ADVISORY COMMISSION ON CHILDHOOD VACCINES
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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

February 10, 2015

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

Teleconference and Adobe Connect

March 5, 2015
(10:00 am – 4:00 pm Eastern Daylight Time)
Dial in: 1-877-917-4913
Passcode: ACCV

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

Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Dr. Kristen Feemster, Chair
10:10 AM	Approval of December 2014 Minutes	Dr. Kristen Feemster, Chair
10:15 AM	Report from the Division Injury Compensation Programs	Dr. A. Melissa Houston Director, DICP
10:45 AM	Report from the Department of Justice	Mr. Vince Matanoski Deputy Director Torts Branch, DOJ
11:30 AM	Report from the Process Workgroup	Ms. Luisita dela Rosa, ACCV Member
12:00 PM	Lunch	
1:00 PM	Report from the Adult Immunization Workgroup	Dr. Sylvia Villarreal, ACCV Member
1:30 PM	Review of Vaccine Information Statements	Mr. Skip Wolfe, CDC
3:00 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimabukuro CDC

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

Charter

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

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

Objectives and Scope of Activities

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

Description of Duties

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

Agency or Official to Whom the Commission Reports

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

Support

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

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Commission, including compensation and travel expenses for members, but excluding staff support, is approximately $39,795. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $256,377.

Designated Federal Official

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

Estimated Number and Frequency of Meetings

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

Duration

Continuing.

Termination

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

Membership and Designation

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

The Commission shall be composed of the following:

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

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

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

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

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

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

Subcommittees

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

Recordkeeping

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

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Filing Date

July 21, 2014

Approved:

JUL 1 2014

Date

Bahar Niakan
Acting Director, Office of Management

Roster

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2015 Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2015 MEETING DATES

March 5, 2015
June 4 & 5, 2015
September 2 & 3, 2015
December 3 & 4, 2015

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Advisory Commission on Childhood Vaccines
December 4, 2014
94th Meeting

Members Present

Kirsten Feemster, Chair ('14)
Jason Smith, J.D., Vice Chair ('14)
Charlene Douglas, Ph.D. ('14)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('13)
Luisita dela Rosa, Ph.D. ('15)
Sylvia Fernandez Villareal, M.D. ('15)

Division of Injury Compensation Programs

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

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

Dr. Feemster called the 94th meeting of the Advisory Commission on Childhood Vaccines (ACCV or Commission) to order and, after roll call and introductions, noted that the Commission had participated in a Government Accountability Office (GAO) study in 2014 and that report has been released and published on the GAO web site. The report was developed through interviews with stakeholders interested in vaccines, vaccine safety and the National Vaccine Injury Compensation Program (VICP).

Dr. Feemster requested approval of the September 2014 meeting minutes. Ms. Herzog noted that the letter from the National Vaccine Information Center (NVIC) that was to be incorporated into the minutes was inadvertently omitted from the draft minutes provided to the members of the ACCV, but she stated it would be incorporated in the version that will be posted on the HRSA web site. With that revision, on motion duly made and seconded, the minutes of the September 4-5, 2014 meeting were unanimously approved.

Update on the 27th Annual Judicial Conference, Chief Special Master Denise K. Vowel

Chief Special Master Vowel of the U.S. Court of Federal Claims (CFC) commented that the vaccine areas covered at the Judicial Conference included recent damage awards, settlements in progress, and her update on the activities of the Office of Special Masters, including a review of the current caseload. One focus was on the effort to reduce the number of outstanding claims filed more than ten years ago (about 3% of the total claims), and most of those should be resolved in 2015.

The conference included a panel to provide a venue for discussing attorney's fees, and two panels led by special masters. Special Master Tom Gowen focused on life care plans, and Special Master Christian Moran looked at emerging issues related to vaccine damage claims.

Chief Special Master Vowel explained that her office had addressed the increased level of claims that has occurred in the last few years. Based on calendar year claims, there were 680 cases in 2014, which was up from 525 in 2013 and above the average of 400 that were filed in the prior four years. She added that her office is capped at eight special masters and a limited staff of attorneys, but that in July a Special Processing Unit (SPU) had been approved with authority to hire permanent staff attorneys. That action followed consultation with the petitioner's and respondent's bars, and there was agreement that the SPU would focus on table injuries or "quasi table injuries", such as Shoulder Injury Related to Vaccine Administration (SIRVA), Guillain-Barrè Syndrome (GBS), and intussusception following rotavirus. These claims are typically processed expeditiously. The program so far appears to be working well.

Chief Special Master Vowel noted that the information on the conference, including the audio recording of the conference sessions, is available on the web. Asked about future increases in the number of special masters, Chief Special Master Vowel stated that she had proposed a increase the number of special masters from 8 to 12. She added that staff attorneys help support the day-to-day management of cases. There are now four such staff attorneys, and there may be increased funding in 2016 that would support more. Dr. Villarreal observed that, as discussed in the GAO report, the Commission should remain aware that adding injuries to the Vaccine Injury Table is an important part of moving claims through the system more quickly and more easily. Chief Special Master Vowel suggested that an increase in Department of Health and Human Services (HHS) staff would also be helpful, since the information required to make decisions about case settlements in part depends on the submission recommendations from HHS.

Dr. Feemster invited the report from the DICP.

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

Dr. Houston welcomed those present on the teleconference and briefly reviewed the meeting agenda. Following Chief Special Master Vowel's discussion of the 27th Annual Judicial Conference and her own report of DICP activities, the agenda includes an update from the Department of Justice (DOJ), reports from the chairs of the Process Workgroup and the Adult Immunization Workgroup, a review of Vaccine Information Statements, and finally updates from the ex officio members from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the National Vaccine Program Office (NVPO).

Dr. Houston commented that her report would reflect the first month of Fiscal Year (FY) 2015, during which 73 claims were filed (projected to be 876 for the fiscal year). There were 19 adjudications (projected to be 228), of which 12 were compensable and 7 were dismissed. She commented that the projected 876 claims for the year was a number considerably larger than any previous year. Concerning awards, petitioners were awarded $17.5 million and attorney's fees totaled $2.3 million. Those amounts are estimated to be $210 million and $27 million

respectively, by the end of FY 2015. Dr. Houston reported that the Vaccine Injury Compensation Trust Fund balance was $3.5 billion as of September 30, 2014.

With regard to significant activities, Dr. Houston noted that there are several VICP regulations going through the clearance process. She also stated that the GAO report was published and can be reviewed on the GAO web site. The National Vaccine Advisory Committee (NVAC) met on September 9-10, 2014, and a summary of that meeting will be included in the NVPO report later in the meeting, and on October 29-30, the Advisory Committee on Immunization Practices (ACIP) met and the summary of that meeting is on the ACIP web site. Finally, the Vaccine Safety Datalink met on November 4-5, and a report is available on their web site.

Dr. Houston announced that the next solicitation will request that an obstetrics-gynecology doctor (preferably a specialist in prenatal health) to serve as a new member of the ACCV. She encouraged ACCV members to submit nominations for that new vacancy. She added that staff would provide a link when the Federal Register Notice is posted. Finally, the Health Insurance Marketplace open enrollment period is November 15, 2014 through February 15, 2015.

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

Mr. Matanoski referenced the Department of Justice PowerPoint materials (DOJ PP), dated December 4, 2014, as part of his presentation. Mr. Matanoski reported that 249 petitions were filed since the last report to the Commission (DOJ PP at 2). Of the 249 petitions, 42 were minor petitioners and 207 were adult petitioners. Although there are seasonal fluctuations in large part because of the effect of influenza claims, the total for the year should exceed that of the previous year. Petitions alleging SIRVA are also increasing. With regard to adjudications, 180 cases were completed during the reporting period, also a new high (DOJ PP at 3). Because of the dramatic increase in claims filed, the gap between claims filed and adjudications is widening. The number of claims voluntarily withdrawn remains at three, a relatively insignificant factor in the statistical snapshot (DOJ PP at 4).

Turning to appeals, Mr. Matanoski reported that *Graves v. HHS* was affirmed by the Court of Appeals for the Federal Circuit (CAFC) (DOJ PP at 5). This case involved a question about the statute of limitations – not only for the late filing of the claim itself, but a late filing of the appeal as well. The CAFC's affirmance supports the original decision by the special master. Of the seven pending cases before the CAFC, three are new and all are entitlement cases filed by petitioners. (DOJ PP at 6). In *Griffin v. HHS*, the issue is whether a contractor working outside the U.S. for the federal government is entitled to file a vaccine injury claim. A federal employee in the same situation is covered, but this contractor's agreement with the federal government clearly stated that the individual involved was not a federal employee, so the special master denied the claim. The CFC affirmed the special master's dismissal. In *Crutchfield v. HHS*, the special master denied petitioner's claim that the measles-mumps-rubella (MMR) vaccine caused type 1 diabetes, which was affirmed by the CFC. Petitioner appealed. In *Stillwell v. HHS*, the special master denied petitioners claim that a flu vaccine caused acute disseminated encephalomyelitis (ADEM) noting that the diagnosis was questioned. The CFC affirmed dismissal.

Turning to the CFC, Mr. Matanoski noted that five cases were recently decided. (DOJ PP at 7). Three of these cases were already discussed (*Griffin*, *Crutchfield*, and *Stillwell*). Of the remaining two, *Harris v. HHS* arose out of a claim that human papillomavirus (HPV) vaccine caused systemic lupus erythematosus, but the special master ruled that there was insufficient evidence to establish a logical sequence of events that would support the development of the disease. In *Somosot v. HHS*, the special master denied a claim that a vaccine caused cerebral palsy because the claim was not filed within the statute of limitations. Evidence showed that the symptoms of the disease predated the time of the diagnosis by three years, which would mean the claim was filed six years after the onset of the disease, outside the timeframe for filing a claim.

There are currently nine cases pending at the CFC, all filed by petitioners (DOJ PP at 8). Of those, five were not previously discussed at prior ACCV meetings. In *Spahn v. HHS,* the special master denied a claim that tetanus vaccine significantly aggravated a preexisting obsessive compulsive disorder. In *Guerrero v. HHS*, the special master reduced petitioner's request for over $66,000 in attorneys' fees and costs to $49,000. In *Hirmiz v. HHS*, the special master decided that respondent's expert's testimony outweighed the testimony by petitioner's experts. In *Moriarty v. HHS*, the special master found that there was insufficient evidence to support petitioner's claim that the MMR vaccine caused seizures through an autoimmune disorder. In *Lerwick v. HHS*, petitioner appealed the special master's damages award, claiming that it provided insufficient funds for attendant care needs.

Two oral arguments were scheduled. (DOJ PP at 9). In a case already discussed at a previous ACCV meeting, *Flores v. HHS*, the oral argument was scheduled for the same timeframe as the ACCV meeting, December 4, 2014. The other, *Lerwick v. HHS*, is scheduled for January 28, 2015.

Turning to settlements, Mr. Matanoski discussed the compilation of adjudicated settlements (by stipulation) during the preceding quarter (DOJ PP at 10-20). There were 106 settlements finalized in the last period, 98 adult cases, and 8 minor child cases. Eighty-one of the cases were flu claims, either flu vaccine alone or in combination with other vaccines. The average processing time was 20 months, about the same as reported at the last ACCV meeting. Cases resolved within a year accounted for 34% of all cases, within the second year 42%, and within the third year 17% -- so a total of 93% of the cases were resolved in three years or less. However, Mr. Matanoski suggested that the settlements may not be as timely in the future because of the rapidly rising number of claims filed, which in combination with a fixed budget for staffing, translates into a larger number of pending cases.

In conclusion, Mr. Matanoski addressed the increasing number of vaccine cases and personnel limitations within his office. He commented that the Office of Special Masters has shifted some of their burden to staff attorneys in effort to more quickly adjudicate cases. He explained that, in spite of efficiencies that have been achieved, the respondent still was faced with a substantially increased workload and limited resources. Proposed changes to the Vaccine Injury Table may help to resolve cases more rapidly, which should alleviate some of the pending case strain. Cases have been conceded at an increasing rate over the past year.

Responding to questions about statutory limitations on DOJ staffing, Mr. Matanoski stated that there are no statutory limitations on the number of people DOJ could use for Vaccine Act work, and added that HHS also is not limited by legislation. Mr. Kraus commented that while petitioners' attorneys may be responsible for some of the delays in case processing, HHS might consider improving efficiencies similar to the efforts of the Office of Special Masters. Dr. Houston indicated that DOJ has 90 days to respond to a claim and rarely violates that deadline, attesting to the fact that HHS is also responsive in the preparation of case documentation. She offered that funding streams are very distinct between HHS and DOJ, making it impractical for the two agencies to develop joint funding proposals. Finally, she assured the ACCV that all three agencies were cognizant of the need for increased funding and all are taking steps to address the issue. Mr. Matanoski reiterated that Congress controls budget approvals, and that DOJ could be reaching the limits of utility of certain new process efficiencies, like the SPU, because of increasing case volume. He noted that the marked increases in caseload must be handled by a DOJ staff that cannot be increased because of a static budget. With fixed staffing levels, pushing DOJ resources to address SPU cases to move them along rapidly, necessarily means that other cases are receiving less resources and focus.

Dr. Feemster expressed appreciation for the presentation, reiterating her previous request for recommendations from the ACCV that might support the efforts of the agencies to expedite claims processing. Mr. Matanoski commented that DOJ's funding requests have been finalized; however, he was open to the ACCV's input for the next funding cycle.

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

Ms. dela Rosa reported that the workgroup met on November 21 and discussed the status of appointments to the ACCV (continues to be a pending issue), reviewed past and future activities, and discussed the May 2009 ACCV Process Workgroup recommendations. Three continue to be of interest to the workgroup -- the statute of limitations, the increase in the benefits cap, and the appointment of a vaccine-injured adult to serve as a member of the ACCV. The remaining eight are less timely now than they were when originally put forth, and the workgroup agreed that further action on those recommendations could be deferred. Ms. dela Rosa stated that the workgroup had requested that Dr. Houston provide information about what transpires after the Secretary receives a formal recommendation from the ACCV.

A representative of the National Association of Pediatric Nurse Practitioners explained that the association supports appropriate immunization of all infants, children, adolescents and adults; and supports assistance for families who have experienced debilitating vaccine injury of a family member.

Another issue discussed by the workgroup was how to gather information through surveys in face of regulations that require extensive and time-consuming review and approval of surveys. Ms. Overby explained that there is an exemption in the Vaccine Act if the survey seeks information that would be required to implement the Vaccine Act. Former ACCV chair Dave King, had suggested establishing a workgroup that could address issues related to that exemption.

During discussion, asked about the progress toward approval of new members of the ACCV, Dr. Houston stated that inquiry was made of the Secretary and it has been clarified that

there is a 6-9 month process to select nominees (which began in September 2014). Three nominees were put forward for approval. That could mean that current members might be asked to extend their terms.

Dr. Feemster commented on the prior discussion of seeking more resources, suggesting that the Process Workgroup could add that issue to its agenda. Mr. Kraus suggested that, although the workgroup's role is not clear, the issue could be placed on the agenda for the next meeting.

Report from the Adult Immunization Workgroup, Dr. Sylvia Villarreal, ACCV Member

Dr. Villarreal reported that the workgroup would meet via teleconference as required. Dr. Feemster, Ms. Williams, Mr. Kraus and Mr. Smith agreed to participate on the workgroup. She stated that Ms. Herzog would provide a table identifying child and adult vaccines not covered by the Vaccine Injury Table. She defined adult as being at least 18 years of age. One of the issues to be addressed will be including adult immunizations in the VICP, which is not the case under the current legislation. Dr. Villarreal stated that she would submit a more formal proposal for the objectives of the workgroup.

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

Mr. Wolfe stated that there would be two influenza VIS's to review, neither of which has been significantly changed. The last time there was a revision was in 2013 and that VIS pertained to the current 2013-2014 flu season. In the past, the VIS was revised annually to include information about the specific ensuing flu season. However the objective now is to make the VIS more general, without customizing it to the specific flu season, therefore making it a more lasting document that could be used for several years. He noted that the title of the VIS included the terms "inactivated" and "recombinant." The latter word was suggested by the subject matter experts, even though only one vaccine (Flublok) is a recombinant vaccine. Whether the vaccine is inactivated or recombinant should not be of concern to the recipient. Of concern is whether a vaccine contains live virus, and none do, and that fact is clearly stated in the VIS. During the discussion there was a suggestion that a phrase used in other VIS that pertain to recombinant vaccines might be easier to understand – vaccines made with parts of the virus.

Asked about whether a discussion should be included about infants under six months of age who cannot receive the vaccine and are therefore vulnerable, Mr. Wolfe commented that, since only prospective vaccine recipients receive the VIS, the parents of a very young infant would not. There was a suggestion that the term "infants" should be include in the sentence that begins, "Flu is more dangerous for some people."

Mr. Wolfe commented that in the second section an introductory sentence emphasizes the importance of receiving the vaccine annually and reminds parents that children may need two doses. He also stated that a suggestion by Mr. Kraus to change the wording in a sentence about thimerosal was inadvertently overlooked, but the changed wording would be included in this revision: Studies have not shown that thimerosal is harmful (instead of studies have shown that thimerosal is not harmful). Mr. Smith noted that in the VIS for live attenuated influenza vaccine (LAIV), which can be given to individuals two through nine, there is a statement that it may be given safely at the same time as other vaccines. That is not included in the VIS under review.

Mr. Wolfe agreed, noting that administering such vaccines in combination is an issue that parents are concerned about.

Dr. Shimabukuro suggested that, to clarify that inactivated or recombinant vaccines are not the same thing, the second sentence in the section be clarified to read: Inactivated and recombinant flu vaccines are given by injection (or shot) and do not contain live influenza virus. There was agreement that the revised wording was easier to understand, and further agreement that the term "recombinant" is a technical term that might be eliminated.

In Section 3, Mr. Wolfe noted that specific allergens, which were identified in the current VIS, had been removed since it was revealed that lay readers were confused about whether the list was complete. Mr. Wolfe stated that there were no substantive changes in either Section 4 or Section 5. Dr. Shimabukuro pointed out that, in Section 4, the statement that shoulder pain being rare is true, but in fact the condition may become chronic. He suggested removing the words "and is temporary."

Under Section 4, there was a brief discussion about moderate problems, and there was agreement that the latest data indicate that receiving flu vaccine in combination with pneumococcal vaccine and/or vaccines containing Dtap, may increase the risk of febrile seizures. Therefore, there was agreement that "Dtap-containing vaccines" should be added to the first sentence.

Mr. Wolfe stated that Sections 5, 6 and 7 were standard for most VIS, and there had been extensive discussion in the past to arrive at the wording in those sections.

Moving to the intranasal, live attenuated influenza vaccine (LAIV) information statement, Mr. Wolfe noted that Section 1 was identical to the VIS just reviewed. Section 2 had been revised to include a definition of "attenuated," and provide the age range for receiving the vaccine. It was noted that the statement that the viruses in the vaccine were weakened to prevent causing flu is repeated. There was agreement that the second duplicative statement should be removed, but that for emphasis the remaining statement should be in boldface type.

In Section 3, a rationale was added to the statement about waiting four weeks between receiving a second live vaccine – that is, vaccines may be less effective if given too close together in time. Also in the same section, there was a recommendation to clarify giving the flu shot instead of the nasal flu vaccine to children with asthma or wheezing problems, since that applies only to children age 2 to 4. Dr. Shimabukuro suggested that a risk warning concerning asthma/wheezing should go in Section 4. Finally, Mr. Wolfe stated that the VIS must include the wording regarding the risk of death, but he welcomed any rewording that would make the statement less threatening. As before, Sections 5, 6 and 7 are pro forma for all VIS.

Mr. Wolfe expressed appreciation for the Commission's comments and recommendations.

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

Dr. Shimabukuro noted that he would summarize the October 2014 ACIP meeting, outline Clinical Immunization Safety Assessment (CISA) research studies, and discuss recent publications germane to vaccines. Currently there is a published Federal Register Notice inviting public comment on the revised Vaccine Adverse Event Reporting System (VAERS) reporting form that will allow public comment through January 23. Then final revisions will be made and the new form 2.0 will be incorporated into the information technology platform. Once implemented, and after a reasonable period of reporting under the new form, there will be a review of the results comparing the old form with the new form.

Dr. Shimabukuro commented that the ACIP meeting also included a summary of the U.S. Flu Vaccine Effectiveness Network. The highlights of that presentation showed that, during the last two flu seasons the relative effectiveness favored the live attenuated influenza vaccine (LAIV) versus inactivated vaccine (IIV) in young children. There is a recommendation that LAIV be used in young children if available, but vaccination should not be delayed, so IIV could be used if there is a scarcity of LAIV. In the last flu season (2013-2014) relative effectiveness favored IIV. Finally, data showed that H1N1 was the predominant virus in 2013-2014. Medimmune reported a post-licensure study showing significant vaccine effectiveness for LAIV4 against the B-Yamagata flu, but not the H1N1 strain.

Dr. Shimabukuro commented that the PharmaJet (PJ) Stratis Needle-Free Injection System was approved in August 2014 (an informational item at the September ACCV meeting). Apparently as effective as standard needle injection, its use in the current season has been limited because most of the product was already distributed. Although injection site reactions were more frequent with the PJ system, other reactions were comparable with standard needle injection. Finally, patients and health care providers appear to be satisfied with the needle-free process.

Dr. Shimabukuro stated that the ACIP update also included an announcement that Novartis submitted a biologic vaccine application for persons 10 to 25 years to receive Bexsero, a meningococcal serogroup B vaccine, in two doses. It is the same vaccine used under an Investigational New Drug (IND) protocol in the Princeton-University of California at Santa Barbara outbreak. He reiterated the announcement that Trumenba was approved in October, also for individuals 10 to 25 years of age, as a three-dose series.

Finally, Dr. Shimabukuro stated that a clinical trial of a 9-valent HPV vaccine showed that it was well tolerated in young men and women, and switching to that vaccine could prove cost effective. Approval is expected in 2015.

Concerning the CISA studies, CISA is a collaboration between CDC and seven medical research centers that conduct vaccine safety studies. Dr. Shimabukuro noted that the studies can be reviewed on the web at clinicaltrials.gov.

Dr. Shimabukuro mentioned six publications of interest, including:

- Haber et al, looking at post-licensure analysis of VAERS surveillance of trivalent live attenuated influenza vaccines in adults, suggested there was little concern, except for a higher than expected incidence of GBS;

- Haber et al, is a follow on to the Haber study concerning reports of expired LAIV vaccine being used (although LAIV has a relatively short expiration date from season to season, which is a mitigating circumstance);
- Kharbanda et al, described a study of the association of maternal pertussis vaccination with obstetric events, showing that Tdap did not appear to be a risk for increased risk of hypertensive disorder or preterm or small for gestational age at birth;
- Duffy et al, described a study showing that influenza vaccines containing A(H1N1)pdm09 virus strain were not associated with an increased risk of narcolepsy;
- Tartof et al, discussed a study of inpatient admissions for febrile seizure that showed no difference in children with vaccine-associated febrile seizure and non-vaccine febrile seizure;
- Kharbanda et al, analyzed increased uptake in Tdap coverage in pregnant women following the California Department of Public Health recommendations.

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

Ms. Schuster explained that NIAID continues to support and conduct research on diagnostics, therapeutics and vaccines for Ebola. NIAID support includes work in West Africa, participation in World Health Organization and United Nations policy meetings, collaborations with pharmaceutical companies and vaccine manufacturers, support for Commissioned Corps officers assigned to provide clinical care, provision of expert advice to federal agencies, and interactions with Congress and the public.

NIAID is supporting clinical trials on candidate vaccines for Ebola, including one co-developed by NIAID and GlaxoSmithKline. Clinical testing began in September 2014. The vaccine was well-tolerated and produced immune responses in the 20 adults who participated in this trial. Additional details are available on the NIAID web site.

NIH is collaborating with Department of Defense in supporting NewLink Genetics Corp. in the conduct of Phase I investigational studies of the recombinant vesicular stomatitis Ebola vaccine, VSV-ZEBOV. This candidate vaccine was developed by researchers at the Public Health Agency of Canada. Clinical trials began in October at Walter Reed Army Institute of Research and at NIH, evaluating the vaccine for safety and efficacy.

NIAID recently sponsored a Phase II clinical trial to look at a candidate vaccine for H7N9 avian influenza, which prompted immune responses when the vaccine was mixed with an adjuvant. The trial enrolled 700 healthy adults at four sites in the U.S. The experimental vaccine is made from inactivated H7N9 virus. The results of the study were published in the Journal of the American Medical Association in October 2014. Finally, NIAID has awarded seven contracts to medical research institutions to discover and characterize new adjuvants. Total funding for the contracts could be as much a $70 million over five years.

Collaborating with the Bill and Melinda Gates Foundation, NIAID co-sponsored a conference on clinical research in pregnant women on September 29-30, 2014. The objective, in the context of pregnancy research, was to identify knowledge gaps in the context of global health vaccines and antimicrobials; and to develop research tools to support the design and implementation of clinical trials to respond to those gaps.

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

LCDR Marshall reported that in September 2014, the package insert for Menactra was revised to include safety and immunogenicity data to support Menactra re-vaccination in individuals 15 through 55 years of age who are at continued risk for meningococcal disease if at least four years have elapsed since the prior dose.

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

In December 2014, a public workshop, "Immunology of Protection from Ebola Virus Infection," was jointly sponsored by FDA, NIAID, Department of Defense, CDC, and the Biomedical Advanced Research and Development Authority (BARDA). The purpose of the workshop is to discuss the Ebola virus and vaccine immunology to help inform future clinical, scientific and regulatory decision-making related to development of vaccines to protect against Ebola.

Finally, in March 2015, the Vaccines and Related Biological Products Committee (VRBPAC) will meet to consider recommendations for the selection of strains to be included in the 2015-2016 influenza season vaccine.

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

Dr. Bok reported that NVPO is working with the Adult Immunization Task Force (under the direction of the HHS Assistant Secretary for Health), to develop a plan to promote a higher uptake of vaccines by adults. Adults significantly lag children in compliance with immunization recommendations. That plan is going through clearance and should be launched in early 2015.

Dr. Bok noted that the September 2014 NVAC meeting included a session on maternal immunization, and NVAC has created a Maternal Immunization Working Group to identify barriers and opportunities to overcome those barriers and for developing vaccines for pregnant women. The new working group follows on a previous working group that was focused on access to existing vaccines by pregnant women.

Public Comment

Dr. Feemster invited public comment.

Ms. Theresa Wrangham, representing the NVIC, expressed appreciation for the Commission's correction of the September 2014 minutes by including the NVIC's letter submitted at that meeting. However, a second correction was not considered, that of clarifying the participation of the NVIC in the Process Workgroup. That request was sent to ACCV staff and Ms. Wrangham asked that the e-mail request be distributed to the full Commission and that the submission of the request be included in the corrections to the September minutes.

Ms. Wrangham stated that the law provides for the information submitted by NVIC be made available to the public. The information would lessen any "new efforts" to implement existing legal reporting requirements. However, if such implementation is necessary, it should not be constrained by budgetary limitations or by defining the implementation as optional. The public should be able to access information easily.

With regard to the GAO report, the ACCV can make recommendations for adequate funding to handle the increased caseload. However, the ACCV should consider the GAO finding that increased caseloads are related to increases in off table injury petitions, which is linked to adding vaccines without adding related vaccine injuries. Ms. Wrangham recommended providing adequate funding for independent research to identify who is at risk for vaccine injury, properly compensating those injured, and developing information on prevention of such injuries in the future. Further, the ACCV should consider the limitations of reliance on the epidemiological data used by surveillance systems such as the Vaccine Safety Datalink (VSD), which do not include the biological data considerations. The ACCV should also be concerned about the limited access to VSD data by independent researchers, which hampers independent replicability studies.

Ms. Wrangham stated that the NVIC is opposed to the opening statement in the Vaccine Information Statements, titled "Why get vaccinated?" The VIS should provide factual information on vaccine risks and benefits, and that statement appears to be a bias in terms of "selling" immunizations. The length of the VIS is also too short to provide complete information about the vaccination decision. The vaccine product insert should also be made available as an attachment to the VIS. Concerning the meeting discussion of the flu VIS and the claim that there are many flu deaths, Ms. Wrangham felt there should be clarification that the flu deaths are actually the result of flu diagnosis and not flu-like illness, since the latter could inflate the number of deaths and be misleading.

There were no further requests to comment.

Future Agenda Items/New Business, Dr. Kristen Feemster, Chair, ACCV

For clarification, Dr. Houston stated that the current nominee cohort of three prospective members was forwarded to the Secretary in September 2014, making it possible that those nominations could be approved by the next ACCV meeting. An invitation for nominations for the second 2014 cohort will be published in the Federal Register in the next few weeks.

Dr. Feemster suggested that consideration of a recommendation to increase funding for the program, to enhance processing the increased number of claims files, be included in the March meeting agenda. The Commission agreed that would be an appropriate topic for discussion.

Adjournment

On motion duly made and seconded, the Commission unanimously approved adjournment.

3

Vaccine Injury Compensation Trust Fund

Balance as of December 31, 2014

$3,510,291,872.74

Figures for October 1, 2014 – December 31, 2014

Excise Tax Revenue: $50,119,000
Interest on Investments: $15,566,195
Net Income: $65,685,195
Interest as a Percentage of Net Income: 23%

Source: U.S. Treasury, Bureau of Public Debt
February 3, 2015

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4.1

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

National Vaccine Injury Compensation Program Statistics Report
For February 2015

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	216
FY 2002	957
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	503
FY 2014	633
FY 2015	232
Total	**15,747**

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

Adjudications[1]

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	233	295
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	121	203
FY 2008	147	134	281
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	265	1,370	1,635
FY 2012	261	2,439	2,700
FY 2013	366	627	993
FY 2014	357	167	524
FY 2015	127	33	160
Total	**3,937**	**9,867**	**13,804**

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

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

Awards Paid[1]

Fiscal Year	Compensated[2]			Dismissed		Interim Fees		Total Outlays
	# of Awards	Petitioners' Award Amount	Attorneys' Fees/ Cost Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	73	$2,511,313.26	2	$117,265.31	$83,536,901.46
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53

Awards Paid[1]

Fiscal Year	Compensated[2]			Dismissed		Interim Fees		Total Outlays
	# of Awards	Petitioners' Award Amount	Attorneys' Fees/ Cost Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,637,927.73
FY 2013	375	$254,666,326.70	$13,333,179.53	703	$6,970,278.84	50	$1,454,851.74	$276,424,636.81
FY 2014	365	$202,084,196.12	$11,973,575.82	505	$6,801,345.79	38	$2,493,460.73	$223,352,578.46
FY 2015	177	$83,067,135.53	$4,474,812.40	45	$1,245,066.01	19	$1,044,486.97	$89,831,500.91
Total	**3941**	**$2,885,038,650.06**	**$121,636,170.55**	**4925**	**$65,353,100.74**	**224**	**$18,752,260.08**	**$3,090,780,181.43**

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

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

4.2

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

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

Vaccine Alleged by Petitioner[2]	No. of Doses Distributed US CY 2006 - CY 2013 (Source: CDC)[3]	Compensable			Compensable Total	Dismissed/ Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
DT	652,327	1		3	4	4	8
DTaP	75,888,233	12	19	75	106	78	184
DTaP-Hep B-IPV	43,929,797	4	7	18	29	38	67
DTaP-HIB	1,135,474				0	1	1
DTaP-IPV-HIB	39,590,896			6	6	11	17
DTP	0[4]		1	2	3	2	5
DTP-HIB	0[4]				0	1	1
Hep A-Hep B	11,662,755			9	9	2	11
Hep B-HIB	4,796,583	1	1	1	3	1	4
Hepatitis A (Hep A)	124,212,280	6	3	22	31	20	51
Hepatitis B (Hep B)	129,820,136	2	10	40	52	38	90
HIB	83,517,849		1	4	5	4	9
HPV	67,250,524	10	1	65	73	85	158
Influenza[5]	944,000,000	73	81	848	1,002	177	1,179
IPV	58,019,052			4	4	2	6
Measles	135,660			1	1		1
Meningococcal	58,412,363	1	2	24	27	4	31
MMR	73,441,556	17	14	56	87	74	161
MMR-Varicella	11,028,270	8		8	16	8	24
Nonqualified[6]	N/A			1	1	22	23
OPV	0	1			1	3	4

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

Vaccine Alleged by Petitioner[2]	No. of Doses Distributed US CY 2006 - CY 2013 (Source: CDC)[3]	Compensable			Compensable Total	Dismissed/ Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
Pneumococcal Conjugate	132,932,107		1	5	6	13	19
Rotavirus	70,719,103	3	3	15	21	6	27
Rubella	422,548		1		1		1
Td	55,742,830	5	6	50	61	16	77
Tdap	155,106,848	19	7	87	113	14	127
TETANUS	3,836,052	3		18	21	11	32
Unspecified[7]	N/A	1		2	3	549	552
Varicella	90,425,492	3	6	23	32	10	42
Grand Total	**2,236,678,735**	**170**	**164**	**1,387**	**1,721**	**1,194**	**2,915**

DEFINITIONS:

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

• Concession: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.

• Court Decision: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).

• For injury claims, compensable court decisions are based in part on one of the following determinations by the court:

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

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

- Settlement: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Claims may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.

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

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

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

[3]Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type.

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

[5]Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

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

[7]Insufficient information submitted by petitioner to make an initial determination. The concession was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the settlements were for multiple vaccines later identified in the Special Master's Decisions.

5

5.1

The National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines
March 5, 2015
A. Melissa Houston, M.D., M.P.H., F.A.A.P

Department of Health and Human Services
Health Resources and Services Administration

ACCV Meeting Highlights

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

Number of Petitions Filed as of February 2, 2015

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

Fiscal Year	Total
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	503
FY 2014	633
FY 2015	232

Number of Adjudications as of February 2, 2015

Fiscal Year	Compensable	Dismissed	Total
FY 2010	180	293	473
FY 2011	265	1,370	1,635
FY 2012	261	2,439	2,700
FY 2013	366	627	993
FY 2014	357	167	524
FY 2015	127	33	160

Adjudication Categories for Non-Autism Claims FY 2013 – FY 2015 as of February 3, 2015

Adjudication Category	FY 2013	FY 2014	FY 2015
Compensable	366 (100%)	357 (100%)	127 (100%)
❖Concession	20 (5%)	36 (10%)	23 (18%)
❖Court Decision (includes proffers)	21 (6%)	35 (10%)	5 (4%)
❖Settlement	325 (89%)	286 (80%)	99 (78%)
Not Compensable	88	123	26
Adjudication Total	454	480	153

Award Amounts Paid as of February 2, 2015

Fiscal Year	Petitioners' Award	Attorneys' Fees & Costs
FY 2010	$179,387,341	$9,826,788
FY 2011	$216,319,428	$17,163,231
FY 2012	$163,491,999	$23,145,929
FY 2013	$254,666,326	$21,758,310
FY 2014	$202,084,196	$21,268,383
FY 2015	$83,067,135	$6,764,365

Vaccine Injury Compensation Trust Fund

- Balance as of December 31, 2014
  - $3,510,291,872.74

- Activity from October 1, 2014 to December 31, 2014
  - Excise Tax Revenue: $50,119,000
  - Interest on Investments: $15,566,195
  - Net Income: $65,685,195
  - Interest as a Percentage of Net Income: 23%

Source: U.S. Treasury, Bureau of Public Debt (February 3, 2015)

Significant Activities

- Status of VICP Regulations
- National Vaccine Advisory Committee
  - February 10 & 11, 2015
- Advisory Committee on Immunization Practices
  - February 25 & 26, 2015
- Measles Inquiries from the Media
- Information on ACCV meetings, presentations and minutes can be found at http://www.hrsa.gov/vaccinecompensation/commissionchildvaccines.html

Public Comment/Participation in Commission Meetings

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

5.2

Report from the Department of Justice

March 5, 2015

Vincent J. Matanoski
Deputy Director, Torts Branch

1

Statistics

Reporting Period: 11/16/14 – 2/15/15

I. Total Petitions Filed in the United States Court of Federal Claims this reporting period: 154

A. Minors: 23

B. Adults: 131

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Statistics

Reporting Period: 11/16/14 – 2/15/15

II. Total Petitions Adjudicated this reporting period: 142

A. Compensated: 117

i. Cases conceded by HHS: 22

1. Decision awarding damages: 0
2. Decision adopting Proffer: 22
3. Decision adopting Settlement: 0

ii. Cases not conceded by HHS: 95

1. Decision awarding damages: 0
2. Decision adopting Proffer: 3
3. Decision adopting Settlement: 92

B. Not Compensated/Dismissed: 25

i. Decision dismissing Non-OAP: 20

ii. Decision dismissing OAP: 5

3

Statistics

Reporting Period: 11/16/14 – 2/15/15

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 2

4

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

Recently Decided Cases

Appeals by Petitioner:

- *Flores v. HHS*: Affirmed
- *Koehn v. HHS*: Affirmed

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

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

Pending Cases

Appeals by Petitioner:

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

Appeals by Respondent:

- *Paluck v. HHS* (Entitlement)

*Yellow cases are new this reporting period

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Appeals: U.S. Court of Federal Claims

Recently Decided Cases

Appeals by Petitioner:

- *Moriarty v. HHS*: Affirmed (Entitlement)
- *Lerwick v. HHS*: Affirmed (Damages)
- *Mosley v. HHS*: Vacated and remanded (Entitlement)
- *Castaldi v. HHS*: Affirmed (Statute of Limitations, Entitlement)
- *Hirmiz v. HHS*: Affirmed (Entitlement)

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

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Appeals: U.S. Court of Federal Claims

Pending Cases

Appeals by Petitioner:

- *Barlcay v. HHS** (Entitlement)
- *Santini v. HHS** (Entitlement)
- *Rowan v. HHS** (Entitlement)
- *Milik v. HHS** (Entitlement)
- *Somosot v. HHS** (Attorneys' Fees and Costs)
- *Contreras v. HHS** (Entitlement)
- *Spahn v. HHS* (Entitlement)
- *Guerrero v. HHS* (Attorneys' Fees and Costs)
- *Godfrey v. HHS* (Entitlement)
- *D'Angiolini v. HHS* (Entitlement)

*Yellow cases are new this reporting period 8

Scheduled Oral Arguments

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

- None scheduled at this time

U.S. Court of Federal Claims:

- None scheduled at this time

9

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Transverse myelitis	2 years, 11 months
Flu	Brachial plexus neuritis	1 year
Flu	Guillain-Barré Syndrome, death	2 years, 10 months
Flu	Injuries resulting in death	1 year, 5 months
Flu	Respiratory distress resulting in severe bronchial, esophageal, and intestinal problems	1 year, 2 months
Meningococcal	Guillain-Barré Syndrome	8 months
HPV	Acute disseminated encephalomyelitis	4 years, 1 month
HPV, Flu	Alopecia	1 year, 7 months
Flu	Guillain-Barré Syndrome	1 year, 2 months
Flu	Brachial plexopathy	1 year, 11 months

*Terms of settlement are memorialized by Stipulation

(continued . . .)

10

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
DTaP, Hib, IPV, PCV	Death	8 years, 2 months
Flu	Guillain-Barré Syndrome	1 year, 4 months
Flu	Guillain-Barré Syndrome	1 year, 2 months
Flu	Limbic encephalitis and its related sequelae	5 months
Flu	Guillain-Barré Syndrome	1 year, 5 months
Flu	Systemic immune response	3 years, 2 months
Flu	Immediate allergic reactions and symptoms as well as chronic neuropathies, including chronic inflammatory demyelinating polyneuropathy	3 years
Flu	Guillain-Barré Syndrome	1 year, 9 months
Flu	Guillain-Barré Syndrome	1 year, 2 months
Flu	Significant aggravation of post-herpetic neuralgia	1 year, 6 months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 11

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Varicella	Recurrent shingles	1 year, 2 months
Hep A, Hep B	Guillain-Barré Syndrome	2 years, 10 months
Flu, Tdap	Neurological injury	1 year, 10 months
Hep B	Polyneuropathy	3 years, 4 months
Flu	Guillain-Barré Syndrome	1 year, 2 months
Flu	Dizziness, hearing loss, ringing in ear, balance problems	1 year, 9 months
Flu	Guillain-Barré Syndrome, death	1 year, 9 months
Flu	Acute inflammatory neurological injury	1 year, 3 months
Flu	Guillain-Barré Syndrome	1 year, 10 months
Flu	Guillain-Barré Syndrome	6 months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 12

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Myelitis	9 months
HPV, Td	Guillain-Barré Syndrome	4 years, 2 months
Flu	Guillain-Barré Syndrome	2 years, 4 months
Flu	Guillain-Barré Syndrome	2 years, 1 month
Flu	Guillain-Barré Syndrome	1 year, 8 months
Flu	Guillain-Barré Syndrome	1 year, 6 months
Tdap	Neurologic injuries	1 year, 9 months
Flu	Guillain-Barré Syndrome	1 year, 3 months
Flu	Guillain-Barré Syndrome	1 year, 3 months
Flu, DTaP, Hep A, Hep B	Guillain-Barré Syndrome	1 year

*Terms of settlement are memorialized by Stipulation

(continued . . .) 13

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Meningococcal	Transverse myelitis	1 year
Flu	Guillain-Barré Syndrome	11 months
Flu	Guillain-Barré Syndrome	8 months
Flu	Guillain-Barré Syndrome	6 months
Flu	Shoulder injury	6 months
Flu	death, or significant aggravation of pre-existing cardiomyopathy, chronic left bundle branch block, and gout, which caused death	1 year, 4 months
Flu	Guillain-Barré Syndrome and/or chronic inflammatory demyelinating polyneuropathy	1 year, 3 months
Flu	Polyarthritis and/or rheumatoid arthritis	1 year, 2 months
Flu	Polyneuropathy	1 year, 1 month
Flu	Guillain-Barré Syndrome	1 year, 1 month

*Terms of settlement are memorialized by Stipulation

(continued . . .) 14

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Shoulder injury	5 months
Flu	Guillain-Barré Syndrome and chronic inflammatory demyelinating polyneuropathy	11 months
Tdap	Guillain-Barré Syndrome	1 year, 5 months
Flu	Guillain-Barré Syndrome	7 months
Flu	Guillain-Barré Syndrome	10 months
Flu	Guillain-Barré Syndrome	4 years, 5 months
DTaP, Hib, IPV, PCV, Hep B, RV	Seizure disorder	3 years, 9 months
Flu, MMR	Acute, bilateral, acquired vestibular neuritis or labyrinthitis primarily attacking the inner left ear	2 years
Flu	Transverse myelitis	1 year, 3 months
Flu	Guillain-Barré Syndrome	1 year, 3 months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 15

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Guillain-Barré Syndrome	1 year, 3 months
Flu	Acute disseminated encephalomyelitis	9 months
Hep A	Death	10 months
Tdap	Guillain-Barré Syndrome	10 months
Flu	Guillain-Barré Syndrome	8 months
Flu	Guillain-Barré Syndrome	6 months
Flu	Guillain-Barré Syndrome	1 year, 10 months
Flu	Guillain-Barré Syndrome	2 years, 11 months
Flu	Acute necrotizing myopathy, polymyositis, and related sequelae	1 year, 3 months
Flu	Paresthesias, a myelopathy, and/or myelitis	1 year, 2 months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 16

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Guillain-Barré Syndrome	5 years, 3 months
DT	Peripheral neuropathy or fibromyalgia	1 year, 6 months
Flu	Guillain-Barré Syndrome	1 year, 5 months
Flu	Guillain-Barré Syndrome	1 year, 3 months
HPV	Systemic lupus erythematosus and a mid-brain stroke	3 years, 9 months
Flu	Transverse myelitis	1 year
Flu	Guillain-Barré Syndrome	1 year, 3 months
Tdap	Guillain-Barré Syndrome	10 months
Flu	Guillain-Barré Syndrome	11 months
Flu	Lipomyonecrosis of left deltoid area	11 months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 17

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Tetanus	Arm pain and lipomas	4 months
DTaP, Hep A	Guillain-Barré Syndrome	4 years, 8 months
Flu	Guillain-Barré Syndrome, Chronic inflammatory demyelinating polyneuropathy, and/or Transverse Myelitis	3 years, 10 months
Flu	Guillain-Barré Syndrome	2 years, 2 months
Flu	Guillain-Barré Syndrome	1 year, 10 months
Flu	Chronic inflammatory demyelinating polyneuropathy	3 years, 11 months
Tdap, Flu	Guillain-Barré Syndrome	3 years, 3 months
Flu	Aggravation of a neurological injury	1 year, 2 months
Flu	Chronic inflammatory demyelinating polyneuropathy	1 year, 10 months
Flu	Transverse myelitis	1 year, 5 months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 18

Adjudicated Settlements*

Reporting Period: 11/16/14 – 2/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Guillain-Barré Syndrome	1 year, 4 months
Tdap, Flu	Guillain-Barré Syndrome	1 year

Total Number of Judgments Adopting Settlement this reporting period: 92

*Terms of settlement are memorialized by Stipulation

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Appendix

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Glossary of Terms

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

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Glossary of Terms

- **Settlement:** Petition is resolved via a negotiated settlement between the parties, and results in the filing of a stipulation that memorializes the terms of the settlement.
- **Decision:** Special Master issues decision on the merits of the petition.
- **Non-compensable/Dismissed:** Petition dismissed.
- **Proffer:** After discussions between the parties regarding a reasonable amount of damages, respondent will file a suggested award of compensation, known within the Program as a "Proffer," which is also agreed to by petitioners and their counsel. The Proffer is reviewed by the presiding special master to determine that it represents a reasonable measure of the amount of the award and describes compensation pursuant to 42 U.S.C. § 300aa-15(a). The special master issues a final decision consistent with the terms of the Proffer.

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Glossary of Terms

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

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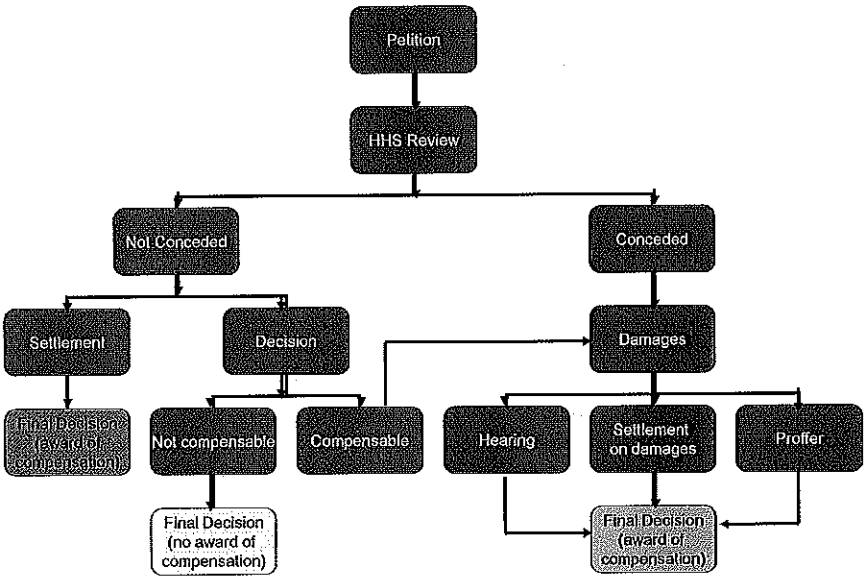
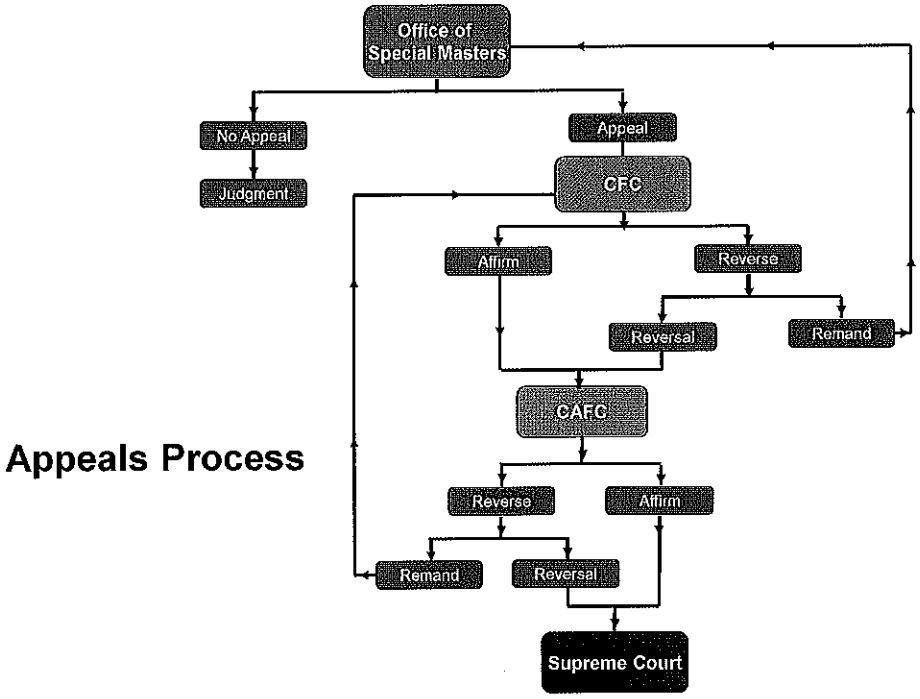
Petition Processing in the Office of Special Masters



24

Levels of Appeal in Vaccine Act Cases

Appeals Process



Updated for the March 2015 ACCV Meeting
Prepared by the U.S. Department of Justice (DOJ)
U.S. Court of Appeals for the Federal Circuit (CAFC) / U.S. Supreme Court

Entitlement

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

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

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

Statute of Limitations

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

Death Benefits/Survivorship

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

Attorneys' Fees and Costs/Interim Fees Requests

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

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

5.3

5.4

5.5

HPV (Human Papillomavirus) Vaccine: What You Need to Know [Gardasil-9®]

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

1. Why get vaccinated?

The vaccine you are getting Gardasil-9 prevents many cancers caused by human papillomavirus (HPV) infections.

Gardasil-9 prevents

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females, and
- **anal cancer** in females and males.
- In addition to these cancers, Gardasil-9 also prevents **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cancers.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans get infected every year. Many infections will go away and not lead to serious problems. But thousands of women and men get cancer and diseases from HPV.

2. HPV vaccine

Gardasil-9 is one of three FDA-approved HPV vaccines. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given through age 26 years for females and through age 15 [or 21] years for males.

Three doses of Gardasil-9 are recommended with the second and third dose 2 months and 6 months after the first dose.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

3. Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.

  Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.

- HPV vaccine is not recommended for pregnant women. But if you learn that you were pregnant when you were vaccinated it is not a reason to end the pregnancy. Women who are breastfeeding may be vaccinated. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's HPV in pregnancy registry at 1-800-986-8999.

- If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any problems with it.

Mild or moderate problems following Gardasil-9

- Reactions in the arm where the shot was given:
  - Pain (about 9 people in 10)
  - Redness or swelling (about 1 person in 3)
- Fever:
  - Mild (100°F) (about 1 person in 10)
  - Moderate (102°F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.

- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely, and is temporary.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

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

5. What if there is a serious reaction?

What should I look for?

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

  Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually 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 to the nearest hospital. Otherwise, call your doctor.

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

VAERS does not give medical advice.

6. The National Vaccine Injury Compensation Program

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

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

7. How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.

- Contact the Centers for Disease Control and Prevention (CDC):

- Call **1-800-232-4636 (1-800-CDC-INFO)** or
- Visit CDC's website at **www.cdc.gov/hpv**

Vaccine Information Statement
HPV Vaccine (Gardasil-9)
[Date]
42 U.S.C. § 300aa-26

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

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Vaccine Information Statement

Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know

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

1. Why get vaccinated?

Vaccination can protect both children and adults from **pneumococcal disease.**

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can lead to serious infections of the:
- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease, but children are at the greatest risk, particularly children under 2 years of age. People with certain medical conditions, adults over 65, and cigarette smokers are also at higher risk.

Before there was a vaccine, the United States saw:
- more than 700 cases of meningitis,
- 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths

from pneumococcal disease each year in children under 5.

Since vaccine became available, cases of invasive pneumococcal disease in these children have fallen from an estimated 16,000 a year to about 1,900 – a drop of 88%.

2. PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13 or Prevnar® 13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for people with certain health conditions and for all adults 65 years of age and older. Your doctor can give you details.

3. Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7 (or Prevnar), or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. *Tell your doctor if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is sick, your healthcare provider might decide to reschedule the shot on another day.

Your healthcare provider can give you more information.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get PCV13 vaccine do not have any problems with it.

Problems reported following PCV13 vary by age and by which dose of the series, but generally:

- About half of children became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported redness, pain, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.

- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely, and is temporary.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

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

5. What if there is a serious reaction?

What should I look for?

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

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually 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 does not give medical advice.

6. The National Vaccine Injury Compensation Program

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

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

7. How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement
PCV13 Vaccine
(Date)
42 U.S.C. § 300aa-26

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

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Vaccine Information Statement

Pneumococcal Polysaccharide Vaccine: What You Need to Know

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

1. Why get vaccinated?

Vaccination can protect adults and some children from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact.

It can lead to serious infections of the:
- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain (meningitis).

Meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease. People with certain medical conditions, adults over 65, and cigarette smokers are also at higher risk for pneumococcal disease.

Pneumococcal pneumonia kills about 1 out of 20 people who get it. Bacteremia kills about 1 person in 5, and meningitis about 3 people in 10.

Treatment of pneumococcal infections with penicillin and other drugs used to be more effective. But some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2. Pneumococcal polysaccharide vaccine (PPSV23)

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

PPSV23 is recommended for:
- All adults 65 years of age and older,
- Anyone 2 through 64 years of age with certain long-term health problems,
- Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.

Most people need only one dose of PPSV. A second dose is recommended for certain high-risk groups. People 65 and older should get a dose even if they have gotten the vaccine before they turned 65.

Your healthcare provider can give you more information about these recommendations.

Most healthy adults develop protection within 2 to 3 weeks of getting the shot.

3. Some people should not get this vaccine

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Children less than 2 years of age.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given, which go away within about two days.

Less than 1% develop a fever, muscle aches, or more severe local reactions.

Problems that could happen after any vaccine:

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

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

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

5. What if there is a severe 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 usually 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 does not give medical advice.

6. How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement
PPSV
(Date)

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

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5.6

Immunization Safety Office Updates

Centers for Disease Control and Prevention

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

Advisory Commission on Childhood Vaccines (ACCV)
March 4, 2015

Topics

- Immunization Safety Office highlights
- February 2015 ACIP meeting preview
- Selected publications

VAERS 2.0 development

- Vaccine Adverse Event Reporting System (VAERS) form 2.0 development
  - 60 day public comment period on the Federal Register closed January 23, 2015
  - 19 comments received (http://www.regulations.gov/#!documentDetail;D=CDC-2014-0015-0001)
  - Immunization Safety Office staff are reviewing comments and making revisions where appropriate

3

Clinical Immunization Safety Assessment (CISA) Project research studies in progress

1. Fever after Inactivated Influenza Vaccine (IIV) and Live Attenuated Influenza Vaccine (LAIV) in Young Children (NCT01764269)*
2. Flares after IIV in Children with Systemic Lupus Erythematosus (SLE) (NCT02006784)*
3. Monitoring Influenza Vaccine Safety in Pregnant Women Using Text Messaging (NCT01974050)*
4. Effect of IIV on Reproductive Hormones (NCT01978262)*
5. Effect of Prophylactic Antipyretics on IIV Immune Response and Fever (NCT02212990)*
6. Clinical Study of Tdap Vaccine Safety in Pregnant Women (NCT02209623)*
7. Assessing Fever and Wheeze after Pediatric Influenza Vaccines Using Text Messaging (NCT02295007)*
8. Post-vaccination Syncope Prevention with Water (NCT02353390)*

* https://clinicaltrials.gov/

4

February 2015 ACIP meeting* preview
(February 25-26, 2015)

- Meningococcal Vaccines
  - Vote on proposed recommendations for use of MenB vaccine in high-risk groups
  - Information and discussion on considerations for routine use of meningitis B vaccines in adolescents
- Influenza
  - Preliminary 2015-14 vaccine effectiveness estimates
  - Presentations concerning LAIV and VE for information and discussion, and for possible vote based upon the findings to be presented at the meeting
  - Vote on re-affirming annual recommendation for influenza vaccination for all people 6 months of age and older

*http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-02.pdf

5

February 2015 ACIP meeting* preview
(February 25-26, 2015)

- Yellow Fever Vaccine
  - Vote on proposed recommendations for yellow fever vaccine booster dose
- Influenza A (H5N1) Vaccine
  - Vote on vaccine policy options
- Human Papillomavirus (HPV) Vaccines
  - Vote on proposed recommendations for use of HPV9 vaccine
- Smallpox Vaccine: use in laboratory personnel
  - Vote on revised smallpox vaccine recommendations

*http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-02.pdf

6

Selected publications

- Klein et al. Safety of Measles-Containing Vaccines in 1-Year-Old Children. Pediatrics. 2015 Jan 5. pii: peds.2014-1822.
  - This study did not identify any new safety concerns comparing MMRV with MMR + V or after either the MMRV or the MMR + V vaccine; outcomes included anaphylaxis, ITP, ataxia, arthritis, meningitis/encephalitis, acute disseminated encephalomyelitis, Kawasaki disease, seizure, and fever. Risks for the 7 main outcomes were not significantly different. Several outcomes had few or zero postvaccination events. This study provides reassurance that these outcomes are unlikely after either vaccine.

7

Selected publications

- Abrams et al. Childhood vaccines and Kawasaki disease, Vaccine Safety Datalink, 1996-2006. Vaccine. 2015 Jan 3;33(2):382-7.
  - Childhood vaccinations studied did not increase the risk of Kawasaki disease; conversely, vaccination was associated with a transient decrease in Kawasaki disease incidence. Verifying and understanding this potential protective effect could yield clues to the underlying etiology of Kawasaki disease.

8

Selected publications

- Sukumaran et al. (Adverse events following measles, mumps, and rubella vaccine in adults reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013. Clin Infect Dis. 2015 Jan 30. pii: civ061. [Epub ahead of print].
  - In this review of VAERS data, there were no new or unexpected safety concerns detected for MMR vaccination in adults. There were reports identified of pregnant women exposed to MMR which is a group in whom the vaccine is contraindicated, suggesting the need for continued provider education on vaccine recommendations and screening

9

Selected publications

- Moro et al. Adverse Events following Haemophilus influenzae Type b Vaccines in the Vaccine Adverse Event Reporting System, 1990-2013. J Pediatr. 2015 Jan 15. pii: S0022-3476(14)01163-9.
  - This review of VAERS reports did not identify any new or unexpected safety concerns for Hib vaccines.
- Moro et al. Safety of quadrivalent human papillomavirus vaccine (Gardasil®) in pregnancy: Adverse events among non-manufacturer reports in the Vaccine Adverse Event Reporting System, 2006-2013. Vaccine. 2015 Jan 15;33(4):519-22.
  - This review of VAERS non-manufacturer reports following vaccination with HPV4 in pregnancy did not find any unexpected patterns in maternal or fetal outcomes.

10

Centers for Disease Control and Prevention
Atlanta, GA

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

Thank You

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

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

5.7

Vaccine Activities Update

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

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

March 2015

National Institute of Allergy and Infectious Diseases

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

National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov
Monday, February 2, 2015

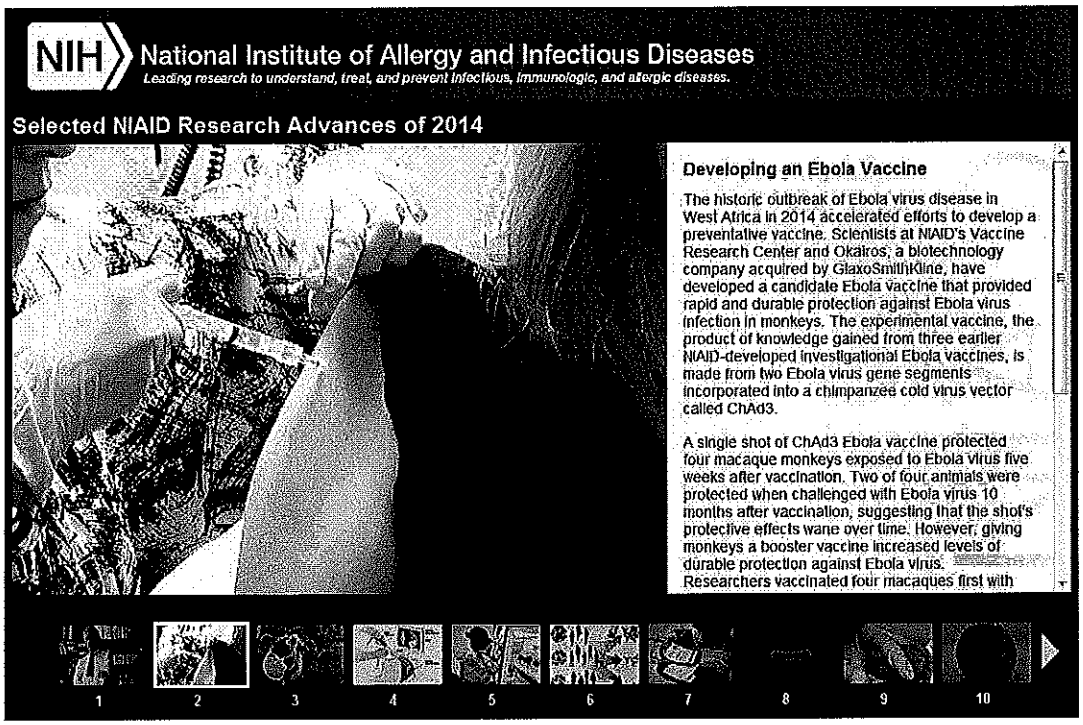
Ebola Vaccine Trial Opens in Liberia

Study Led by Liberia-NIH Partnership Will Test Two Experimental Vaccines

Including Pregnant Women in Clinical Trials: Antimicrobials & Vaccines

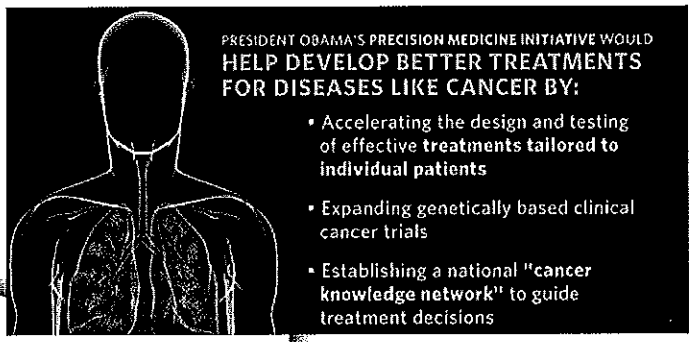
Nesin M, Frew PM, Read JS (editors). Including Pregnant Women in Clinical Trials of Antimicrobials and Vaccines. *Clinical Infectious Diseases.* 2014 Dec 15;59 Suppl 7: S395 - S444

NIAID Showcase



www.niaid.nih.gov/about/Pages/2014.aspx

Precision Medicine Initiative



January 30, 2015

The NEW ENGLAND JOURNAL of MEDICINE

A New Initiative on Precision Medicine

Francis S. Collins, M.D., Ph.D. & Harold Varmus, M.D.

www.nih.gov/precisionmedicine

NIH National Institute of Allergy and Infectious Diseases

5.8

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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

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

Outline

- Recent Approvals
- Pregnancy and Lactation Labeling Rule
- Upcoming Meetings and Events
- Global Public Health Activities

Vaccine Approvals

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

Trumenba, Meningococcal Vaccine

- Approved in October 2014
- First vaccine licensed in the United States to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B
- Age Indication:
  - Individuals 10 through 25 years of age.
- Trumenba was granted Breakthrough therapy status, which is intended to expedite the development and review of medical products that address a serious or life-threatening condition.

Bexsero, Meningococcal Vaccine

- Approved in January 2015,
- For the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B
- Age Indication: individuals 10 through 25 years of age.
- It is the second vaccine approved by FDA in the past three months to prevent this disease.
- Bexsero was designated Breakthrough therapy and this BLA was reviewed under the Priority Review schedule.

5

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

Human Papillomavirus 9-valent Vaccine, Recombinant, Gardasil 9

- Approved in December 2014
- Indication: For prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, and for the prevention of genital warts caused by HPV types 6 or 11.
- Age indication
  - Females ages 9 through 26
  - Males ages 9 through 15
- Gardasil 9 adds protection against five additional HPV types—31, 33, 45, 52 and 58— which cause approximately 20 percent of cervical cancers and are not covered by previously FDA-approved HPV vaccines.

6

Prevnar 13 - BLA Supplement

- In January 2015, OVRR approved a supplement to the BLA for Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein), Prevnar 13®
  - To include language in the US Package Insert (USPI) regarding the effect of prophylactic antipyretic medication on the immunogenicity of Prevnar 13 when given with routine pediatric vaccinations in healthy infants.
- The PCV13 immunogenicity data suggest that acetaminophen used prophylactically, but not for treatment of fever, in infants, may result in reduced antibody responses to certain vaccine serotypes following PCV13 immunization.

7

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

Pneumovax 23 - BLA Supplement

- In December 2014, OVRR approved a supplement to the BLA for Pneumococcal Vaccine, Polyvalent, PNEUMOVAX ® 23, to include a 2D barcode on the single dose pre-filled syringe label.
- 2D barcodes contain the vaccine product identification information as well as the lot number and expiration date.

8

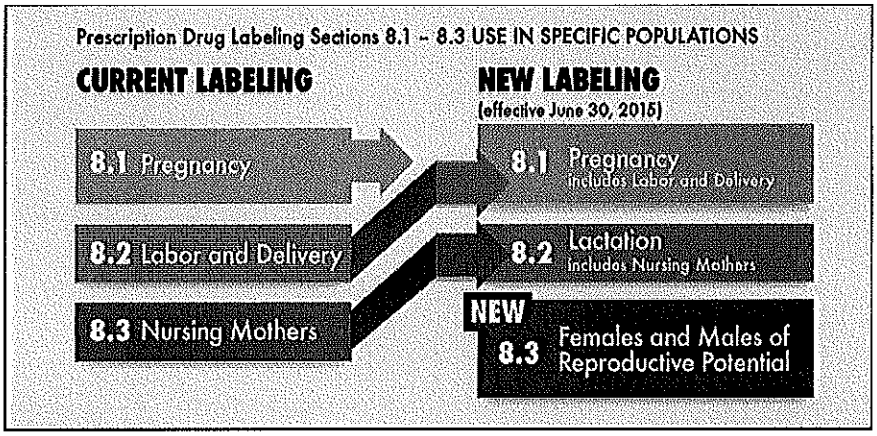
Pregnancy and Lactation Labeling Rule

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

Pregnancy and Lactation Labeling Rule

- In December 2014, the FDA published the *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling*
- The PLLR requires changes to the content and format for information presented in prescription drug labeling in the Physician Labeling Rule (PLR) format to assist health care providers in assessing benefit versus risk and in subsequent counseling of pregnant women and nursing mothers who need to take medication, thus allowing them to make informed and educated decisions for themselves and their children.
- The PLLR removes pregnancy letter categories – A, B, C, D and X. The PLLR also requires the label to be updated when information becomes outdated.

Pregnancy and Lactation Labeling Rule



11

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

Upcoming Meeting

12

Advisory Committee Meeting

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

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

Global Public Health Activities

Global Public Health

In response to the Ebola epidemic in West Africa, FDA is continuing to work with federal partners, the medical and scientific community, industry, and international organizations and regulators to assess investigational products and provide regulatory pathways that may expedite the development and availability of products.

5.9

National Vaccine Program Office Update

ACCV, March 2015

Dr. Karin Bok

National Vaccine Program Office

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

NV-VSR-15-001: Our objective is to conduct research in vaccine safety that:

- determines the safety profile of new vaccines during the early development stage,
- develops or modifies existing vaccines to improve their safety,
- directly impacts the current vaccine safety monitoring system, and/or
- produces consensus definitions of vaccine safety outcomes that could be utilized to collect consensus data in clinical research conducted globally

National Vaccine Program Office

COOPERATIVE AGREEMENT: RESEARCH, MONITORING AND OUTCOMES DEFINITIONS FOR VACCINE SAFETY

- **Projects Related to Pregnant Women and Newborns**

Of particular interest are projects related to researching, establishing or testing the vaccine safety profile of vaccines that are either currently recommended for, or are expected to be, routinely administered to pregnant women and/or newborns. Topics of research may cover establishing the safety of a vaccine in either the pregnant woman, her newborn or both, at any stage of the vaccine development, testing and/or pre-clinical or clinical research and monitoring of vaccine safety.

National Vaccine Program Office

COOPERATIVE AGREEMENT: RESEARCH, MONITORING AND OUTCOMES DEFINITIONS FOR VACCINE SAFETY

PILOT COOPERATIVE AGREEMENT

- TWO AWARDS OF $250,00 EACH

- ONE YEAR DURATION

http://www.grants.gov/web/grants/view-opportunity.html?oppId=271393

National Vaccine Program Office

VACCINE SAFETY SCIENTIFIC AGENDA:
IMMUNIZATION SAFETY TASK FORCE

- All Federal partners involved in vaccine safety drafted this document

Anderson, Steven Food and Drug Administration	**Bok, Karin** Office of the Assistant Secretary for Health	**Carrillo, Jorge** Department of Defense	**Collins, Limone** Department of Defense	**Conlin, Ava** Department of Defense
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Leading Institution	Safety System	Objectives
CDC and FDA	*Vaccine Adverse Event Reporting System (VAERS)*	*Receives reports of possible adverse events from a variety of sources, including parents, providers, manufacturers, pharmacists, and the military, and rapidly detects "signals": possible adverse events for follow up. http://vaers.hhs.gov/about/index*
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DOD	*Defense Health Agency-Immunization Healthcare Branch (DHA-IHB)*	*Researches adverse events using electronic health records and can contact individuals when consultation for follow-up or care is needed. Can follow up on VAERS signal detections. https://www.vaccines.mil/*
DOD	*Armed Forces Health Surveillance Center (AFHSC)*	*Supports post-marketing database studies http://www.afhsc.mil/home*
VA	*Adverse Drug Event Reporting System (ADERS)*	*Reports, tracks and monitors adverse events caused by medications and vaccines across the entire VA health care system using a passive surveillance system comparable and linked to VAERS. http://www.pbm.va.gov/PBM/vacenterformedicationsafety/vacenterformedicationsafetyadverseeventtrackingtools.asp*
VA	*Center for Medication Safety (VAMedSAFE)*	*Obtains data from VA ADERS and VA Integrated Databases to track the safety of vaccines administered in the VA healthcare system. http://www.pbm.va.gov/vacenterformedicationsafety/vacenterformedicationsafetyaboutus.asp*

Leading Institution	Vaccine Safety Research Topic	Research Plan
CDC and FDA	Vaccine recipient's individual risk factors	(1) improve safety monitoring and assessment by defining which sub-populations should be monitored, (2) identify individuals at increased risk for AEFIs, (3) improve the clinical approaches to treating AEFIs, (4) develop advanced vaccines with a decreased likelihood of AEFI occurrence, and (5) enhance risk communication about the safety of vaccines, particularly with regard to groups identified at higher risk for AEFIs.
FDA	General vaccine safety studies	Research potential safety concerns of newly licensed products such as autoimmune diseases or anaphylaxis
FDA	Concomitant and multiple dose vaccine administration	Study potential AEFIs that may arise after administering concomitant vaccine doses and multiple dose vaccines given at recommended intervals
FDA	Study of vulnerable populations	Vaccine safety research on special populations such as pregnant women
FDA	Safety evaluation methodology testing	Improve sensitivity and eliminate analytic bias when studying vaccine administration outcomes
CDC	Prevention of AEFI	Assessment of vaccine products, dosing and administration to identify factors that could be modified to avoid AEFIs
CDC	Assessing safety of new vaccines	CDC monitors new vaccines after their introduction using spontaneous reporting systems, and conducts population-based surveillance using electronic health data
CDC	Assessing vaccine safety in understudied populations	Special populations, such as pregnant women, immune deficient patients, and special ethnicities, have been historically excluded from vaccine clinical trials. CDC evaluates vaccine safety among these populations as well
CDC	Continued research on statistical methods and study design	Because of the complexity of studying populations receiving vaccines, sophisticated statistical methods and study designs are being developed and refined for both active and passive surveillance. Continuing to refine near real-time surveillance techniques (e.g., rapid cycle analysis, RCA)
CDC	Communications Research	Research on knowledge, attitudes, beliefs, and behaviors related to vaccine safety and AEFI reporting, and continuously improving strategies for communicating risks
DOD and VA	Pandemic Vaccination Safety	Utilizes near real-time analysis to identify possible safety signals
DOD	Detecting AEFIs in special populations	Pregnancy registries are mined to assess maternal and fetal/infant outcomes after vaccination
VA	Seasonal flu active safety surveillance	Identify possible adverse outcomes in the VA healthcare system such as GBS, anaphylaxis, Bell's palsy, encephalitis, meningitis, idiopathic thrombocytopenia, optic neuritis, seizures and convulsions
VA	End of season analysis	Yearly assessment of influenza vaccine associated AEFIs in the VA healthcare system

National Vaccine Program Office

THANK YOU

National Vaccine Program Office

Vaccine Safety Scientific Agenda

Vaccines are one of the most important measures available to support and protect public health. While vaccines have substantial benefits, it is also important to assess their safety during discovery and development, regulatory approval, recommendations for use, and subsequent post-marketing surveillance. In the U.S. vaccine safety evaluation is overseen and coordinated by federal departments and agencies. The key federal departments with a role in vaccine safety activities include the U.S. Department of Health and Human Service (**HHS**, which includes the Centers for Disease Control and Prevention, **CDC**; the Food and Drug Administration, **FDA**; the Health Resources and Services Administration, **HRSA**; the National Institutes of Health, **NIH**; the Centers for Medicare and Medicaid Services, **CMS**; the Indian Health Service, **IHS**; the National Vaccine Program Office, **NVPO**, and the Biomedical Advanced Research and Development Authority, **BARDA**), the U.S Department of Defense (**DoD**), and the U.S. Department of Veteran Affairs (**VA**). While no medical intervention is 100 percent safe, the many components of the safety system provide multiple and overlapping levels of assurance of the safety of vaccines in the U.S.

NVPO's **National Vaccine Advisory Committee (NVAC)** advises the HHS' Assistant Secretary for Health on prevention of human infectious diseases through vaccine development, provides advice regarding how to evaluate and prevent adverse reactions to vaccines, and has recently evaluated and made recommendations on the state of the U.S. Vaccine Safety System (NVAC, 2011). NVPO also coordinates the **Immunization Safety Task Force (ISTF)** which promotes collaboration among all federal partners invested in vaccine safety activities. Highlighting the importance of vaccine safety, the 2010 National Vaccine Plan called for the development of a vaccine safety scientific agenda that would summarize the contributions of the federal partners to the overall safety of vaccines in the U.S. This document outlines the efforts of federal agencies on vaccine safety and the ongoing and planned associated scientific activities and interagency coordination that contribute to the safety system.

Pre-licensure (Discovery/Research and Development) Vaccine Safety Scientific Activities

The evaluation of vaccine safety is an important component of vaccine research and development. The NIH is the main federal partner during this stage, focusing on and supporting the basic and applied research that forms the foundation of vaccine development. As promising ideas develop into potential vaccine candidates, safety is considered during every step of the vaccine development pipeline. Consistent with FDA regulations and guidance documents, vaccine candidates are evaluated for safety in relevant animal models and other laboratory assessments before moving into clinical trials. All trials include a rigorous assessment of vaccine safety as a primary study objective, and study participants are closely monitored for any adverse events associated with vaccination (commonly referred to as adverse events following immunization or AEFIs). In addition to research on new vaccines, the NIH devotes substantial resources to developing improved vaccines that are more effective and have fewer side effects than currently licensed vaccines.

During the pre-licensure phase of vaccine development, when clinical trials are underway, the U.S. FDA's **Center for Biologics Evaluation and Research (CBER)** also plays a critical role in helping assure safety for research subjects, the quality of the scientific investigation, and that the vaccine clinical trial designs are adequate to permit an evaluation of vaccine safety and effectiveness. CBER's **Office of Vaccines Research and Review (OVRR)** research programs develop testing methods, reference materials, and other tools to evaluate the safety of vaccines, including the cell substrates used to manufacture vaccines. OVRR also develops and evaluates predictive pre-clinical models and other methods to screen novel vaccine components for potential adverse effects prior to clinical trials. A summary of the scientific activities at this stage of vaccine development is shown in Table 1 (please refer to the web links for updated and additional information).

Table 1.Pre-licensure Vaccine Safety Scientific Activities

Leading Institution	Vaccine Safety Activity	Scientific Agenda
NIH	*Identification and development of vaccine candidates*	*Develop and provide resources to facilitate basic and applied research including the ability to assess vaccines for safety and immunogenicity http://www.niaid.nih.gov/about/organization/vrc/Pages/default.aspx http://www.niaid.nih.gov/labsandresources/labs/aboutlabs/lid/Pages/default.aspx http://www.niaid.nih.gov/about/organization/dmid/Pages/default.aspx*
NIH	*Design of novel vaccine strategies*	*Support research to explore novel vaccine technologies and strategies to improve the immunization profile http://www.niaid.nih.gov/about/organization/dait/programs/Pages/basicImmunology.aspx*
NIH	*Investigate the variability in human immune responses*	*Support research to understand the range of variability in the human population that impacts responses to vaccines and potential associations with AEFIs*
NIH	*Improving vaccine immunomodulators, administration, and formulations*	*Discover and develop novel adjuvants, alternative routes of administration, and formulations*
FDA	*Vaccine development*	*Develop pre-clinical models, and vaccine efficacy and safety screening methodology http://www.fda.gov/BiologicsBloodVaccines/default.htm http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm350562.htm http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm*
FDA	*Study of pathogenicity*	*Study molecular mechanisms of pathogenicity and determine biomarkers of virulence that might improve the safety profile*

Regulatory Review and Licensure Vaccine Safety Scientific Activities

When an entity, usually a manufacturer, believes that a vaccine candidate has been shown to be safe and effective based on analysis of safety and efficacy in clinical trials and other data, it can submit a license application to the FDA for review. As part of the license application review process, CBER may convene the **Vaccines and Related Biological Products Advisory Committee (VRBPAC)** where the vaccine sponsor and the FDA present their findings. The VRBPAC, whose members are experts external to FDA, provides advice to the Agency regarding the safety and efficacy of the vaccine for the proposed indication. As part of its assessment of the license application, CBER conducts a rigorous review of manufacturing and product information, non-clinical pharmacology and toxicology data, and clinical studies to make a determination regarding licensure (or approval). If the data support the safety and effectiveness of the vaccine, it is licensed, which means that it can be commercially marketed. Following vaccine licensure, CBER and manufacturers conduct ongoing surveillance of the vaccine, including assessment of adverse events, lot release activities, and inspections of manufacturing facilities.

Post-Licensure Vaccine Safety Scientific Activities

Vaccine licensure does not guarantee that a vaccine will be recommended for routine use, and vaccines must undergo an additional step of expert review in order to be routinely recommended. The CDC's **Advisory Committee on Immunization Practices or ACIP** is an independent advisory committee that develops recommendations on how to use vaccines to control diseases in the U.S. (http://www.cdc.gov/vaccines/acip/index.html).

In addition, the federal agencies and departments that oversee and coordinate vaccine safety evaluation continuously monitor and conduct research on the safety of marketed vaccines being administered to the public. Continuing safety monitoring and research after a vaccine is introduced into the market and administered to the population is essential to detect rare adverse events that might have remained undetected during the developmental phase. A summary of the routine federal vaccine safety systems is detailed in Table 2 (please refer to the web links for details on specific scientific activities related to vaccine safety conducted by these systems).

Table 2. Routine Vaccine Safety Monitoring and Research Systems

Leading Institution	Safety System	Objectives
CDC and FDA	*Vaccine Adverse Event Reporting System (VAERS)*	*Receives reports of possible adverse events from a variety of sources, including parents, providers, manufacturers, pharmacists, and the military, and rapidly detects "signals": possible adverse events for follow up. http://vaers.hhs.gov/about/index*
CDC	*Vaccine Safety Datalink (VSD)*	*Rapidly tests, and confirms or rejects VAERS-generated signals. It links databases, including vaccination and medical records and allows for near real-time surveillance. http://www.cdc.gov/vaccinesafety/Activities/vsd.html*
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Following vaccine licensure, all the federal partners, HHS, DoD and VA also collaborate to conduct comprehensive product-specific safety research. Specific vaccine safety studies are developed based on questions or concerns raised from the medical literature, when there are new vaccines that have been recommended for use, if there are changes in how a vaccine is recommended, or there are reports to the Vaccine Adverse Event Reporting System (VAERS). Continued vaccine safety research is essential to advance knowledge of vaccine safety and inform clinical and public health practice.

Some of the current key projects are detailed in Table 3.

Table 3. Post-Licensure Vaccine Safety Research of Special Interest

Leading Institution	Vaccine Safety Research Topic	Research Plan
CDC and FDA	*Vaccine recipient's individual risk factors*	*(1) improve safety monitoring and assessment by defining which sub-populations should be monitored, (2) identify individuals at increased risk for AEFIs, (3) improve the clinical approaches to treating AEFIs, (4) develop advanced vaccines with a decreased likelihood of AEFI occurrence, and (5) enhance risk communication about the safety of vaccines, particularly with regard to groups identified at higher risk for AEFIs*
FDA	*General vaccine safety studies*	*Research potential safety concerns of newly licensed products such as autoimmune diseases or anaphylaxis*
FDA	*Concomitant and multiple dose vaccine administration*	*Study potential AEFIs that may arise after administering concomitant vaccine doses and multiple dose vaccines given at recommended intervals*
FDA	*Study of vulnerable populations*	*Vaccine safety research on special populations such as pregnant women*
FDA	*Safety evaluation methodology testing*	*Improve sensitivity and eliminate analytic bias when studying vaccine administration outcomes*
CDC	*Prevention of AEFI*	*Assessment of vaccine products, dosing and administration to identify factors that could be modified to avoid AEFIs*
CDC	*Assessing safety of new vaccines*	*CDC monitors new vaccines after their introduction using spontaneous reporting systems, and conducts population-based surveillance using electronic health data*
CDC	*Assessing vaccine safety in understudied populations*	*Special populations, such as pregnant women, immune deficient patients, and special ethnicities, have been historically excluded from vaccine clinical trials. CDC evaluates vaccine safety among these populations as well*
CDC	*Continued research on statistical methods and study design*	*Because of the complexity of studying populations receiving vaccines, sophisticated statistical methods and study designs are being developed and refined for both active and passive surveillance. Continuing to refine near real-time surveillance techniques (e.g., rapid cycle analysis, RCA)*
CDC	*Communications Research*	*Research on knowledge, attitudes, beliefs, and behaviors related to vaccine safety and AEFI reporting, and continuously improving strategies for communicating risks*
DOD and VA	*Pandemic Vaccination Safety*	*Utilizes near real-time analysis to identify possible safety signals*
DOD	*Detecting AEFIs in special populations*	*Pregnancy registries are mined to assess maternal and fetal/infant outcomes after vaccination*
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VA	*End of season analysis*	*Yearly assessment of influenza vaccine associated AEFIs in the VA healthcare system*

Final Remarks

The mechanisms employed by federal departments and agencies at each stage of a vaccine's development, its licensure, and during the post-marketing evaluation phase comprise a comprehensive vaccine safety enterprise. The individual components of the safety network are

designed to overlap and complement each other to ensure the highest degree of synergy and effectiveness possible as the safety of vaccines is evaluated and monitored.

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National Vaccine Advisory Committee-Vaccine Safety Working Group (2011). *U.S. Vaccine Safety System.* http://www.hhs.gov/nvpo/nvac/nvac_vswp.pdf

Abbreviations

VRBPAC: *Vaccines and Related Biological Products Advisory Committee*
CBER: *Center for Biologics Evaluation and Research*
PRISM: *Rapid Immunization Safety Monitoring*
ACIP: *Advisory Committee on Immunization Practices*
VAERS: *Vaccine Adverse Event Reporting System*
VSD: *Vaccine Safety Datalink*
CISA: *Clinical Immunization Safety Assessment Network*
NVAC: *National Vaccine Advisory Committee*
AEFI: *Adverse Event Following Immunization*
MILVAX-VHCN: *Military Vaccine Agency-Vaccine Healthcare Centers Network*
AFHSC: *Armed Forces Health Surveillance Center*
ADERS: *VA's Adverse Drug Event Reporting System*
VAMedSAFE: *Center for Medication Safety*
RCA: *Rapid Cycle Analysis*

6

6.1

» Print

Flu widespread in 43 U.S. states: CDC report

Mon, Jan 5 2015

By Julie Steenhuysen

CHICAGO (Reuters) - Flu is widespread in 43 U.S. states, up from 36 states in the prior week, the U.S. Centers for Disease Control and Prevention reported on Monday.

Six children died from the flu during the last full week in December, bringing the total flu deaths to 21 this season, the report showed.

Last week the CDC reported for the first time that deaths from flu and pneumonia reached an epidemic level, comprising 6.8 percent of all deaths. That figure slipped slightly below the epidemic level in this week's report, the CDC said.

"Last week was the first week that this particular number exceeded the epidemic threshold, but we've been in a flu epidemic for weeks now," said Dr. Michael Jhung, medical officer in the Centers for Disease Control and Prevention's Influenza Division.

The statistic is just one of many clues the CDC uses to gauge the severity of flu in the United States, which has a widespread outbreak - or an epidemic - every year.

Jhung reviews several factors when determining whether the flu season has started, suggesting the nation is in a period of epidemic. Initially, he considers the percentage of positive flu tests. When that exceeds 10 percent for 2 weeks, the season is starting. That happened around mid-November this season.

He also looks at the proportion of patients seeking care for influenza-related illnesses. When that exceeds 2 percent of visits, it is another sign of a flu epidemic.

This season, flu watchers are keenly focusing on hospital admissions because the current vaccine may not be a good match for the most common seasonal flu strain circulating in the United States known as influenza A (H3N2) virus.

Flu seasons dominated by H3N2 tend to have higher overall hospitalization rates and more flu-related deaths, especially among older people and very young children compared with flu seasons dominated by the H1N1 virus or influenza B viruses.

In the latest CDC report, flu hospitalizations, a key measure of severity, have reached 12.6 per 100,000 for all ages. Last season, the rate was 5.8 per 100,000 and in 2012, the most recent season dominated by H2N3, the rate was 8.1 percent.

"We are above that now," Jhung said, suggesting this flu season "is at least as severe as 2012 was."

(Reporting by Julie Steenhuysen; Editing by Richard Chang)

6.2

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA News Release

FDA approves a second vaccine to prevent serogroup B meningococcal disease

For Immediate Release

January 23, 2015

Release

The U.S. Food and Drug Administration today approved Bexsero, a vaccine to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B in individuals 10 through 25 years of age.

Bexsero is the second vaccine approved by the FDA in the past three months to prevent this disease. The agency approved the first meningococcal serogroup B vaccine in October 2014. Before these approvals, existing approved meningococcal vaccines in the U.S. covered only four of the five main serogroups of N. meningitidis bacteria that cause meningococcal disease: A, C, Y and W.

Meningococcal disease is a life-threatening illness caused by bacteria that can infect the bloodstream (sepsis) and the lining that surrounds the brain and spinal cord (meningitis). N. meningitidis is a leading cause of bacterial meningitis. The bacteria are transmitted from person to person through respiratory or throat secretions (e.g., by coughing, kissing or sharing eating utensils). According to the Centers for Disease Control and Prevention, about 500 total cases of meningococcal disease were reported in the U.S. in 2012, of which 160 were caused by serogroup B.

"With today's approval of Bexsero, the U.S. now has two vaccines for the prevention of serogroup B meningococcal disease," said Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research. "The approval of these vaccines represents a major public health accomplishment toward preventing this life-threatening disease."

Meningococcal disease can be treated with antibiotics to reduce the risk of death or serious long-term problems, but even with immediate medical attention these outcomes are not always prevented. Vaccination is the most effective way to prevent meningococcal disease.

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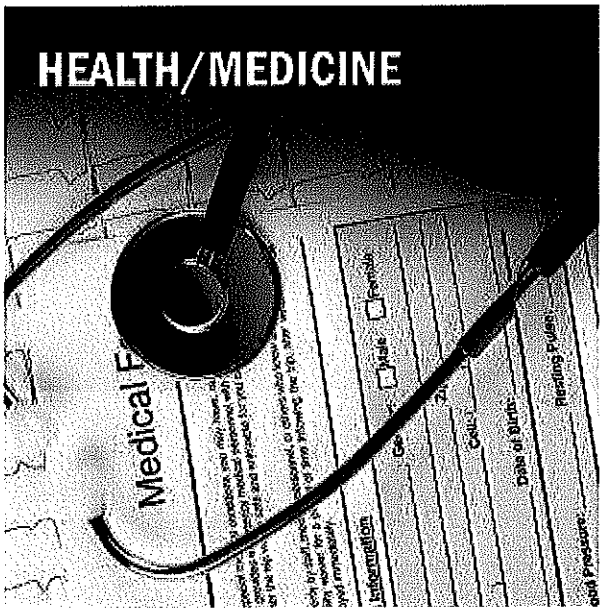
Related Information

- FDA: Vaccines (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm)
- CDC Information on Meningococcal Disease (http://www.cdc.gov/meningococcal/about/index.html)

6.3

215 cases of whooping cough in January; vaccinations urged



FEBRUARY 02, 2015 10:30 PM • BY ERIN ANDERSEN | LINCOLN JOURNAL STAR

In January, 215 cases of whooping cough were diagnosed in Nebraska and, as case numbers continue to rise, parents are being encouraged to vaccinate their children.

"There were more than 200 whooping cough cases in January, which is higher than some of our total case numbers for previous years, and that's concerning," said Dr. Joseph Acierno, chief medical officer and director of public health for the Department of Health and Human Services.

"Parents should check their children's vaccination records, as well as their own, to make sure everyone is protected," he said.

Of those cases, 162 were in Lancaster County, said Tim Timmons, communicable disease specialist with the Lincoln-Lancaster County Health Department. Of those cases, 51 have been confirmed, the remainder are probable cases of whooping cough, Timmons said.

In all of 2014, there were 395 confirmed and probable cases of whooping cough in Nebraska -- a significantly higher number than in previous years, dating back to 2004. Of those, 198 were Lancaster County cases and 104 of those were in December, Timmons said.

In a typical year, the county sees about 40 cases, Timmons said.

Whooping cough, also known as pertussis, is a highly contagious disease marked by severe coughing. Pertussis is caused by bacteria found in the mouth, nose and throat of an infected person, and is spread through close contact -- particularly when a person coughs or sneezes.

Whooping cough can affect people of all ages, but can be life-threatening for infants under a year old. Older children, teens and adults can spread the disease to infants and young children, which is why the state is encouraging anyone who has contact with babies, toddlers and school-age children to be vaccinated against whooping cough.

Children are vaccinated against diphtheria, tetanus and whooping cough as part of a five-shot series given at ages 2, 4, 6 and 15 to 18 months of age, and just before starting school. Nebraska law also requires a booster shot before entering the seventh grade.

Because many of the current cases of whooping cough are among children ages 6 to 19, who were up-to-date on vaccinations, the thought is the vaccine may lose its effectiveness over time. Health workers have also identified a new strain of pertussis.

Medical professionals recommend anyone under the age of 65 who has not received a pertussis-containing vaccine as an adult, to get a Tdap (tetanus, diphtheria and pertussis) booster vaccine.

People diagnosed with pertussis should also be prescribed antibiotics. While the medication will not shorten the bout of pertussis, which is often called "the 100-day cough" it can lessen the length of time a person is contagious.

To limit the spread, people with whooping cough should stay home from work, school and other public places for the full five-day course of antibiotic treatment. Those not receiving antibiotics should stay home for three weeks after the first onset of violent coughing, Timmons said.

For vaccination information, contact your healthcare provider or health department. Information can also be found at dhhs.ne.gov/immunization or by calling 402-471-6423.

6.4

www.medscape.com

The 2015 Child/Teen Immunization Schedule: Changes You Should Know

William T. Basco, Jr., MD, MS | February 02, 2015

Update on the 2015 Child and Adolescent Vaccine Schedule Recommendations

It's that time of year, when pediatric providers begin to look for any vaccine schedule changes recommended by the Advisory Committee on Immunization Practices (ACIP) at the Centers for Disease Control and Prevention (CDC). The most recent recommendations[1] were released on January 26 but will not be published in *Pediatrics* as they have been in the past. Instead, the schedules will be provided only online, allowing for real-time updates as any recommendations or products change. For those who are wedded to having a wall chart, however, color PDFs of the recommended schedule and the usual accompanying footnotes can be downloaded, printed, and placed on the office wall.

Compared with last year, there are relatively few changes to the recommendations or footnotes.

For some extensive past footnote revisions that still may be worth reviewing, see my commentary from last year related to changes in hepatitis A vaccine recommendations for infants who will be traveling and important changes in recommendations regarding when and how to sequence pneumococcal polysaccharide vaccine (PPSV23) and pneumococcal conjugate vaccine (PCV13). Given the small number of changes to the actual vaccine schedule, I will emphasize some of the new footnote details and some of the specific changes.

Advantages of Online Charts

One of the advantages of the online schedule is that the footnotes are now links within the chart.

First, both the main and catch-up online charts are broken up into smaller age groups, allowing more detail to be placed on the charts themselves, thereby decreasing the need to always refer to the footnotes.

The first routine chart covers birth to 15 months, with the second covering 18 months to 18 years. The sequential footnotes can be accessed by simply scrolling down after the charts. The catch-up vaccine charts are divided into small age windows, such as 4 months to 6 years, and provide catch-up recommendations for all of the preschool vaccinations. In addition, each of these catch-up vaccine charts is appropriately indexed with hyperlinks to its own footnotes and other resources.

Another advantage of the online chart is that each numerical footnote on the chart is hyperlinked to the corresponding footnote text, allowing quick navigation to the needed information. In addition, the end of each footnote section contains a link to the catch-up vaccination schedule. When clicking on the catch-up vaccination schedule link, the chart appears again and is much easier to follow than were the old footnotes.

As an example of the additional detail displayed on the charts themselves, previously the ages at which some children would "age out" of the need for specific vaccines (eg, only one *Haemophilus influenzae* B vaccine is recommended after age 15 months) were conveyed in the footnotes. However, these age-out provisions are now shown directly on the charts.

Influenza vaccine. Most of the changes to the influenza vaccine section include additional clarifications and some contraindications. Previously, the guidance had listed asthma, a history of wheezing in the 12 months prior to vaccination, or any underlying medical condition that predisposed to influenza complications as contraindications. Additional contraindications listed this year that are specific to live-attenuated influenza vaccine (LAIV) include:

1. Persons who have experienced severe allergic reactions to LAIV, to any of its components, or to a previous dose of any other influenza vaccine;

2. Children 2 through 17 years receiving aspirin or aspirin-containing products;

3. Persons who are allergic to eggs;

4. Pregnant women;

5. Immunosuppressed persons;

6. Children 2 through 4 years of age with asthma or who had wheezing in the past 12 months; or

7. Persons who have taken influenza antiviral medications in the previous 48 hours.

The updated chart graphically offers additional detail about what vaccines should be given at 6 months to 2 years (inactivated only), the fact that many children 6 months to 9 years will need two vaccines, and the fact that children ≥ 9 years need only one, all providing much more detail than the 2014 chart.

Measles, mumps, rubella (MMR). This chart now displays a purple bar that hyperlinks to a footnote, detailing specific MMR vaccination recommendations for infants < 12 months old. Children < 12 months old who travel internationally should receive one dose before departure. However, note that these children will *still* require the usual two-dose schedule, beginning at the usual age of 12 months, as they age. In a similar vein, any child who is 12 months or older and travelling internationally should receive two doses of MMR vaccine starting at 12 months, and given at least 4 weeks apart, all prior to departure.

Meningococcal vaccine. There are no changes in the recommendations for which patients should receive the meningococcal vaccine on a routine basis or for the "high-risk" groups who should also receive it. The high-risk groups include children with functional or anatomic asplenia, children with persistent complement component deficiency, and children traveling to endemic areas. The major change here is the change in the footnote display. The new footnote section for meningococcal vaccine is almost chart-like, with clearer distinctions of what each child should receive based on which of the three approved preparations (MenACWY-CRM, MenACWY-D, or Hib-MenCY-TT) the child received.

Overall, the 2015 schedule contains minor alterations to the actual recommendations but some substantial improvements in the "user-friendliness" of the charts. Finally, the online schedule includes links to some great parental vaccine resources, including parent- and child-friendly graphical charts of vaccine recommendations and a tool that one can use to give parents a dated schedule specific to their child about when each of the vaccines should be received. Check it out!

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6.5

Parents of Vaccine-Injured Children Speak Out: 'The Guilt Is Huge'

Beth Greenfield | Senior Writer | February 17, 2015

Susan Lawson and her daughter Julia. Photo courtesy of Susan Lawson.

When Susan Lawson of Colorado hears parents declaring, unequivocally, that everyone should vaccinate their children because it's perfectly safe, she says it feels "like a punch in the gut." That's because she's seen another side of the story: Her daughter Julia, now 9, was left with permanent brain damage — an injury acknowledged by a federal court payout — after receiving her MMRV (measles-mumps-rubella-varicella) shot when she was a year old.

***STORY:** Why You Should, and Shouldn't, Worry About Measles*

Lawson tells Yahoo Parenting that one morning, about a week after Julia received the shot, her now-ex-husband found their daughter in a terrifying state. "She was blue and cold and her body was arched, her eyes were looking in opposite directions, and she was covered in feces and vomit," she recalls. "We thought she was dead." She was rushed to the hospital, where doctors said she was having seizures, and she was put into a medically induced coma. Julia spent many days in intensive care and the neurology ward before being sent home with the diagnosis of encephalitis, or swelling of the brain.

STORY: Please Vaccinate Your Healthy Kid — to Keep Mine Safe

Lawson, a veterinarian who had the utmost faith in medicine, had never before questioned vaccinations, and had always inoculated Julia right on schedule. But now she began to wonder. Hospital doctors dismissed any thought of a connection. But when Lawson asked a pediatrician about it, she was told it could be a possibility. Every family featured in this story received a payment by the United States Court of Federal Claims, which concluded that their rare injuries were caused by the vaccines.

***STORY:** Should Pediatricians Refuse to Treat Unvaccinated Families?*

"I felt shocked, bewildered, and guilty," Lawson recalls. "We were trying to protect her, and instead I destroyed her. The guilt is huge."

The pediatrician helped Lawson file a notice through the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Lawson then hired a vaccine-injury attorney and began what became a trying, four-year journey through the country's National Vaccine Injury Compensation Program of the US Court of Federal Claims — a specific, no-fault forum for vaccine injuries or

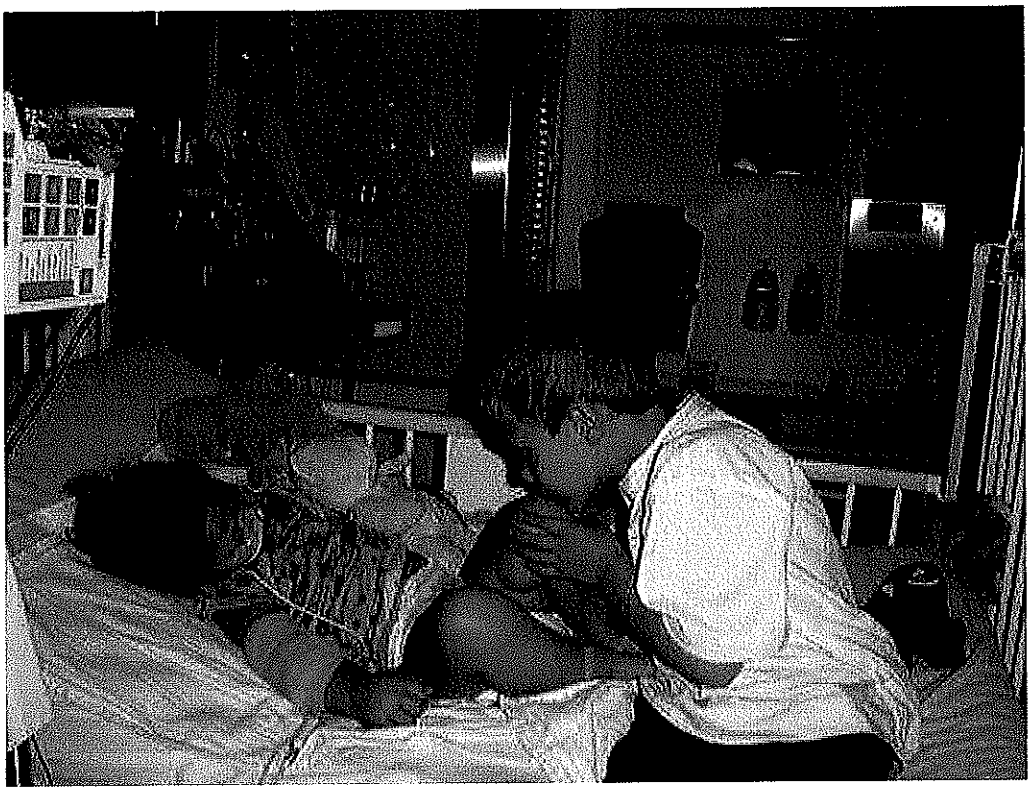
deaths, set up by Congress in 1986 to ensure justice for children (and, as clarified by the Supreme Court recently, to protect vaccine manufacturers from being sued). At the end of it, in 2011, Lawson was awarded nearly $1.5 million for lost future wages, future life care, and pain and suffering on behalf of her daughter, whom she describes as "an eternal toddler," with little language skills, constant medications, and daily seizures.

"Was it justice? I mean, they could have done nothing," Lawson says. "But I just want my kid back."

THE RISKS

Serious vaccine injuries and deaths are few and far between, according to the CDC. "Like any medication, vaccines can cause side effects," a spokesperson tells Yahoo Parenting through an email. "The side effects associated with getting vaccines are almost always mild (such as redness and swelling where the shot was given) and go away within a few days. Severe reactions, such as a severe allergic reaction, are rare."

How rare? A CDC list of possible vaccine side effects notes that, for MMRV, the risk of a severe allergic reaction is "fewer than 4 per million," while the risk of serious incidents including brain damage, it says, "occur so rarely, we can't be sure whether they are caused by the vaccine or not." Other possible risks range from febrile seizures (about one child in 1,250 for MMRV) to a fever of 105 or higher (about one child per 16,000 for DTaP). Notes the CDC spokesperson, "Years of testing are required by law before a vaccine is licensed and distributed. Once in use, vaccines are continually monitored for safety and efficacy. As a result, the United States currently has the safest, most effective vaccine supply in history."



Julia and her brother during a period of hospitalization in 2008. Photo courtesy of Susan Lawson.

An overwhelming majority of Americans agree: A just released Pew Research Survey found that 83 percent of the public says vaccines for diseases such as measles, mumps, and rubella (MMR) are safe for healthy children, while about nine percent think such vaccines are not safe; an additional seven percent say that they don't know.

A 2012 study out of Boston Medical Center, meanwhile, found that, in a random sampling of 100 VAERS reports, only 3 percent of side effects (mostly allergic reactions) were classified as definitely caused by the vaccine; 20 percent were determined as "probably" related, another 20 percent as "possibly" related and a majority were classified as "unlikely" or "unrelated."

But, says the CDC representative, "Individuals react differently to vaccines, and there is no way to absolutely predict the reaction of a specific individual to

a particular vaccine. Anyone who takes a vaccine should be fully informed about both the benefits and the risks of vaccination." Dr. Mobeen Rathore, a Florida pediatrician and member of the American Academy of Pediatrics' Committee on Infectious Diseases, agrees, stressing to Yahoo Parenting that, "while most people wouldn't say there's absolutely no risk of complications from vaccines, the benefits outweigh the risks of any complication, which are rare." In the cases where they do unfortunately occur, he says, "It's appropriate that the families are compensated."

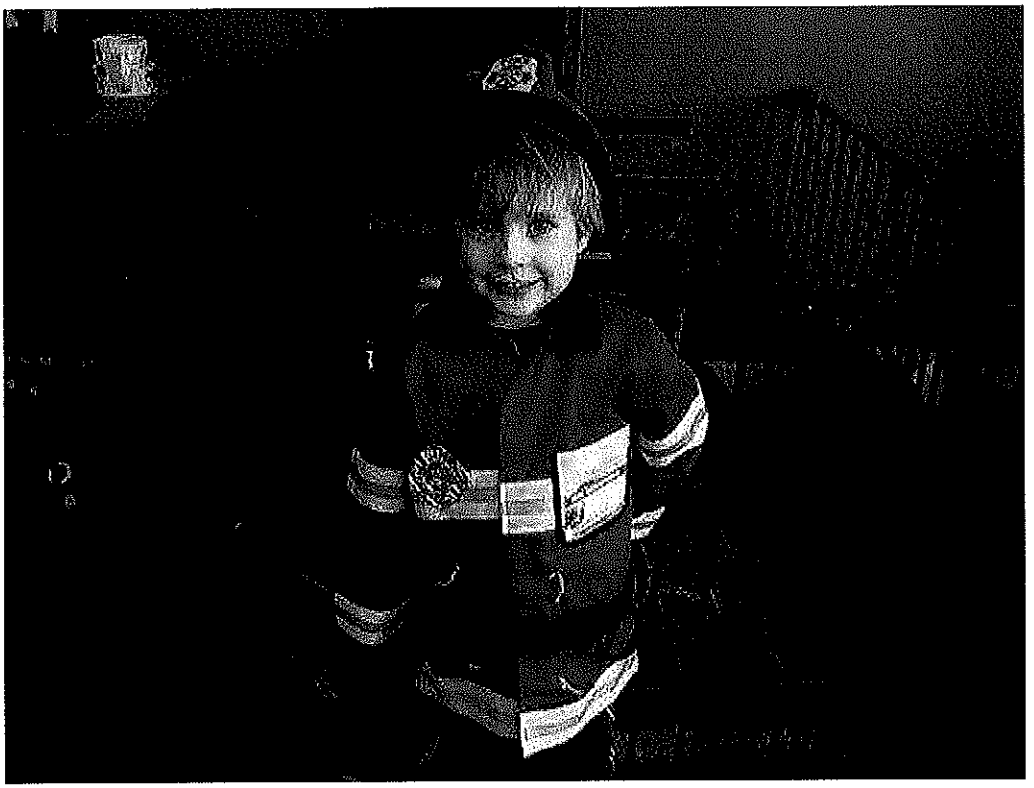
Renee Gentry, a Washington D.C.–based vaccine-injury attorney and president of the Vaccine Injury Petitioners Bar Association, believes that injuries, however rare, should be a part of the public conversation. "Vaccines are incredibly important, but we should treat them as they are — man-made pharmaceuticals that carry risk. The fear is that if you talk about that at all, people won't vaccinate." But not discussing it, she says, is to deny reality. "To say there is nothing unsafe about vaccines — when you can have a reaction to an aspirin — makes no sense." She adds, "Informed consent is the underlying basis of medical care, and parents shouldn't have to be afraid to raise questions with their doctors. Because yes, vaccine injuries are rare, but they do exist."

RECENT INJURY CASES

Alisa Pittaluga, a pediatric occupational therapist and mother of three in upstate New York, had always felt a bit cautious when it came to vaccinations. "I've questioned it because of my profession," she explains, noting that many parents over the years have expressed beliefs that their child's medical conditions were somehow related to vaccines. Pittaluga believed in vaccinating, though, and compromised by delaying and spacing out the shots for her youngest child, Daniel, now 7. He had his first MMR shot right before he turned 4 (rather than at the CDC-recommended age of 12 to 15 months).

"He was a totally healthy 3-year-old," she says. But within two weeks of

Daniel's shot, his mom began to notice he had bruises in strange places — on his chin, along his spine. One night, while bathing him, she saw that his whole upper body appeared to be bruised. "He looked like he'd been in a car accident — his arms and back were purple with bruises," she recalls, adding that she became an instant "wreck," as she'd worked with kids who had leukemia, and knew that excessive bruising was an early symptom. During a doctor's exam to rule out the cancer, she recalls, "I was shaking from head to toe for an hour."



Daniel Pittaluga several years ago, before receiving his shot. Photo courtesy of Alisa Pittaluga.

Leukemia was ruled out; instead, he was diagnosed with the disorder idiopathic thrombocytopenic purpura (ITP), which leads to excessive bleeding or bruising because of low blood platelets that help to clot the blood. His pediatrician mentioned that it could have been associated with his MMR vaccination — as it has been found to be, according to the CDC's list of MMR side effects, for about 1 in 30,000 doses.

"I was devastated," Pittaluga recalls. "I cried. I felt so guilty that I took this kid in and made him get his shot."

Luckily, Daniel's condition resolved itself in a year (as do the majority of MMR-related cases). But during that time, he had to be monitored with weekly blood tests, hooked up to a IV blood bag for dangerously low platelet levels, and supervised constantly to make sure he never fell down and hit his head, which could have been deadly. "The hardest part was having a 3-year-old boy who was not allowed to run or jump," Pittaluga says. She filed a claim with the vaccine-injury court and, at the end of 2014, was awarded compensation (a sum she requested be kept private), to be put into a trust for Daniel.

Pittaluga, now pregnant with her fourth child, says she feels validated by the ruling, but forever changed. "I understand that with measles, people can have complications," she says. "But watching your 3-year-old not being able to clot his blood for a year is much more terrifying to me." She's uncertain, for now, how she'll proceed with vaccinations for her newborn, and admits to feeling "furious" regarding the anti-anti-vaxxer sentiments that dominate the media.

Harry Tembenis of Massachusetts has similar reactions to the discourse. His only child, a son named Elias, developed a seizure disorder as the result of a routine DTaP shot at four months old; he eventually died, at the age of 7, during a major seizure, while his case with the Vaccine Injury Compensation Program court was still pending. The court, after seven years, eventually determined that the vaccine caused his disorder, agreeing to pay out more than $1 million in 2013. "We got justice, we got closure," Tembenis tells Yahoo Parenting. But he takes umbrage when he hears medical experts saying that vaccines are completely safe, noting that when they took Elias in for his shots, on schedule, they knew nothing about any possible risks. "We took the pediatrician's word as gospel," he says. "Unfortunately, my wife and I learned the hard way."

Since the first Vaccine Injury Compensation Program (VICP) claims were filed

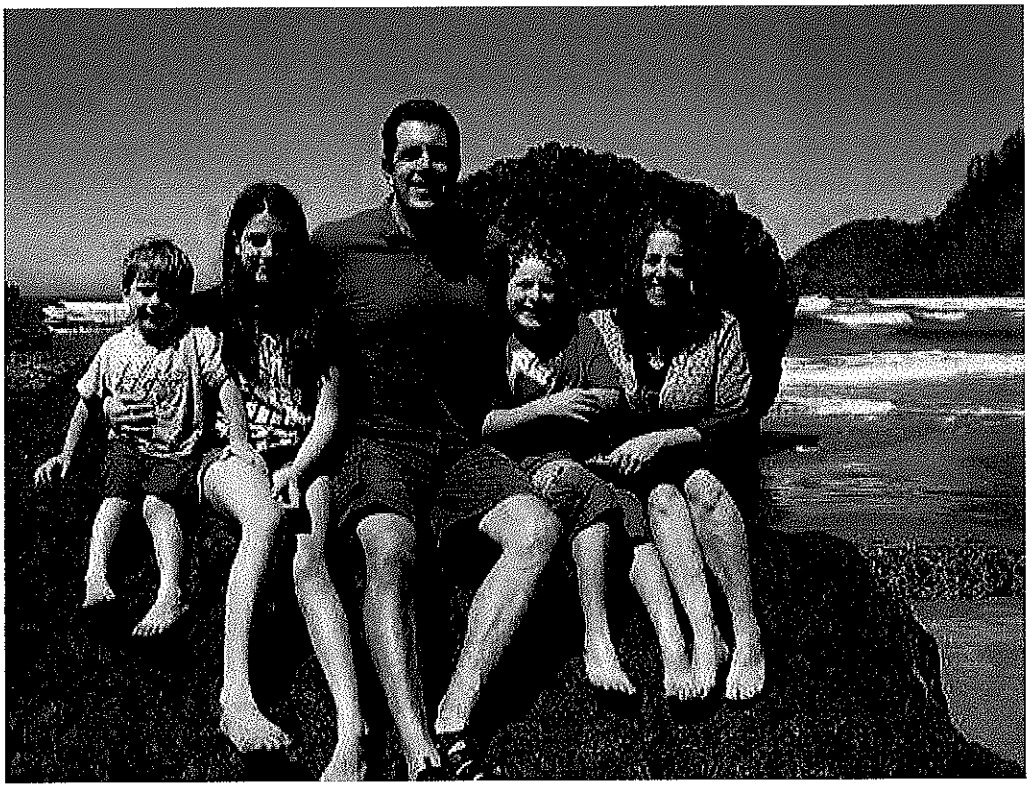
in 1989, nearly 4,000 compensation awards have been made, totaling nearly $3 billion; nearly 10,000 claims, meanwhile, have been dismissed. In 2014, the court made 365 awards totaling more than $223 million (counting both petitioner payouts and attorney fees); the totals represent payouts both in which the court concedes a vaccine connection and those that were simply settlements. In cases where petitioners win concession, payout amounts vary wildly due to severity of injury and whether a child dies or not. Deaths, Gentry explains, usually receive less, because when a child survives but sustains serious injury (as in Julia's situation), the court makes payouts for future life care and future lost wages, as well as for pain and suffering. (Although the $250,000 caps for both death and pain-and-suffering payouts have not changed since 1986, Gentry notes). To date, the majority of compensated claims stem from reactions to DTP (1,270 injuries), influenza (985), and MMR (367) vaccines.

Some injuries fall within what's called the Vaccine Injury Table — a collection of conditions that, if they occur within a specified amount of time, "it is presumed that the vaccine was the cause of the injury or condition unless another cause is found." Injuries that fall within the Table — including anaphylactic shock, encephalitis, chronic arthritis, and ITP (what Daniel had) — are meant to go through the court system more quickly (although it doesn't always happen that way, as with Julia's four-year case). Other cases become more drawn-out and complex, with many feeling "adversarial," Gentry notes.

"There are few Table injuries, so you almost always need to get an expert," she says, noting that there have been no Table updates since the late '90s — although additions are currently being considered, according to a spokesperson for the U.S. Department of Health Resources and Services Administration (which oversees the VICP), including the immune disorder Guillain-Barré Syndrome in relation to the influenza shot. "And," Gentry says, "it's incredibly difficult to get experts, as their reputations wind up getting viciously attacked." Attorneys often pay for experts and medical records up front and get reimbursed at the end of a case. Many petitioners wind up taking

settlements, Gentry notes, rather than risk getting into what can often turn into a three-year court dispute.

"Basically, you can move cases through very quickly if you want to lose," Gentry notes. "It's not a workable model."



The Pittaluga family, with Daniel at left. Photo courtesy of Alisa Pittaluga.

According to Lisa Reyes, chief deputy clerk at the US Court of Federal Claims, the Vaccine Program was created with the expectation that most cases would involve Table injuries. "About 90 percent of the petitions filed in the early days of the Program presented Table injuries, and with a few exceptions, the question of entitlement to compensation in these cases was easily resolved," she explains to Yahoo Parenting in an email. But today, she continues, "About 98 percent of cases filed represent these off-Table claims. The effect of these changes is that more cases require evidentiary hearings, giving the perception the process is more 'adversarial.'" As for reports about lagging cases, Reyes

points to a 2014 analysis of the Vaccine Program by the US Government Accountability Office, which found that "In all but 1 year since fiscal year 2009, the program has met the target for the average time to adjudicate claims (about 3.5 years)."

The case over Daniel's ITP was one of 357 awards granted in fiscal year 2014. Others include one that garnered more than $2.3 million in compensation to a young North Carolina boy with encephalitis and permanent brain damage following a chicken pox vaccine (one of 127 awards so far in 2015); an Arkansas girl who was awarded $1.3 million for neurological damage sustained following MMR, hepatitis-A, and chicken pox vaccines; and an 8-year-old Kansas boy who, the court conceded, had a seizure disorder triggered by an underlying immune deficiency following a round of 12-month shots that included DTaP, HiB, MMR, Varicella (chicken pox), and Prevnar (pneumonia). The complicated court case took six years to reach a decision from the time it was filed in 2008.

"The doctors couldn't stop his seizures," says his mother Ann, a stay-at-home mom to four children (who did not want her surname printed because of family privacy concerns). "But I didn't attribute it to the shots. My mind didn't go there." At some point during her rounds of visits with baffled doctors, endless tests, her son losing his ability to speak and walk, large doses of steroids, and various diagnoses ranging from epilepsy to mitochondrial encephalomyopathy (a complex genetic disorder), a neurologist posited the vaccine-link theory. That led her to hire a vaccine-injury attorney and go through the court system; she's still awaiting a decision on the amount of damages her son — who remains on anti-seizure medication — will be awarded. But, Ann says, she's not anti-vaccine, and has since partially vaccinated her youngest children on a delayed schedule.

"I was scared to death to do it, but I still think they're important," she tells Yahoo Parenting. "I do think people should be educated, and that no one should go into vaccines blindly."

Lawson, meanwhile, has been forever changed by the reality of becoming one of the rare statistics. "I feel betrayed by the trust I had put in my pediatrician, the medical establishment, and my education," she says. Since her daughter's injury, she's not allowed her son, 12, to have any of his remaining shots. "Julia qualifies for a medical exemption. My son, however, does not. I exercise my personal belief exemption for him, for obvious reasons," she says. "If vaccines become mandated, am I really expected to risk this happening to him? I won't. They can fine me, jail me, whatever they want. I'm not vaccinating him. We will move out of the country if necessary. That's how seriously I take this. It has to be a choice."

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6.6

National Geographic News

Pro-Vaccine but Afraid to Vaccinate: Inside One Family's Doubts

Daughter's disability left a legacy of wariness for Los Angeles household.

Sophie Beglinger, 19, walks unsteadily, and left on her own she will amble aimlessly. Her mother, Elizabeth Aquino, 51, supports and guides Sophie around the backyard of their Los Angeles home on a sunny winter's day.

PHOTOGRAPH BY EMILY BERL, NATIONAL GEOGRAPHIC

By Karen Lowe
for National Geographic

PUBLISHED FEBRUARY 14, 2015

Elizabeth Aquino, 51, is not opposed to vaccines. But when she takes her boys, ages 13 and 16, for a vaccination, it's often years later than most doctors recommend.

She and her husband, Michael Beglinger, 51, live with their three children in Los Angeles, where a measles outbreak has pushed some parents to extremes in a heated debate over vaccination.

The area is one of a few pockets across the United States where a small but significant number of parents delay vaccinations until they believe their children's immune systems are strong, or refuse them altogether, citing much-disputed reports that vaccines can cripple children. Other parents, and much of the medical establishment, accuse them of endangering the larger population.

The U.S. Centers for Disease Control and Prevention (CDC) and medical experts say that at least 92 percent of children should be vaccinated to create enough of a herd-immunity effect to protect a community. So even a fairly small number of unvaccinated children can be a big issue in places like

California, where statewide vaccination rates with the MMR (measles, mumps, and rubella) shot hover right around 92 percent.

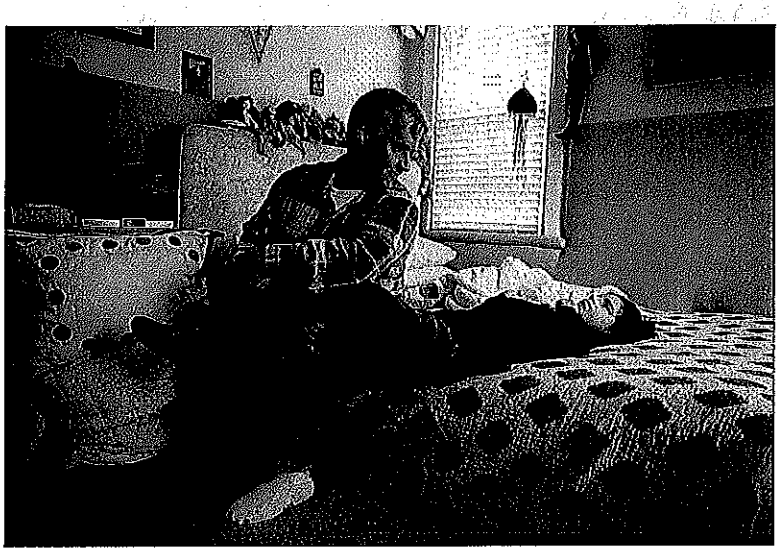
To Aquino, the debate over vaccinations isn't political, or even religious, as it is for many others who view immunizations warily. Twenty years ago, her daughter, Sophie Beglinger, received her first round of the diphtheria, pertussis, and tetanus (DPT) vaccine. Days later, Sophie developed spasms. The doctor withheld the second round of the pertussis vaccine because in rare cases, febrile seizures can be one of the side effects.

According to the CDC, the DTaP vaccine (the updated version of the DPT shot Sophie got) can cause mild to moderate side effects, including fever in one in four cases and mild seizures in 1 in 14,000. The agency describes long-term seizures and permanent brain damage as being "so rare it is hard to tell if they are caused by the vaccine."

For nearly 20 years, Sophie has had multiple grand mal seizures and hundreds of smaller seizures every day. She is unable to express herself or care for her own bodily needs. She convulses so routinely during dinner that when her brothers sense a seizure coming on, one automatically gets a pillow while the other lays her down on the floor.

"I don't even know if the vaccine caused her seizures," Aquino said. But the onset of Sophie's seizures "was suspiciously close. The doctor said it might be [related]."

For Aquino and her family, the doubts and fears linger to this day. "No doctor of Sophie's has said, absolutely not, it wasn't the vaccine."



Michael Beglinger, 51, ties Sophie's shoes as he prepares her to go outside for a walk. The walls of her bedroom are covered with purple padding to protect her when she falls or butts her head against them.

PHOTOGRAPH BY EMILY BERL, NATIONAL GEOGRAPHIC

Playing the Odds

Right now, the debate over vaccinations is focused on one disease: highly contagious measles. The current national outbreak is believed to have started at the Disneyland amusement park in Anaheim, California, spread by an infected visitor who was at the park in December.

Alan R. Hinman, director of the Center for Vaccine Equity at the Task Force for Global Health, in Decatur, Georgia, says the likelihood of a debilitating reaction to the measles vaccine is "near vanishing." Before the measles vaccine was introduced in 1963, he adds, measles killed 400 to 500 people a year in the United States. The disease was considered eliminated by 2000.

Some doctors recommend single-dose vaccines and delaying vaccinations until a child's immune system is stronger, and that is the approach that Aquino and Beglinger use, along with some parents like them.

But Hinman says that delaying vaccines leaves a child vulnerable to disease for a longer period of time and makes that child a risk to other children too young to get the vaccine, as well as to people who can't be inoculated because they have immune deficiencies.

"This is not just a individual decision," Hinman said. "It's a decision that affects the whole community."

The whole family helps care for Sophie amid active lives outside the home. The family dog, Valentine, watches as Henry Beglinger, 16, leaves for lacrosse tryouts. Oliver Beglinger, 13, adjusts his bicycle helmet.

PHOTOGRAPH BY EMILY BERL, NATIONAL GEOGRAPHIC

A Generational Decision

Sophie's 13-year-old brother, Oliver—like any teenager—wants to be like his friends. And his friends are vaccinated against measles (most children receive two doses of the MMR vaccine before age six). But when Aquino told her son it was time for him to do the same, he balked.

"He's conflicted," Aquino said. "He sees what his sister is like, and it's not that far a stretch for him to imagine, 'What if that happened to me?'"

Aquino has encouraged him to go through with the vaccinations because his immune system is strong, but they've decided to wait until Oliver feels ready.

Aquino sounds conflicted too. She's certain she is doing the right thing by her children. But when asked how she would respond to parents who might say her unvaccinated children are endangering their children, she swings between angst and reproach.

"I know that there is a small chance that you could get something even if you're vaccinated ... I'd be horror-stricken," she said of the prospect that her child could spread preventable disease. "I'd be so upset. But it wouldn't be intentional. I don't think the risk is that great, frankly."

She said she's not worried, in part, because she comes from a generation in which she and most of her friends all got measles without serious complications. According to a recent Pew Research Center study, about 9 percent of the population isn't fully convinced about the safety of vaccines.

Some poll respondents expressed skepticism about the effectiveness of vaccines, while others question why healthy children should be given the vaccines. Others say they distrust pharmaceutical companies. (See "Young Adults Most Worried About Vaccines, Poll Finds.")

Aquino is part of an even smaller subset of this 9 percent: those who aren't "anti-vaccine" but worry about potential health effects enough to delay or skip some vaccinations.

A hallway photo gallery in the Beglinger home captures the benchmarks of their kids growing up, including Sophie's moments of joy and tranquility.

PHOTOGRAPH BY EMILY BERL, NATIONAL GEOGRAPHIC

Rare Cases

At the time Sophie developed seizures, her mother couldn't just check the Internet for information.

Instead, Aquino went to a bookstore, where she found a single book with a two -line mention of infantile spasm. She learned there was a 92 percent chance that Sophie would not only be epileptic, but mentally retarded as well.

Aquino and Beglinger have not been able to prove a causal link between their daughter's condition and the vaccine. If they could, they might be eligible for compensation from the National Vaccine Injury Compensation Program, or NVICP, which is funded by pharmaceutical companies.

NVICP was formed in 1988 to create a federal no-fault, non-adversarial alternative to suing vaccine manufacturers and providers in civil court. The

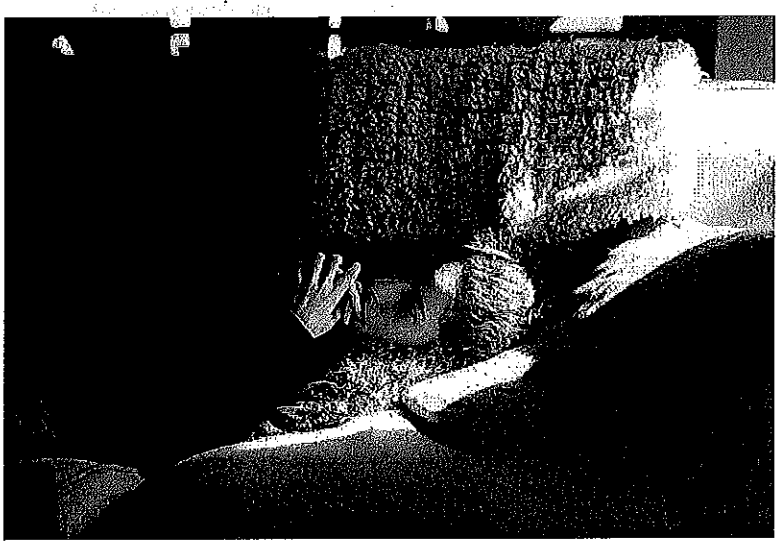
program is funded by a 75-cent tax collected by pharmaceutical companies on every vaccine.

A 2014 report by the U.S. Government Accountability Office faulted the NVICP for not making its existence more widely known, noting that from 2005 to 2010 the general public, attorneys, and health care professionals were unaware of the fund.

Since the program began, the GAO says, some 15,000 people have filed claims. The program's website reports that 3,941 compensation awards have been made, with $2.8 billion awarded. As of 2013, there was $3.3 billion in the fund.

Marcia Cross, director of health care for the GAO and author of the report, said the paperwork accompanying vaccines includes descriptions of potential side effects as well as a mention of the program. But most patients take the word of their doctor, and don't read the accompanying material.

"Without awareness of the program, individuals who might otherwise receive compensation for a vaccine-related injury or death could be denied compensation because of a failure to file their claim within the statutory deadlines," she said in the report.



Sophie lies quietly on the living room couch as the family gets ready to enjoy their Sunday activities. She can't talk or communicate much, but her mother sometimes wonders whether, maybe, she understands everything.

PHOTOGRAPH BY EMILY BERL, NATIONAL GEOGRAPHIC

When Only Marijuana Helps

On the frontiers of dealing with such a difficult condition, Aquino and Beglinger take solutions wherever they find them. And sometimes that puts them squarely in yet more controversial territory.

Sophie's family has spent thousands of dollars on medical expenses and 24-hour care, most of it performed by the family. Sophie has been on 22 different drugs, in complex combinations. Nothing has helped, Aquino says, except a cannabinoid tincture known as "Charlotte's Web." It has very little THC, so Sophie experiences the calming effect without the high. Now, she only has occasional seizures.

But Sophie still requires help with all of her physical needs and cannot verbally communicate. She turns her face away to show displeasure. She appears to enjoy whatever her father, a chef, prepares, though. And she spends much of her time in her bedroom, where the walls and door are covered in lavender padding to keep her from hurting herself when she butts her head against them.

A wood cutout above her bed says "Miracle." Whenever the family goes to the beach, Sophie makes her desire to go to the water understood. Floating mermaids—in paintings and on pillows and wall hangings—adorn her room.

At Sophie's high school, she attends a special day class for neurologically impaired children. Using an iPad, she communicates a bit, though inconsistently. Aquino says it's impossible to know if she understands much, but she thinks Sophie understands more than is apparent.

"Sometimes, I think she might understand everything. And she's an incredible woman. She has had tens of thousands of seizures, and she still gets up every day," Aquino says.

Berlinger, a full-time chef, takes a walk with Sophie before heading off to work. Someone must always accompany her, holding a hand or shoulder.

PHOTOGRAPH BY EMILY BERL, NATIONAL GEOGRAPHIC

Aquino, however, says she's tired. She's tired of fighting to get her daughter proper care, to get insurance coverage, to avoid bankruptcy and dismissive doctors. Some doctors are refusing to take patients who aren't vaccinated. But there are doctors who work with cautious parents like Aquino.

Aquino's sons have been getting some, but not all, of their vaccines. Her eldest is almost fully vaccinated, but her youngest has more to go. She said that they will receive all of their vaccinations before they travel or head to college.

Jay Gordon, Aquino's doctor, recommends giving vaccines when a child's immune system is strong enough to handle them, and using single-dose vaccines, instead of combined vaccines.

Aquino, like other parents in this sliver of society that has had a bad experience involving vaccines, walks a fine line. "The larger argument is that the risk is worth taking ... for public health reasons," Aquino said. "I get that you have to

vaccinate the population. There has to be some measure of public health. And yeah, I don't want my kids to get polio or diphtheria or tetanus."

Aquino wants no part in the current blame wars, but she says it's definitely time to change the tone of discussion so that parents—whatever their views on vaccinating—don't feel ridiculed and patronized.

She may never know for sure whether a vaccination triggered her daughter's seizures, but she believes Sophie is one of those rare few whose life has been "if not ruined, at least irrevocably changed by that rare reaction."

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Elizabeth Aquino

Thanks for the spirited discussion. I found this opinion piece particularly relevant -- not so much as to where it "comes down" but more about the process of discussion about vaccinations. I think we all can learn from it -- **https://medium.com/@therebootedbody/bringing-much-needed-sanity-to-the-vaccine-debate-e143f089bfd1**

Prairie Douglas

Would someone be able to shed light on how this current trend will affect those with compromised immune systems or if it will at all? For example an auto immune disorder? In light of the fact that that individual does not have a choice regarding vaccinations, what steps would be in place to protect them from getting something like the measles etc or is it that it's simply something that comes with the tbe territory?

Tami T.

As a parent of 7 children I have seen both sides of the controversy....Their are both risks in vaccinating children and also serious but rare complications from "childhood diseases. When my now adult son was starting Kindergarten, he received his vaccinations as required for school admission. During his preschool years he had some significant health issues but that doctor familiar wit his history did not consider his past history a risk. the evening after the vaccination he had to be rushed to the hospital after he spiked a fever of 104, was having seizures and hallucinating bugs crawling all over himself. He spent three days in the hospital and has a minor seizure disorder to this day. The doctors strongly suspected but could not prove it was connected to the vaccine.

Even after this experience I continued to get my children vaccinated but when the chicken pox vaccine came out I declined it for my daughter until it was a required vaccine thinking that chicken pox was not a bad thing to get. When she did get chicken pox, although she was miserable she seemed to recover well enough from it. BUT after about 4 weeks from the onset she developed a high fever and ataxic gait when she walked. I rushed her to the emergency room and after seeing the pox marks were able to diagnose her with encephalitis (swelling and infection in the brain) caused by chicken pox lesions in the brain. (my lay person understanding of the condition) She was hospitalized and serious for several days. She did recover fully.

I guess what this has shown me is that both sides of the vaccination debate have valid points. In rare cases vaccines can be harmful, and on the other hand childhood illness can have serious complications.

When choosing to vaccinate or not each person must understand all of the risks involved from the vaccines, illnesses, legal issues and impact on the community and make an informed decision.

Dorit Reiss

I feel for this mother's fear. I am so sorry her daughter suffered. She should know that research suggests the vaccine does not cause seizure disorder, though I completely understand how hard it would be to think otherwise given what she has been through.

Fear is understandable but I hope she - and other parents - find their way to protecting their children from disease, in spite of the very, very rare chance of an adverse reaction. Because the risk of not vaccinating is simply so much greater.

I wish the mother all the best.

Debra Heston

A small percentage of the population may be at risk for adverse effects. If someone in the family has had adverse effects (or is suspected of having an adverse reaction) then other genetically related individuals may be at heightened risk. It just makes sense to think that heightened sensitivity or vulnerability to an environmental factor may have a hereditary component.

How far should parents be allowed to go to keep their kids safe? Perhaps more important - why is that even a question?

Sandie Fischer

The link http://www.greenmedinfo.com/blog/2013-measles-outbreak-failing-vaccine-not-failure-vaccinate1 is an article called "The 2013 Measles Outbreak: A Failing Vaccine, Not A Failure To Vaccinate." An article that is superb.

At the end of the second page are 13 references to medical publications (PMID #'s provided). Open each of them. You will notice on a number of them, that they are a collection of further medical publications. For each reference, note the "additional links" to more medical publications.

There is a sea of vaccine injury evidence, lack of efficacy, vaccine mortality rates, etc that http://www.greenmedinfo.com/ has compiled for quick access. An excellent watchdog, this website is worth bookmarking.

Paul H Hebner

Unless any of you have an MD or a PhD after your names AND have demonstrated expertise in virology and public health policy, none of you--not even one of you--have any business discussing vaccination as a controversy. The science/medical community has declared the matter settled. No view you express on this matter is anything other than uninformed opinion. You certainly have a right to express your opinions, but you have no right to claim any factual basis for those opinions. Doing so fosters doubt and non-compliance, which endangers society as a whole, and is criminal by any reasonable standard.

Sandie Fischer

My heart goes out to Sophie. She has amazing strength. The trial and error of trying anything and everything to help your child is really tough and there is no doubt the Aquino family is a loving home. I hope that Sophie's future is filled with miracles.

Wayne Rohde

To the Aquino family, may God Bless your family. It is a very tragic story that is all too common. My family is similar. Our son now 17 was vaccine injured and confirmed by ped neurologist as injured from the MMR admin at 13 months. He suffered a brain encephalopathy, lost his language, and slowly declined over the course of 2 years into a diagnosis of severe regressive autism.

One thing about this article has not been addressed. The writer quoted a few different doctors talking about vaccine injury as very rare or even to the degree that injury is not related. Question to the docs. How in the hell do you know this?

During a congressional hearing in the OGR cmte a couple of years ago, a CDC representative was asked by 2 different congressman about vax vs un vax study and the response was the CDC has not conducted one. A follow up question. Why do not conduct a medical outcome study of those who have been injured? The CDC representative once again said that they have not.

So for the docs to claim that injury is very rare and use the CDC talking points, how would they know.

In researching for my book, The Vaccine Court, I spent 3.5 years interviewing over 285 families that deal with vaccine injury. In the NVICP, one of the intentions of Congress was to get HHS / CDC to conduct medical outcome studies on those who submit petitions. NOT ONE has been done. And NOT ONE of the families that I have spoken to have been contacted by the CDC.

So for the medical community to continue to state that vaccine injury is very rare, they are lying to the public. Vaccine injury is something that does happen. And the majority of people who are described as anti-vax, we are the ones dealing with vaccine injury.

Ashu Singhal

Elizabeth Aquino "Therapeutic index" is considered for any drug or vaccine before releasing for community use. FDA regulate drugs safety and etc. People who believe vaccine is a conspiracy and are harmful for health. I ask one question--- do you also not take any medicine? If yes, every medicine has its side effect and at least 1 person is affected in thousands. considering the benefits vs harms any potential drug is tested for drug-ability. Even, people volunteer in hope for new treatment for themselves as well as for future generation when they have terminal diseases like cancer.

Sarah Verkuil Turner

No one will ever know if the vaccine caused the seizures, or if this would have occurred naturally, and I doubt there will ever be a way to find out. It is reasonable for this family, under a doctor's guidance, to take precautions with future vaccinations. I completely agree. However, this family is then relying mainly on herd immunity to protect them from these diseases. Therefore, they should be strongly pro-vaccination with others in their community in order to ensure a high level of herd immunity so that they can be protected. When I got my children vaccinated, we are not only vaccinating for ourselves, but to also to protect others in the community, that for various reasons, can not have a vaccination, be it that they have cancer, AIDS, or had a previous severe reaction to a vaccination. What has finally happened, is that so many people, especially in areas such as Southern California, have stopped getting their children vaccinated, due to unfounded fears, that the level of herd immunity has dropped to a low enough level that now when measles was exposed in Disneyland, enough of the people did not have immunity and so it was able to gain a foothold. What greatly weakened this article was when it stated "She said she's not worried, in part, because she comes from a generation in which she and most of her friends all got measles without serious complications." Well, tell that to people, who one, aren't here to share their side of the story because they died from measles, and two, people who suffered serious complications like deafness from the measles from "her generation". What an ignorant statement that was.

There should be enough wiggle room with herd immunity to allow medical exemptions. However, this will only be the case if only TRUE medical exemptions are allowed. Otherwise, this will keep happening.

Connie Grounds

@Prairie Douglas At this point, evidence for a trend is mostly anecdotal. The CDC's surveys show that vaccine coverage for children is at or near all-time highs. We do a better job than we used to at vaccinating poor children and with the Affordable Care Act, even more poor children are likely to be vaccinated. Even if there are small increases in the number of parents who are skipping or delaying some vaccines, it seems decreases in the number of kids who are unintentionally missing vaccines will keep coverage relatively stable.

My daughter has an autoimmune disorder and other immune dysfunction. Because there are so many diseases for which we have no vaccines, we have to take precautions in general to keep her from getting sick. We all practice frequent handwashing, for instance.

Also, there are very few people who can't get any vaccines. Some people with immune dysfunction can't get live virus vaccines but can get others. Measles is a live virus vaccine but measles in incredibly rare in the U.S. There have been 150 cases this year and our population is almost 320 million. Unless you leave the country, the chance of being struck by lightning are likely higher than being exposed to measles.

Also, people who have immune dysfunction can receive post-exposure prophylaxis to help protect them after exposure. That's one of the reasons why public health officials try, without always succeeding, to identify contacts of identified measles cases.

Sandie Fischer

@Dorit Reiss Your caring thoughts are heartfully sincere but your belief that the vaccine does not cause seizures is based on bad science and is therefore just a belief and not truth.

Sandie Fischer

@Debra Heston Totally agree! A woman I chat with at my health food store has four boys. Her first became autistic after a vaccine (not sure which one), so for her second child, it was decided that the vaccine schedule would start later. They eliminated the vaccine that caused the first child's autism. The second child too is autistic. The third and fourth children had less and less vaccine exposure, yet still have degrees of autism following vaccination. Depending on where you live, public health can be militarily forceful and it sickens me that the family was not advised of the exemption process.What was her doctor thinking?

My children both had serious reactions to the DPT so the remaining of their schedule had the pertussis removed. Had I known there was a way to exempt at that time I would have. I refused the pertussis in the remaining of my children's vaccinations because I knew that it was going to get serious if they had any more pertussis.

After looking at the research and statistics on diphtheria, tetanus, and pertussis, there is no reason to be continuing this vaccine.

Danchi ElNura

@Paul H Hebner

The science/medical community has declared the matter settled.

Remember Doctors used to promote cigarettes because they were good for you:

-Unbellevable: doctors recommend smoking I 60 years ago...**https://www.youtube** (dot)com/watch?v=D-y_N4u0uRQ

- PROOF Chesterfield Cigarettes have no adverse effects on nose, throat, sinuses: **https://www.youtube.com/watch?v=TOKc6TNwlj4**

The science was settled.

Vioxx was said to be safe and effective. The science was settled. Merck withdrew the drug after disclosures that it withheld information about rofecoxib's risks from doctors and patients for over five years, resulting in between 88,000 and 140,000 cases of serious heart disease. It's estimated Vioxx killed close to 100,00 people worldwide--and Merck knew the drug caused heart attacks.

"Science is a process, not a conclusion"

Sarah Verkull Turner

@Paul H Hebner Thank you! As you can see, all of the tin-foil hat anti-vaxxers are out in force with this article and all of the same, tired "conspiracies." . National Geographic should be ashamed of themselves for running this so called "balanced article." These people aren't balanced at all. As this article states, "There is no need for "balance." There is no reason for "choice." Because believing in anti-vaccination is an indefensible position. The benefit of vaccinating yourself against infectious diseases isn't a theory or proposition or a position. It's a fact. There's no reason to even "debate" the issue. Debating vaccination versus anti-vaccination is like debating whether 2 + 2 = 4 or whether Hooch was the dog in *Turner & Hooch*. Look at a graph charting reported cases of measles in the United States. It's like looking at the first pitch of an especially terrifying roller coaster. Following the introduction of the vaccine in 1963, cases of measles dropped from the hundreds of thousands to the tens of thousands. (Reporting in Canada was a bit spottier for the years immediately following the vaccine's licensing, but the general downslope remains consistent.)"
http://www.thestar.com/opinion/commentary/2015/02/08/the-high-cost-of-balance-in-the-vaccination-debate.html

Maggie Ethridge

@Paul H Hebner Thank you for explaining to us why critical thinking is now a crime in America.

Elizabeth Aquino

@Paul H Hebner Thanks for your comment. Contrary to you, I have learned never to trust or even take seriously anyone who claims certainty or is an absolutist about any issue. I have also always believed science to be a fluid and dynamic, quite beautiful expression of not absolutes but mystery inherent in the universe in which we live.

Sandie Fischer

@Paul H Hebner Your statement "The science/medical community has declared the matter settled" and your opinion on endangerment both

demonstrate ignorance. You have MD/PhD on a pedestal; The public can discern that something is wrong with the science when their own child is directly affected by a vaccine. And then an uneducated MD states the vaccine is not the cause without investigation. This is what endangers society as a whole. Any statistical study based on history is therefore invalid. When research is designed to support a specific outcome, that is what is criminal. Scientists around the world are speaking up on there concerns over vaccine research.

Elizabeth Aquino

@Sandie Fischer Thank you Sandie. I appreciate your support and hopes for healing for our Sophie.

Elizabeth Aquino

@Wayne Rohde Thank you for your kind words and powerful testament, Mr. Rohde. Our experience with the NVICP was frustrating, to say the least, and indicative of most of the experiences we've had over two decades dealing with nearly all the systems of care in this country -- medical, educational, insurance, etc. -- or lack thereof for those with disability.

Sandie Fischer

@Ashu Singhal The studies on drugs use a placebo as a control. The studies on vaccinations use other vaccinations as a control. What the CDC is doing is criminal.

Elizabeth Aquino

@Ashu Singhal Perhaps there's some difficulty in translation, but I don't understand your question or remarks.

Rita Palma

@Sarah Verkuil Turner There was nothing ignorant coming from Ms. Aquino. Your post, on the other hand, had so much narrow-minded nonsense in it, it's hard to know where to start. But here's a couple of points-

1.) WV has a lower vax rate and all they have is a medical exemption- so don't blame CA. According to your theory, WV should have far more outbreaks.Check CDC data instead of mainstream media

2.) Do you have 49 shots representing 14 different vaccines? Up-to-date on Hep-B? Does anyone reading this? Whoops- better stay home! You and about 200 million other adults are jeopardizing us all.

Ms. Aquino is reasonable and rational and I sense she has a lot more to say. I thank her family for sharing and NG's even-handed approach.

Sandie Fischer

@Sarah Verkuil Turner Herd immunity is bogus concept. Of the healthy population, 39% have a defect in either their humoral or cellular immunity. Now factor in unhealthy subjects and immunity compromised subjects. When you hear herd immunity, your listening to a sales person.

Maggie Ethridge

@Sarah Verkuil Turner Regarding your ignorant statement that ' what has happened is that so many people...have stopped getting their children vaccinated...measles was exposed and so it was able to gain a foothold.'

We've had cases of measles every single year since the vaccination was intro duced. This has nothing to do with an increase in people not vaccinating this year. We've had outbreaks just like this one in the past. 1991 we had many measles cases. No one died or was injured as a result. The measles will not be gone in America even with 100% vaccination because 88% of measles cases are brought in from other countries, and people still catch the measles who are vaccinated- some of the Disney cases were vaccinated.

Elizabeth Aquino

@Sarah Verkuil Turner I should thank you for your referring to me as "ignorant," Ms. Turner, as it so perfectly captures the very reason I consented to be interviewed for this magazine. Your patronizing remarks about "herd immunity" don't mitigate my very real concern about vaccine safety overall and particularly the schedule that the CDC thrusts on the public. Let's debate on the real issue - is my daughter's sacrifice necessary for the larger good? I don't have an answer for that, but what I do know is that trundling out the herd immunity "facts" doesn't persuade people like me -- far from ignorant -- that their children will be unscathed.

Anna arkspur

@Sandie Fischer @Dorit Reiss Sandie Fischer I am quite certain that you don't quite understand critical reasoning and have agreed with bunk articles from the get-go once you've determined that they support your position. (For an actual examination of what 'bad science' is, see Ben Goldacre's splendid little book by the same name:'Bad Science'.) While clearly you feel self-important in your Googling marathon, your fearmongering is tripe and clogs this thread.

Anna arkspur

@Sandie Fischer @Debra Heston ...After looking at the research? Or your anecdotal evidence as per chats at the market? Unfortunately, parents who have children with Autism Spectrum Disorder have a statistically higher probability of having another child with ASD as well. Correlation does not imply causation.

Sandie Fischer

@Sarah Verkuil Turner @Paul H Hebner A commentary from The Star does not support your claim nor do your analogies on twisted reasoning. The benefits of vaccinations are outweighed by the risks for most vaccinations and that is a fact when supported by all data including injuries and deaths by vaccines that have been negated within studies for benign excuses to support pro-vaccine outcomes. Researchers and scientists who have been in the field for decades and have now become whistle blowers provide credible evidence to prove fraud & questionable research practices within pro-vaccinie research and statistics.

From **http://articles.mercola.com/sites/articles/archive/2011/05/22/cdc-autism-researcher-indicted-for-fraud.aspx** , Dr. Mercola states well "When two of the biggest names in vaccine research and support turn out to be guilty of fraud, major deception, lying and making unsubstantiated statements, it really calls into question the validity of their work on the vaccine front ... and that's putting it mildly.

Internet Resources Where You Can Learn More:

- **NVIC Memorial for Vaccine Victims**: View descriptions and photos of children and adults, who have suffered vaccine reactions, injuries, and deaths. If you or your child experiences an adverse vaccine event, please consider posting and sharing your story here. (National Vaccine
Information Center)
- **If You Vaccinate, Ask 8 Questions**: Learn how to recognize vaccine reaction symptoms and prevent vaccine injuries.
- **Vaccine Freedom Wall**: View or post descriptions of harassment and sanctions by doctors, employers, and school and health officials for making independent vaccine choices."

Links that provide a plethora of references:

https://www.youtube.com/watch?v=mpx8-Rmf8bc Flu And Flu Vaccines What's Coming Through That Needle DVD 1,
https://www.youtube.com/watch?v=djxoq KD5p Flu And Flu Vaccines What's Coming Through That Needle DVD 2 (34:25 minutes into video states that four Canadian studies involved about 2,000 people found those who had received the seasonal flu vaccine in the past were more likely to get sick with the H1N1 Swine Flu by 1.4 to 5.0 times.

https://www.youtube.com/watch?v=I GyN3gCs g
https://www.youtube.com/watch?v=SF Ov-Ol6
https://www.youtube.com/watch?v=heugwnCGI E

VACCINATIONS

-The genetic and epigenetic changes caused by a vaccination are immediate after being injected into the body.

-There is no recovery. Genetic and epigenetic changes are permanent. Illness can trigger dangerous conditions, such as swelling of the brain leading to seizures, hearing loss or even death.

-There is no cure.

-During 2014, about 85% (120 million) of infants worldwide were affected by some form of immunization.

Paul H Hebner

@Maggie Ethridge @Paul H Hebner No, critical thinking isn't a crime, but it has gained a rather unfortunate stigma at the hands of science deniers who think their beliefs represent a superior form of knowledge. I encourage you to try some critical thinking.

eth Clarkson

@Elizabeth Aquino

Thanks for both sharing your story and for your beautifully phrased comments. You have a way with words.

Paul H Hebner

@Sandie Fischer @Paul H Hebner Sorry, but the ignorance is all yours.

Sarah Verkuil Turner

@Rita Palma @Sarah Verkuil Turner Yep, Rita. I have been vaccinated with Heb B, and am up-to-date with the DTAP. And I am thinking of getting my titers checked for MMR, so if I am not immune, I will get vaccinated again. **http://www.huffingtonpost.com/2015/02/03/measles-us-facts_n_6581922.html**

Elizabeth Aquino

@Rita Palma @Sarah Verkuil Turner Thank you, Rita! I appreciate your support and have wondered myself what more draconian laws relating to vaccination would mean for the entire population. In some ways, ceding to authority and government and the absolutists about vaccinations reminds me of the endless controversies regarding a woman's freedom to control her body and reproductive capacities. We've watched those rights be whittled away gradually over many years, and given the tenor of much of this debate, I feel pretty pessimistic that autonomy over one's own body and children's will remain intact. I actually always have a lot to say, but not only about this "issue." I am interested in and writing about what it means to be disabled and oft invisible in our culture, how our identities, particularly in the western world, are very much wrapped up in this notion of "ability" and wellness and how our impulse, particularly as Americans, is to "fix." I'm also interested in the notions of control and authority and how they relate to my own experiences dealing with my daughter. Thank you so much for your comment! National Geographic honored our family's experience by doing this interview, and I'm grateful for that.

Sarah Verkuil Turner

@Maggie Ethridge @Sarah Verkuil Turner You are absolutely wrong about the 1989/.1991 outbreak of measles. There were approximately 55,000 cases reported, over 11,000 hospitalizations and over 166 deaths. And the CDC concluded that the reason for this outbreak was the low rate of vaccinations in lower income communities. This lead to the Vaccines for Children Program, which was and has been widely successful, leading to more than 300,000,000 reduction in vaccine preventable illnesses and helped avoid over 700,000 deaths, just in the US alone. So guess what happened after this program. Measles cases have gone down drastically. However, starting in 2014,due again, to anti-vaxxers, there has been a large increase in the number of cases, which unfortunately, will spill over into 2015. **http://www.cdc.gov/measles/cases-outbreaks.html**

Sarah Verkuil Turner

@Elizabeth Aquino @Sarah Verkuil Turner Sorry, you absolutely need people like me, who live near by you in Southern California, to vaccinate my children, which I have done, using the recommended CDC schedule, on time, in order that your son, who is not vaccinated, has had some protection. I won't wait for a thank you, though. I was on your side, except for your laughably false statement that measles are no big deal. I believe that people like your family should have a medical exemption available. However, you and others have shot yourself in the foot, because of spreading fear about vaccinations and the recommended CDC schedule, you have lowered herd immunity so low, that now, we have to deal with these diseases again. And so I now have zero sympathy for you after that comment, because I can see that you are no where near as "moderate" as the article makes you out as being. Vaccinations are the greatest health benefit that has ever been invented, saving literally millions of lives. Yes, there are rare reactions and there have been deaths. No one has ever denied that. However, it's like saying that you aren't willing to use a seat belt, because there have been accidents that occurred where if the person wasn't wearing a seat belt , they would have survived. It's rare, sure, but it happens.

Scott Taylor

@Sarah Verkuil Turner @Maggie Ethridge According to CDC there have been ZERO deaths from measles in the US in the last10 years. In the same period there have been 83 doctor reported deaths from the measles vaccine to the VAERS database. All medications come with risks. Some may not be worth it. And that's a choice you have to make for yourself.

Asking GM to fix their faulty switches that lead to accidents and death is not "anti-car" its "pro-safety". BTW automobile-related deaths are close to 30,000 per year -- so in the US, cars have caused 300,000 more deaths than measles in the last decade, to put this hysteria in perspective.

Maggie Ethridge

@Sarah Verkuil Turner @Maggie Ethridge There were no deaths in the U.S, which is what I assume we are talking about, since this is the vaccine policy we are discussing, the U.S. policy. And no one has died of the measles in the U.S. in a long time, including in the 1991 outbreak.

Scott Taylor

@Sarah Verkuil Turner @Elizabeth Aquino

Elizabeth Aquino

@Sarah Verkuil Turner @Elizabeth Aquino At no point did I say measles was no big deal. I understand that measles is a serious illness and in rare cases can result in serious complications and even death. I am, again, concerned with the safety of vaccinations overall, and my concern is based on direct experience. I'm not sure why I need to thank you, nor will I respond to your sarcasm. As for the loss of your sympathy, I imagine any sympathy you gave to me was probably disingenuous to begin with and certainly not empathy, a far more powerful emotion.

Hanna In

@Sarah Verkuil Turner @Elizabeth Aquino @Sarah Verkuil Turner@Elizabeth Aquino I know 5 people who either died or became "vegetables" after getting vaccinated. How "rare" is that. BTW if you did your research you would find that Dr. Schuchat (Director of CDC) says diseases have peak-wane cycles meaning that these could be coinciding with the "recurrance" of "preventable" diseases. Not only that but vaccines have a surprisingly low rate of effectiveness. DTaP has 41% effectiveness for toddlers, and 24% effectiveness for elementary students (Oxford journal paper). Chickenpox, a relatively harmless disease has a 90% effectiveness verses the 100% lifetime effectiveness if you "acquired" the disease naturally. That's another thing, the majority of vaccines have a short lifespan. Most vaccines (if they work) have a protection lifespan from 2-15 years. That means adults who don't usually get vaccinated again have been "unvaccinated" for decades (which also makes the "herd immunity" argument null). Recurrence is from poor vaccines, superbugs (over-prescribed antibiotics), and the environment (fertilizers) not necessarily "negligent parents."

Elizabeth Aquino

Ah. I envy your confidence and certainty, your faith in the system and your sense of control. It clearly has never been tested, and it's my hope that it never will be. All the best to you --

Sandie Fischer

@Scott Taylor @Sarah Verkuil Turner @Maggie Ethridge

I would also like to add that according to the CDC that only 1% to 10% of adverse reactions and deaths are reported to the CDC. And in some CDC studies, the CDC makes an adjustment to their numbers sometimes by 100% correction when it favors supporting vaccines in order to market their objectives. When they do this, they state they have made a correction in the research paper but they do not say what the correction value is. So let's be CDC objective and suggest instead of 83 doctor reported vaccine deaths and add two zero's to that number to 8300.

We all know that doctors have zero training in vaccines other than how to vaccinate and when. And even if a doctor takes the time to read any research, they read the objective and the conclusion or the abstract. There could be 1000 deaths in a study but a researcher often negates those deaths for benign reasons in order to manipulate the outcome. The system is broken and no-one is stopping the fraud despite legitimate researchers and whistle blowers who have abandoned their careers to go independent.

From an actuarial perspective, it is cheaper to be sued than to announce a recall. At least with GM faults, they can be sued but for vaccines, the government gave the fraudsters a pass at our children's expense.

Sarah Verkuil Turner

@Maggie Ethridge @Sarah Verkuil Turner Not true. There have been measles deaths in the US, including in the 1991 outbreak and afterwords. Here is a NYT article from 1991 talking about the 5 deaths that happened alone in Philadelphia. **http://www.nytimes.com/1991/02/16/us/measles-and-faith-combine-in-5-deaths-in-philadelphia.html**

Sarah Verkuil Turner

Really, it's not hard to understand. Neither one of your sons were vaccinated on time, and yet have not come down with a vaccine preventable illness. And the reason this is because of people like me, who are vaccinated myself, and have gotten my children vaccinated on time and with every recommended vaccine. I , and others like me, have given your family the opportunity to delay vaccination without overly worrying about coming down with polio, or measles, mumps, etc etc etc. And given a high level of herd immunity, there is room for families who have medical issues not to get vaccinated. the more however, you spread your misinformation about the "safety" of vaccines, the less safe you have made it for your son. And no, I don't believe that I control everything. Tell that to my friend who lost her 6 year old to a brain tumor in 9 months. Or to my other friend who just lost her full term baby to a stillbirth. However, I am completely confident in my decision to get my children (who are sort of similar ages to yours), fully vaccinated.

Maggie Ethridge

@Sarah Verkuil Turner @Maggie Ethridge I stand duly corrected. I have been doing so much research lately and somehow this was not correctly stored in my brain.

Sarah Verkuil Turner

@Maggie Ethridge Here is the CDC data about the 1991 outbreak.

Measles Resurgence in 1989–1991Measles Resurgence - United States, 1989-1991

- Cases - 55,622
- Age group affected - Children <5 yrs
- Deaths - 123

From 1989 through 1991, a dramatic increase in cases occurred. During these 3 years a total of 55,622 cases were reported (18,193 in 1989; 27,786 in 1990; 9,643 in 1991). In addition to the increased number of cases, a change occurred in their age distribution. Prior to the resurgence, school-aged children had accounted for the largest proportion of reported cases. During the resurgence, 45% of all reported cases were in children younger than 5 years of age. In 1990, 48% of patients were in this age group, the first time that the proportion of cases in children younger than 5 years of age exceeded the proportion of cases in 5–19-year-olds (35%).

Overall incidence rates were highest for Hispanics and blacks and lowest for non-Hispanic whites. Among children younger than 5 years of age, the incidence of measles among blacks and Hispanics was four to seven times higher than among non-Hispanic whites.

A total of 123 measles-associated deaths were reported (death-to-case ratio of 2.2 per 1,000 cases). Forty-nine percent of deaths were among children younger than 5 years of age. Ninety percent of fatal cases occurred among persons with no history of vaccination. Sixty-four deaths were reported in 1990, the largest annual number of deaths from measles since 1971.

The most important cause of the measles resurgence of 1989–1991 was low vaccination coverage. Measles vaccine coverage was low in many cities, including some that experienced large outbreaks among preschool-aged children throughout the early to mid-1980s. Surveys in areas experiencing outbreaks among preschool-aged children indicated that as few as 50% of children had been vaccinated against measles by their second birthday, and that black and Hispanic children were less likely to be age-appropriately vaccinated than were white children.

Scott Taylor

@Sarah Verkuil Turner There is currently a federal lawsuit against Merck by its own scientists who created the mumps portion of the MMR vaccine. The scientists claim that Merck faked the efficacy data on the vaccine in order to gain FDA approval. The scientists claim the vaccine doesn't work, so if you believe that you are protected from mumps because of the vaccine you are listening to Merck's marketing dept, not the scientists. And I'd rather not take medical advice from a salesman.

Elizabeth Aquino

@Sarah Verkuil Turner For the record, my sons have actually both had a "vaccine-preventable" illness. I'd prefer not to engage with you any longer but appreciate your zealous attention to every thing I say and even things I don't say. I seriously doubt you and I are going to come to some magic agreement.

As the article stated, despite our daughter's reaction to her vaccines as an infant, we indeed choose to vaccinate our sons, judiciously and on the schedule agreed upon by our doctor and ourselves. I am more than gravely concerned with the safety of vaccines overall, and I'm not alone in questioning that. My intention in agreeing to this article, whether you like it or not, was an attempt to inject some nuance into the raging and oft-hysterical debate. Unlike yourself, I have learned to and would never claim certainty over anything, particularly when it pertains to the medical system.

Maggie Ethridge

@Sarah Verkuil Turner @Maggie Ethridge All the reading I've done on the MMR reveals a complicated vaccine history as well as a complicated resulting immunity. For instance, the CDC themselves state that most measles cases are brought in from overseas. The measles vaccine alone has shown to have beneficial effects on the immune system, but the MMR has not, and in fact, there are studies that indicate serious complications with the wrong sequencing of vaccines, and we have no studies on the long term NSE of the MMR.

The MMR might not be able to hold back measles.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905323/

http://cid.oxfordjournals.org/content/early/2014/02/27/cid.ciu105

We don't understand the long term consequences of these vaccines.

http://jid.oxfordjournals.org/content/early/2013/04/29/infdis.jit143.full

http://www.nvic.org/vaccines-and-diseases/measles/measles-vaccine-injury-death.aspx

In addition, the whistleblower situation with this vaccine is worth keeping an eye on.

I have four children and partially vac. on delayed schedule because there are real concerns.

Sarah Verkuil Turner

I have actually read about that lawsuit in the WSJ. Basically, they aren't claiming that the vaccine doesn't work, just that it doesnt have a 95% efficiency rate. So, let's give you the benefit of the doubt, and say the vaccine is only 80 to 90% effective. What's better, not taking a vaccine and having a zero percent chance that it works or taking the vaccine, and having a 80 to 90% chance that it will protect you against the mumps.
http://blogs.wsj.com/pharmalot/2014/09/10/did-merck-unfairly-monopolize-the-market-for-a-mumps-vaccine/

Sarah Verkuil Turner

Please don't bother replying. My intention in commenting was NOT to convince you of anything, as you have so aptly demonstrated is impossible; sort of like arguing with a brick wall, , but for others who are much more open minded to realize what people like you are doing to our public health in this country, and especially in pockets of Southern California, like the area that I live in as well. I responded because you happened to comment back. You however, have completely convinced me to support eliminating the personal exemption from vaccinations in order to attend public school. Your intention has failed completely with this article, "trying to add nuance"; all you have shown is how close-minded you are and others like you are. . I had hope differently, but I should have known better when I read that your doctor is Dr. Jay Gordon.

Elizabeth Aquino

@Sarah Verkuil Turner Yikes! A friend of mine reminded me today of the great Bob Dylan's line: "To live outside the law you must be honest."

Thanks, again, for an invigorating discussion.

6.7

News

I-Team: Can Flu Shots Be Risky?

February 20, 2015 11:45 PM

Related Tags: Flu Shots, health, I-team, Pharmacy Flu Shots, Risky Flu Shots

BOSTON (CBS) – Flu shots save lives. But the I-Team discovered that the vaccine also comes with a potential risk that few people know about; and the results can mean months or years of debilitating pain.

Raul DeJesus got his flu shot a year-and-a-half ago. He now has nerve damage in his left arm and has very limited motion.

The pain is so debilitating he takes powerful medications like a fentanyl patch, oxycodone and hydrocodone.

"That's just some of them; the list goes on and on," he said.

Debby Russo needed surgery to fix damage to her shoulder after her flu shot.

"It was a lot of pain," she said.

According to Lahey Medical Center infectious disease specialist, Dr. Robert Duncan, this kind of injury is not common but it can happen. It is usually the result of placing the shot too high in the arm.

Shoulder injuries have recently been recognized by the Federal Government's Vaccine Injury Compensation Program. Sometimes referred to as "vaccine court," it awards cash damages to people who are hurt by vaccines.

Shoulder injury is referred to as SIRVA or shoulder injury related to vaccine administration.

Attorney Paul Brazil has represented dozens of clients with shoulder problems who have received cash awards.

"Most cases fall somewhere in the $20,000 to $150,000 range," he said.

While any injectable vaccine can cause this damage, Brazil says most of his cases involved the flu shot.

"In my personal experience, it seems that a lot of vaccine petitioners get the vaccine at a pharmacy," he said.

Debby got her shot from a pharmacy and was awarded $108,000.

"I tell everyone. Do not get a shot of any kind at a pharmacy," she said.

The Journal of the American Pharmacists association recently published an article outlining this danger and offering tips to pharmacists on the proper procedure for giving a flu shot, including the ideal spot for an injection.

According to Brazil, this kind of education is critical.

"I think it's a lack of awareness," he said.

"I think if people know about SIRVA, if it was publicized more, then people administering vaccines might be more careful."

Raul wished that was the case at the health care clinic where he got his shot. His case is still pending.

"This has affected every single aspect of my life," he said. "Not to be able to do the things that I was able to do because of a simple flu shot."

Follow

7

National Vaccine Information Center

www.NVIC.org

***** VIA EMAIL*****

August 27, 2014

Mr. Dave King, Chairman
Advisory Commission on Childhood Vaccines (ACCV)
Division Of Vaccine Injury Compensation (DVIC)
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, MD 20857
Email: dking@salesmotion.com

Re: Request for ACCV to reconsider encephalopathy definition recommendation relating to the Vaccine Injury Table

Dear Mr. King,

Acute and chronic encephalopathy is one of the most serious vaccine adverse events on the Vaccine Injury Table (VIT) eligible for compensation under the federal Vaccine Injury Compensation Program (VICP). The Secretary of the Department of Health and Human Services (DHHS) is the legal respondent in the vaccine injury compensation process, is defended by the Department of Justice (DOJ) in claims proceedings and DHHS officials determine eligibility, administer the Trust Fund and make compensation payments awarded by the U.S. Court of Claims. Any revision of the definition of encephalopathy by DHHS officials is of great concern to the National Vaccine Information Center (NVIC), whose co-founders worked with Congress on the National Childhood Vaccine Injury Act of 1986 [1] to help ensure that the VICP would be a non-adversarial, expedited, less traumatic and more reliable alternative to a vaccine injury lawsuit in civil court.[2 3 4]

NVIC requests that ACCV carefully reconsider pending recommendations to change the definition of encephalopathy, which will be used as a guide by officials at DHHS and Department of Justice (DOJ), as well as by special masters in the Claims Court, to either award or deny compensation to plaintiffs filing vaccine injury and death claims. We make this request in hopes that ACCV will reaffirm and maintain the spirit and intent of the National Childhood Vaccine Injury Act, which is to err on the side of the petitioner in order to provide an economic safety net for those for whom the risks of vaccination are 100% and to address eroding public trust in the integrity of the vaccination system.

First, it is important to put NVIC's objections to changing the definition of encephalopathy in context by reviewing the history of the 1986 National Childhood Vaccine Injury Act and the VIT.

NVIC's History with the National Childhood Vaccine Injury Act of 1986

NVIC co-founders Jeffrey Schwartz, Barbara Loe Fisher and Kathi Williams, whose children had suffered serious reactions to DPT vaccine, founded the charitable non-profit Dissatisfied Parents Together (DPT) in the spring of 1982 with the mission of "preventing vaccine injuries and deaths through public education." Subsequently, they worked for four years with parents and Congress on the

1986 law at the request of congressional legislative staff.[5] In 1989, they established the National Vaccine Information Center (NVIC) and expanded the mission to include defending the ethical principle of informed consent to medical risk-taking, including vaccine risk-taking. For the past 25 years, NVIC has called for the institution of informed consent protections in U.S. vaccine policies and laws.[6]

The participation of parents of vaccine injured children during the legislative process creating the 1986 National Childhood Vaccine Injury Act was to ensure that the legislation would balance ***prevention*** of vaccine injuries and deaths with ***compensation*** for children suffering serious injury and for families of children who died after receipt of government recommended and mandated vaccines.

Importantly, the key to creating a no-fault, non-adversarial federal compensation alternative to a civil lawsuit was that the VICP would avoid compelling most plaintiff's to prove "causation in fact," which is the standard used in personal injury and product liability lawsuits filed in the tort system. There was to be a "presumption" of causation in the absence of a more biologically plausible explanation for the child's injury or death. Compensation was also to be awarded if there was evidence that a vaccination significantly aggravated a pre-existing health condition in the child leading to a substantial deterioration of health.[7]

Presumption of causation was key to making the VICP primarily an administrative, rather than an adversarial, system in order for:

(1) parents to want to select the no-fault, non-adversarial federal compensation alternative as the preferred legal option for obtaining compensation for their vaccine injured children, thereby reducing product liability and malpractice lawsuits; and

(2) to make the VICP less burdensome than a long, contentious, expensive and emotionally draining lawsuit for families caring for a severely vaccine injured child.

In addition to securing important vaccine safety informing,[8] recording and reporting provisions[9] in the 1986 law, among the unique contributions that NVIC parent co-founders made to the Act was to secure a provision in the Act that Congress would ask the Institute of Medicine (IOM), National Academy of Sciences, to review the medical literature and publish reports evaluating evidence regarding federally recommended vaccines and brain dysfunction, immune system disorders and death.[10] Parents of vaccine injured children participating in the legislative process were very concerned that those evaluating vaccine safety science be independent from influence by pharmaceutical corporations marketing vaccines in the U.S. and federal health agencies responsible for developing, regulating, making policy for and promoting state mandated vaccine use.

The IOM was selected as the entity included in the Act for conducting review and analysis of the vaccine safety science for several important reasons. While IOM receives funding from government and industry, IOM has a history of making efforts to assemble committees with broad representation utilizing a deliberative process that includes transparency and public engagement when addressing scientific and controversial public policy issues, unlike other government and industry funded organizations.[11]

Development of the VIT

The Vaccine Injury Table (VIT) included in the 1986 law was created primarily based on published scientific evidence in the medical literature and through a collaborative process that included participation by medical trade associations, whose memberships administer vaccines to children, such as the American Academy of Pediatrics. At the time the VIT was created, there were only seven vaccines federally recommended and state mandated for children and administered between the ages

of two months and six years: diphtheria, tetanus and pertussis (DPT); measles, mumps and rubella (MMR); and oral polio vaccine (OPV).[12]

The VIT incorporated clinical symptoms of vaccine reactions, injuries and deaths published in the medical literature and time periods within which most symptoms generally appeared following receipt of DPT, MMR and OPV vaccines. The purpose of the VIT was to provide officials at DHHS, DOJ and the U.S. Court of Claims with an administrative guideline for awarding no-fault, non-adversarial compensation to those children filing claims with evidence of serious health deterioration after receipt of government recommended and mandated vaccines or to families whose children died following vaccination. Causation is presumed for conditions listed in the VIT.

Encephalopathy: The VIT Centerpiece

The centerpiece of the VIT was a list of clinical symptoms associated with acute and chronic encephalopathy because encephalopathy[13] is one of the most serious complications of vaccination and can lead to permanent brain dysfunction. Acute encephalopathy or brain inflammation (encephalitis,[14 15] encephalomyelitis[16]) and chronic encephalopathy (persistent brain dysfunction) has been a long acknowledged serious reaction to vaccination since the first vaccines for smallpox and rabies[17 18] were developed and used in humans.

Acute and chronic encephalopathy also has been an acknowledged reaction to pertussis vaccine, a vaccine originally developed in 1912 and administered as a single component vaccine[19] before being combined with diphtheria vaccine[20] and tetanus vaccines (DPT) in the late 1940's[21] and recommended by federal health and AAP officials for children since the early 1950s.[22 23 24] Acute and chronic encephalopathy is also an acknowledged reaction to measles vaccine and measles containing vaccines (MR, MMR)[25] and has been reported following receipt of other federally recommended vaccines.[26 27]

Many of the children most in need of vaccine injury compensation have experienced acute encephalopathy with or without brain inflammation (encephalitis, encephalomyelitis) following vaccination[28 29 30 31]because brain inflammation or acute encephalopathy – irrespective of the cause - can lead to chronic encephalopathy (permanent neurological dysfunction).[32 33 34 35 36] Encephalopathy or chronic brain dysfunction can result in the most serious manifestations of brain injury, including physical and mental regression and failure to meet developmental milestones; dramatic personality and behavior changes; loss of muscle control, speech and other abilities; multiple learning disabilities and ADHD/ADD; medication resistant seizure disorders; behavior disorders and profound mental retardation.

The scientific literature has long recognized that neurological symptoms of acute encephalopathy can include:

- the sudden onset of convulsions (seizures);
- high pitched screaming *(cri encephalique*) resulting from cerebral irritation;
- and altered state of consciousness.

The literature has also historically recognized that seizures may be a manifestation of acute encephalopathy and that chronic encephalopathy can include residual seizure disorders that over time can cause irreversible brain damage. Chronic encephalopathy can render the child incapable of functioning independently in society as an adult, requiring lifelong economic support. Families caring for vaccine injured children with severe brain injury have little money, time or physical and emotional energy to spend on expensive and drawn out legal proceedings and the VIT was one mechanism for making the VICP a less burdensome legal alternative for petitioners.

Below is the original VIT that was included in the 1986 National Childhood Vaccine Injury Act with definitions for encephalopathy. The original VIT definition of encephalopathy and clinical signs and symptoms indicating encephalopathy remain consistent with the definitions of encephalopathy in past and current scientific literature.

VACCINE INJURY TABLE [37]

I. DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	3 days
C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
E. 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
II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine

		containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. 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
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. 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
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a) of this section:

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of

less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) **The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain**. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d) of this section, such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

Department of Health & Human Services (DHHS) Changes VIT Definition of Encephalopathy

In 1995, the Secretary of DHHS removed long recognized symptoms of acute and chronic encephalopathy, including seizures, from the VIT[38] *despite* (1) an IOM report published in 1991, which acknowledged that DPT vaccine can cause acute encephalopathy[39] and is associated with clinical symptoms such as seizures, collapse and protracted inconsolable crying (includes high pitched screaming or *encephalitic cry*) and (2) an IOM report published in 1994 that acknowledged DPT vaccine can cause chronic encephalopathy.[40]

When the 1986 law was enacted, encephalopathy was defined in the VIT as "*any acute or chronic significant acquired abnormality of, or injury to, or impairment of function of, the brain*". In 1995, DHHS rewrote the VIT definition for acute encephalopathy as "*a significantly decreased level of consciousness lasting for at least 24 hours*" and specifically excluded clinical signs and symptoms of acute encephalopathy that have been reported in the medical literature for a century.

Contrary to the IOM's definition of encephalopathy, the new VIT definition re-written by DHHS in 1995 and still in effect today states:

> "*The following clinical features alone or in combination do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.*"

Encephalopathy Defined: Institute of Medicine Reports (1991-2012)

1991: IOM Report on Adverse Effects of Pertussis and Rubella Vaccines

The 1991 IOM committee report *Adverse Effects of Pertussis and Rubella Vaccines*[41] identified a causal relationship between DPT vaccine and acute encephalopathy. This report went into great detail when describing clinical symptoms and scientific definitions of encephalopathy, with the committee noting that "acute or subacute encephalitis, encephalomyelitis and encephalopathy" were used in various published studies to describe a "constellation of symptoms and signs reflecting a generalized disturbance in brain function" that may include:

- altered levels of consciousness;
- confusion;
- irritability;
- headaches;
- changes in behavior;
- screaming attacks;
- neck stiffness;
- sudden onset of convulsions;
- visual, auditory or speech disturbances;
- motor and sensory deficit;
- other neurological abnormality of the brain.

Knowledge Gaps: The 1991 IOM report also for the first time pointed out to the medical community and the public that there is a serious lack of quality basic science research and methodologically sound epidemiological studies evaluating the biological mechanisms and frequency of vaccine adverse events and natural history of conditions, such as encephalopathy. These knowledge gaps hampered the IOM committee's investigation into reported serious health problems associated with the two federally recommended childhood vaccines (DPT, rubella). The committee stated:

> *"In the course of its review the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. Such shortcomings relate, for*

example, to pathologic mechanisms of specific infectious agents, the molecular basis for vaccine injury, and the natural history of conditions such as ***encephalopathy****, mental retardation and chronic arthritis."* [42]

1994: IOM Report on Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality

The Institute of Medicine issued two important reports in 1994 and both fell within the congressional vaccine research mandate under the 1986 law for IOM to review medical literature and other evidence that there are health risks to children associated with federally recommended vaccines.

Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality was a report that reviewed evidence related to seven federally recommended childhood vaccines: diphtheria, tetanus, measles, mumps, polio, hepatitis B and H. influenza type b (Hib) vaccines.[43]

Continuing Knowledge Gaps: For more than 30 reported serious brain and immune system problems associated with the seven federally recommended vaccines under examination, the 1994 IOM committee was unable to come to a conclusion about *whether or not* there was a causal relationship, including for **encephalopathy and residual seizure disorders** related to several vaccines. Once again, an IOM committee was frustrated by gaps in vaccine safety science and made statements such as:

> *"For the vast majority of vaccine-adverse event relations studied, the data came predominantly from uncontrolled studies and case reports."* [44]

This 1994 report echoed concerns expressed in the 1991 IOM report about lack of scientific knowledge about vaccine adverse events and why there is individual susceptibility to suffering vaccine harm:

> *"The lack of adequate data regarding many of the adverse events under study was of major concern to the committee....The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."* [45]

In a concluding chapter "Need for Research and Surveillance," the committee stated:

> *"The committee found that a judgment regarding causality was often limited by the absence of background data for the occurrence of the pathologic condition (the putative adverse event) in apparently normal individuals not recently exposed to the vaccine."* [46]

This lack of background data for the occurrence of acute encephalopathy in unvaccinated children or those receiving fewer vaccines, such as learning disabilities, ADD/ADHD, seizure disorders, developmental delays and other chronic brain and immune disorders, continues today to hamper causality conclusions about encephalopathy and vaccination.

1994: IOM Report on DPT Vaccine & Chronic Nervous System Dysfunction

The second report issued by IOM in 1994, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* was groundbreaking.[47] This report affirmed the conclusions of the *National Childhood Encephalopathy Study (NCES)* published by the British government in 1981.[48]

More than three decades after *NCES* was published, it remains the largest well-conducted prospective, case controlled study of neurological disorders in children. The *NCES* included evaluation of cases of

acute and chronic encephalopathy that developed after children received DPT or measles vaccines and, in 1981, *NCES* authors concluded that receipt of DPT vaccine was causally related to the development of acute encephalopathy (encephalitis, encephalomyelitis) and permanent brain damage in some previously healthy children enrolled in *NCES*, as well as those with underlying brain or metabolic disorders after the DPT vaccine "triggered" expression of the underlying disorder.

Attributable risk estimates in for participants in *NCES* were that:

- **1 in 110,000 DPT shots was followed by an acute encephalopathy within seven days of administration of the vaccine**; and

- **1 in 310,000 DPT shots was followed by persistent neurological damage one year later.**

It is notable that in 1981, the same year that the *NCES* was published confirming that DPT vaccine can cause acute and chronic encephalopathy, an FDA-sponsored case controlled study conducted at UCLA was published reporting the results of a head-to-head comparison of the reactivity of whole cell DPT vaccines and DT vaccines.[49] That U.S. study found that DPT vaccine was far more reactive than DT vaccine and estimated that 1 in 1,750 DPT shots was followed by a convulsion or a hypotonic-hyporesponsive episode (HHE).

In 1993, *NCES* authors published a 10-year follow up of the children, who had developed an acute encephalopathy after DPT vaccination during the study.[50] They found that many of the children were continuing to suffer clinical symptoms of neurologic, behavioral, educational, motor, sensory and self care dysfunctions, including:

- low scores for global educational abilities assessed by intelligence, vocabulary, spelling, reading and arithmetic tests;
- epilepsy/seizure disorder;
- tremor;
- fine or gross motor incoordination;
- muscle weakness or spasticity in one or more limbs;
- hearing and vision problems;
- behavioral dysfunction (problem, hyperactive or unsociable behavior);
- lack of bladder or bowel control.

The *NCES* authors said:

> ***"Our results provide good evidence that illnesses such as those studied in the national childhood encephalopathy study, including a variety of encephalopathies and severe convulsions, both febrile and afebrile, can have lasting sequelae as measured by various indices of brain function. This seems to be true for cases associated in time with diphtheria, tetanus and pertussis immunization as for other cases."*** [51]

The 1994 IOM Committee to Study New Research on Vaccines reviewed the 10-Year follow up of *NCES* and determined that, in addition to the evidence about acute and chronic encephalopathy they had collected for the 1991 IOM report on DPT vaccine, there was compelling scientific evidence to conclude that children with or without underlying brain or metabolic abnormalities can experience an acute encephalopathy within 7 days after receipt of DPT vaccine and go on to suffer chronic neurological dysfunction.

The IOM committee stated:

> ***"The NCES data are consistent with the possibility that some children without underlying brain or metabolic abnormalities might experience serious acute neurologic illness within 7 days after receiving DPT and that acute illness could have chronic nervous system sequelae. The NCES data are also consistent with the possibility that some children with underlying brain or metabolic abnormalities (which foster a "triggering" by DPT of an acute neurologic illness) might go on to develop chronic neurological dysfunction due to a DPT-triggered acute illness. Therefore, the committee concludes that the balance of evidence is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine."*** [52]

[In September 2006, DHHS officials and four health maintenance organizations (HMOs) participating in the DHHS-operated Vaccine Safety Datalink Group published a retrospective study that concluded DPT and MMR vaccines do not cause encephalopathy.[53] The study has never been replicated and part of the reason may be that non-DHHS, independent scientists are unable to get access to raw data used in Vaccine Safety Datalink Group studies to confirm VSD vaccine safety findings.

In 2005, the IOM Committee on the Review of the National Immunization Program's Research Procedures and Data Sharing Program published a report, *Vaccine Safety Research, Data Access, and Public Trust*. [54] The IOM Committee concluded that there is "limited ability of independent external researchers to conduct high quality corroborative studies or studies of new hypotheses" [55] using VSD data:

> ***"There are legitimate concerns about the independence and fairness of the implementation of review procedures applied to VSD data sharing proposals and of determination about the release of preliminary findings from VSD analyses. The lack of transparency of some of the processes also affects the trust relationship between the National Immunization Program Office (NIP) and the general public."*** [56]

Prospective studies, such as NCES, are superior to retrospective studies and replication is a gold standard in science. The DHHS-conducted 2006 study rejecting a causal association between DPT and MMR vaccines and encephalopathy, a study which has never been replicated and contradicts conclusions of more transparent studies adhering to higher scientific standards, should not influence the revision of the VIT definition of encephalopathy or be used to deny compensation to those suffering encephalopathy following receipt of MMR or pertussis containing vaccines.]

The 1991 and 1994 IOM reports reaffirmed the evidence base for the definition of encephalopathy embedded in the original VIT in the VICP, including acknowledgement of the fact that some children have pre-existing identified and unidentified genetic or biological risk factors that can be triggered by administration of vaccines or have pre-existing medical conditions that can be significantly aggravated by vaccination. Appropriately, there have been vaccine injury compensation awards made to children, who were born with genetic or biological high risk factors, such as an undiagnosed brain or metabolic disorder, that increased their susceptibility to suffering harm from federally recommended vaccines.[57]

2012: IOM Report on Adverse Effects of Vaccines: Evidence and Causality

In 2012, two decades after the first congressionally mandated 1991 IOM report was published, the IOM published a report *Adverse Effects of Vaccines: Evidence and Causality*[58] again reviewing the medical literature for scientific evidence that federally recommended vaccines can cause brain and immune system dysfunction and death. The report reviewed a total of 158 vaccine-related adverse events - including **encephalitis, acute disseminated encephalomyelitis (ADEM) and encephalopathy** - reported following receipt of varicella zoster (chickenpox) vaccine; influenza vaccines; hepatitis B vaccine; human papillomavirus vaccine (HPV); tetanus toxoid-containing vaccines other than those containing the whole cell pertussis component; measles, mumps and rubella vaccines; hepatitis A vaccine; and meningococcal vaccines.

In 2009, the Health Resources and Services Administration (HRSA) had contracted with IOM to conduct what would become the largest assessment of epidemiologic, clinical and biological mechanism evidence about vaccine adverse event outcomes conducted by IOM since the 1986 Childhood Vaccine Injury Act became law and IOM published the 1991 and 1994 reports requested by Congress under the Act. The CDC and National Vaccine Program Office (NVPO) also contributed funding for the 2012 IOM study.[59]

The stated purpose of the 2012 IOM study was to provide scientific basis for review and adjudication of claims of vaccine injury by the VICP. At the study outset, HRSA presented a list of specific adverse events for the committee to review, which HRSA indicated represented the majority of adverse events listed in VICP petitioner claims. During the course of its review of the medical literature, the IOM committee added to the report the following adverse events for which epidemiological studies or case reports were identified:

- all cause mortality and seizures following influenza vaccine;
- optic neuritis following MMR, influenza, hepatitis B and DTaP vaccines;
- neuromyelitis optica following MMR vaccine;
- erythema nodosum following hepatitis B vaccine;
- stroke and small fiber neuropathy following varicella vaccine.

The 2012 IOM Committee to Review Adverse Effects of Vaccines concluded that "the evidence convincingly supports" or "favors acceptance of" a causal relationship between:

- varicella vaccine and Oka varicella zoster vaccine reactivation;
- MMR vaccine and measles inclusion body encephalitis;
- MMR vaccine and febrile seizures;
- Anaphylaxis and MMR, varicella, influenza, hepatitis B, meningococcal, HPV and tetanus toxoid vaccine;
- MMR vaccine and transient arthralgia in female adults and children;
- Any of the vaccines and syncope (sudden loss of consciousness)
- Any of the vaccines and deltoid bursitis;

However, significantly for 135 (85%)[60] of serious adverse health outcomes associated with one or more of the federally recommended vaccines under examination there was either an absence of or too little biological mechanism evidence and/or methodologically sound epidemiologic studies related to the vaccine and reported serious adverse health outcome for the committee to make a causation conclusion. This lack of enough scientific evidence to make a causation

determination between a number of the vaccines being studied and a wide range of brain and immune system disorders included:

- **Encephalitis; encephalopathy; acute disseminated encephalomyelitis (ADEM);** meningitis; traverse myelitis; optic neuritis; chronic inflammatory disseminated polyneuropathy; Bell's palsy; small fiber neuropathy; Guillain Barre Syndrome GBS); afebrile seizures; infantile spasms; opsoclonus/myoclonus syndrome; ataxia; first demyelinating event in children and adults; multiple sclerosis in children and adults.

Like the previous IOM committees, this committee was unable to come to conclusions about causation for the majority of vaccine-related adverse health outcomes because of continuing gaps in scientific knowledge about the biological mechanisms for vaccine adverse effects. Chapter 3 "Evaluating Biological Mechanisms of Adverse Events" is a thoughtful description of the outstanding biological mechanism questions that need to be answered before there can be a better understanding of how and why vaccines can cause acute and chronic brain and immune system dysfunction and death.

The 2012 report highlights the lack of understanding of biological, genetic, environmental and other high risk factors, which increase an individual's susceptibility to vaccine reactions:

> ***"Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a pre-existing susceptibility. These predispositions can exist for a number of reasons – genetic variants (in human or microbiome DNA), environmental exposures, behaviors, illness or developmental stage, to name just a few, all of which can interact. Some of these adverse reactions are specific to the particular vaccines, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not."*** [61]

In the Preface of the published 2012 study, the IOM committee chair, Ellen Wright Clayton, M.D., stated that the committee "had a herculean task, requiring long and thoughtful discussions of our approach to analyzing the studies culled from more than 12,000 peer-reviewed articles." She said "some issues simply cannot be resolved with current available epidemiological data" and emphasized that scientific conclusions about cause and effect relationships between vaccines and reported adverse events requires a combination of biological mechanism and epidemiological evidence, particularly when it comes to identifying individual susceptibility risk factors:

> *"Even very large epidemiologic studies may not detect or rule out rare events. Subgroup analysis or more focused epidemiologic studies, informed by as yet incomplete knowledge of the biological mechanisms of vaccine-induced injury, may be required....The value of dialogue between both epidemiologic and mechanism approaches cannot be overstated. Epidemiologic studies can identify particular high risk groups, who can then be examined with more in depth testing to explore predisposing factors. The findings of such studies can then inform more focused epidemiologic research as well as efforts to reduce risks. These conversations between different types of research can be difficult, but the results are worth it."*

While the 2012 IOM Committee noted recent discoveries relating to SCN1A mutations, Dravet syndrome and encephalopathy, they were cautious in drawing any conclusions and stated:

> "This list of factors that are known to confer susceptibility is by no means definitive or exhaustive. Rather, we hypothesize that continued study of alleged vaccine-related injuries, the committee informed by epidemiologic studies that identify vulnerable populations and exploration of underlying mechanisms of susceptibility, will provide greater insight into these and other mechanisms and will identify more factors that contribute to vaccine susceptibility." [62]

More recent studies with regard to Dravet syndrome have noted de novo genetic mutations of SCN1A may occur at any time, from the embryonic premorula stage to adulthood[63] and the syndrome "encompasses different epileptic and cognitive phenotypes that probably result from both genetic and epigenetic factors."[64] Coupled with the 2012 IOM Committee's acknowledgement that fever induced by vaccines may trigger Dravet syndrome, these studies indicate that there are as yet unidentified genetic, biological and environment factors involved in expression of Dravet syndrome in some individuals and leaves open the possibility that individuals may go through their whole lifetime without exhibiting symptoms of Dravet syndrome.

In the IOM 2012 report the following statements were made regarding Dravet syndrome and whole cell pertussis vaccine:

> *"In some metabolically vulnerable children, receiving vaccines may be the largely nonspecific "last straw" that leads these children to reveal their underlying genotype. It was recently discovered that a large majority of children who developed encephalopathy after receiving whole cell pertussis vaccine have mutations in SCN1A, which are associated with Dravet syndrome or severe myoclonic epilepsy of childhood (Berkovic et al., 2006; McIntosh et al., 2010). While it seems likely that the vaccine triggered symptoms in these children by causing high fever, the particular vaccine antigens do not appear to alter the course of the disease. Rather, the ensuing phenotype could and probably would have been precipitated by multiple other fever-inducing triggers (McIntosh et al., 2010; Wiznitzer, 2010)."* [65]

At issue is the implication that "a large majority of children" who develop encephalopathy after receiving whole cell pertussis vaccine have mutations in SCN1A, when the 2006 Bercovic et al study examined only 14 patients and the 2010 McIntosh study examined 40 patients. This dataset is not large enough to make that sweeping conclusion and certainly not enough justification to change the definition of encephalopathy for the purpose of denying vaccine injury compensation to those children with that genotype.

In 2011, a study by Tro-Baumann et al retrospectively examined the relationship between vaccination and occurrence of seizures in 70 children with Dravet syndrome. The authors pointed out that 27% of patients suffered seizures post-vaccination (primarily after DPT vaccine) and in 58% vaccine-related seizures represented the first clinical manifestation. Appropriately, the study authors called for "preventive measures for seizures triggered by vaccination or fever in these children." [66]

There can be no assumption that *all* individuals with SCN1A mutations associated with Dravet, who develop encephalopathic symptoms after vaccination, including seizures, would have developed encephalopathy even if no vaccines had been given. Children born with SCN1A mutations, who develop acute and chronic encephalopathy after vaccination, should not be precluded from receiving vaccine injury compensation simply because of the genes they were born with, genes which may or may not have been expressed had one or more federally recommended vaccines not been given.

Definitions for Encephalopathy Align with IOM Findings

The IOM is not alone in their acknowledgment of signs, symptoms and definitions of encephalopathy long recognized in the medical literature.

- **The National Institutes of Health's National Library of Medicine** states encephalitis complications can lead to permanent brain damage with symptoms that can include mild fever, mild to severe headache, low energy, poor appetite, clumsiness, unsteady gait, confusion, disorientation, drowsiness, irritability, light sensitivity, stiff neck and back, vomiting, fontanel bulging (infant), loss of consciousness, stupor, coma, muscle weakness, paralysis, seizures, flat mood, inappropriate mood, memory loss that may be caused by the following vaccines: MMR, Polio, Varicella.[67]

- **The National Institute of Neurological Disorders and Stroke (NINDS)** uses the following definitions and symptoms for the following conditions:
    - **Encephalitis** is an inflammation of the membranes surrounding the brain and spinal cord with symptoms that can include sudden fever, headache, vomiting, light sensitivity, stiff neck and back, confusion and impaired judgment, drowsiness, weak muscles, clumsy and unsteady gait, irritability, loss of consciousness, seizures, muscle weakness, and/or sudden severe dementia. Complications can include permanent impairment or death.[68]
    - **Encephalopathy** is a condition that results in the altering of the structure or function of the brain that may include the following symptoms: altered mental state, progressive loss of memory and cognition, involuntary muscle twitching, subtle personality changes, rapid involuntary eye movement, tremor, muscle atrophy and weakness, dementia, seizures, apraxia (loss of speech), and/or inability to swallow. This condition may cause permanent changes and irreversible damage to the brain and can be fatal. [69]
    - **Acute Disseminated Encephalomyelitis** is characterized as an attack of inflammation of the brain and spinal cord that damages the protective covering of nerve fibers. This condition can result from the MMR vaccine with encephalitis-like symptoms appearing rapidly that can include fever, fatigue, headache, nausea, vomiting, seizures and coma. The damage to nerve fibers typically lead to neurological symptoms that can include vision loss, paralysis, muscular coordination difficulties. Some ADEM patients will have lifelong impairment such as cognitive difficulties, weakness, loss of vision, numbness, and can be fatal.[70]

Current VIT Language Under Consideration

The current language the ACCV is being asked to approve relating to the VIT and encephalopathy and are additions to the QAI that would stating

> "Individuals who return to their baseline neurologic state, as confirmed by clinical findings, in **less than** 6 months **from the date of vaccination** shall not be presumed to have suffered residual neurologic damage from that event..."
>
> and
>
> "...an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by: (A) An underlying condition or systemic disease

shown to be unrelated to the vaccine (such as a malignancy, structural lesions, psychiatric illness, dementia, genetic disorder..."

This restrictive and exclusionary encephalopathy guideline change unfairly discriminates against children and adults born with certain genes or pre-existing medical conditions that may be triggered or significantly aggravated following receipt of government recommended and mandated vaccines. There is no ethical, scientific or legal justification for denying compensation to susceptible individuals because of the genes they were born with, especially in light of the fact that significant knowledge gaps about the biological mechanisms and high risk factors for vaccine injury remain. The VICP cannot and should not be a vehicle for discrimination against those most vulnerable to vaccine injury and death.

Knowledge Gaps, Biodiversity & Individual Susceptibility Being Ignored

Science is not static but continually evolves. In the coming years, there will be more information about genetic and other high risk factors that predispose some individuals to suffering vaccine induced encephalopathy and other serious, life altering brain and immune system disorders. The emerging new microbiome and epigenetics science, which is focusing on biodiversity and how it affects individual health outcomes, will change the practice of medicine.

Microbiome Individual Differences: Resident microbes add another 100 trillion cells to the 10 million cells that make up the human body and contributing 8 million genes that interact with 21,000 human genes to help our body grow, digest food, develop and mount immune responses and perform many other normal bodily functions.[71] [72] [73] In 2014, researchers in Ireland studying the microbiome, stress, health and disease observed that the microbiome is established during the first three years of life but that it evolves throughout our lives as we constantly respond to our environment and there are microbiome differences between individuals:

> *"The microbiome is a dynamic entity that is under continuous evolution throughout the host's lifetime in particular during the first three years of life during which time a stable microbiome is established. It is sensitive to a whole array of manipulations such as diet, stress, infection, pharmacological interventions and thus is it clear that the composition of the microbiota is distinct at different milestones of life."*[74]

Epigenetics & Individual Differences: Together with a better understanding of the complexity of the microbiome, the new field of epigenetics is highlighting the importance of respecting biodiversity.[75] Epigenetics, which can be defined as stimuli-triggered changes in gene expression that are inheritable and occur independent of changes to the underlying DNA sequence[76] provides compelling evidence for the urgent need to fill in knowledge gaps about individual susceptibility to vaccine reactions. Scientists have discovered that differing external environmental exposures (such as nutrients, chemicals, infections) and individual responses to trauma and fear, for example, can trigger changes in chromatin structure and gene expression to uniquely affect each individual's susceptibility to certain illnesses and disorders and these susceptibilities can be passed on to future generations.[77] [78]

Microbiome and epigenetics science highlights why there is an urgent need to acknowledge and adjust for individual differences in responses to vaccines and to respect individual susceptibilities, not ignore or punish those with them when considering awards for development of encephalopathy after vaccination. Hopefully the new science will lead to a move away from the current one-size-fits-all approach to vaccine policies and in the future fewer individuals will need to apply for vaccine injury compensation.

In the meantime, vaccine manufacturers protected from civil liability by the 1986 law should make greater efforts to better define the biological mechanisms for adverse events and potential genetic,

biological and environmental high risk factors that place some individuals at higher risk than others for suffering encephalopathy and other types of brain and immune system damage from both existing and new vaccines being developed so fewer children and adults will become vaccine injured VICP claimants.[79] [80]

NVIC urges the ACCV to vote against the DHHS recommendations for the revision of the definition of encephalopathy because it is not based on sound science and will unfairly discriminate against those most susceptible to vaccine injury and death, as well as further erode parent and public confidence in the integrity of the vaccine system.

Sincerely,

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/s/Theresa Wrangham
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