being addressed. Dr. Bende described the Interagency Immunization Safety Task Force, coordinated by NVPO to ensure effective and consistent discussion of immunization safety issues among the various concerned federal agencies.

The Institute of Medicine will present a discussion of safety of the childhood immunization schedule at the upcoming NVAC meeting. The IOM report recommends continuation of childhood immunization on the present schedule. The IOM report also maintains that randomized, controlled trials of children who are immunized vs. unimmunized would be unethical considering the risks versus benefits of the present program. The current surveillance programs, such as the Vaccine Safety Datalink, are sufficient to provide answers to the question of whether or not to immunize all children and should be further leveraged. The IOM has also accepted a charge from NVPO to develop a prioritization tool that would help researchers decide on which vaccines should be developed and in what order. The IOM is developing a software tool that includes 29 parameters for making that decision.

Dr. Bende commented that there are several working groups active in the immunization area that would be heard from at the NVAC meeting, including the Global Immunization Working Group that develops policy recommendations for the Department's involvement in global programs; the Maternal

Immunization Working Group described earlier in the meeting; a working group focused on vaccine hesitancy. It seems that there are isolated areas where hesitancy can lead to lower overall population immunity and make possible isolated outbreaks of disease that can and should be prevented through broad immunization coverage. Finally, there is a new working group on HPV virus that recently issued its first report, discussing the reasons that the initial acceptance of HPV vaccine has been disappointing.

**Public Comment**

Mr. Wayne Rohde, parent of a vaccine-injured child, reiterated his earlier suggestion that public comments should be welcomed from individuals interested in making a comment without having to be present at the meeting, that is, perhaps by e-mail. His main point concerned a proposal by Dr. Caserta to link vaccine dosage to claims that are compensated or dismissed. Mr. Rohde felt that it would minimize the number of petitions to make vaccine injury appear to be fewer than is actually the case. He added that VAERS data is difficult to interpret – the number of actual injuries that would qualify for a claim versus the number of individuals who approach attorneys to discuss filing claims versus the number of claims actually filed. He recommended developing a way by which the actual number of doses administered could be compared with the claims filed.

Ms. Theresa Wrangham, representing the National Vaccine Information Center, commented that in light of the need for transparency the public should be able to glean information about the types of compensation awarded by vaccine and by injury, and that information should be aggregated and explained perhaps on an appropriate web site. She added that the same web site might contain information that would explain the various terms related to compensation, injury and vaccines.

Mr. King reiterated an earlier announcement that individuals may submit written comments for inclusion in the public record by sending them to Ms. Andrea Herzog at e-mail address aherzog@hrsa.gov

**Future Agenda Items/New Business**

Considering the increasing number of claims made by adults, Dr. Pron suggested discussing the charter and the name of the commission at a future meeting. Dr. Caserta commented that currently all of the vaccines covered are childhood vaccines, regardless of the age of the recipient. He added that as the nature of coverage changes, for example, with the addition of obstetrical vaccines for pregnant women, it might be appropriate to look at the issue.

**Adjournment**

Whereupon, on motion made and unanimously approved, the meeting was adjourned.

_____ _____

Vito Caserta, M.D. Date
Executive Secretary, ACCV

# 3

# Vaccine Injury Compensation Trust Fund

**Balance as of July 31, 2013**

$3,405,148,061.14

**Figures for October 1, 2012 – July 31, 2013**

Excise Tax Revenue: $109,288,181.07
Interest on Investments: $51,397,653.57
Net Income: $160,685,834.64
Interest as a Percentage of Income: 32%

*Source: U.S. Treasury, Bureau of Public Debt*
*August 22, 2013*

# 4

# 4.1

# NATIONAL VACCINE INJURY COMPENSATION PROGRAM [1]

PROGRAM STATISTICS REPORT

As of Tuesday, August 13, 2013

## I. PETITIONS FILED

| Fiscal Year | Totals |
|---|---|
| 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 | 417 |
| FY 2009 | 397 |
| FY 2010 | 449 |
| FY 2011 | 386 |
| FY 2012 | 399 |
| FY 2013 | 353 |
| **Totals:** | **14,731** |

# NATIONAL VACCINE INJURY COMPENSATION PROGRAM [1]

PROGRAM STATISTICS REPORT

As of Tuesday, August 13, 2013

## II. ADJUDICATIONS [2]

| Fiscal Year | Compensable | Dismissed | Totals |
|---|---|---|---|
| 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 | 83 | 120 | 203 |
| FY 2008 | 147 | 134 | 281 |
| FY 2009 | 134 | 231 | 365 |
| FY 2010 | 181 | 292 | 473 |
| FY 2011 | 261 | 1,371 | 1,632 |
| FY 2012 | 258 | 2,437 | 2,695 |
| FY 2013 | 286 | 605 | 891 |
| **Totals:** | **3,368** | **9,642** | **13,010** |

# NATIONAL VACCINE INJURY COMPENSATION PROGRAM [1]

PROGRAM STATISTICS REPORT

**As of Tuesday, August 13, 2013**

## III. AWARDS PAID [3]

| Fiscal Year | Compensated | | | Dismissed | | Interim Fees | | Total Outlays |
|---|---|---|---|---|---|---|---|---|
| | No. of Awards | Petitioners' Award Amounts | Attorneys' Fees/Costs Payments | No. of Payments to Attorneys | Attorneys' Fees/Costs Payments | No. of Payments | Attorneys' Fees/Costs Payments | |
| FY 1989 | 0 | $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 | $119,893,267.67 | $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 | $2,799,810.85 | 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 | $105,678,632.57 | $3,373,865.88 | 57 | $2,066,224.67 | 0 | $0.00 | $111,318,723.12 |
| FY 2002 | 80 | $59,799,604.39 | $2,653,598.99 | 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 | 68 | $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 | $5,270,237.04 | 72 | $2,432,847.05 | 2 | $117,265.31 | $83,536,901.46 |
| FY 2009 | 131 | $74,142,490.58 | $5,404,711.98 | 36 | $1,557,138.53 | 28 | $4,241,362.55 | $85,345,704.64 |
| FY 2010 | 173 | $179,387,341.30 | $5,961,744.40 | 56 | $1,886,239.95 | 22 | $1,978,803.88 | $189,214,129.53 |
| FY 2011 | 251 | $216,323,760.31 | $9,736,216.87 | 402 | $6,425,243.19 | 28 | $2,001,770.91 | $233,486,991.28 |
| FY 2012 | 250 | $163,511,998.82 | $9,106,720.30 | 1,017 | $8,621,182.32 | 37 | $5,420,257.99 | $186,660,159.43 |
| FY 2013 | 323 | $215,023,417.10 | $11,519,456.02 | 599 | $5,667,099.47 | 46 | $1,305,846.78 | $233,535,819.37 |
| Totals: | 3,348 | $2,560,268,740.65 | $103,618,930.73 | 4,269 | $55,780,869.36 | 163 | $15,065,107.42 | $2,734,733,648.16 |

1. Fiscal year statistics for petitions/claims alleging injuries or deaths resulting from vaccines administered on or after 10/1/1988.

2. 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.

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

# 4.2

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

| | | Compensable | | | Compensable Total | Dismissed/Non-Compensable Total | Grand Total |
|---|---|---|---|---|---|---|---|
| Vaccine Alleged by Petitioner[2] | No. of Doses Distributed US CY 2006 - CY 2012 (Source: CDC)[3] | Concession | Court Decision | Settlement | | | |
| DT | 592,707 | 1 | 0 | 2 | 3 | 3 | 6 |
| DTaP | 68,113,573 | 13 | 15 | 60 | 88 | 61 | 149 |
| DTaP-Hep B-IPV | 38,347,667 | 5 | 5 | 14 | 24 | 26 | 50 |
| DTaP-HIB | 1,135,474 | 0 | 0 | 0 | 0 | 1 | 1 |
| DTaP-IPV-HIB | 46,633,881 | 0 | 0 | 4 | 4 | 4 | 8 |
| DTP | 0[4] | 0 | 1 | 2 | 3 | 1 | 4 |
| DTP-HIB | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hep A-Hep B | 10,405,325 | 0 | 0 | 8 | 8 | 0 | 8 |
| Hep B-HIB | 4;621,999 | 0 | 1 | 1 | 2 | 1 | 3 |
| Hepatitis A (Hep A) | 110,596,300 | 1 | 5 | 16 | 22 | 12 | 34 |
| Hepatitis B (Hep B) | 116,853,062 | 3 | 8 | 30 | 41 | 29 | 70 |
| HIB | 70,755,674 | 0 | 1 | 3 | 4 | 3 | 7 |
| HPV | 55,168,454 | 9 | 1 | 54 | 64 | 63 | 127 |
| Influenza[5] | 809,000,000 | 24 | 56 | 513 | 593 | 121 | 714 |
| IPV | 52,439,162 | 0 | 0 | 3 | 3 | 2 | 5 |
| Measles | 135,660 | 0 | 0 | 1 | 1 | 0 | 1 |
| Meningococcal | 51,173,032 | 1 | 1 | 17 | 19 | 3 | 22 |
| MMR | 65,864,745 | 16 | 12 | 43 | 71 | 60 | 131 |

[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.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| MMR-Varicella | 8,073,618 | 6 | 0 | 5 | 11 | 7 | 18 |
| Nonqualified[6] | N/A | 0 | 0 | 0 | 0 | 17 | 17 |
| OPV | 0 | 1 | 0 | 0 | 1 | 3 | 4 |
| Pneumococcal Conjugate | 123,606,306 | 0 | 1 | 4 | 5 | 10 | 15 |
| Rotavirus | 61,336,583 | 0 | 2 | 13 | 15 | 5 | 20 |
| Rubella | 422,548 | 0 | 1 | 0 | 1 | 0 | 1 |
| Td | 53,009,015 | 4 | 5 | 42 | 51 | 14 | 65 |
| Tdap | 133,744,203 | 6 | 5 | 48 | 59 | 6 | 65 |
| TETANUS | 3,836,052 | 2 | 0 | 11 | 13 | 8 | 21 |
| Unspecified[7] | N/A | 1 | 0 | 2 | 3 | 530 | 533 |
| Varicella | 82,534,257 | 4 | 5 | 13 | 22 | 9 | 31 |
| **Grand Total** | **1,968,399,297** | **97** | **125** | **909** | **1131** | **999** | **2130** |

**DEFINITIONS:**

1. 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.
    a. 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.
    b. 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).
        i. For injury claims, compensable court decisions are based in part on one of the following determinations by the court:

[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.

1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.

c. 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.

2. Non-compensable/Dismissed – The injured person who filed a claim was ultimately not paid money.
   a. Non-compensable Court decisions include the following:
      i. 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).
      ii. 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).
      iii. The injured person voluntarily withdrew his or her claim.

# 5

Dated: July 3, 2013.

Bahar Niakan,

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013–16557 Filed 7–9–13; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Notice of Availability of Policy Document

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

**ACTION:** Final Agency Guidance and Opportunity for Public Comments on Draft Section.

**SUMMARY:** HRSA is publishing Agency Guidance ("Policy Information Notice" (PIN) 2013–01) to provide clarification on the budgeting and accounting requirements for federally-funded health centers and Look-Alikes. The PIN, "Health Center Budgeting and Accounting Requirements" is available on the Internet at *http://bphc.hrsa.gov/policiesregulations/policies/pin201301.html.*

*Background:* HHS' Health Resources and Services Administration (HRSA) provides grants to eligible health centers under section 330 of the Public Health Service Act to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. In 2012, grants helped fund more than 1,200 health center grantees that provided services at nearly 9,000 health care delivery sites and served more than 21 million people. There are also over 100 Look-Alikes. Look-Alikes, as described in section 1861(aa)(4) and section 1905(l)(2)(B) of the Social Security Act, do not receive federal funding under section 330 of the PHS Act; however, to receive the Look-Alike designation and benefits, Look-Alikes must meet the statutory, regulatory, and policy requirements for health centers programs under section 330.

Under 45 CFR Part 74, a key requirement of the Health Center Program is for a health center to establish a budget that reflects the cost of operations, expenses, and revenues necessary to accomplish the service delivery plan. All section 330-funded health centers and Look-Alikes must prepare a budget that meets these requirements. The purpose of this PIN is to provide clarification regarding budgeting and accounting requirements for health centers to ensure transparency and accountability.

In addition to making the final PIN available on HRSA's Web site, HRSA is also making available a section of this PIN for public comment. HRSA will review and analyze all comments on this section and issue final PIN. When finalized, this section of the PIN will supersede all other previous Health Center Program guidance and policy issued on this program requirement.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at *OPPDBudgetPIN@hrsa.gov.*

Dated: July 2, 2013.

Mary K. Wakefield,

*Administrator.*

[FR Doc. 2013–16505 Filed 7–9–13; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Migrant Health.

*Dates and Times:* August 19, 2013, 8:30 a.m. to 4:30 p.m. August 20, 2013, 8:00 a.m. to 5:00 p.m.

*Place:* Health Resources and Services Administration, 5600 Fishers Lane, Room 14–72, Rockville, Maryland 20857, Telephone: 301–594–0367, Fax: 301–443–9477.

*Status:* The meeting will be open to the public.

*Purpose:* The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal agricultural workers and their families and to formulate recommendations for the Secretary of Health and Human Services.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on agricultural worker issues, including the status of agricultural worker health at the local and national levels.

In addition, the council will be holding a public hearing at which migrant agricultural workers will have the opportunity to testify before the Council regarding matters that affect the health of migrant agricultural workers. The hearing is scheduled for Monday, August 19, from 1:30 p.m. to 4:30 p.m., at the Health Resources and Services Administration.

Agenda items are subject to change as priorities indicate.

*FOR FURTHER INFORMATION CONTACT:* Gladys Cate, Office of National Assistance and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Room 6–41, Maryland 20857; telephone (301) 594–0367.

Dated: July 3, 2013.

Bahar Niakan,

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013–16558 Filed 7–9–13; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99–660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

**DATES:** The agency must receive nominations on or before August 9, 2013.

**ADDRESSES:** All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau (HSB), HRSA, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** Ms. Annie Herzog, Principal Staff Liaison, Division of Vaccine Injury Compensation, HSB, HRSA, at (301) 443–6634 or email: *aherzog@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463) and section 2119 of the Act, 42 U.S.C. 300aa–19, as added by Public Law 99–660 and amended, HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of the Vaccine Information Statements; and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows:

(1) Three health professionals, who are not employees of the United States Government, and who have expertise in the health care of children, and the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians; (2) three members from the general public, of whom at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine related injury or death; and (3) three 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. In addition, 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) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A health professional, who has expertise in the health care of children and the epidemiology, etiology, and prevention of childhood diseases; (2) a member of the general public who is the legal representative (parent or guardian) of a child who has suffered a vaccine related injury or death; and (3) an attorney with no specific affiliation. Nominees will be invited to serve a 3-year term beginning January 1, 2014, and ending December 31, 2016.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to serve as a member of the ACCV and appears to have no conflict of interest that would preclude the ACCV membership. Potential candidates will be asked to provide detailed information concerning consultancies, research grants, or contracts to permit evaluation of possible sources of conflicts of interest. A curriculum vitae or resume should be submitted with the nomination.

The Department of Health and Human Services (HHS) strives to ensure that the membership of the HHS Federal Advisory Committee is fairly balanced in terms of points of view presented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal Advisory Committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Dated: July 3, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013–16603 Filed 7–9–13; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4085–DR; Docket ID FEMA–2013–0001]**

### New York; Amendment No. 10 to Notice of a Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for State of New York (FEMA–4085–DR), dated October 30, 2012, and related determinations.

**DATES:** *Effective Date:* June 24, 2013.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Willie G. Nunn, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Michael F. Byrne as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2013–16472 Filed 7–9–13; 8:45 am]

BILLING CODE 9111–23–P

## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

**[Docket No. TSA–2011–0008]**

### Aviation Security Advisory Committee (ASAC) Meeting

**AGENCY:** Transportation Security Administration, DHS.

**ACTION:** Committee Management; Notice of Federal Advisory Committee Meeting.

**SUMMARY:** The Transportation Security Administration (TSA) will hold a meeting of the Aviation Security Advisory Committee (ASAC) on Monday, July 22, to discuss the recommendations of its subcommittees. This meeting will be open to the public.

**DATES:** The Committee will meet on Monday, July 22, 2013, from 1:00 p.m.

# 6

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[EPA–HQ–SFUND–1990–0010; FRL–9836–8]

## National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Sola Optical U.S.A., Inc. Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule; notice of intent.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 9 is issuing a Notice of Intent to Delete the Sola Optical U.S.A., Inc. Superfund Site (Site) located in Petaluma, California, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of California, through the Regional Water Quality Control Board—San Francisco Bay Region, have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

**DATES:** Comments must be received by August 23, 2013.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1990–0010, by one of the following methods:

- *http://www.regulations.gov.* Follow on-line instructions for submitting comments.
- *Email: rodriguez.dante@epa.gov.*
- *Fax:* (415) 947–3528.
- *Mail:* Dante Rodriguez, U.S. EPA Region 9, Mail code SFD–8–2, 75 Hawthorne Street, San Francisco, CA 94105.
- *Hand delivery:* U.S. EPA Region 9, 75 Hawthorne Street, Mail code SFD–8–2, San Francisco, CA 94105.

Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1990–0010. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

### Docket

All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statue. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

Superfund Records Center, 95 Hawthorne St., Room 403, Mail Stop SFD–7C, San Francisco, CA 94105, (415) 536–2000, Mon–Fri: 8:00 a.m. to 5:00 p.m. or

Petaluma Public Library, 100 Fairgrounds Drive, Petaluma CA 94952, (707) 763–9801, Mon, Thurs, Fri, Sat: 10:00 a.m. to 6:00 p.m., Tues, Wed: 10:00 a.m. to 9:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Dante Rodriguez, Remedial Project Manager, U.S. Environmental Protection Agency, Region 9, SFD–8–2, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3166, email: *rodriguez.dante@epa.gov.*

**SUPPLEMENTARY INFORMATION:** In the "Rules and Regulations" Section of today's **Federal Register**, we are publishing a direct final Notice of Deletion of Sola Optical U.S.A., Inc. Superfund Site without prior Notice of Intent to Delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the *Rules* section of this **Federal Register**.

### List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

**Authority:** 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: July 15, 2013.

**Jane Diamond,**

*Director, Water Division, U.S. EPA Region 9.*

[FR Doc. 2013–17826 Filed 7–23–13; 8:45 am]

BILLING CODE P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 100

RIN 0906–AB00

## National Vaccine Injury Compensation Program

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Secretary has made findings as to intussusceptions that can reasonably be determined in some circumstances to be caused or

significantly aggravated by rotavirus vaccines. Based on these findings, the Secretary proposes to amend the Vaccine Injury Table (Table) by regulation. These proposed regulations will apply only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the final regulations become effective. The Secretary is seeking public comment on the proposed revisions to the Table.

**DATES:** Written comments must be submitted on or before January 21, 2014. A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the **Federal Register** to provide the details of this hearing. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

**ADDRESSES:** You may submit comments in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only *one* of these ways to minimize the receipt of duplicate submissions.

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

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

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

Because of staffing and resource limitations, and to ensure that no comments are misplaced, HRSA cannot accept comments by facsimile (FAX) transmission. In commenting, by any of the above methods, please refer to file code (HRSA #0906–AB00). All comments received on a timely basis will be available for public inspection without charge, including any personal information provided, in Room 14–101 of the Health Resources and Services Administration's offices at 5600 Fishers Lane, Rockville, MD., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (excluding federal holidays). Phone: (301) 443–1785. This is not a toll-free number.

**FOR FURTHER INFORMATION CONTACT:** Please visit the National Vaccine Injury Compensation Program's Web site, *http://www.hrsa.gov/vaccinecompensation/*, or contact Dr. Catherine Shaer, Acting Chief Medical Officer, National Vaccine Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857. Phone calls can be directed to (855) 266–2427. This is a toll-free number.

**SUPPLEMENTARY INFORMATION:**

## Background

Under Title XXI of the Public Health Service (PHS) Act, individuals who demonstrate a vaccine-related injury or death may receive compensation through the National Vaccine Injury Compensation Program (VICP). To gain entitlement to compensation in the VICP, a petitioner must demonstrate that the injured or deceased individual received a vaccine set forth in the Vaccine Injury Table (a "covered vaccine") and sustained a vaccine-related injury or death. A petitioner can prove a vaccine-related injury or death in two ways: (1) The petitioner can show that the vaccine recipient suffered an injury listed in the Vaccine Injury Table corresponding with the vaccine received, and that the onset of such injury occurred within the time period specified in the Table (a "Table injury"). As set out in sections 2111(c)(1)(C)(i), 2113(a)(1)(B), and 2114(a) of the PHS Act, a Table injury or death is given the legal presumption that it was caused by the vaccination. (2) If the petitioner cannot demonstrate a Table injury, the petitioner can prevail by proving, by a preponderance of the evidence, that the vaccine caused the injury or death (an "off-Table injury"). In either case, a petitioner must also show that the injury was sufficiently severe by demonstrating that such person suffered the residual effects of the injury for more than 6 months; died from the administration of the vaccine; or that the alleged injury resulted in inpatient hospitalization and surgical intervention. Section 2111(c) of the PHS Act. If the petitioner can prove a Table injury or off-Table injury, the petitioner is entitled to compensation unless it is affirmatively shown by the Secretary that the injury was caused by some factor unrelated to the vaccination.

Under section 2114(e)(2) of the PHS Act, when the Centers for Disease Control and Prevention (CDC) recommends a vaccine for routine administration to children, the Secretary is required to amend the Vaccine Injury Table to include such vaccine. Coverage becomes effective when an excise tax is imposed on the vaccine. Additionally, the Secretary is authorized to include specific adverse events on the Table with respect to each covered vaccine, including the time period when the first symptoms or manifestations of onset or other significant aggravation of such adverse event may occur. Under section 2114(c) of the PHS Act, the Secretary may make such modifications to the Table by promulgating regulations, with notice and opportunity for a public hearing, and at least 180 days of public comment.

### Coverage for Rotavirus Vaccines on the Vaccine Injury Table

The general category of rotavirus vaccines was added for coverage under the VICP, effective October 22, 1998. The prerequisites for adding rotavirus vaccines to the VICP were satisfied by the enactment of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. 105–277 (October 21, 1998), which imposed an excise tax of 75 cents per dose on "any vaccine against rotavirus gastroenteritis," and the publication of the CDC recommendation of the vaccine for "routine use in children" in the "Morbidity and Mortality Weekly Report" (MMWR), 1999:48 (March 19, 1999).

When the general category of rotavirus vaccines was added to the Table, it was added with "no condition specified." 64 FR 40517. In other words, at the time rotavirus vaccines were first included for coverage under the Program, the Secretary had not identified any adverse events to include in the Table. Therefore, individuals who received the rotavirus vaccine did not receive a legal presumption of causation for any claimed injury and were required to prove that the vaccine actually caused the claimed injury.

### History of Rotashield Vaccine

On August 31, 1998, the Food and Drug Administration (FDA) licensed a live, oral, rhesus-based rotavirus tetravalent vaccine (trade name

"Rotashield") for use in infants between the ages of 6 weeks and 1 year. Distribution of the vaccine began on October 1, 1998. At the time, this was the only U.S.-licensed rotavirus vaccine on the market. Following a review by the Advisory Committee on Immunization Practices (ACIP), the CDC published its rotavirus recommendation in the March 19, 1999, issue of the MMWR (1999:48), calling for doses to be administered at 2, 4, and 6 months of age, with the first dose to be administered between 6 weeks and 6 months. The series was not to be initiated in children who were 7 months of age or older due to an increased rate of febrile (fever) reactions after the first dose among older infants.

Over the next eight months, the Secretary's Vaccine Adverse Event Reporting System (VAERS) began receiving reports of intussusception (a type of bowel obstruction that occurs when the bowel folds into itself) in infants receiving the Rotashield vaccine after the first dose. Based on an analysis of 15 reports, the CDC, in the July 16, 1999, issue of the MMWR, recommended that health care providers and parents postpone use of this rotavirus vaccine. The CDC undertook additional epidemiological studies to determine if there was a true association between the vaccine and intussusception. Also, at that time, the manufacturer, in consultation with the FDA, voluntarily ceased further distribution of the vaccine. Upon further consideration, and following consultation with CDC officials in preparation for the upcoming ACIP meeting, the manufacturer announced the withdrawal of the Rotashield vaccine (which was still the only U.S.-licensed rotavirus vaccine at that time) from the market on October 15, 1999, and requested the immediate return of all doses of the vaccine.

At its October 22, 1999, meeting, the ACIP reviewed scientific data from several sources, including a 19-state case-control study which showed a statistically significant rate of intussusception among recipients of the live, oral, rhesus-based rotavirus vaccine in the 2 week period following vaccine administration, with the highest risk period in the 3–14 days after the first dose of vaccine, and a much smaller risk in the same time period after dose two. Beyond 14 days, there did not appear to be more cases than might occur by chance alone. The ACIP concluded that intussusception occurs with significantly increased frequency in the first 14 days following administration of the Rotashield vaccine and withdrew its recommendation for use of this vaccine in infants. The CDC adopted and published the Committee's decision in the November 5, 1999, issue of the MMWR.

By December 2000, VAERS had received over 100 reports of confirmed intussusception cases, 58 of which had onset within 7 days of vaccine receipt. Of the cases reported, approximately one-half required surgical intervention. Nearly all of the other cases of bowel obstruction were relieved through barium enema, a radiological procedure used to both diagnose and often rectify the telescoped bowel segment, or resolved spontaneously without any intervention. At least one death associated with rotavirus vaccine was reported to VAERS.

The Secretary reviewed the epidemiological data, and in a notice of proposed rulemaking published on July 13, 2001, the Secretary announced his findings that the condition of intussusception could reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus (66 FR 36735). Based on those findings, the Secretary proposed to amend the Table by adding the specific category of vaccines containing live, oral, rhesus-based rotavirus as a distinct category, with intussusception listed as a covered Table injury. This proposal was based on data indicating a strong association between Rotashield and intussusception in the two weeks following vaccination.

In a final rule published July 25, 2002 (67 FR 48558), the Secretary made final the changes proposed in the earlier notice. After these amendments, the Table included two categories of rotavirus vaccines. The first, the general category of rotavirus vaccines, did not include an associated injury. This category of vaccines was effective as of October 22, 1998, the effective date of the excise tax imposed for rotavirus vaccines. See 42 CFR 100.3(a), 100.3(c)(3). The second, more specific category of vaccines containing live, oral, rhesus-based rotavirus, contained an associated injury of intussusception with an onset interval of 0–30 days. The live, oral, rhesus-based rotavirus vaccine was covered in the VICP effective October 22, 1998, but the Table injury could only be claimed by those petitioners that had the vaccine administered on or before August 26, 2002 (the effective date of the final rule adding this category of vaccine), and beginning on August 26, 1994, the period of the eight-year "look back" prescribed in the statute. Because the manufacturer of the only U.S.-licensed rotavirus vaccine at the time voluntarily ceased distribution of the vaccine in July 1999, and because the CDC recommended that this vaccine no longer be routinely administered to children in the United States in October 1999, the Secretary concluded that it was unlikely that potential claims under this specific category would arise after the rule's publication. Because of this, the final rule limited the Table injury of intussusception to live, oral, rhesus-based rotavirus vaccines administered on or before the effective date of the final rule (August 26, 2002). Individuals who sought compensation for injuries related to such a vaccine administered after the effective date of the final rule were not entitled to the presumption of a Table injury for intussusception, but such individuals could still file claims under the Table's general category for rotavirus vaccines.

Through an interim final rule published October 9, 2008 (73 FR 59528), the Secretary removed the specific category of vaccines containing live, oral, rhesus-based rotavirus from the Table. Given the applicable statute of limitations and the fact that this category limited its application to vaccines administered on or before August 26, 2002, the Secretary believed that any potential Table claim under this category would have been time-barred, so no persons could have had claims under that category.

**Subsequent Rotavirus Vaccines**

On February 3, 2006, the FDA licensed a pentavalent human-bovine reassortant rotavirus vaccine (trade name "RotaTeq"). Following a review by ACIP, the CDC published its recommendation for routine vaccination of U.S. infants with three doses of this rotavirus vaccine administered orally at ages 2, 4, and 6 months (MMWR 2006:55; RR12). On April 3, 2008, the FDA licensed a monovalent rotavirus vaccine derived from the human rotavirus strain (trade name "Rotarix"). In June 2008, the CDC updated its recommendation to include use of the newly licensed Rotarix (MMWR 2009:58; RR02). The prelicensure clinical trials for RotaTeq examined 70,000 infants, and did not identify an increased risk of intussusception in the 1–42 days post immunization. In addition, the prelicensure clinical trials for Rotarix examined over 60,000 infants, and found no increased risk in the 1–31 days after vaccination with either dose. Because of the prior association of intussusception with Rotashield, multiple post-marketing studies regarding RotaTeq, Rotarix, and intussusception were conducted to evaluate the possibility of a small risk

of intussusception as utilization increased.

**RotaTeq Scientific History**

In February 2007, the FDA notified health care providers and consumers about 28 post-marketing reports of intussusception following administration of RotaTeq. The notification stated that of the reported 28 cases of intussusception, the number that may have been caused by the vaccine, or occurred by coincidence, was unknown. The FDA issued this notification both to encourage the reporting of any additional cases of intussusception that may have occurred in the past or will occur in the future after administration of RotaTeq, and to remind people that intussusception may be a potential complication of RotaTeq.

In 2008, the Vaccine Safety Datalink (VSD) published their experience from the first 111,521 doses of RotaTeq given from 2006 to 2007, and in 2012, the VSD and the CDC published data in "The Journal of the American Medical Association" (JAMA), from 786,725 doses of RotaTeq given from 2006 to 2010. There was no identifiable risk in the 1–7 day or 1–30 day periods following administration of RotaTeq in either analysis. The final post-marketing study of RotaTeq in the U.S. was performed by Merck and found no association with intussusception and RotaTeq. Post-marketing clinical trials of RotaTeq performed after U.S. licensure included two smaller efficacy studies from Africa and Asia. The African study had no cases of intussusception in either vaccine or placebo groups, and the Asian study had one case 97 days following the third dose of the placebo, and no cases in the vaccine group.

A 2011 post-marketing study of RotaTeq published in "Vaccine," from the Australian National Immunization Program, suggests an association between RotaTeq and intussusception. Approximately 295,000 doses of RotaTeq were given in two states. In 1–3 month old infants, the expected number of intussusception cases was exceeded for the 1–7 and 1–21 day periods following the first dose of RotaTeq. In the 1–7 days following the first dose, three cases were found, compared to an expected 0.57 cases (relative risk of 5.26 [confidence interval (CI), 1.1–15.4]). (Relative risk is the ratio of the chance of a disease developing among members of a population exposed to a factor compared with a similar population not exposed to the factor.) [Confidence Intervals are a measure of estimation that represents the possible range of values in a population estimated from a given sample drawn from that population (in this case ranging from a relative risk value of 1.1 to 15.4)].

When the 1–21 day interval following the first dose was examined, six cases of intussusception were found, compared to an expected 1.71 cases (relative risk 3.5 [CI, 1.3–7.6]). There was no increase from the expected cases after dose two of RotaTeq, and actually a decrease from expected cases after dose three. Also important to note is that there was no evidence of increased risk of intussusception when examining the entire period of 1–9 months of age.

**Rotarix Scientific History**

Rotarix was given in the other two states evaluated in the Australian post-marketing study, totaling approximately 302,000 doses. The study demonstrated an increased risk in both the 1–7 day and the 1–21 day windows following the first dose of Rotarix (relative risk of 3.45 [CI 0.7–10] and 1.53 [CI, 0.4–3.9], respectively). Neither of these risks showed statistical significance. There were no excess cases of intussusception associated with dose two of Rotarix. Similar to RotaTeq, the number of observed cases in the post-vaccine windows was small, with three cases observed in the 1–7 days after first dose vaccination versus 0.9 cases expected for the 1–3 month old infants. Since Rotarix constitutes a small percentage of total rotavirus vaccine given in the U.S. (3 million doses of Rotarix versus 35 million doses of RotaTeq as of 2010), comparable U.S. post-licensure studies of Rotarix are not currently available.

Post-marketing studies (case series and case-control analysis) performed in Mexico and Brazil, and published in "The New England Journal of Medicine" in 2011, identified an association between Rotarix and intussusception. In Mexico, there was an increased rate of intussusception during the 1–7 day period after the first dose of Rotarix with an incidence rate ratio of 5.3 (CI, 3–9.3). (Incidence rate ratio compares two incidence rates. Incidence rate is the number of new cases per population in a given time period.) There was no increase in the rate 1–7 days after the second dose, but a small increase by a factor of two was identified in the second and third week following the second dose. This contrasts with the Brazil data where there was no increase in the rate of intussusception found after the first dose of Rotarix, but a small elevation of the rate was identified 1–7 days following the second dose (incidence ratio of 2.6 [CI, 1.3–5.2]). The reason behind the variation between the data from Mexico and Brazil is unclear, but one potential explanation could be a result of Brazil's administering Rotarix and the oral polio virus vaccine (OPV) together, which has been shown to decrease the immunogenicity of the first dose of Rotarix, perhaps making the second dose function more like the initial dose.

The commentary in "The New England Journal of Medicine" in 2011 regarding the Rotarix data from Mexico and Brazil summarized the small attributable risk of intussusception as 1/51,000 vaccinated infants in Mexico and 1/68,000 vaccinated infants in Brazil. [Attributable risk is the difference in rate of a condition (intussusception in this case) between an exposed population (those who received rotavirus vaccine in this case) and an unexposed population.] The article raised the possibility that any live, oral, rotavirus vaccine, along with natural rotavirus infection, could carry a detectable risk of intussusception, although the risk is demonstrably quite low, based on the available studies. It is also biologically plausible that the different vaccines have differing intrinsic risks of intussusception based on the distinct strains in each vaccine, and that the same vaccine could manifest different risks in different populations. It is also possible that with small risks overall (resulting in a small number of excess intussusception cases in the specific narrow age groups receiving vaccine) and variability in background numbers of cases of intussusception year to year, an increase in overall burden of intussusception in infants aged < 1 year may not be detectable. The article raised the point that the small increase of intussusception after vaccination does not seem to increase the overall burden of intussusception, and that perhaps the rotavirus vaccination has a preventive role in long-term intussusception risk.

Because of these findings, the prescribing information in the U.S. for Rotarix was amended in September 2010 to reflect the above increased risk and the potential implications for U.S. infants. (GlaxosmithKline Biologicals Package Insert (PI) and Patient Package Information (PPI)). The PI and PPI were further amended in February 2011 to include "history of intussusception" as a contraindication to vaccination. (Statement available for viewing at *http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm245491.htm*). A "history of intussusception" was also made a contraindication for Rotateq in July 2011.

In addition, a large post-marketing surveillance study of intussusception in Mexico published in "The Pediatric Infectious Disease Journal" in July 2012 reported an "attributable risk of 3 to 4 additional cases of intussusception per 100,000 vaccinated infants after receipt if Rotarix.

**CDC Response**

In November 2010, the CDC issued a statement noting that some, but not all, studies suggest RotaTeq and Rotarix may possibly cause a small increase in the risk of intussusception; however, the CDC concluded that the benefits of these vaccines far outweigh this possible risk. The CDC continues to recommend routine rotavirus vaccination of U.S. infants to prevent severe rotavirus disease in U.S. infants and children. (Statement available for viewing at *http://www.cdc.gov/vaccines/vpd-vac/rotavirus/intussusception-studies-acip.htm*).

The FDA's mini-sentinel "Post-Licensure Rapid Immunizations Safety Monitoring Program" (PRISM) is currently performing a study to assess the risk of intussusception from both Rotarix and RotaTeq vaccines in the United States. This self-controlled and case-centered study targets approximately 1 million infants. Results are expected late in 2012.

**Proposed Rule**

The Secretary has reviewed all the currently available data regarding the Rotarix and RotaTeq vaccines and the risk of intussusception. The background of the Rotashield experience in the U.S. and the recently published literature from Mexico, Brazil, and Australia supports a small attributable risk of intussusception after the first and second doses of Rotarix and RotaTeq (with a greater amount of data supporting an association with the first dose of both vaccines). Therefore, the Secretary proposes that the injury of intussusception be added to the general Table category of "rotavirus vaccines" to allow a presumption of causation for claims that meet the requirements set forth in the Table for that injury. Current U.S. studies of RotaTeq do not show a statistically identifiable risk of intussusception, but the number of study patients exposed to the vaccine in the U.S. may not be large enough (even with the results expected from the ongoing PRISM study) to rule out a very small attributable risk to the vaccine. Platforms like VSD in the U.S. have not been able to evaluate the possible small risk associated with Rotarix to date because of the low numbers of doses of Rotarix administered in settings captured by the surveillance program. To allow for a generous timeframe, the Secretary proposes that the Table injury for intussusception have an onset interval of 1–21 days under sections 2114(c) and (e) of the PHS Act, since evidence shows the increased risk within the 1–7 days following immunization with peaks in the fourth and fifth days.

The Qualifications and Aids to Interpretation section of the table will define the injury of "intussusception" as the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus. The definition for presumption of vaccine causation only applies to the first and second dose of vaccine, and excludes intussusception occurring with or after the third dose. The third dose of rotavirus vaccines lacks sufficient evidence showing risk.

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

Cases of intussusception in a person with a pre-existing condition identified as the lead point for intussusception, such as intestinal masses and cystic structures (e.g., polyps; tumors; Meckel's diverticulum; lymphoma; or duplication cysts), would not qualify as a Table injury. Additionally, cases of intussusception in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease) would not qualify as a Table injury.

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

Petitions must also be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed with the VICP, set forth in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)), continues to apply. In addition, section 2116(b) of the PHS Act identifies a specific exception to this statute of limitations that applies when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this section, individuals who may be eligible to file petitions based on the revised Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)).

The Advisory Commission on Childhood Vaccines (ACCV) voted unanimously to approve this proposal at its December 9, 2011, meeting. The Secretary, while moving forward with this proposal, understands that additional science is still forthcoming and recognizes the importance of keeping the Vaccine Injury Table in conformance with science. In addition, the Secretary recognizes that one goal of

the VICP is to provide generous compensation to petitioners harmed by vaccines through a less adversarial system. Although post-marketing studies in the U.S. have not identified an increased risk of intussusception associated with rotavirus vaccine, a small risk cannot be ruled out. Therefore, the Secretary feels that the balance between science and policy is best met by acting now, on the basis of the studies outside the U.S. that have detected an increased risk of intussusception following Rotarix and RotaTeq vaccines, rather than waiting to see if the PRISM, VSD, and other studies further bolsters the already published findings.

**Economic and Regulatory Impact**

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

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

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

The Secretary has also determined that this proposed rule does not meet the criteria for a major rule as defined by Executive Order 12866, and it would not have a major effect on the economy or federal expenditures. The Department has determined that the proposed rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. § 801. Similarly, it will not have effects on state, local, and tribal governments, or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

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

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

As stated above, this proposed rule would modify the Vaccine Injury Table based on legal authority.

**Impact of the New Rule**

To date, 17 petitions have been filed alleging a vaccine-related injury of intussusception caused or aggravated by a rotavirus vaccine, not including the currently unavailable Rotashield vaccine. This proposed rule will have the effect of decreasing the burden of proof for future petitioners. Under this proposed rule, future petitioners alleging the injury of intussusception as the result of a rotavirus vaccine that meets the criteria in the Vaccine Injury Table will be afforded a presumption of causation. This proposed rule will not change the burden of proof applicable to petitioners alleging other injuries related to a rotavirus vaccine who must rely on a causation-in-fact analysis.

**Paperwork Reduction Act of 1980**

This proposed rule has no information collection requirements.

**List of Subjects in 42 CFR Part 100**

Biologics, Health Insurance, and Immunization.

Dated: June 26, 2013.

**Mary Wakefield,**

*Administrator, Health Resources and Services Administration.*

Approved: July 17, 2013.

**Kathleen Sebelius,**

*Secretary.*

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

## PART 100—VACCINE INJURY COMPENSATION.

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

**Authority:** Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act; 100 Stat. 3767, as revised (42 U.S.C. 300aa–15); § 100.3 Vaccine Injury Table, issued under secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); and sec. 2114(c) and (3) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645 (42 U.S.C. 300aa–14(c) and (e)); sec. 904(b) of Pub. L. 105–34, 111 Stat. 873; and sec. 523(a) of Pub. L. 106–170, 113 Stat. 1860.

■ 2. Amend § 100.3 in the paragraph (a) table by revising Item XI and by adding paragraph (b)(3) to read as follows:

**§ 100.3 Vaccine injury table.**

(a) * * *

VACCINE INJURY TABLE

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

VACCINE INJURY TABLE—Continued

| Vaccine | Illness, disability, injury, or condition covered | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration |
|---|---|---|
| * * * * * * * | | |

(b) * * *

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

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

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

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

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

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

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

* * * * *

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BILLING CODE 4165–15–P

# 7

# 7.1

VACCINE INFORMATION STATEMENT

# Influenza Vaccine

(Flu Vaccine, Inactivated)

## *What You Need to Know*

**2013-2014**

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Informaciáu Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite 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 the influenza virus, and can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

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

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions—such as heart, lung or kidney disease, or a weakened immune system. Flu vaccine is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

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

**Flu vaccine** is the best protection we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

## 2 Inactivated flu vaccine

There are two types of influenza vaccine:

You are getting an **inactivated** flu vaccine, which does not contain any live influenza virus. It is given by injection with a needle, and often called the "flu shot."

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

Flu vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year's flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. Inactivated flu vaccine protects against 3 or 4 different influenza viruses.

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

Some illnesses that are not caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

A "high-dose" flu vaccine is available for people 65 years of age and older. The person giving you the vaccine can tell you more about it.

Some inactivated flu vaccine contains 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.

## 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 a dose. Most, but not all, types of flu vaccine contain a small amount of egg.
- **If you ever had Guillain-Barré Syndrome** (a severe paralyzing illness, 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.** They might suggest waiting until you feel better. But you should come back.

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

## 4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Serious side effects are also possible, but are very rare. Inactivated flu vaccine does not contain live flu virus, so **getting flu from this vaccine is not possible.**

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

**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.

**Severe problems** following inactivated flu vaccine:

- A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).
- There is a small possibility that inactivated flu vaccine could be associated with Guillain-Barré Syndrome (GBS), no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.

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 or 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 might 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 is only for reporting reactions. They do 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.**

## 7 How can I learn more?

- Ask your doctor.
- 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**

# 7.2

VACCINE INFORMATION STATEMENT

# Influenza Vaccine

(Flu Vaccine, Live, Intranasal)

## *What You Need to Know*

**2013-2014**

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite www.immunize.org/vis

## 1 Why get vaccinated?

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

Flu is caused by the influenza virus, and can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

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

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions—such as heart, lung or kidney disease, or a weakened immune system. Flu vaccine is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

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

**Flu vaccine** is the best protection we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

## 2 Live, attenuated flu vaccine—LAIV, Nasal Spray

There are two types of influenza vaccine:

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 can't make you sick.

A different vaccine, the "flu shot," is an **inactivated** vaccine (not containing live virus). It is given by injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year's flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. LAIV protects against 4 different influenza viruses.

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

Some illnesses that are **not** caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

LAIV may be given to people **2 through 49 years of age**, who are not pregnant. It may safely be given at the same time as other vaccines.

LAIV does not contain thimerosal or other preservatives.

## 3 Some people should not get this vaccine

Tell the person who gives you the vaccine:

- **If you have any severe (life-threatening) allergies**, including an allergy to eggs. 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 should not get a dose.
- **If you ever had Guillain-Barré Syndrome** (a severe paralyzing illness, 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 gotten any other vaccines in the past 4 weeks, or if you are not feeling well.** They might suggest waiting. But you should come back.

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

- **You should get the flu shot instead of the nasal spray if you:**
  - are pregnant
  - have a weakened immune system
  - have certain long-term health problems
  - are a young child with asthma or wheezing problems
  - are a child or adolescent on long-term aspirin therapy
  - have close contact with someone who needs special care for an extremely weakened immune system
  - are younger than 2 or older than 49 years. (Children 6 months and older can get the flu shot. Children younger than 6 months can't get either vaccine.)

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

## 4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Serious side effects are also possible, but are very rare. LAIV is made from weakened virus and **does not cause flu**.

**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

**Severe problems** that could follow LAIV:

- A severe allergic reaction could occur after any vaccine (estimated less than 1 in a million doses).

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 or 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 might 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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# 8

# 8.1

# MMR: ACIP Vaccine Recommendations, Japan Rubella Outbreak

Larry Hand | Jun 18, 2013

Clinicians have new guidance for scheduling patient vaccinations, courtesy of an updated report from the Advisory Committee on Immunization Practices (ACIP). The recommendations were published online June 14 in the *Morbidity and Mortality Weekly Report*, a publication of the Centers for Disease Control and Prevention (CDC).

Huong Q. McLean, PhD, from the Marshfield Clinic Research Foundation in Wisconsin, and colleagues provide the first published summary recommendations adopted during an October 24, 2012, ACIP meeting. A working group of ACIP members and specialists from 10 other organizations, including the CDC, developed the recommendations.

ACIP-adopted recommendations include:

- Making laboratory confirmation of disease, rather than physician-diagnosed disease, a criterion for "acceptable evidence of immunity for measles, rubella, and mumps."
- Expanding vaccinations to all persons with HIV 1 year old or older who are not currently immunosuppressed; revaccinating persons with perinatal HIV who were vaccinated before development of effective antiretroviral therapy with 2 spaced doses of measles, mumps, and rubella (MMR) if antiretroviral therapy has been established; and changing the timing of the doses to ages 12 to 15 months and 4 to 6 years.
- Expanding the use of immune globulin administered intramuscularly (IGIM) to include infants from birth to age 6 months if they have been exposed to measles, increasing the recommended dose of IGIM for immunocompetent persons, and using immune globulin administered intravenously for severely immunocompromised persons and pregnant women who do not have evidence of measles immunity but have been exposed to it.

Although the United States has virtually eliminated measles and rubella and made great progress in lessening the burden of mumps, the authors write, the diseases "are still common diseases in many countries. Importations will continue to occur and cause outbreaks in communities that have clusters of unvaccinated persons."

The authors also write that studies have shown that current vaccines are safe, effective, and cost-effective.

**Current Outbreak**

In a report published in the same issue of *Morbidity and Mortality Weekly Report*, Keiko Tanaka-Taya, MD, from the National Institute of Infectious Diseases of Japan, and colleagues write that an outbreak of rubella there involved 5442 cases reported between January 1 and May 1 this year. Of those, 3936 (72.3%) were laboratory confirmed infections. Males accounted for more than three quarters of the cases 4213 (77.4%), and nearly all (92.0%) of those were in men older than 20 years. For 1904 reported rubella cases for which vaccination records existed, 1566 (82%) occurred in unvaccinated individuals.

Japan began a vaccine program targeted at junior-high-aged girls in 1976 and introduced a MMR vaccine for children aged 12 to 72 months in 1989; that vaccine was withdrawn in 1993. A MR combined vaccine was reintroduced in 2006. However, adult males aged 20 to 39 years have not been targeted for rubella vaccination.

Japan also has had 10 cases of congenital rubella syndrome reported since October 2012, after having only 3 cases reported between 2008 and 2011. Japan's Ministry of Health, Labor, and Welfare has advised authorities to provide

rubella and congenital rubella syndrome information to family members of pregnant women and vaccinations to women planning to get pregnant. About 100 cities and local governments are funding vaccination programs.

*Morb Mortal Wkly Rep*. 2013;62:1-46, 457-462. McLean full text, Tanaka-Taya full text



Send comments and news tips to news@medscape.net.

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# 8.2

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# Pneumonia vaccine said to reduce U.S. hospitalizations

URL of this page: http://www.nlm.nih.gov/medlineplus/news/fullstory_138597.html (*this news item will not be available after 10/08/2013)

Wednesday, July 10, 2013

REUTERS HEALTH INFORMATION

By Gene Emery

NEW YORK (Reuters Health) - The seven-strain pneumonia vaccine used in the U.S. beginning in 2000 has prevented 168,000 hospitalizations for the disease each year since, and its effectiveness showed no signs of waning, a new study concludes.

The biggest benefit, by far, was seen among people age 85 and older, for whom the so-called 7-valent pneumococcal conjugate vaccine, marketed as Prevnar, prevented 73,000 hospitalizations annually.

Children under two years old were also major beneficiaries - an estimated 47,000 pneumonia hospitalizations were prevented per year - a reduction of 43 percent compared to before the vaccine was available, according to the findings published in the New England Journal of Medicine.

"This is only the hospitalizations," lead author Dr. Marie Griffin of Vanderbilt University Medical Center in Nashville, Tennessee, told Reuters Health. "This is only one piece of what this vaccine is doing. It's also preventing ear infections and outpatient visits. It's really an amazing vaccine."

She and her colleagues calculated that in all age groups, about 12,000 deaths were also prevented annually over the past 12 years, but most were among people 75 years and older. In that age group, pneumonia is fatal for 7 to 12 percent of those who get it.

A newer vaccine, Prevnar 13, that protects against six additional pneumonia strains has been in use since 2010. As a result, "there's an expectation there will be another big decline," Griffin said in a telephone interview.

The fact that hospitalization rates declined - and remained low - after the seven-strain vaccine was added to U.S. immunization schedules alleviates concerns that other strains not covered by the vaccine would become more common, the researchers said.

"The worry was that the (strains) not included in the vaccine may actually take over and that didn't happen, so this was good news," Dr. Paul Goepfert, director of the Vaccine Research Clinic at the University of Alabama at Birmingham, told Reuters Health by phone. He was not involved in the new study.

Griffin and her colleagues also found that, for all age groups, the time spent in the hospital for pneumonia treatment was a bit shorter after the vaccine was introduced.

The vaccine's effect on hospitalization rates for children ages 5 to 17 years old and adults 18 to 39 was not significant, but those groups had the lowest rates before the vaccine was introduced.

Pneumonia accounted for just over four percent of all U.S. hospitalizations that didn't involve childbirth before the original seven-strain vaccine was introduced.

Griffin pointed out that the reduction in elderly hospitalization rates happened despite the fact that children are the only group who are routinely vaccinated against pneumonia.

"This was a very nice demonstration of herd immunity," Goepfert said. "It's neat that a vaccine in kids can protect adults."

He added that the findings offer more evidence that doctors can use to encourage parents who may be reluctant to get their kids vaccinated.

"The clinician can say, 'This is not only helping your child, it's helping the adults around your child,'" said Goepfert.

SOURCE: http://bit.ly/12liYyX New England Journal of Medicine, online July 10, 2013.

Reuters Health



**Related MedlinePlus Pages**

Immunization
Pneumonia [http://www.nlm.nih.gov/medlineplus/pneumonia.html]

Page last updated on 11 July 2013

# 8.3

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*Web address:*
**http://www.sciencedaily.com/releases/2013/07/130718111335.htm**

# Electronic Health Records Help Fight Vaccine-Preventable Diseases

July 18, 2013 — Using an Electronic Health Record (EHR) system to automate the immunization data shared between health providers and public health agencies enables physicians to assist individual patients faster and more effectively, while also providing more immediate, cohesive community data to the agencies tasked with promoting public health.

Those are the findings of a new study conducted by researchers from Columbia University School of Nursing and partner institutions. The researchers also found that automated reporting reduced the lag time historically associated with data submitted on vaccinations and, in some cases, reduced the paperwork and staff time traditionally devoted to managing these required submissions. In short, a robust records automation program increased knowledge about both individuals and communities, allowing medical and public health officials at all levels to make more informed decisions.

"The efficiency offered by automation has significant implications for managing public health, whether it is by informing a local physician on the health of an individual or informing policymakers on health trends within a whole community," said lead researcher and CU Nursing professor Jacqueline Merrill, RN, MPH, DNSc. "For example, EHRs greatly enhance our ability to help at-risk populations for whom up-to-date immunizations are critical, such as children, immunosuppressed individuals, or the chronically ill. Before automated registries, reporting was less structured and data submittal was less consistent."

Currently, health officials in the U.S. recommend that the public be immunized against 17 vaccine-preventable diseases. However, tracking vaccinations is difficult, especially among underserved populations whose care is often managed by multiple providers. Various state and local health agencies set up immunization registries to consolidate scattered patient records and thus reduce unnecessary vaccinations; however, registries frequently report slow and incomplete data submission by health providers, who in many areas still submit information via paper files. Automated reports via EHRs provide readily available immunization histories and thus can help officials and providers determine which patients have been adequately immunized. Registries also track and provide the basis for decisions on vaccine formulations, vaccine supplies and delivery schedules.

The study analyzed 1.7 million records submitted by 217 primary care practices to the NY Citywide Immunizations Registry between January 2007 and June 2011 -- both before and after the launch of automated reporting via an EHR. The study examined differences in records submitted by day, by lag time, and by documentation of eligibility for subsidized vaccines.

Among the findings: although mean submissions per day did not change, the patterns of submission changed significantly. Automated submissions of new and historical records increased by 18% and 98%, respectively. The number of submissions within 14 days (as required in NYC) also increased, as did the number of submissions within 2 days. Median lag time was reduced from 13 to 10 days.

These findings give an idea of the benefits of health information technology. The launch of automated reporting via an EHR prompted significant improvements in use of the registry and in the efficiency of reporting from the field.

"Automating the process appears very successful," said Merrill. "In fact, it's so successful that we believe it would be beneficial to retrofit data from the past so it can also be included in the EHR."

The process of setting up healthcare data so it can be exchanged electronically is well underway in NYC and in NYS. It is, in fact, integral to the technology transformation occurring within health reform -- activities intended to make healthcare more efficient for patients and providers and to help the overall system create better conditions for keeping people healthy.

Merrill's current research focuses on understanding the processes of public health organizations, and this is one of the first (if not the first) studies of registry efficiency and EHR-based reporting. The article, which appears as a "Case Report" in the journal Applied Clinical Informatics (www.aci-journal.org), documents the efficiencies provided by automated reporting to a registry that tracks immunizations for the NYC Department of Health and Mental Hygiene. The study was conducted by researchers from Columbia University, MGH Institute of Health Professions, and Weill Cornell Medical College.



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**Story Source:**

The above story is based on materials provided by **Columbia University School of Nursing**, via Newswise.

*Note: Materials may be edited for content and length. For further information, please contact the source cited above.*

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# 8.4

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

# Press Release

Embargoed Until: Thursday, July 25, 2013 at Noon ET
Contact: Division of News & Electronic Media (http://www.cdc.gov/media), Office of Communication
(404) 639-3286

## HPV vaccine: Safe, effective, and grossly underutilized

In a press conference held today, top officials from CDC and the American Academy of Pediatrics announced that HPV vaccination rates in girls aged 13-17 years failed to increase between 2011 and 2012, according to data from the Centers for Disease Control and Prevention (CDC). Three-dose coverage actually declined slightly from 2011 to 2012.

The article in CDC's Morbidity and Mortality Weekly Report (MMWR) drew on data from the 2012 National Immunization Survey-Teen (NIS-Teen).

Among girls unvaccinated for HPV, 84 percent had a healthcare visit where they received another vaccine (such as one aimed at meningitis or pertussis) but not HPV vaccine. If HPV vaccine had been administered, vaccination coverage for ≥1 dose could be nearly 93 percent rather than 54 percent.

"Progress increasing HPV vaccination has stalled, risking the health of the next generation.," said CDC Director Tom Frieden M.D., M.P.H. "Doctors need to step up their efforts by talking to parents about the importance of HPV vaccine just as they do other vaccines and ensure its given at every opportunity."

According to CDC, for each year the 3-dose HPV vaccine series coverage remains near the current level of 33 perccent instead of achieving the Healthy People 2020 goal of 80 percent coverage, an additional 4,400 women will be diagnosed with cervical cancer and 1,400 cervical cancer-attributable deaths will occur in the future.

The 2012 NIS-Teen data show that not receiving a healthcare provider's recommendation for HPV vaccine was one of the five main reasons parents reported for not vaccinating daughters. Healthcare providers are urged to give a strong recommendation for HPV vaccination for boys and girls aged 11 or 12 years.

The other responses parents provided indicate gaps in understanding about the vaccine, including why vaccination is recommended at ages 11 or 12.

"Parents need reassurance that HPV vaccine is recommended at 11 or 12 because it *should* be given well in advance of any sexual activity," said Dr. Frieden. "We don't wait for exposure to occur before we vaccinate with any other routinely recommended vaccine."

Parents also reported safety concerns as a reason for not vaccinating. In the seven years of post-licensure vaccine safety monitoring and evaluation conducted independently by federal agencies and vaccine manufacturers, no serious safety concerns have been identified. According to today's MMWR article, reports of adverse events after HPV vaccination to the Vaccine

Adverse Event Reporting System (VAERS) have steadily decreased from 2008 to 2012 and the numbers of serious adverse events reported has also declined since 2009.

Approximately 79 million Americans are currently infected with HPV. About 14 million people become newly infected each year. HPV is so common that nearly all sexually-active men and women will get at least one type of HPV at some point in their lives.

Parents and caregivers are encouraged to ask about vaccination every time they take children for a healthcare visit. If a preteen boy or girl (aged 11 or 12 years) has not started the HPV vaccine series, make an appointment to get him or her vaccinated. Teens who haven't started or finished the 3-dose series should do so—it's not too late for them to receive HPV vaccine.

For many, it's easier than ever to get the HPV vaccine. Because of the Affordable Care Act, most private health insurance plans must cover the HPV vaccine at no out-of-pocket cost, meaning no co-pay or deductible. Visit https://www.healthcare.gov/what-are-my-preventive-care-benefits/#part=3 (https://www.healthcare.gov/what-are-my-preventive-care-benefits/#part=3) (http://www.cdc.gov/Other/disclaimer.html) for more information.

CDC officials urge healthcare providers to increase the consistency and strength of how they recommend HPV vaccine, especially when patients are 11 or 12 years old. Reviewing vaccination status at every healthcare encounter and taking advantage of every visit, including acute care visits, can increase HPV vaccine coverage in the United States.

HPV vaccine is an anti-cancer vaccine. Preteen and teens are relying on the adults in their lives to help protect them.

National and state vaccination coverage data for adolescent immunization will be released late August 2013 in the MMWR and will include HPV vaccine coverage for both girls and boys.

Today's article will be available on the Morbidity and Mortality Weekly Report website at http://www.cdc.gov/mmwr/ (http://www.cdc.gov/mmwr/) after the embargo lifts. For the HPV vaccination Digital Press Kit, visit http://www.cdc.gov/media/dpk/2013/dpk-hpv.html (http://www.cdc.gov/media/dpk/2013/dpk-hpv.html)

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