ADVISORY COMMISSION ON CHILDHOOD VACCINES
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December 05, 2013

- Bio, Chief Special Master Denise K. Vowell

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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

DRAFT November 25, 2013

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

Teleconference and Adobe Connect

December 05, 2013
(10:00 am – 4:00 pm Eastern Daylight Time)
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Thursday, December 05, 2013

Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Mr. David King, Chair
10:10 AM	Public Comment on Agenda Items	
10:15 AM	Approval of September 2013 Minutes	Mr. David King, Chair
10:20 AM	Report from the Division of Vaccine Injury Compensation	Dr. Vito Caserta Acting Director, DVIC
10:50 AM	Presentation: Making the ACCV Most Effective	Dr. Vito Caserta, DVIC Mr. Vince Matanoski, DOJ Ms. Denise K. Vowell, OSM, Chief Special Master
11:50 AM	Lunch	
12:50 PM	Discussion regarding In-Person Meetings	TBD
1:20 PM	Report from the Process Workgroup	Ms. Luisita dela Rosa, ACCV Member
2:20 PM	Report from the Department of Justice	Mr. Vince Matanoski Deputy Director Torts Branch, DOJ

Time	Agenda Item	Presenter
3:00 PM	Review of Vaccine Information Statements	Mr. Skip Wolfe, CDC
3:50 PM	Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Ms. Barbara Mulach NIAID, NIH
4:05 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	LT. Valerie Marshall CBER, FDA
4:20 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimabukuro CDC
4:35 PM	Update from the National Vaccine Program Office (NVPO)	Dr. Steve Bende NVPO
4:45 PM	Public Comment (follows the preceding topic and may commence earlier or later the 4:45 pm)	
5:00 PM	Future Agenda Items/New Business	Mr. David King, Chair
5:15 PM	Adjournment of the ACCV December Quarterly Meeting	Mr. David King, Chair

Charter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

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

Objectives and Scope of Activities

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

Description of Duties

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

Agency or Official to Whom the Commission Reports

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

Support

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

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Commission, including compensation and travel expenses for members, but excluding staff support, is approximately $84,685. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $257,582.

Designated Federal Officer

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

Estimated Number and Frequency of Meetings

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

Duration

Continuing.

Termination

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

Membership and Designation

The Secretary shall select members of the Commission. The members of the Commission shall select a Chair and Vice Chair from among the members. Appointed members of the Commission shall be appointed for a term of office of 3 years. Members may serve after the expiration of their term until their successors have taken office.

The Commission shall be composed of the following:

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

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

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

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

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

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

Subcommittees

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

Recordkeeping

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

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Filing Date
July 21, 2012

Approved:

July 17, 2012
Date

for Jennifer Rizzle
Wendy Ponton
Director, Office of Management

Roster

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2014 Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2013 MEETING DATES

December 5, 2013

2014 MEETING DATES

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

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Advisory Commission on Childhood Vaccines

September 5, 2013

88th Meeting

Teleconference Minutes

Members Present

David King, Chair
Charlene Douglas, Ph.D.
Kristen Feemster, M.D.
Edward Kraus, J.D.
Ann Linguiti Pron, DNP, CPNP, PNP-BC
Luisita dela Rosa
Jason Smith, J.D.
Michelle Williams, J.D.

Division of Vaccine Injury Compensation

Vito Caserta, MD., Acting Director, DVIC
Andrea Herzog, Staff Liaison
Amber Berrian, DVIC staff

Federal Government Representatives

Steve Bende, M.D., NVPO, DHHS
Valerie Marshall, Office of Vaccines, FDA
Vince Matanoksi, Office of the General Counsel, DOJ
Barbara Mulach, NIAID, NIH
Tom Shimabukuro, M.D., Immunization Safety Office, CDC

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

Noting a quorum present, Mr. King called the meeting to order and, after introductions, reminded the members of the charge to the Commission, to advise the Secretary of the Department of Health and Human Services (DHHS) particularly with regard to the Vaccine Compensation Act, which has the purpose of providing financial support for anyone injured by the vaccination process. He added that, at the end of the meeting when new business is discussed, one item will be how the Commission can be most effective in fulfilling its mission in the relatively new virtual meeting environment.

Public Comment on Agenda

Mr. King invited public comments regarding items on the day's agenda. James Lidier(?) commented that making the meeting materials available on the web site was helpful, particularly the ACCV work book, but requested that the materials be made available to the public at least the day before the meeting to allow time for review before the meeting begins. He added it would also be helpful to leave the materials on the web site after the meeting for future use.

Dawn Loughboro, parent of two vaccine-injured children, supported the addition of Guillain Barre syndrome (GBS) to the Vaccine Injury Table (table) (an agenda discussion scheduled for 11:20). She also stated the she would support the addition of Type 1 diabetes for Hib vaccine, regressive autism or thimerosol-related injury, both retroactive for 15 years; MMR encephalopathy leading to autism; and mitochondrial disorders to the table. Ms. Loughboro encouraged the conduct of a retrospective study of vaccinated versus unvaccinated children, innovation related to genetic and metabolic predictors prior to vaccination, and an active education program about VAERS, particularly for parents and pregnant women, and for pediatricians for whom there are few incentives to report adverse events to the VAERS. Finally, she encouraged holding "face-to-face" meetings.

Approval of June 2013 ACCV Meeting Minutes

There being no further requests to comment, Mr. King closed the public comment section of the agenda and invited approval of the June 2013 meeting minutes. Mr. King noted a discrepancy in wording on page 7 of the minutes, a reference to the Department of Justice being responsible for determining "legislative strategy." In fact, legislative strategy is determined by the Secretary of HHS. Mr. Matanoski, representing the Department of Justice, confirmed that the minutes should be corrected to read "litigative strategy."

There was a suggestion that the reference to "various data" in the Report of the Chair on page 1 was vague. After discussion there was agreement that the term referred to various types of information pertaining to specific cases and that the wording should be revised to read "various case data." Mr. King reiterated that, as was noted in the June minutes, no Commission member was willing to assume the responsibility of chairing the work group, making it impractical to consider the proposal further.

On motion duly made and seconded, the minutes were unanimously approved with the corrections discussed above.

Report from the Division of Vaccine Injury Compensation (DVIC), Dr. Vito Caserta, Acting Director, DVIC

Dr. Caserta briefly reviewed the day's agenda, noting that the Commission would consider the addition of GBS to the Vaccine Injury Table. Turning to the statistics since the last meeting, Dr. Caserta noted that 353 petitions had been filed to date, which indicates that the number of petitions filed this year will be similar to the number filed in the past several fiscal years (FY).

Compensable adjudications were 286, which is slightly higher than in the last two fiscal years. Continuing an upward trend, settlements represented 87% of adjudications (82% in fiscal year 2012 and 75% in fiscal year 2011). Finally, awards paid as of August 13 were $215 million and, with two pending awards of $48 million (which should be paid before the end of the fiscal year) and $40 million, the awards should hit an historic high. Dr. Caserta announced that a new table had been added to the VICP web site, breaking out the adjudicated categories by vaccine for claims filed since calendar year 2006.

Dr. Caserta commented that the Vaccine Injury Compensation Trust Fund balance was $3.4 billion with net income through July 31 of about $161 million. Asked why U.S, Office of Management (OMB) approval was required to pay the higher awards obligation, Dr. Caserta explained that, although there are more than sufficient funds in the Trust Fund, DVIC must request approval from the Secretary DHHS, who must request authorization from OMB to expend those funds. He added that rarely the level of funding may fall so low that there are very brief delays in issuing awards, usually only a few days. Although that actually occurred in the recent past because of the very high awards, petitioners are not affected since if payments must be delayed, attorney's fees payments will be delayed. He reiterated that these issues are very short-lived, usually only a day or so.

In terms of significant activities, Dr. Caserta noted that the nomination deadline for new Commission members was extended 60 days because of a lack of qualified nominations in all of the categories required. He stated that the American Academy of Pediatrics had submitted a nomination for the provider category, but there were no others. Mr. King observed that the charter requires three attorneys on the Commission, one of whom must represent vaccine-injured individuals, one of whom must represent the vaccine manufacturers – but there is no specification of the third and no requirement for balance. He suggested that, as a matter of fairness and policy, the third attorney should represent vaccine-injured individuals. Ms. Williams expressed concern with that recommendation and suggested moving the discussion of the issue to the Process Work Group. Asked when the 60-day extension would end, Ms. Herzog explained that the clock would run from the day the announcement is published in the Federal Register, which should be within the next two weeks. The wording would be the same as the notice published on July 10, with a possible clarification of the term "qualified individual," a modification that would not affect any aspect of the announcement. Dr. Caserta added that, if the Commission is not able to fill slots being vacated by current Commission members, those members would be asked to extend their terms until a replacement could be confirmed. Ms. Pron requested that the Commission be informed when the announcement was published.

Asked to comment on increased efforts to recruit nominees, Amber Berrian explained that there would be an effort to publicize the requirement beyond the Federal Register by taking advantage of the HRSA web site and list serve.

Dr. Caserta announced that the rotavirus Notice of Proposed Rulemaking was published on July 24th, with public comments welcomed until January 21st, at which time there would be a public hearing on the matter. Under the heading Other Significant Activities, Kristen Feemster and Anna Jacobs made presentations at the June 11-12 National Vaccine Advisory Committee

(NVAC) meeting, which were considered outstanding by the NVAC Chair, and the Advisory Committee on Immunization Practices met on June 19-20.

Finally, Dr. Caserta confirmed that Amber Berrian would be transitioning into the staff position that Annie Herzog had covered so capably. Annie would continue with DVIC in a supporting role until that transition was complete. He concluded his presentation with contact information.

During discussion, on a presumption that he would become the DVIC director, Mr. David Kings, ACCV Chair, asked Dr. Caserta what he felt would be required to make the Commission most effective, Dr. Caserta suggested that he consider the question and formulate a complete response that he could present at the next Commission meeting.

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

Mr. Matanoski referenced the DOJ Power Point materials (DOJ PP), dated September 5, 2013, as part of his presentation.

Mr. Matanoski began with DOJ's statistical report for the time period of May 16, 2013 – August 15, 2013 (DOJ PP at 2-4). During this reporting period, 113 new petitions were filed. No autism petitions were filed. The historical dip in filings in the summer months did not appear, which could portent a higher rate of filings for this year than in the past. Of the 113 new petitions, 86 were filed on behalf of adults and 27 for minors. (DOJ PP at 2). For this quarter, 120 petitions were adjudicated with 88 compensated and 32 not compensated/dismissed. Of the 88 claims compensated, 9 were conceded by HHS (all 9 were by decision adopting a proffer). Of the 79 cases compensated but not conceded by HHS, 1 was by decision awarding damages, 1 was by decision adopting a proffer, and 77 were by decision adopting a stipulation. Of the 32 non compensated/dismissed, 13 were non-autism dismissals by decision. Because the court worked through most of the autism backlog, the number of non-compensated cases dropped dramatically from 228 reported in the preceding reporting period to only 19 in this reporting period. There was 1 petition voluntarily withdrawn without judgment entering; no autism claims were withdrawn.

Mr. Kraus commented that the distinction between autism and non-autism cases may no longer be applicable or appropriate as a descriptor since autism cases had been identified as part of the Omnibus Autism Proceeding (OAP). Mr. Matanoski acknowledged the point but noted that autism cases were still being dismissed. However, continuing to identify a category of autism filings might not be germane as there has not been any autism petitions filed.

Ms. Pron commented on the low number of conceded cases, suggesting that the number might increase as the Injury Table is expanded. Mr. Matanoski agreed, pointing out that the number reported as this time was nearly double the number reported at the last meeting, but still a very small number. He added that a significant number of petitions do not allege a Table injury.

Mr. Matanoski identified the glossary of terms (DOJ PP at 5-7) together with the wire diagram depicting case processing (DOJ PP at 8) and the appeals chart (DOJ PP at 9-10). These have been presented at past meetings.
Turning to appellate activity at the U.S. Court of Appeals for the Federal Circuit (CAFC), Mr. Matanoski discussed two recently decided cases in one case brought by petitioner and one by respondent. (DOJ PP at 11). *Deribeaux v. HHS*, involved a medical question about the cause of a child's seizure condition and whether or not the seizure was a symptom of an underlying genetic SCN1A mutation, known as Dravet's Syndrome. The question became whether or not the vaccines precipitated or significantly worsened the child's SCN1A/Dravet's Syndrome. The special master determined that the preponderant evidence showed that the initial seizure triggered by the child's vaccination was a symptom not a cause of her neurological condition, which was unaffected by the vaccine, and that respondent successfully met her burden of proving a factor unrelated – SCN1A/Dravet's Syndrome - caused the child's injuries. On review to the U.S. Court of Federal Claims (CFC), the judge upheld the special master'sdecision. The CAFC affirmed the dismissal, confirming that the special master's findings of fact are entitled to deference. In *Paterek v. HHS*, an appeal brought by respondent, the CAFC reversed the CFC's decision, which had reversed and remanded the special master's decision dismissing the case. In reversing the CFC, and reinstating the special master's decision dismissing the petition, the CAFC reiterated that the special master's factual findings are to be accorded deference on review. There was one new appeal to the CAFC, filed by DOJ. (DOJ PP at 12). *Dobrydnev v. HHS*, also involves the level of deference to be accorded a special master's fact finding, and was filed by the government seeking review of the CFC's reversal of the special master's decision denying entitlement based on evaluation of expert testimony.

Turning to appellate activity at the CFC, Mr. Matanoski noted that two cases were recently decided. (DOJ PP at 13). In *Ponzio v. HHS*, the CFC affirmed the special master's decision denying entitlement in this *pro se* autism case because if was filed outside the statute of limitation, and equitable tolling did not apply. In *Caves v. HHS*, the CFC affirmed the special master's reduction of attorneys' fees and costs. There were five appeals filed by petitioners in the CFC, and all involve dismissals based on factual, medical, and/or injuries alleged. (DOJ PP at 14). There is one oral argument scheduled at the CAFC in *Tembenis v. HHS* on September 12, 2013, and one oral argument scheduled at the CFC in *Koehn v. HHS*, on October 15, 2013. (DOJ PP at 15).

Turning to the slides entitled Adjudicated Settlements (DOJ PP at 16-24), Mr. Matanoski noted that 77 cases were settled during the current reporting period. Of those, it appeared that 60 were for adults and 17 for minors. Approximately 2/3 were for flu vaccine related injuries. Mr. Matanoski compared this quarter's settlement processing times remained consistent with past reporting periods. Referencing the past meeting statistics, Mr. Matanoski noted that 80% of the settlements were resolved within three years. Broken down, 27% resolved within a year; 38% within two years; and 18% within three years. Turning to this reporting period, he noted that while there were also 77 cases settled, 84% were resolved within three years. Broken down, 40% were settled within the first year; 34% within two years; and 10% in the third year. In discussing the increased number of cases settled within a year of being filed, Mr. Matanoski reiterated that cases filed with medical records or filed shortly thereafter are usually processed faster. Further, there is a Court initiative to "fast track" selected cases that appear to be good candidates for

settlement. He indicated that DOJ would continue to track early processing times to look for potential trends.
Mr. Kraus observed that Guillain-Barre Syndrome (GBS) appeared to be the alleged injury in about 28 cases. Mr. Matanoski agreed noting that, if GBS is added to the Table, statistics may reflect an increase in concessions and drop in settlements.

Mr. King reiterated the question he posed to Dr. Caserta, inviting Mr. Matanoski to comment on how the Commission could be "most effective" in discharging its responsiblities. Mr. Matanoski responded that becoming "most effective" might be unattainable, and that consideration of becoming "more effective" might be more feasible. He also expressed concern about providing advice to the Commission without significant contemplation. Dr. Caserta suggested that he and Mr. Matanoski confer and perhaps make a joint presentation. After a brief discussion of the alternatives, agreement was reached that the joint presentation would be appropriate, at least for the initial report. There was a suggestion that the Office of the Special Masters should participate in the process and Jocelyn McIntosh agreed to broach the subject with the Chief Special Master. Mr. Matanoski commented that any presentation by the Office of Special Masters would most appropriately be made separately from that of DVIC and the DOJ.

Adding GBS to the Vaccine Injury Table,
Ahmed Calvo, M.D., Medical Officer, DVIC

Dr. Calvo stated that his purpose was to provide information about the proposed recommendation to add Guillain Barre Syndrome (GBS) to the Vaccine Injury Table, in anticipation of accepting advice from the Commission and obtaining Commission approval for the recommendation. He said that the changes proposed are based on established policy and that they apply specifically to GBS in relation to seasonal influenza vaccines

Describing GBS, Dr. Calvo said that GBS is a rare disorder caused by damage to the myelin sheath of the peripheral nervous system, which may result in paralysis, weakness and abnormal responses in the autonomic nervous system. People with GBS usually fully recover, although some may develop chronic symptoms that include respiratory distress caused by paralysis of parts of the breathing mechanism, and some of those may die of respiratory failure.

Dr. Calvo provided a physiologic explanation of the mechanism of action in GBS, explaining that the individual nerve cell develops a number of axons, which are protected by a myelin sheath, which is a multi-layer wrapping of Schwann cells. The wrappings are segmented by nodes at short intervals that provide a pathway for axon signals to move more rapidly from the nerve cell down the axon to the muscle the nerve controls. In effect the signal "skips" from node to node faster than would be the case if the signal had to traverse the entire length of each segment. If the myelin sheath is damaged, the signal to the muscle can be significantly slowed or even stopped. Although GBS is generally thought of as a single disorder, it is in fact several nerve-related disorders; hence the designation as a syndrome.

With regard to the vaccine involved, the H1N1 antigen has been included in each seasonal flu vaccine since 2010 and will be included in the formulation for the 2013-2014 flu season. In 2012 an Institute of Medicine report found that evidence in the scientific literature was

insufficient to accept or reject a linkage between GBS and the vaccine, and the ACCV approved delay of consideration of a Table change until there was additional peer-reviewed evidence of the linkage. There were several studies thereafter, culminating in a meta-study published in March 2013 that showed a small increase in risk, an additional 1.6 cases per million vaccinations. The Agency for Healthcare Research and Quality (AHRQ) has a report (not yet published) that concludes that there is insufficient power in the studies to date to resolve the science issues related to risk of vaccine-related GBS. The report basically states that the strength of evidence that there is an increased risk is high, but post-licensure studies report mixed results with regard to the significance of that risk.

Although the scientific basis for adding GBS to the Vaccine Injury Table has not been resolved, the DVIC recommends the addition of GBS as an injury for seasonal influenza vaccines based on policy and the scientific data that has been published to date. Although not yet approved for inclusion in the Table, the following injuries have been approved by ACCV and are in the final Federal Register process of approval: anaphylaxis, shoulder injury related to vaccine administration (SIRVA) and vasovagal syncope. The recommendation would add GBS with a symptoms time window of 3 to 42 days.

The National Childhood Vaccine Injury Act of 1986 authorizes the Secretary of HHS to promulgate regulations to amend the Vaccine Injury Table. Anyone may petition the Secretary to revise the Table, and in all cases the ACCV must review the proposed revisions. The outcome of that review may be one of three determinations: ACCV concurs with the proposed revisions and recommends moving forward with or without comments; ACCV does not concur and recommends not moving forward; or ACCV recommends deferral of the recommendations pending further review at this or the next scheduled ACCV meeting.

In 2006, the ACCV developed "Guiding Principles" for recommending revisions to the Table: the recommendation should be scientifically and medically credible (there are criteria that define such credibility); and when such credibility is shown, either to recommend for or against a revision, the change should be made based on benefit to the petitioners. Dr. Calvo reminded the Commission that if there is conflict in judging credibility, ACCV members should lean towards adding or retaining the proposed injury.

Concluding his remarks, Dr. Calvo invited questions and/or discussion. Ms. Pron asked if there was precedent for a revision based solely on policy. Dr. Caserta affirmed that a finding in an early IOM report that there was evidence to support removing encephalopathy after DTP was not recommended by the ACCV based on policy. Later he noted that the Commission had approved the rotavirus vaccine as a policy action because, similar to this case, the hard epidemiologic evidence had not been developed (although it subsequently was published and supported the Commission's recommendation). Ms. Feemster asked if a briefing on the Agency for Healthcare Research and Quality (AHRQ) report could be made to the ACCV and Dr. Caserta said he would look into the request. She also asked about the potential relationship of risk in the large monovalent studies and a similarity of risk in the seasonal vaccine. And Dr. Caserta commented that risk could not be extrapolated that way, and that in the large Vaccine Safety Datalink (VSD) study in 2009 the risk of GBS was shown in the monovalent vaccine but not in the seasonal

vaccine. Dr. Shimabukuro added that there was a more intense focus on GBS in the surveillance programs at that time, which could affect results.

Mr. Kraus commented that it would be inappropriate to discount the reports of GBS within a short period of time after vaccination. Just because an epidemiologic study fails to show a risk is not justification for a presumption that the vaccine does not cause the injury. He added that the fact that 90% of injury claims filed in that context are supported by the Program. He recommended concurring with the proposed change to the Vaccine Injury Table and offered a motion to that effect. The motion was seconded by Dr. Williams. Mr. King invited discussion about the motion.

Dr. Shimabukuro commented on the three large 2009 studies that were characterized on Dr. Calvo's slides as "showing compelling evidence" for a rare, small increased risk of GBS after H1N1 flu vaccine. He noted that there were also two large studies which did not identify any such risk, and a finding by the Principal Ivestigators of one of the VSD studies that, after considering preexisting infection, the GBS risk disappeared. He also expressed concern about the language in another slide that the "strength of the evidence and association is high between the 2009 H1N1 vaccine and GBS, commenting that such a statement could be a matter of interpretation by various experts. He recommended toning the statements down with words like "weight of evidence supports" and avoiding terms like "compelling." He also noted that injuries related to flu vaccine are not covered by the DVIC, but by another Federal program, the Countermeasures Injury Compensation Program.

There was an extensive discussion concerning the issues involved, including the fact that the information about the vaccine risk was only received immediately before the meeting giving the members little time to consider the issues; the AHRQ report, although published for public comment, would not be available in final form until a later date; and the fact that the Commission can reconsider the issue and the decision made at any time during the complete revision process. Dr. Caserta observed that acting on the motion, rather than deferring consideration until the December meeting, would allow the Division to begin the clearance process, and if necessary at a later date the ACCV could change its position. Dr. King noted that the vote either way would not necessarily have a final impact on the ultimate objective of revising the Table.

Mr. King called for the vote and the final count was five in favor of the motion, three opposed to the motion. The motion carried. There was agreement that the opposing votes were based on the position that there was insufficient time to properly consider the issues.

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

Ms. Dela Rosa reported that the Process Workgroup had scheduled three meetings since the last ACCV meeting, but two were unavoidably cancelled and could not be rescheduled. The one meeting held on September 4 reviewed the progress of the Workgroup, which was established in June 2012. Three recommendations developed by the Commission were reviewed and affirmed: the addition to the Commission of a vaccine-injured adult (or his or her representative); the

extension of the statute of limitations for filing a claim; and an increase in the cap for pain and suffering. The Workgroup agreed to continue to review the 2009 recommendations. There was also a brief discussion of the virtual format that has been adopted for the regular ACCV meetings.

Mr. King, noting that the virtual meeting format might be discussed later in the meeting, suggested that the Process Workgroup add a review of that meeting format to their own agenda, and Ms. dela Rosa agreed.

Report from the Maternal Immunization Workgroup,
Kristen Feemster, M.D., ACCV member

Dr. Feemster stated that the Workgroup had not formally met since the last ACCV meeting, but had nonetheless conferred in various ways to arrive at a final draft of the report and recommendations proposed previously. That report was presented to the Commission for review and approval at the June 7 meeting and relates to vaccines that pregnant women may receive that are not recommended for routine administration in children, which would therefore not be covered by the Program. There was a suggestion by National Vaccine Advisory Committee (NVAC) that the Commission might want to look at adult vaccines in general, beyond the narrow focus on pregnant women and vaccines recommended for children. The Commission might want to consider a new working group to address that issue. Mr. King observed that this would be an issue that could in some cases be outside the basic charge to the Commission.

Dr. Caserta noted that the broader recommendation involving adult vaccines was considered but that the final decision was to submit the more narrow recommendation because its approval would be more likely. He added that the Commission could still address the broader recommendation, noting that the only two vaccines not covered by the Program are the shingles vaccine and the polysaccharide pneumococcal vaccine, both of which are routinely recommended only for adults. Dr. Caserta emphasized that covering these adult-only vaccines would require a statutory change to the law. Congress, through OMB, would also have to consider the cost burden of adding adult vaccines to the Program. The Commission agreed that the issue should be discussed during the next commission meeting.

Vaccine Information Statements (VIS), Centers for Disease Control and Prevention (CDC), Skip Wolfe

Mr. Wolfe began with a proposed general statement about problems that could happen after any vaccine – syncope after any medical procedure of vaccination, severe shoulder pain and severe allergic reactions – all of which are possible with any vaccination. He proposed that this wording could be added universally to all VIS's. There were minor wording changes recommended. Dizziness, vision changes or ringing in the ears were clarified as being precursor symptoms of potential syncope; and the sentence about shoulder pain was revised to read "shoulder pain and loss of range of motion." The Commission approved the new wording and the insertion of the statement in any VIS related to an injectable vaccine.

Turning to the two VIS's pertaining to flu vaccines, Mr. Wolfe explained that both had been recently reviewed and published as interim information statements. The objective of the review is to move the document from an interim to a permanent status. Beginning with the inactivated vaccine, Mr. Wolfe stated that, except for a few recommendations made by the Commission at the last meeting that were incorporated in this version, the document is substantially unchanged from that review. In Section 2, Mr. Kraus suggested a minor change to the statement about thimerasol. He suggested that studies have not shown that thimerasol is harmful, be changed to studies have shown that thimerasol is not harmful. Mr. Smith commented that the paragraph about "high dose" vaccine for older people might be more appropriately placed in Section 2 immediately following the definitions of inactivated and live, attenuated vaccine. Dr. Caserta noted that the paragraph about vaccinating children under 8 should be clarified to indicate that the two doses should be given the first year they are vaccinated *for influenza*, not simply vaccinated.

There was a brief discussion about the bar code at the bottom of the last page of the VIS, which is placed there to allow providers to scan the information into a patient's electronic medical record. In the future it may also be able to allow patients to scan the VIS information.

Turning to the VIS for live, attenuated influenza vaccine, Mr. Wolfe stated that the only changes since the last review were made in sections 2, 3 and 4. Dr. Caserta took exception to the statement in section 2 that "the viruses in the vaccine have been weakened so they can't make you sick." The vaccine can certainly cause problems such as sinusitis. It was noted that there is a perception that flu vaccines can actually cause mild flu, so that some wording that explains that would be appropriate. Mr. King suggested explaining that the live vaccine could cause mild flu symptoms but that the symptoms are evidence that the immune system is working properly. There was a suggestion to word the statement to the effect that "the weakened virus will not give you the flu." Mr. Wolfe agreed and indicated he would pass the objection on and work on a statement that would accurately reflect the advice of the Commission. He added that the statement in section 4, that the vaccine "does not cause flu" would also be revised.

(Ms. Michelle Williams left the meeting at 2:30 p.m.)

Update from the Immunization Safety Office (ISO),
Tom Shimabukuro, M.D., CDC

Dr. Shimabukuro began his report with a review of the June 2013 meeting of the Advisory Committee on Immunization Practices (ACIP), noting that the PowerPoint presentations and the video of the meeting are available on the web. There were several safety presentations, the first of which concerned the human papillomavirus (HPV) vaccine. The manufacturer, Merck, made a presentation about the Pregnancy Register maintained as required by Food and Drug Adminstration (FDA), and the data that pertained to exposure during pregnancy. Although the HPV vaccine, Gardasil is not recommended for pregnant women, there is inadvertent exposure when, for example, a woman receives the vaccine with no knowledge that she is pregnant. The Registry data from more than six years are reassuring with regard to safety, showing that spontaneous abortion, fetal deaths and congenital anomalies are no greater than background rates

for those anomalies. The Registry, the largest vaccine pregnancy registry to date, will be discontinued because it has fulfilled its regulatory requirement of operating for five years.

Dr. Shimabukuro commented that there were five presentations on rotavirus vaccines and the risk of intussusception covering data from the Vaccine Safety Datalink (VSD) studies, a six-year assessment of data from the Vaccine Adverse Events Reporting System (VAERS), a Post-licensure Rapid Immunization Safety Monitoring System (PRISM) study, data from the Australian experience, and a general summary of intussusception risk and benefits of rotavirus vaccination in the U.S. The conclusions drawn from these presentations are that there is a small risk of intussusception following Rotateq or ROTARIX; the benefits of receiving the vaccine outweigh the small risk of intussusception; and the CDC continues to recommend rotavirus vaccines for all infants in the U.S.

The third major presentation concerned influenza, and end-of-season update on surveillance data on the 2012-2013 flu season. The presentation confirmed that there were no new safety concerns detected for either inactivated or live vaccines, the review of pregnancy data showed no unusual patterns, and no safety signals or increased risk was observed for febrile seizures in young children following inoculation with inactivated vaccine.

Dr. Shimabukuro announced the availability of four communications updates – one on the VAERS website that provides summary information about the 2013-2014 flu vaccine; another on the CDC web site that that deals with the risk of febrile seizure in children; a third on the CDC web site that provides general information on the 2013-2014 flu season; and the fourth on the CDC web site, a press release about HPV vaccine, emphasizing its underutilization among adults in the U.S..

Listing several publications of interest, Dr. Shimabukuro mentioned a paper by Dodd et al on the international collaboration to assess the risk of GBS following the 2009 H1N1 monovalent vaccines. That paper concluded that international collaboration to evaluate serious outcomes using a common protocol was feasible, and relying on pooled data there is evidence of an association between that vaccine and GBS. The paper also concluded that, given the rarity of the event, there is no evidence that international recommendations for continued use of influenza should be ignored.

Kharbanda et al described a large cohort of pregnant women who received inactivated flu vaccine, which did not increase risks for "medically attended adverse obstetric events." Iqbal et al showed that there were no adverse associations between antigens children received through vaccines in the first two years of life and neuropsychological outcomes in later childhood. Greene et al, as was mentioned earlier in the meeting, demonstrated that after adjusting for antecedent infections, there was no evidence of elevated GBS risk following influenza vaccines given in 2009-2010 (MIV) and 2010-2011 (TIV). However, the association between GBS and antecedent infections was strongly elevated.

Finally, concerning cause-of-death patterns in a an older vaccinated populations, McCarthy et al looking at a VSD study showed mortality rates were lowest in the days following vaccination,

and the mortality rate was lower than in the general population, although the causes of death were similar in both.

Dr. Shimabukuro commented that the CDC looked at HPV vaccine coverage in adolescent girls and reported that despite the availability of safe and effective vaccines, and ample opportunities to obtain the vaccine in the health care setting, vaccination coverage among adolescent girls did not increase from 2011 to 2012.

Asked whether links to the papers discussed were available, Dr. Shimabukuro indicated that he would try to provide those links. There was a suggestion that the papers could be sent to the members in electronic format, if available.

Dr. Shimabukuro concluded his report and added that he would have to leave the meeting, but that Dr. Pedro Moro from his office would represent the CDC for the remainder of the meeting.

Update from the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
Ms. Barbara Mulach Ph.D.

Ms. Mulach stated that NIAID was working with other federal agencies to support efforts to develop an H7N9 influenza vaccine, should that strain become an issue. There will be clinical trials in the near future. Dr. Caserta interjected that H7N9 was covered by the Countermeasures Injury Compensation Program, because it is assumed to be a vaccine for a pandemic..

Ms. Mulach explained that there was a recent Phase I clinical trial of a newly developed malaria drug, PfSPZ manufactured by Sanaria, Inc., which showed some efficacy. In a small cohort immunization against one strain of malaria was demonstrated. There will be additional studies in the near future.

Finally, NIH has been supporting studies of a vaccine developed by Bavarian Nordic to create immunity from smallpox. The vaccine, IMVANEX, has been approved for use in adults. It appears to cause fewer adverse events than earlier smallpox vaccines, and it is particularly appropriate for individuals with compromised immune systems.

In the area of genomics, a unique cell line, HeLa cells, came from a woman, Henrietta Lacks, who died of cervical cancer in 1951. Those cells have survived in research and for the first time NIH has contacted her family to discuss the privacy issues related to the use of those cells for research purposes. Ms. Mulach stated that she could provide more information if the Commission members were interested.

Also, NIH has established a new program with regard to expanding the understanding of newborn genomes, and three awards have been made for research projects in that arena. Finally, NIH has partnered with the Smithsonian Institution to support an exhibit on genome science -- Genome: Unlocking Life's Code, which opened recently. Hopefully it will expand awareness of genome science.

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

LT Marshall reported that in June and July the FDA approved strain chain supplements for the 2013-2014 formulations for Afluria, Flulaval, Fluarix, Flucelvax, Fluvirin and Fluzone. On June 7, the age window for Sanofi's Fluzone was expanded to infants 6 months of age and up. On August 1 the age recommendation for Mimbo, a meningococcal oligosaccharide, was expanded to 2 months to 23 months and up to 55 years) it had previously been 2 years to 10 years, and 11 years to 55 years. On August 16, for the supplement trivalent influenza vaccine made by GSK, the age was expanded to be from 3 years of age and up (previously 18 years and up). Finally, Flulaval, a quadrivalent flu vaccine, was approved for children 3 years of age and up.

Update from the National Vaccine Program Office (NVPO), Steve Bende, M.D.

Dr. Bende announced that the upcoming NVAC meeting has an important historical aspect in that it is the 25th anniversary of the advisory committee. The agenda will include an historical overview; a review of Healthy People 2020 (with a focus on adult immunization); a discussion of the Affordable Care Act (ACA), which includes a provision that providers must cover preventive health care services without requiring co-pay or co-insurance; and a look at immunization registries. With regard to immunizations, providers who offer vaccines will be asked to incorporate into routine clinical care an assessment of adult immunization status and to stock all vaccines recommended by ACIP for adults. Providers who do not normally make vaccines available will be asked to do so or to refer patients to other providers who are able to provide immunizations. Public health departments will be asked to maintain professional practice standards and to assess immunization program needs.

Next on the agenda will be a session on influenza, which will include a component on the importance of communicating information to health care professional and the public. There will be a session on viral hepatitis that will refer to the Healthy People 2020 goals of a doubling of individual awareness of hep A and B status (from 33% to 66%), a similar increase in awareness of hep C (from 40% to 6-%), a reduction in hepatitis infections by 25% and elimination of mother-to-child hep B transmission. There will also be a presentation on maternal and child health issues, including an update from the ACCV Maternal Immunization Workgroup.

The NVAC has a working group focused on the Healthy People 2020 goals related to HPV vaccine coverage, which is well below where it should be. Finally, the NVAC Global Working Group will present its recommendations for a vote at the meeting.

Dr. Bende noted that the AHRQ study discussed earlier in the meeting was commissioned by the NVPO. It is out in the public domain for comment and the final versions should be released sometime in October.

Public Comment

Mr. King invited public comment.

Dawn Loughboro, mother of two vaccine-injured children, questioned whether or not the ACCV has any legal authority to address adult-only vaccines, since they are not included in the basic legislation that established the VICP. Secondly, the ACCV should look at procedures that would be related to vaccines given to pregnant women that could affect the mother's unborn child. In addition, Ms. Loughboro was concerned about the statement in the Influenza VIS that was discussed earlier, that thimerasol in vaccines causes no harm. She stated that over 600 studies contradict that statement. Pregnant women should be informed of any risk related to thimerasol in vaccines.

Ms. Loughboro expressed concern that the Merck self-regulation of its HPV registry could present a conflict of interest, since there are no external controls for the registry. She also asked who would continue to manage the registry once Merck was no long involved. Finally, she commended the Commission for approving the recommendation to add GBS to the Vaccine Injury Table.

Theresa Wrangham, representing the National Vaccine Information Center, also commended the Commission for approving the addition of GBS to the Vaccine Injury Table, adding that the recommendation submitted to the Secretary should include a comment that the three votes in opposition related to a the timeliness of providing information to the Commissioners for consideration, and not to any other objection to the proposal.

Ms. Wrangham recommended an increased transparency in reporting information that should be available from the VICP. She noted that reporting doses distributed versus claims can be misleading, since the vaccine reactions reported to VAERS are not included in the report, nor is the fact that vaccine adverse events are underreported in general. There is also a lack of awareness of the VICP that detracts from its effectiveness. The report should include published and unpublished awards. Although much the information is presented to the ACCV during its meeting, and is thereafter placed in the public domain, it is not reasonable to expect members of the public to compile consolidated information from various meeting documents and resources.

The revision process for the VIS's requires providing an opportunity for parent groups to participate in the process. At the last meeting NVIC volunteered to participate, but that fact was not included in the meeting minutes. NVIC requests that the minutes be amended to indicate that action. Concerning the VIS review, there should be a brief statement in every VIS about the lack of research related to many vaccine adverse events. And each VIS should be explicit about the vaccines covered by the VICP, and not use the general words "certain vaccines" are covered. Finally, Ms. Wrangham recommended that the ACCV provide information on the number of claims dismissed because of the statute of limitations, and consider ways to reduce that number.

In closing, Ms. Wrangham commended the Commission for putting historical information about recommendations to the Secretary on the VICP web site, noting that some of the recommendations have been made more than once at different times. Only one response from the Secretary was included, and it would be helpful to include all of the Secretary's responses, and each action taken by the Department with regard to each recommendation.

Mr. James Moody commended the DVIC staff for bringing the issue of GBS to the ACCV agenda. He also commended the chair for addressing issues related to research. A critical part of that research is developing baseline data on unvaccinated children. He requested that the ACCV specifically add that issue to its agenda.

Mr. Moody noted that the government apparently directed the IOM panel on adverse events to exclude consideration of the mercury risks. He commented that this was an issue that the ACCV should also add to its agenda.

There being no other requests, Mr. King declared the time for public comment closed.

Future Agenda Items

Mr. King commented that the effectiveness of the virtual meeting versus the face-to-face meeting was an issue discussed earlier, and referred to the Process Workgroup. Asked about the budget component of the issue, Dr. Caserta commented that, even though ACCV travel is paid through a mechanism that draws the funds from the Trust Fund, there is a government-wide policy that travel should be restricted to only the highest priorities. It is a matter of policy, not availability of funds. Mr. King expressed concern that all of the interpersonal events that occur at a face-to-face meeting are lost in the virtual environment, which detracts from the effectiveness of the Commission's mission. Dr. Caserta agreed, but noted that even presenting that kind of argument within the Department, the policy still prevents many of those types of meetings. The annual budget for DVIC's bureau was originally about $100,000 and was reduced to $25,000. He added that he had been able to reserve one face-to-face meeting per year.

Mr. King called for a comment from each Commission member present to develop a sense of the Commission. Dr. Douglas stated that, since she has had training is using virtual environments, she is comfortable with the teleconference process. However, the remaining members of the Commission generally agreed that at least one in-person meeting per year would be preferable. The consensus of these six members was that the in-person meeting fosters a working relationship that cannot be built with phone-only discussions. The personal interaction during the meeting and during breaks is important to developing a sense of commitment and a cohesiveness that is necessary for conducting Commission business. Dr. Caserta committed to representing this position to the senior management of the bureau that makes decisions concerning travel. He added that one such meeting had been approved, which he intended to schedule when new Commission members were appointed.

Mr. King proposed creating a recommendation to the Secretary conveying the position of the Commission. Dr. Caserta conceded that the recommendation would promote the Commission's objectives, and it is likely that the Secretary would take the recommendation into consideration. On motion made by Mr. Kraus and seconded by Mr. Smith, the Commission unanimously empowered the Chair, David King, to draft a recommendation expressing the feelings of the Commission with regard to in person meetings.

Turning to new business, Mr. Kraus commented that the statement by Theresa Wrangham was correct that the Commission had discussed the importance of public input and collaboration in

reviewing the VIS's. He recommended that staff investigate the situation and that Dr. Caserta investigate the CDC's position in the matter. Ms. Pron suggested that the topic be put on the agenda of the next meeting, particularly the issue of including adult vaccines in the program. There was a reminder that if the Commission wanted to recommend including adult vaccines the recommendation from the Commission would have to include a recommendation that the appropriate new legislation be considered.

There being no other business to discuss, Mr. King invited a motion to adjourn.

Adjournment

Whereupon, on motion made and seconded, there was unanimous approval to adjourn.

3

Vaccine Injury Compensation Trust Fund

Balance as of September 30, 2013

$3,451,869,770.62

Figures for October 1, 2012 – September 30, 2013

Excise Tax Revenue: $204,531,836
Interest on Investments: $61,531,206
Net Income: $266,067,677
Interest as a Percentage of Income: 23%

Source: U.S. Treasury, Bureau of Public Debt
November 7, 2013

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4.1

NATIONAL VACCINE INJURY COMPENSATION PROGRAM [1]

PROGRAM STATISTICS REPORT

As of Thursday, November 07, 2013

I. PETITIONS FILED	
Fiscal Year	**Totals**
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	216
FY 2002	957
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	449
FY 2011	386
FY 2012	400
FY 2013	501
FY 2014	54
Totals:	**14,934**

NATIONAL VACCINE INJURY COMPENSATION PROGRAM[1]

PROGRAM STATISTICS REPORT

As of Thursday, November 07, 2013

II. ADJUDICATIONS[2]

Fiscal Year	Compensable	Dismissed	Totals
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	233	295
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	83	120	203
FY 2008	147	134	281
FY 2009	134	231	365
FY 2010	181	292	473
FY 2011	261	1,372	1,633
FY 2012	258	2,439	2,697
FY 2013	351	626	977
FY 2014	15	14	29
Totals:	**3,448**	**9,680**	**13,128**

NATIONAL VACCINE INJURY COMPENSATION PROGRAM [1]

PROGRAM STATISTICS REPORT

As of Thursday, November 07, 2013

III. AWARDS PAID [3]

	Compensated			Dismissed		Interim Fees		
Fiscal Year	No. of Awards	Petitioners' Award Amounts	Attorneys' Fees/Costs Payments	No. of Payments to Attorneys	Attorneys' Fees/Costs Payments	No. of Payments	Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,270,237.04	72	$2,432,847.05	2	$117,265.31	$83,536,901.46
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53
FY 2011	251	$216,323,760.31	$9,736,216.87	402	$5,425,243.19	28	$2,001,770.91	$233,486,991.28
FY 2012	250	$163,511,998.82	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,657,927.73
FY 2013	375	$254,666,326.70	$13,250,679.53	704	$7,052,778.84	50	$1,454,851.74	$276,424,636.81
FY 2014	32	$7,322,260.31	$1,001,127.77	92	$1,474,196.78	4	$593,445.07	$10,391,029.93
Totals:	**3,432**	**$2,607,233,910.56**	**$106,349,050.31**	**4,466**	**$58,620,745.51**	**171**	**$15,807,757.45**	**$2,788,011,463.83**

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

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

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

4.2

November 4, 2013

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

		Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
Vaccine Alleged by Petitioner[2]	No. of Doses Distributed US CY 2006 - CY 2012 (Source: CDC)[3]	Concession	Court Decision	Settlement			
DT	592,707	1	0	2	3	3	6
DTaP	68,113,573	13	15	65	93	63	156
DTaP-Hep B-IPV	38,347,667	5	5	15	25	28	53
DTaP-HIB	1,135,474	0	0	0	0	1	1
DTaP-IPV-HIB	46,633,881	0	0	4	4	5	10
DTP	0[4]	0	1	2	3	1	4
DTP-HIB	0	0	0	0	0	0	0
Hep A-Hep B	10,405,325	0	0	8	8	0	8
Hep B-HIB	4,621,999	0	1	1	2	1	3
Hepatitis A (Hep A)	110,596,300	1	5	16	22	13	3
Hepatitis B (Hep B)	116,853,062	3	9	31	43	29	72
HIB	70,755,674	0	1	4	5	3	8
HPV	55,168,454	9	1	56	68	64	132
Influenza[5]	809,000,000	24	60	554	638	124	762
IPV	52,439,162	0	0	3	3	2	5
Measles	135,660	0	0	1	1	0	1

[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.

Meningococcal	51,173,032	1	1	18	20	3	23
MMR	65,864,745	16	12	43	71	60	131
MMR-Varicella	8,073,618	6	0	6	12	7	19
Nonqualified[6]	N/A	0	0	0	0	18	18
OPV	0	1	0	0	1	3	4
Pneumococcal Conjugate	123,606,306	0	1	4	5	10	15
Rotavirus	61,336,583	0	2	13	15	5	20
Rubella	422,548	0	1	0	1	0	1
Td	53,009,015	4	5	46	55	15	70
Tdap	133,744,203	6	5	55	66	7	73
TETANUS	3,836,052	2	0	14	16	8	24
Unspecified[7]	N/A	1	0	2	3	532	535
Varicella	82,534,257	4	5	14	23	9	32
Grand Total	**1,968,399,297**	**97**	**130**	**979**	**1206**	**1015**	**2221**

DEFINITIONS:

1. Compensable – The injured person who filed a claim was paid money by the VICP. Compensation can be achieved through a concession by the Department of Health and Human Services (HHS), a decision on the merits of the claim by a special master or a judge of the United States Court of Federal Claims (Court), or a settlement between the parties.
    a. Concession: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
    b. Court Decision: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).

[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.

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

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

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

5

5.1

Vaccine Information Statement

Td (Tetanus, Diphtheria) Vaccine: What You Need to Know

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

1. Why get vaccinated?

Tetanus and **diphtheria** are very serious diseases. They are rare in the United States today, but people who do become infected often have severe complications. Td vaccine is used to protect adolescents and adults from both of these diseases.

TETANUS (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA can cause a thick coating to form in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and death.

Both diseases are caused by bacteria. Diphtheria spreads from person to person through coughing or sneezing. Tetanus-causing bacteria enter the body through cuts, scratches, or wounds.

Before vaccines, the United States saw as many as 200,000 cases a year of diphtheria and hundreds of cases of tetanus. Since vaccination began, cases of both diseases have dropped by about 99%.

2. Td vaccine

Td vaccine can protect adolescents and adults from tetanus and diphtheria. Td is usually given as a booster dose every 10 years but it can also be given earlier after a severe and dirty wound or burn.

A similar vaccine, called Tdap, gives protection from pertussis, in addition to tetanus and diphtheria. Tdap is usually given only once in a person's life, either at age 11 or 12, or as a substitute for one of the 10-year Td boosters. Women who are pregnant should get Tdap during every pregnancy.

Your doctor can give you more information about both vaccines.

Td may safely be given at the same time as other vaccines.

3. Some people should not get this vaccine

- If you ever had a life-threatening allergic reaction after a dose of any tetanus or diphtheria containing vaccine, OR if you have a severe allergy to any part of this vaccine, you should not get Td. *Tell your doctor if you have any severe allergies.*

- Talk to your doctor if you:
  - have epilepsy or another nervous system problem,
  - had *severe* pain or swelling after any vaccine containing diphtheria or tetanus,
  - ever had Guillain Barré Syndrome (GBS),
  - aren't feeling well on the day the shot is scheduled.

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.

Brief **fainting spells** can follow a vaccination, leading to injuries from falling. Sitting or lying down for about 15 minutes can help prevent these. Tell your doctor if you feel dizzy or light-headed, or have vision changes or ringing in the ears.

Mild Problems following Td
(Did not interfere with activities)
- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Moderate Problems following Td
(Interfered with activities, but did not require medical attention)
- Pain where the shot was given (about 1 in 5 adolescents or 1 in 100 adults)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 3 in 20 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 3 in 100).

Severe Problems following Td
(Unable to perform usual activities; required medical attention)
- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

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

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 can start a few minutes to a few hours after the vaccination.

What should I do?

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

VAERS is only for reporting reactions. They do not give medical advice.

6. The National Vaccine Injury Compensation Program

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

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

7. How can I learn more?

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

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

Vaccine Information Statement (Interim)
Td Vaccine

(date)
42 U.S.C. § 300aa-26

5.2

Vaccine Information Statement

Haemophilus influenzae type b (Hib) 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 www.immunize.org/vis

1. Why get vaccinated?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by bacteria. It usually strikes children under 5 years old.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the brain and spinal cord coverings, which can lead to brain damage and deafness. Hib disease can also cause:

- pneumonia
- severe swelling in the throat, making it hard to breathe
- infections of the blood, joints, bones, and covering of the heart
- death

Before Hib vaccine, about **20,000 children in the United States under 5 years old got severe Hib disease each year, and nearly 1,000 people died.**

Hib vaccine can prevent Hib disease. Since the Hib vaccine was licensed, the number of cases of invasive Hib disease has decreased by more than 99%. Many more children would get Hib disease if we stopped vaccinating.

2. Hib vaccine

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used.

Doses of Hib vaccine are usually recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed, depending on brand of vaccine)
- Final Dose: 12–15 months of age

Hib vaccine may safely be given at the same time as other vaccines.

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a single shot, so that one vaccination can protect against more than one disease. Ask your doctor for more information.

People over 5 years old usually do not need Hib vaccine. But some older children or adults with special health conditions should get it. These conditions include sickle cell disease, HIV/AIDS, removal of the spleen, or bone marrow transplant. Ask your doctor for details.

3. Some people should not get this vaccine

Hib vaccine should not be given to infants younger than 6 weeks of age.

Tell your doctor:

- **If the patient has any severe (life-threatening) allergies.** If the patient has ever had a life-threatening allergic reaction after a dose of Hib vaccine, or has a severe allergy to any part of this vaccine, he or she may be advised not to get a dose.
- **If the patient is not feeling well.** Your doctor might suggest waiting until the patient feels better. But you should come back.

4. Risks of a vaccine reaction

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

Serious side effects are also possible, but are very rare.

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

Mild Problems following Hib vaccine:

- redness, warmth, or swelling where the shot was given
- fever

If these problems occur, they usually begin soon after the shot and last 2 or 3 days.

Problems that could happen after any vaccine:

- Brief fainting spells can happen after any 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.
- Severe shoulder pain and temporary loss of range of motion in the arm where a shot was given can happen, very rarely, after a vaccination.
- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would be within a few minutes to a few hours after the vaccination.

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

5. What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

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7. How can I learn more?

- Ask your doctor.
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Vaccine Information Statement (Interim)
Hib Vaccine
(date of publication)
42 U.S.C. § 300aa-26

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

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6

6.1

Congressional Briefing Attempts to Discredit Vaccine Injury Compensation

November 8, 2013 Christine Vara Leave a comment Go to comments

On November 7th, a congressional briefing, entitled "The Injustice of the Vaccine Injury Compensation Program (VICP)" was sponsored by "The Canary Party" and billed as a precursor to a hearing scheduled on December 4th in the Committee of Government Oversight and Reform.

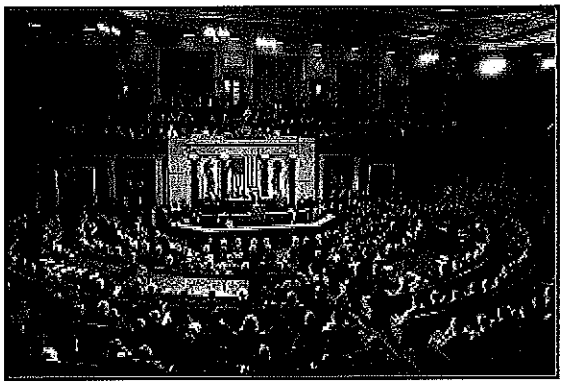
Dorit Rubinstein Reiss, a passionate vaccine advocate with intimate knowledge of the legal system and Professor at University of California Hastings College of the Law, attended the briefing and provided the following post as her personal response to comments she heard there.

Doing Away With NVICP: Bad For Plaintiffs, Bad For Society

by Dorit Rubinstein Reiss

At a briefing in Congress about the National Vaccine Injury Compensation Program (NVICP), Ms. Mary Holland and Mr. Rolf Hazelhurst criticized the program's operation. Ms. Holland, addressing several possible reform options, rejected improving the program (what she called "tinkering at the edges") as a way to fix the problems she identified. Her solution was to have claims of vaccine injuries litigated in the regular courts, either through making NVICP optional, limiting it to the original 7 vaccines it covered in 1986, or repealing the act completely. Doing so would be an error. From plaintiffs' perspective, adjudication through NVICP is either equivalent to the courts or better. For society, too, vaccine injuries are better handled by NVICP than by the regular courts.

What is NVICP?



In 1986, Congress passed the National Childhood Vaccine Injury Compensation Act, creating NVICP as a no-fault alternative to the tort system. NVICP provides an administrative scheme to compensate those who claimed they were injured by a vaccine. Parallel schemes exist in other countries. The initial determination is made by a special master, but petitioners can appeal to a judge of the U.S. Court of Federal Claims, which also appoints the special master. A decision of that judge can then be appealed to the relevant Federal Circuit. The program was established to allow plaintiffs to sue the federal government rather than individual vaccine manufacturers in order to ensure the continued supply and development of new vaccines.

Since its creation the program has compensated 3412 claims to the tune of $2,777,620,433.90 (these numbers were accurate as of November 7, 2013). If those numbers look large to you, a reality check is in order: whether compared to the number of vaccine doses administered or to injuries from other sources, 3412 claims in 25 years is a tiny number. And while close to $2.8 billion sounds like a lot, the costs of motor vehicle accidents in 2009 alone – one year v. NVICP's 25 – was $244.7 billion.

The Plaintiffs' Perspective:

Ms. Holland's case focuses on the claim that NVICP is unjust and painful for plaintiffs. There is probably room for improving the program (or any other administrative program). But Ms. Holland is not interested in improving the program: she wants to abolish it and send plaintiffs to the courts. As pointed out by Neil Komesar in his book "Imperfect Alternatives", when choosing between institutions, the question is not whether one of the choices is good or bad in abstract, but which one is better at handling the problem at hand. And on every aspect she raised, NVICP is equivalent to or better than the civil courts for any plaintiff with a valid claim.

Ms. Holland highlights that most petitioners lose. She said 80% of cases lose, which means only 20% of plaintiffs win. My calculations were slightly different – I calculated the rate of winning to be 26% (3412 claims compensated out of 13077 adjudicated). While that might seem low, again a comparison is in order: In 2005, the last year for which we have data, plaintiffs won only 20% of non-asbestos product liability claims. Product liability claims are simply hard to win. In whatever forum. Sending plaintiffs to the regular courts would not make proving the claims easier for plaintiffs. One reason for that was mentioned by Ms. Holland herself: showing causation for product liability can be hard. NVICP actually gives plaintiffs a break on that: if they have a table injury (a table listing conditions likely to be caused by vaccines, if occurring within a set time) within the defined time, causation is assumed. While many plaintiffs bring injuries that are not on the table, requiring them to prove causation does not disadvantage them compared to the regular courts: there, too, plaintiffs would have to show that more likely than not the defect in question caused their injuries.

The real problem Ms. Holland and her colleagues face – a problem glossed over in the Canary Party video and her presentation, (as addressed in detail here, here and here) is that for the main injury they want to address, the claim that vaccines cause autism, they have no credible evidence for causation , and there is abundant evidence on the other side. Many, many studies examined that question – finding no link. Claims that vaccines cause autism were also rejected in several lengthy decisions by NVICP as part of the Autism Omnibus Proceeding. Mr. Hazlehurst argued that the rejection was because of government corruption; but the lengthy, detailed, thoughtful decisions of the special masters show differently. The special masters carefully examined plaintiffs' evidence. It simply did not support the alleged causal link. In fact in one opinion, Special Master George Hastings wrote,

> "This case, however, is *not a close case*. The overall weight of the evidence is *overwhelmingly contrary* to the petitioners' causation theories…In short, this is a case in which the evidence is so one-sided that any nuances in the interpretation of the causation case law would make no difference to the outcome of the case."

Similarly, the other conditions Ms. Holland wants to connect to vaccines – a large array of chronic conditions – lack evidence of a causal connection.

A causation problem also exists for the HPV cases in the video Ms. Holland ended her presentation with. In the video, multiple girls suffering from various conditions – or parents of deceased young girls – say to the camera that it is not a coincidence. Sincere as their belief in the causal connection to the HPV is, and painful as their conditions are, belief is not enough, and none of these cases has objective evidence of such a connection. Studies examining the HPV vaccine did not find that it caused the harms claimed – for example, a large study from the United States and an even larger study from Sweden. With no credible evidence, these claims too face very high hurdles in the civil courts. In NVICP, the government – following Congress' mandate to compensate even cases in doubt – settled a small number of HPV cases. A private litigant would not be operating under such a mandate.

Moving to the civil courts will not solve this problem. The same requirement of showing that the vaccine more likely than not caused the harm will apply. The same outcome should result.

Other problems raised by Ms. Holland are procedural. She says that the program forecloses access to other forums. That's only partly accurate – while after Brusewitz v. Wyeth suits for design defect cannot be brought in state courts, a plaintiff can reject the special master's determination and sue in state courts if her claim is based on a manufacturing defect or warning defect. And at any rate, by itself, the lack of an alternative forum is not a problem if the proposed forum is good enough.

She complains the NVICP has become adversarial in a way that Congress did not intend. First, a quick glance at the cases published online shows that most cases – as with the civil courts – settle; and second, if a plaintiff is interested in a non-adversarial process, sending them to the civil courts is hardly the solution: our trial system is an adversarial one.

Ms. Holland complains about the length of the trials. Ideally, victims would be compensated swiftly, but product liability trials are complicated, and can easily take a long time in the courts: of the trials lasting more than 3 years in the federal courts in 2009-2011, about half are product liability cases. (See examples here and here.) We just cannot assume trials will be quick in the civil courts. In one example, Mr. Tenuto contracted paralytic polio from his daughter's Oral Polio Vaccine. He had the choice of suing through NVICP but chose to go through the regular federal courts. Mr. Tenuto was injured in 1979. The case ended thirty years later in 2010. The NVICP has the infrastructure to more rapidly adjudicate cases – as Ms. Holland points out, the rules of procedure are relaxed, making the process easier on plaintiffs, and there is no discovery or jury trial, again streamlining the process. If

even under those conditions the process takes a long time, imagine the length in the civil courts for these complicated cases.

Ms. Holland attacks the lack of judicial independence of the special masters; it's true that neither the special masters nor the judges of the Court of Federal Claims are appointed for life, as federal judges are. But the judges who appoint the special masters are appointed by the President and confirmed by the Senate for 15 years; and the judges of the Circuit Courts to which the decision can be appealed do enjoy life tenure. In contrast, the state civil courts have judges who may be elected or appointed politically subject to retention election.

She complains about lawyer fees being slashed and delayed and expert fees delayed and reduced as well. I would like to see some evidence that fees are lower at NVICP than elsewhere. If they are, and it affects the ability of families to find representation, a modest reform might be in order – but Ms. Holland had not made that case. At any rate, this criticism ignores an important aspect of the process: NVICP covers lawyer fees and costs, **even if you lose**. This means that lawyers appearing before NVICP have guaranteed income, which may compensate for a lower return (it may also provide an incentive to lawyers to bring cases with lower chances of success to the program, thus increasing the number of unjustified claims. A reform addressing lawyer fees should probably examine the entire framework and its effect on cases). It also means plaintiffs receive the full award directly instead of paying the lawyer 30-50% as a contingency fee.

Ms. Holland also highlights the statute of limitations, with a period of three years (which Mr. Hazelhurst erroneously suggested starts on the date of vaccination. Actually, the clock of limitations starts "after the first symptom of the vaccine injury". But statutes of limitation exist in civil courts too, and may even be shorter. One example is in California where the statute of limitations for personal injuries is "Two years from the injury. If the injury was not discovered right away, then it is 1 year from the date the injury was discovered."

Finally, plaintiffs going through the civil courts would have to prove a design defect. Proving a design defect is done under principles of negligence, and is not easy. This would be an additional burden facing plaintiffs before they can recover.

In short, NVICP offers plaintiffs substantial advantages over the regular courts. Is the process perfect? Certainly not. But neither would a court process be, and it would impose substantial burdens on plaintiffs.

The Social Perspective

From a social perspective, NVICP offers substantial advantages. The most obvious is that by protecting manufacturers from liability, NVICP reduces the risk of manufacturers leaving the market and of vaccine shortages. This is not a theoretical risk: vaccine shortages – and resultant diseases outbreaks, harming children – were behind the original act.

In addition, handling such cases by a specialized court allows for more expert determination, and the simplified procedures can guarantee quicker, more efficient compensation (the process may need reforming, and it is worth examining; but the potential for a more streamlined and efficient process than a regular court proceeding is there).

Ms. Holland suggests that an advantage of going through the courts will be to incentivize manufacturers to make vaccines safer. But vaccine safety is already regulated in other ways, with important safeguards in place to assure safety: vaccines have to go through three stages of clinical trials before they go on the market, the last stage involving tens of thousands of people and they are carefully monitored after market. A vaccine can be pulled off the market (as has happened in the past) if a serious safety problem arises. Ms. Holland does not explain why that's not enough of a safeguard.

Two groups would benefit from abolishing NVICP: plaintiffs who cannot prove causation and lawyers who would like more control of the fee structure.

Plaintiffs who cannot prove causation may, in the regular court system, come across a judge who will let the claim go forward in spite of the lack of evidence. Judges should not: if plaintiff does not bring credible evidence that more likely than not defendants caused their harm, a claim should be dismissed. But even judges can make mistakes, so it is possible for a judge to wrongly accept flawed studies or let a case go forth with insufficient evidence, and a judge unfamiliar with the subject matter is more likely to do so than a judge in a forum that specializes in vaccine injury cases. And a jury may accept a claim with insufficient evidence, especially when faced with a child suffering a severe disability.

It's easy to feel sympathy for a child with serious disabilities, and for the family having to support and help that child. And it may be appropriate for society to provide for such children, regardless of the cause of their problem. That's a discussion worth having. But that's not what the United States' torts system is set up to do: the torts system is not a government insurance or assistance problem. It would, in fact, be very bad at it. It's adversarial, it's formalized and technical (leading to delays and costs), and because decisions are made by individual decision makers and not subject to any close centralized control, it's inconsistent. It would be an expensive, inefficient, and probably unjust way to administer social assistance.

What the tort system is supposed to do is compensate plaintiffs who can show that a tort by the defendant caused their harm. As sad as their plight might be, plaintiffs who cannot show causation should not be compensated through the tort system. And the possibility that the system might err and compensate them anyway is not a reason to replace NVICP with a civil trial. If anything, it's a reason not to.

The other group that may benefit from replacing NVICP with a court trial is lawyers who will be willing to take these cases on contingency fees and absent the program's regulation will be have freedom to set costs (e.g. for expert reports). They will also collect 30-50% of whatever is awarded at trial.

I teach at a law school. I have friends, colleagues, and students who are lawyers. Most of the people I know in the legal field are highly ethical, bright, well-intentioned and professional. I would be the last person to attack lawyers' desire to make a living. But the ability of lawyers to be able to get more money at the expense of the plaintiffs is not a good policy reason to want to move away from NVICP.

Every Child By Two is galvanizing support among their large base of vaccine advocates while also working with various national immunization organizations to address any concerns raised at the December 4th hearing, They will be following these concerns, educating congressional leaders about the benefits of vaccines and keeping you informed via future posts.

6.2

Whooping cough boosters recommended after outbreak

abqjournal.com/299952/news/whooping-cough-boosters-recommended-after-abq-outbreak.html

Olivier Uyttebrouck / Journal Staff Writer

A whooping cough outbreak responsible for 30 illnesses at La Cueva High School this fall has prompted health officials to encourage students and family members to get a Tdap booster and watch for symptoms.

Pertussis, also called whooping cough, typically is not life-threatening to high school students or adults, said David Selvage, the state's infectious disease epidemiologist.

But students infected with the highly contagious bacterial illness can sicken household members susceptible to deadly complications, he said. In particular, pertussis can be deadly for infants who have not completed a series of vaccinations.

"The big focus is the infant population and women who are close to delivering," he said.

Tdap vaccinations
A Tdap booster guards against tetanus, diphtheria and pertussis. New Mexicans can contact their health care providers or a pharmacy to get vaccinated. To find a clinic, call 866-681-5872 or go to www.immunizenm.org.

APS recently sent a letter to parents of La Cueva students alerting them to symptoms and treatments for whooping cough. The school also is using nasal swabs to quickly diagnose students, said Laura Case, director of nursing for Albuquerque Public Schools.

The outbreak has not resulted in any hospitalizations, said Selvage.

"We are having an ongoing outbreak at La Cueva High School, and are working very well and very closely with the staff there," he said Tuesday.

If a student is diagnosed with pertussis, health officials also examine the student's family members and treat everyone in the household with antibiotics, Selvage said.

"Early detection is the key," Selvage said. Prompt treatment with antibiotics shortens to about five days the time that someone can infect others, he said. Without treatment, a person may remain contagious for up to three weeks, according to the CDC.

La Cueva is the only school in the state affected by a pertussis outbreak, although small clusters of illness have cropped up in other schools, Selvage said.

"Anymore, it just seems to be par for the course," he said. Selvage had no explanation for why La Cueva experienced the outbreak.

Health officials have asked parents, teachers and other school personnel to remain vigilant for students with symptoms, said Case.

"The main thing we're trying to do is protect the infants in the community," she said.

The chief symptom of pertussis is a cough that may be mild at first but typically worsens into an uncontrolled cough that can persist for months. Other symptoms include a runny nose, sneezing and mild fever.

People with pertussis usually spread the disease by coughing or sneezing while in close contact with others, who then breathe in the pertussis bacteria.

Schools are ideal for spreading pertussis because students are in close contact in buses, cafeterias and classrooms, Selvage said.

The Centers for Disease Control and Prevention recommends all pregnant women get the Tdap booster to provide immunity to their newborn infants.

The Tdap booster protects against tetanus, diphtheria and pertussis. Infants and young children should receive a primary series of vaccines called DTaP, at 2 months, 4 months, 6 months and 12 to 18 months of age.

In addition to pregnant women, anyone who expects to be around infants should receive the booster shot, including family members, baby sitters and health professionals, the agency recommends.

In New Mexico, pertussis appears to have diminished somewhat from 2012 levels, when the state reported 898 cases for the year, Selvage said. So far this year, the state has had 472 confirmed and probable cases, he said.

The CDC last year reported the largest spike in pertussis case since 1955 – 48,277 cases in the U.S., up from 18,719 in 2011. Most of the nation's 18 pertussis deaths in 2012 were among infants younger than 3 months.

A possible explanation for the increase in pertussis cases in recent years is the waning immunity of pertussis vaccines, Selvage said. About 30 percent of kids are susceptible to the illness five years after completing their childhood vaccinations, he said.

6.3

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The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits

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The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits

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KEY WORDS
immunization, health communication, preventive health services

ABBREVIATIONS
CA—conversation analysis
NVHP—non–vaccine-hesitant parent
PACV—Parent Attitudes about Childhood Vaccine
VHP—vaccine-hesitant parent

Dr Opel conceptualized and designed the study, coordinated and supervised data collection, performed data analysis, drafted the initial manuscript, and revised the manuscript; Dr Heritage contributed to the study design, developed the coding scheme, and reviewed and revised the manuscript; Dr Taylor contributed to the study design, assisted in the coordination and supervision of data collection, supervised data analysis, and reviewed and revised the manuscript; Dr Mangione-Smith contributed to the study design, supervised data collection, and reviewed and revised the manuscript; Ms Salas conducted qualitative data analysis and reviewed and revised the manuscript; Ms Nguyen conducted and coordinated data collection, assisted in drafting portions of the initial manuscript, and reviewed and revised the manuscript; Dr Zhou contributed to the study design, assisted in data analysis, and reviewed and revised the manuscript; Dr Robinson contributed to the study design, developed the coding scheme, performed data analyses, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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(Continued on last page)

WHAT'S KNOWN ON THIS SUBJECT: An increasing number of parents have concerns about childhood vaccines. Parents consistently cite their child's provider as influential in their vaccine decision-making. Little is known about how providers communicate with parents about vaccines and which communication strategies are important.

WHAT THIS STUDY ADDS: How providers initiate the vaccine recommendation at health supervision visits appears to be an important determinant of parent resistance. Also, when providers pursue their original vaccine recommendations in the face of parental resistance, many parents subsequently agree to vaccination.

abstract

OBJECTIVE: To characterize provider-parent vaccine communication and determine the influence of specific provider communication practices on parent resistance to vaccine recommendations.

METHODS: We conducted a cross-sectional observational study in which we videotaped provider-parent vaccine discussions during health supervision visits. Parents of children aged 1 to 19 months old were screened by using the Parent Attitudes about Childhood Vaccines survey. We oversampled vaccine-hesitant parents (VHPs), defined as a score ≥50. We developed a coding scheme of 15 communication practices and applied it to all visits. We used multivariate logistic regression to explore the association between provider communication practices and parent resistance to vaccines, controlling for parental hesitancy status and demographic and visit characteristics.

RESULTS: We analyzed 111 vaccine discussions involving 16 providers from 9 practices; 50% included VHPs. Most providers (74%) initiated vaccine recommendations with presumptive (eg, "Well, we have to do some shots") rather than participatory (eg, "What do you want to do about shots?") formats. Among parents who voiced resistance to provider initiation (41%), significantly more were VHPs than non-VHPs. Parents had significantly higher odds of resisting vaccine recommendations if the provider used a participatory rather than a presumptive initiation format (adjusted odds ratio: 17.5; 95% confidence interval: 1.2–253.5). When parents resisted, 50% of providers pursued their original recommendations (eg, "He really needs these shots"), and 47% of initially resistant parents subsequently accepted recommendations when they did.

CONCLUSIONS: How providers initiate and pursue vaccine recommendations is associated with parental vaccine acceptance. *Pediatrics* 2013;132:1–10

National estimates for the percentage of children aged 19 to 35 months old who have received the recommended doses of diphtheria-tetanus-acellular pertussis, inactivated poliovirus, measles-mumps-rubella, *Haemophilus influenza* serotype b, hepatitis B, varicella, and pneumococcal conjugate vaccines[1] remain below the Healthy People 2020 goal of 80%.[2] In addition, evidence from national surveys and school vaccination coverage surveillance suggests that the proportion of parents who have concerns about childhood vaccines remains high[3,4] and rates for nonmedical exemptions for required school-entry vaccines are increasing annually.[5] For these reasons, it remains a national priority to sustain and improve childhood vaccine coverage.[2,6]

Emerging evidence suggests that provider-parent communication is important to achieving this goal. A child's provider is consistently cited as a key factor in parental vaccine decision-making[3,4,7,8] and is a trusted source of vaccine information.[9,10] In addition, many vaccine-hesitant parents (VHPs) cite reassurance and vaccine information from their child's provider as the reason they changed their minds to ultimately accept vaccines.[11]

Despite the influence of the child's provider on parental vaccine decision-making, little is known regarding how providers communicate with VHPs about vaccines.[12–14] In a preliminary study, we identified several provider vaccine communication practices that theoretically had the potential to impact parents' vaccination behavior, including how providers initiated their vaccine recommendations (ie, using a presumptive or participatory format) and whether providers pursued their original recommendations when parents voiced initial resistance.[15] The primary aims of the current study were to assess the prevalence of these and other provider and parent vaccine communication practices as well as to determine which communication practices were associated with parents' verbalized resistance to vaccination. We hypothesized that a presumptive format for provider initiations of vaccine recommendations and provider pursuit of original vaccine recommendations would be associated with increased parental resistance.

METHODS

Study Participants

Pediatric providers (pediatricians and nurse practitioners) were recruited from both the Puget Sound Pediatric Research Network, a practice-based research group of primary care practices based in Seattle, WA, and other Seattle area primary care practices. Providers were eligible if they had not participated in our pilot study.[15] To minimize the Hawthorne effect (the influence of observation on behavior),[16] the study was described to providers in general terms as one aimed at understanding parent-provider communication regarding general health topics at health supervision visits. Each provider gave written informed consent. Providers received a $300 gift card for their participation.

Parents identified on the clinic's daily appointment schedule as having a child 1 to 19 months old being seen for a health supervision visit with a participating provider during the study period of September 2011 through August 2012 were approached by trained research assistants in the clinic's waiting room. Research assistants were in the clinic of each participating provider, on average, 1 to 2 times per week. We chose children aged of 1 to 19 months because they correspond to health supervision visits in which the majority of the recommended vaccines for the primary series are administered.[17] Parents who met additional inclusion criteria (≥18 years old and English-speaking) and who agreed to participate were screened by using the Parent Attitudes about Childhood Vaccine (PACV) survey, a valid and reliable tool for identifying VHPs.[18,19] Parents were considered to be hesitant if they scored ≥50 on the 100-point PACV survey.[19] We oversampled VHPs because it is their vaccination behavior that is most relevant.[20] The study was described generally to parents to minimize the Hawthorne effect. In addition, the PACV was embedded into a larger survey about parental perceptions of common childhood topics (including vitamin D, breastfeeding, and sleep). Parents provided written informed consent upon enrollment and received a $20 gift card for their participation.

Data Collection

Health supervision visits were videotaped with small, battery-operated camcorders that were equipped with wide-angle lenses and positioned in ceiling corners of examination rooms. Recording began just before provider entry into the examination room and ended at visit completion after parents exited the room. We considered vaccine discussions to begin with the first mention of vaccines by any participant and to end after the resolution of the last mention of vaccines, even if other topics were discussed in the interim. Vaccine discussions were fully transcribed. Before leaving the clinic after their visit, parents completed a self-administered survey asking for demographic information (birth order of their child, parent age, income, marital status, race/ethnicity, gender, and number of children in their household) and whether this was their first vaccine discussion with their child's provider. The Seattle Children's Institutional Review Board reviewed and approved all study procedures.

Data Analysis

Qualitative

We refined the preliminary coding scheme developed in the pilot study[15] by using conversation analysis (CA)[21–23] to identify recurrent physician vaccine communication practices, especially those that seemed to promote or hinder parental vaccination acceptance, and patterns of parent responses to those physician practices. Two investigators with CA expertise who were involved in the development of the preliminary coding scheme (J.D.R. and J.H.) analyzed 70% of the total number of videotaped encounters to develop the final coding scheme. This proportion of videotaped encounters represented ≥75% of VHPs and first-time vaccine discussion visits and ≥1 encounter from each participating provider. Both CA investigators were blinded to the parents' hesitancy status during their analysis. The final coding scheme contained 15 vaccine communication practices (see Appendix).

Two investigators (D.J.O. and H.S.S.) received a 1-day, in-person training session on the coding scheme from 1 of the CA investigators (J.D.R.) using 10% of the data. Intercoder reliability was subsequently tested on 20% of the data that did not include initial training data, with κ scores ranging from 0.70 to 1.0 (mean $\kappa = 0.76$). Both coders continued to code all remaining data (and recoded the initial 10% of training data) using the turn of talk (the entire length of time 1 person speaks until another begins to speak) as their unit of analysis.[24,25] Both coders were blinded to the parents' hesitancy status. All discrepancies were resolved through discussion with the 2 CA investigators (J.D.R. and J.H.).

Quantitative

Our main outcome was parent verbal resistance to provider vaccine recommendations. Parent resistance was binary (yes/no) and determined at the time of coding by assessing resistance to all or some of the provider's recommendations at 2 time points in the vaccine conversation: first, in response to the provider's initiation of the vaccine recommendations, and second, in response to the provider's pursuit of his or her original recommendations. In line with previous research on how verbal actions or recommendations are resisted,[26,27] several different types of parent verbal behaviors were coded as resistance at each of these time points: (1) when parents explicitly rejected some or all of the provider's vaccine recommendations (eg, "I want to go slow and just do the MMR [measles-mumps-rubella]" or "I don't want him vaccinated today"), (2) when parents claimed to not be able to make a decision ("I don't know"), (3) when parents responded with contingencies that they perceived to be a barrier to vaccination at the current visit (eg, "His father's away at the moment" or "We're flying tomorrow"), or (4) when parents responded by raising concerns or questions about vaccines (eg, "That's a lot of shots" or "Well, where would he get Hep [hepatitis] B?"). These 4 types of parental resistance were subsequently dichotomized into explicit (code 1 above) and nonexplicit (codes 2–4) rejections.

Our 2 primary predictors were the format providers used to initiate vaccine recommendations and how they pursued their original vaccine recommendations when encountering parent resistance. Provider initiation formats were dichotomized into presumptive and participatory formats. Consistent with our pilot study,[15] presumptive formats were ones that linguistically presupposed that parents would vaccinate, such as declarations that shots would be given (eg, "Well, we have to do some shots"), even if providers added "tag questions" to the ends of such verbal moves (eg, "So, we'll do 3 shots and the drink. Is this okay?").[28,29] Participatory formats were ones that linguistically provided parents with relatively more decision-making latitude, such as polar interrogatives (eg, "Are we going to do shots today?") and open interrogatives (eg, "What do you want to do about shots?"), or ones that presupposed that parents would not vaccinate (eg, "You're still declining shots?").

Provider pursuit of their original vaccine recommendations in the face of parental resistance was dichotomized into pursuing and not pursuing. Pursuit included moves such as "He really needs these shots," "If he was my child I would definitely go ahead," "Whooping cough can be a killer in the kid under 1," and "It's way less shots than it used to be." Not pursuing included providers either accepting parents' resistance (eg, "Okay" or "Alright" and moving on) or pursuing vaccine recommendations that were mitigated relative to their original recommendations, such as pursuing fewer vaccines (eg, "We could split them up") or delaying shots (eg, "We could do them when you come back in 2 months").

For the analysis, we used Pearson's χ^2 tests (or Fisher's exact tests) to compare demographic and visit characteristics among VHPs and non-VHPs (NVHPs) and to compare communication practices between both VHPs and NVHPs as well as among first-time and non–first-time vaccine discussions. Pearson's χ^2 tests (or Fisher's exact tests) were also used to explore the bivariate association between our outcome of parent resistance to the provider's vaccine recommendation and the provider communication practices of initiation and pursuit.

We used backward stepwise logistic regression to identify potential demographic and visit characteristic confounders of this relationship using a significance level for removal of >.2

and for the addition of <.1. We did not include individual provider and clinic/practice categorical variables in our modeling because their association with our main outcome and predictors was not found to be significant in bivariate analyses ($P > .1$). We performed multivariate logistic regression to examine the association between provider initiation and parental resistance while adjusting for confounders that were retained in backward stepwise modeling and that were not narrowly distributed[30] (parent hesitancy status, parent race, parent age, child age, length of vaccine discussion, and first-time vaccine discussion). For all regression analysis, robust SEs were used to account for within-provider clustering.

TABLE 1 Demographic Characteristics of Study Population

Characteristics	Total ($N = 111$)	VHP ($n = 55$)	NVHP ($n = 56$)	P[a]
Parent aged ≥30 years[b]	75 (77)	36 (72)	39 (83)	.2
Mother[b]	86 (89)	47 (94)	39 (83)	.11
Parent's marital status				
Married or living with a partner[b]	89 (92)	46 (92)	43 (91)	1.0
Parent education				
Some college/2-year degree or more[b]	84 (87)	41 (84)	43 (91)	.36
Household income				
>$75 000[b]	59 (62)	28 (57)	31 (67)	.30
Parent race/ethnicity				
White[b]	79 (81)	40 (80)	39 (83)	.71
Number of children in household				
1 child[b]	55 (57)	28 (56)	27 (57)	.89
Child eligible for study is first-born[b]	60 (62)	28 (56)	32 (68)	.22
First immunization discussion[b]	18 (26)	8 (21)	10 (34)	.2
Child aged ≤2 months	42 (38)	20 (37)	22 (39)	.75
Length of immunization discussion <5 minutes	44 (40)	23 (42)	21 (38)	.64

Data are presented as *n* (%).
[a] χ^2 test (or Fisher's exact test).
[b] Numbers do not equal total 111 because of missing data.

RESULTS

We enrolled 16 pediatric providers from 9 primary care practices. Among the enrolled providers, 10 were women and 1 was a nurse practitioner. Practice settings of participating providers included university-based ($n = 2$), community hospital–based ($n = 1$), multispecialty group ($n = 2$), urban private ($n = 1$), and suburban private ($n = 3$) practices.

We videotaped 113 health supervision visits between participating providers and enrolled parents; 2 (2%) videos did not contain a vaccine discussion and were excluded from further analysis. Among the 111 videotaped visits that were analyzed, 55 (50%) included VHPs (Table 1). The majority of participating parents were married, white mothers who were ≥30 years old and had a household income >$75 000. There were no significant differences in demographic characteristics between participating VHPs and NVHPs.

The frequencies of provider general vaccine communication practices are shown in Table 2. The majority of providers did not explicitly solicit parental questions or concerns about vaccines (62%) but did discuss the rationale (55%) and potential side effects (55%) of the recommended vaccines. Providers used general communication practices with similar frequencies among both VHPs and NVHPs and when having first-time and non–first-time vaccine discussions.

How providers initiated their vaccine recommendations and how parents responded to these initiations are shown in Fig 1. The majority of providers (74%) initiated vaccine recommendations by using presumptive formats, but significantly more providers used participatory initiation formats with VHPs than with NVHPs (41% vs 11%; $P = .001$). Of the parents who voiced resistance (41%), the majority did so by explicitly rejecting some or all of the provider's recommendations (53%). Significantly more VHPs than NVHPs resisted (54% vs 28%; $P = .009$).

Among all parents, a larger proportion resisted vaccine recommendations when providers used a participatory rather than presumptive initiation format (83% vs 26%; $P < .001$). This finding remained true among VHPs (89% vs 30%; $P < .001$). In regression analysis, provider use of participatory initiation formats for their vaccine recommendations was associated with a significantly increased odds of parental resistance to those recommendations in both unadjusted (odds ratio: 14.2; 95% confidence interval: 4.9–41.0) and adjusted models that

TABLE 2 General Vaccine Communication Practices by Parental Hesitancy Status

Provider Communication Practice	Frequency			P[a]
	Total ($N = 111$)	VHP ($n = 55$)	NVHP ($n = 56$)	
Does provider explicitly solicit parent questions or concerns about shots? Yes	42 (38)	20 (36)	22 (39)	.75
Does provider give rationale for shots? Yes	61 (55)	30 (55)	31 (55)	.93
Does provider discuss side effects? Yes	61 (55)	28 (51)	33 (59)	.40

Data are presented as *n* (%).
[a] χ^2 test.

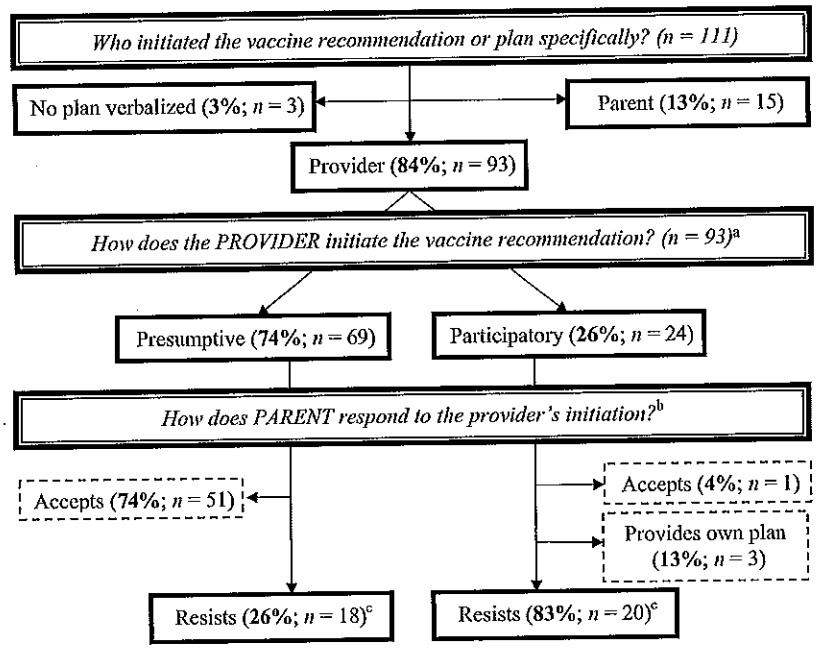

FIGURE 1

How providers initiated the visit vaccine recommendation and how parents respond. [a]Provider use of participatory initiation formats with VHPs and NVHPs was 41% vs 11%, respectively ($P = .001$, χ^2 test). [b]Parent resistance to provider initiation among VHPs and NVHPs was 54% vs 28%, respectively ($P = .009$, χ^2 test). [c]$P < .001$ (Fisher's exact test).

controlled for parental hesitancy status, parent and child demographic characteristics, and visit characteristics (adjusted odds ratio: 17.5; 95% confidence interval: 1.2–253.5).

How providers responded when parents voiced resistance to original vaccine recommendations is shown in Fig 2. Half of the providers pursued their original recommendation with no significant difference in doing so between resisting VHPs and NVHPs ($P = .31$). Significantly more providers pursued their original recommendation when parents resisted with an explicit rejection than when parents used a less explicit type of resistance (80% vs 17%; $P < .001$).

Despite initial resistance, 9 of 19 (47%) parents accepted the provider's vaccine recommendation immediately after providers pursued it. This number included 27% of VHPs (3 of 11) and 75% of NVHPs (6 of 8) ($P = .07$). For those parents who continued to resist ($n = 10$), 30% of providers continued to pursue their original vaccine recommendation.

DISCUSSION

This is the first study to our knowledge that examines the frequency of specific communication practices during provider-parent vaccine discussions at pediatric health supervision visits and their association with parental vaccine resistance. As such, it is the first to address the existing gap in evidence for provider communication behaviors that are effective in increasing parental acceptance of childhood vaccines. These results provide foundational information to help guide the development of quality improvement interventions aimed at increasing vaccination rates among VHPs.

Our finding that use of participatory initiation formats when making vaccine recommendations was associated with increased odds of parental resistance highlights the significance of initiation as a communication practice in vaccine discussions. Although the linguistic format of how a topic is introduced has received attention in other medical settings,[31–34] it has not yet been explored in the context of vaccine discussions. In fact, no previous reference on how to communicate with VHPs[35–40] includes mention of how a provider should initiate the vaccine recommendation.

In addition, this result seems to stimulate reflection on what collaborative communication and shared decision-making connote in the context of childhood vaccines. Although a participatory approach may be aligned with expectations parents have of providers in vaccine discussions[41,42] and be consistent with consensus recommendations that promote collaborative communication as a best practice with VHPs,[35,40,43] use of this approach may need to be reconsidered if it leads to fewer children being fully vaccinated and/or vaccinated on time. Furthermore, there appears to be a need for resolving the incongruity that currently exists with respect to the use of shared decision-making in the childhood vaccine context. Shared decision-making is typically not indicated when there is only 1 medically acceptable choice.[44] Childhood vaccines fulfill this criterion. Yet, shared decision-making is appropriate when a decision is value-laden.[45] In an era of vaccine hesitancy, vaccines also fulfill this criterion. Whether shared decision-making is appropriate in childhood vaccine discussions is likely central to the existing disagreement among pediatricians regarding the appropriateness of dismissing families for refusing vaccines.[46–50]

Relatedly, our finding that many providers did not give a rationale for the vaccine(s) recommended and did not discuss potential side effects of these vaccines (and did not do so significantly more often during first-time vaccine conversations) raises issues regarding

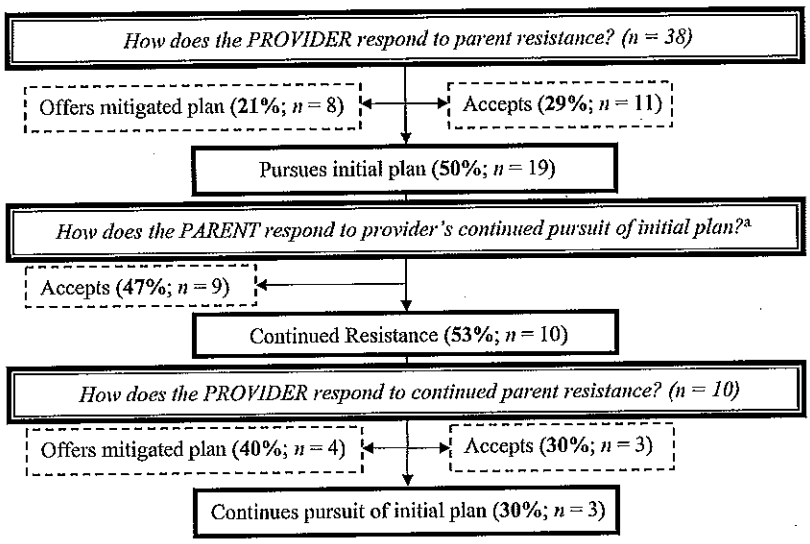

FIGURE 2
How providers pursued their original vaccine recommendation among parents who verbally resisted the provider's initiation. [a]Parent acceptance after provider pursuit among VHPs and NVHPs was 27% vs 75%, respectively ($P = .07$, Fisher's exact test).

the type and quality of parental consent obtained by providers. The typical conversation that we observed can be described as simple consent: explanation of an intervention followed by expressed or implied agreement.[44] Simple consent may be appropriate because vaccines represent a low-risk intervention administered according to a schedule in which there are currently no known acceptable alternatives. Furthermore, it is a conversation that is supplemented by written material (eg, the Vaccine Information Sheet) on the risks and benefits of each vaccine. However, as real and perceived risks of vaccines become evident and the absolute risk of vaccine-preventable disease remains low, a conversation that better approximates informed consent may be more appropriate, especially among VHPs.

Another interesting finding was that nearly half of initially resistant parents accepted the provider's original vaccine recommendation if the provider continued to pursue it. These findings seem especially important given that only 50% of providers pursued their original recommendation after initial parent resistance. Although persistence may pay off, it should be acknowledged that doing so is not without burden. Engaging in conflict with VHPs takes an emotional toll on providers.[13]

There are several limitations to this study. First, it is possible that under normal, nonvideotaped circumstances, provider-parent interaction involves different communication behaviors than those identified. However, other studies have revealed a negligible effect of the videotape on provider and parent behavior,[51] and we used several maneuvers to minimize the Hawthorne effect. Second, we videotaped only a single vaccine encounter and therefore could not assess how specific provider communication practices varied or were associated with vaccination outcomes over time. Because vaccine administration and communication is a longitudinal issue, there may be instances along this continuum in which a participatory initiation or lack of pursuit of a vaccine recommendation is most appropriate to develop rapport and establish trust at the risk of temporarily enabling parent refusal. Third, although we controlled for several confounding variables related to parent acceptance of childhood vaccines and provider vaccine communication behavior, other unmeasured confounders may exist. There were also too few observations to perform an adjusted analysis of the association of parent acceptance and provider pursuit. Fourth, our outcome of parent resistance was not based on an examination of the child's vaccine records, and therefore is a proxy of their immunization behavior. Last, the coding scheme was developed by using a relatively homogenous sample of providers and English-speaking, white parents with high socioeconomic status from 1 geographic location; therefore, the communication behaviors it is meant to reflect may not be representative or generalizable.

CONCLUSIONS

How providers initiate their vaccine recommendations at health supervision visits appears to be an important determinant of parent resistance to that recommendation. Also, if providers continue to pursue their original recommendation after encountering parental resistance, many parents eventually agree to it. These associations require confirmation in longitudinal studies with a more diverse population of parents and providers.

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APPENDIX Coding Scheme

Communication-Behavior Description	Codes	Examples
1. Who initiates vaccine topic generally, in any way?	1 = Pediatrician	See 3a and 4a below
	2 = Guardian	"So what about vaccines?"
2. Who initiates vaccine recommendation or plan specifically?	1 = Pediatrician	
	2 = Guardian in a way that allows or provides doctor to initiate the recommendation/plan	"We know he's getting shots today."
	3 = Guardian proposes a plan that complies with or endorses recommended plan; if 3, go to 5a and 4a–c = 99	"We're going on vacation so I think I would like to get all the vaccines today."
	4 = Guardian proposes a plan that resists vaccines or resists recommended plan; if 4, go to 5a and 4a–c = 99	"So we wanted to wait on Hep B and the polio and just do the other ones."
	99 = No verbal recommendation or plan	
3a. Does the pediatrician lead with a prevaccine discussion move?	0 = No	
• This must be an initiating action like a question that demands a response, not the beginning of an initiation.	1 = Yes	"It's time for shots" or "How did he do with the vaccines last time?" or "Do you have questions about the vaccines?"
	99 = N/A due to guardian initiation (see code 2 above)	
3b. What type of response does the guardian give to the prevaccine move?	1 = Unmitigated go-ahead	Go-ahead = "Fine," "No"
	2 = Raises question regarding "fact" of immunization	"What are the vaccines he has to have?"
	3 = Raises issue of "concern" regarding immunization	"It's 3 at once—all today?"
	4 = Raises opinion/plan regarding immunization (go to 5a)	"We do want to be vaccinated against whooping cough."
	5 = Raises multiple issues (1–4 above)	
	99 = N/A due to no pre-move	
4a. Initiation: How does the pediatrician initiate the vaccine recommendation (key)? Must be an initiating action (T1). Note: sometimes doctors do this over the course of multiple sequences of talk because the recommendation has multiple parts; code on overall recommendation, especially at its end. However, if resistance comes earlier, code at that point.	1 = Presuppositional (in favor of shots)	"Well we have to do some shots"; "The vaccines we would give today can cause fever"
	2 = Presuppositional + tag (in favor of shots) or strongly rising questioning intonation	"So we'll do 3 shots and the drink. Is that okay?"
Rule: code on most recent/proximate action	3 = Polar interrogative	"Are we going to do the shots today?" or "Here is option X: Do you want to do that?"; "Are we gonna do some immunizations today?"
	4 = Open interrogative	"How do you feel about the immunizations?" or "What do you want to do about shots?"
	5 = Initiation designed against immunization (note that parent acceptance/agreement with this will be coded as resistance in 4b)	"You're still declining shots"; "And you're choosing right now not to?"
	99 = N/A due to code 3 in 2 or code 4 in 3b; or no verbal recommendation or plan at all	
4b. Response: How does the guardian respond to the pediatrician's initial initiation move? (T2)	0 = Resistance: go to 4c below (note that acceptance of code 5 in 4a is resistance)	
	1 = Unmarked "response" (eg, continuer, simple acknowledgment of speaking)	"Mm hm," (if not a response to a question); "Oh"; "Uh huh"
	2 = Accepts verbally or implicitly accepts by virtue of moving on in next turn	"Yes" or "Yeah" (if response to question or proposal); "Okay"; "Right"; "Good"; "That's fine"; "If he gets a fever, can I give him Tylenol?"; or just remaining silent/nonverbally acquiescing
	3 = Responds to polar or open interrogative by providing a vaccine plan (go to 5a)	Provider: "Are we gonna do some vaccines today?" Parent: "Yes, the Rota … and the Pentacel"
	99 = N/A due to no 4a or no recommendation or plan at all	
4c. Resistant response: If 4b = 0, what is the nature of the resistance in the guardian's response to the pediatrician's initial initiation move?	1 = Explicit rejection of some/all of proposal	"I don't want him vaccinated today"; "I want to go slow and just do the MMR"
	2 = Demurral	"I haven't really thought about it"; "I don't know"
	3 = Cites contingency	"We're flying tomorrow."

APPENDIX Continued

Communication-Behavior Description	Codes	Examples
	4 = Raises questions or concerns, brief	"Well, where would he get Hep B?" or "What are the side effects?"
	5 = Raises concern, extended (3 or more)	3 or more concerns
	99 = N/A due to no code 0 in 4b	
5a. Pursuit #1: How does the pediatrician respond to or pursue the guardian's response to the initial initiation move? (T3)	1 = Pursues initial bid (ie, does not back down); resists completely (code 1 if 2b = 3 and doctor resists in any way)	"He really needs these shots"; "If he was my child I would definitely go ahead"
	2 = Pursues mitigated version of initial bid, but still more than what parent is going for; resists partially (note: code this when doctors ask parents if they can answer any questions/ concerns to get them to change mind)	"We could do them when you come back in 2 months"; "We could split them up"
	3 = Accepts verbally or implicitly accepts by virtue of moving on in next turn	"Okay"; "Let's check him over" (new activity)
	99 = No recommendation or plan at all	
5b. Response to pursuit #1: If pediatrician's pursuit involves another "bid," how does the guardian respond to the pediatrician's pursuit? (T4)	0 = Resistance: go to 5b1 below	
	1 = Unmarked "response" (eg, continuer, simple acknowledgment of speaking)	"Mm hm"; "Yeah"
	2 = Accept	"Yes" (if response to question), "Okay"; "Right" ; "Good"
	3 = Accept presupposed in next turn	"If he gets a fever, can I give him Tylenol?"
	99 = N/A due to no pursuit (ie, 5a = 3)	
5c. Resistant response to pursuit #1: If pediatrician's pursuit involves another "bid," what is the nature of the resistance in the guardian's response?	1 = Explicit rejection of some/all of proposal	I don't want him vaccinated today"; "I want to go slow and just do the MMR"
	2 = Demurral	"I haven't really thought about it"; "I don't know"
	3 = Cites contingency	We're flying tomorrow"
	4 = Raises questions or concerns, brief	"That's a lot of shots" or "pained" reaction
	5 = Raises concern, extended (3 or more)	
	99 = N/A (no code 0 in 5b)	
6. Pediatrician's final move: How does the pediatrician respond to or pursue the guardian's response to the subsequent move? (T5)	1 = Pursues previous bid (ie, does not back down); resists completely	"He really needs these shots"; "If he was my child I would definitely go ahead"
	2 = Pursues mitigated version of previous bid, but still more than what parent is going for; resists partially	"We could them when you come back in 2 months"; "We could spilt them up"
	3 = Accepts verbally or implicitly accepts by virtue of moving on in next turn	"Let's check him over" (new activity)
	99 = N/A due to no pursuit (ie, 5a = 3)	
7a. Global: Number of guardians' vaccine-related questions asked before acceptance of vaccination	Code frequency (0–X); ratio-level data	Note that, by "question," we mean any move that solicits information about vaccines, directly or indirectly.
7b. Global: Number of guardians' vaccine-related questions asked after acceptance of vaccination	Code frequency (0–X); ratio-level data	
8. Global: Does doctor explicitly solicit some/any questions/concerns?	0 = No 1 = Yes	See 3a: "Do you have questions about the vaccines?"
9. Global: Does pediatrician give rationale for immunization?	0 = No 1 = Yes	"Haemophilus is a bacteria that lives in our noses and throats and when I was a kid growing up it was the number 1 cause of meningitis in babies"
10. Global: Does pediatrician discuss side effects?	0 = No 1 = Yes	"We've got the Tylenol and Motrin dosing back here so if she does seem to have any fussiness or fever or soreness after today's shots go ahead and do that."

Hep B, hepatitis B; MMR, measles-mumps-rubella; N/A, not applicable; T1, 1st turn of talk; T2, 2nd turn of talk; T3, 3rd turn of talk; T4, 4th turn of talk; T5, 5th turn of talk.

The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits

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Study: One dose of HPV vaccine Cervarix might be enough to prevent cervical cancer

Angela Townsend, The Plain Dealer By **Angela Townsend, The Plain Dealer**

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on November 04, 2013 at 12:05 AM, updated November 04, 2013 at 10:39 AM

CLEVELAND, Ohio -- Findings from a study published Monday in the journal **Cancer Prevention Research** show that just one dose of the **human papillomavirus** vaccine **Cervarix** may be all that is needed to provide protection against cervical cancer.

Mahboobeh Safaelan NCI

The study, sponsored by the National Cancer Institute, is the first to show that women who received a single dose of the three-dose regimen had antibodies against the HPV viruses that remained stable in their blood for four years.

Additional research is being planned to see if that protection can extend for an even longer period of time. The findings have the potential to simplify the vaccine process for a population that, for the most part, does not currently complete the three-dose regimen.

The study also could have more wide-reaching implications.

"Obviously this research is really exciting," Mahboobeh Safaeian, an investigator in the NCI's Division of Cancer Epidemiology and Genetics who led the study, told The Plain Dealer. "The application of it in the whole world will be really important.

"Vaccination with two doses, or even one dose, could simplify the logistics and reduce the cost of vaccination, which could be especially important in the developing world, where more than 85 percent of

cervical cancers occur, and where cervical cancer is one of the most common causes of cancer-related deaths," she said.

In 2006, the U.S. Food and Drug Administration approved the **Gardasil** vaccine to help protect girls and women ages 9-26 against HPV types 6, 8, 16 and 18 – the strains that can cause cervical, vaginal or vulvular cancers, and genital warts.

In 2009 the FDA approved the vaccine Cervarix for use in girls and women ages 10-25 to prevent against HPV types 16 and 18, the two strains that account for about 70 percent of all cervical cancers in the United States.

Since 2007, the percent of girls in the U.S. between ages 13-17 who received at least one dose of Cervarix or Gardasil, the other vaccine approved by the Food and Drug Administration, has increased from 25 percent in 2007 to nearly 54 percent in 2012, **according to the U.S. Centers for Disease Control and Prevention**. Only one-third of that population received all three doses of the vaccine.

With that in mind, Safaeian and her colleagues sought to see if one dose was enough to provide adequate protection against HPV.

They analyzed data from a Phase 3 clinical trial that tested the effectiveness of Cervarix in women in Costa Rica. In that trial, about 20 percent of women didn't receive all three doses of the vaccine. A significant number of women who did not get all three doses became pregnant or were referred for a colposcopy following an abnormal Pap test before follow-up doses could be given.

The researchers looked for the presence of an immune response to the vaccine (measured by antibody levels) in blood samples drawn from 78, 192, and 120 women who received one, two, and three doses of the vaccine, respectively. They compared the results with data from 113 women who did not receive vaccination but had antibodies against the viruses in their blood because they were infected with HPV in the past.

What they found surprised them:

- All of the women in all three dosing groups had antibodies against HPV 16 and 18 in their blood for up to four years.
- Antibody levels were comparable for women receiving two doses six months apart and those receiving the full three doses.
- While antibody levels among women who received one dose were lower than among those who received the full three doses, the levels appeared stable, suggesting that these are lasting responses.
- The levels of antibodies in women from the one- and two-dose groups were five to 24 times higher than the levels of antibodies in women who did not receive vaccination, but had prior HPV infection.

Safaeian said she and her colleagues hope to continue their research of Cervarix by looking at samples six years out to measure the level of protection.

"If we can show in the one-dose group stability beyond four years, that would be interesting and important," she said. "In the next year or two, we will have that data."

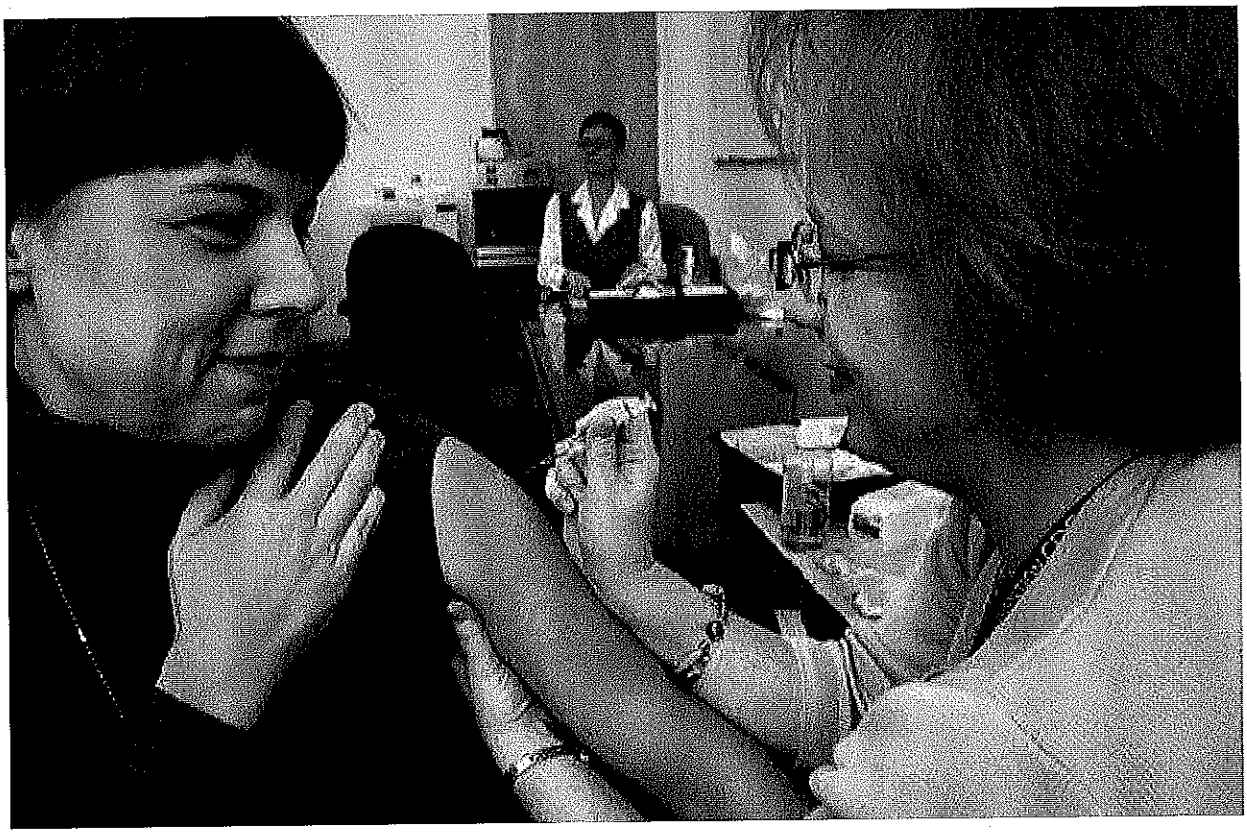
The researchers also are interested to see if the same findings apply to Gardasil as well.

"Nobody really knows the response to one dose of Gardasil," Safaeian said. "We're hoping to begin collaborations [with others] and look at settings for those studies."

6.5

CommonHealth

Mass. Rolling Out Registry To Track Who Got Which Vaccines



(James Gathany/CDC)

"Hello. Just for your information, Massachusetts is rolling out a statewide database that will track everybody's vaccines — it's expected within the next few months — and you can opt out if you want, but otherwise, it will keep track of which vaccines you've gotten."

That shpiel was my assignment at our school's flu vaccine clinic yesterday, and I dutifully reeled it off several hundreds times to people waiting in line for their shots and sprays. Most commonly, the response was an indifferent nod; a few people seemed downright pleased and grateful, and one — exactly one — person sounded incensed and asked for more information about opting out.

In case you, too, are potentially incensed, or just naturally curious, the new vaccine registry is called the **Massachusetts Immunization Information System**, and I'm happy to report that **its helpdesk** actually did answer helpfully and promptly when I just called its number, 617-983-4335. The registry has been in the process of enrolling health-care providers over the last couple of years, I was told, and now has about one-third of the state's providers enrolled.

Also: The law that creates the registry stipulates that patients must be informed when their doctor starts sharing their vaccine information with the state, and can limit that sharing if they choose.

The Boston Globe wrote back in 2011 that Massachusetts, normally a frontrunner on public health issues, is oddly lagging on its vaccine registry. Public health reporter Kay Lazar wrote:

> *State lawmakers, facing opposition from insurers, failed for the past two years to act on the proposal, which would assess a fee on health insurance plans to raise the estimated $1 million to $2 million a year needed to run a registry.*
>
> *But now insurers have dropped their opposition, and supporters, worried that federal funding for the project will dry up, have ratcheted up their lobbying for the state's financial support, suggesting that, for the first time, Massachusetts will join the rest of the country with a registry that physicians say is essential.*
>
> *Massachusetts and New Hampshire are the only states without statewide registries to track who gets vaccinated, according to the US Centers for Disease Control and Prevention.*
>
> *Physicians have long pushed for a centralized registry, saying it will make it possible for busy parents to be notified when their children are due – or overdue – for vaccines.*
>
> *The need, physicians say, is especially acute for lower-income families who may not have reliable access to routine medical care. Public health officials hope to use this registry for targeting education campaigns and other programs to promote vaccination in underserved areas.*

One vaccine recipient asked me, "Why would I want to opt out?" And I could only hazard, "Privacy? Though you figure the NSA already knows which vaccines you get, so..." But seriously, readers, if anyone plans to opt out, could you explain why in the Comments below?

7

Dated: November 4, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–27006 Filed 11–8–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Addition to the Vaccine Injury Table to Include All Vaccines Against Seasonal Influenza

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Through this notice, the Secretary of the U.S. Department of Health and Human Services (the Secretary) announces that all FDA-approved vaccines against seasonal influenza are covered under the National Vaccine Injury Compensation Program (VICP), which provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. Prior to this publication, trivalent influenza vaccines were included under Category XIV on the Vaccine Injury Table (Table) and will continue to be listed in that category. This notice serves to include all vaccines against seasonal influenza (not already covered under Category XIV) as covered vaccines under Category XVII of the Table (new vaccines covered under the VICP). This notice ensures that petitioners may file petitions relating to all vaccines against seasonal influenza (not already covered under the VICP) with the VICP even before such vaccines are added as a separate and distinct category to the Table through rulemaking.

DATES: This notice is effective on November 12, 2013. As described below, all vaccines against seasonal influenza (except trivalent influenza vaccines, which are already covered under the VICP) will be covered under the VICP on November 12, 2013.

FOR FURTHER INFORMATION CONTACT: Vito Caserta, M.D., M.P.H., Acting Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–5287.

SUPPLEMENTARY INFORMATION: The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) to the Secretary for routine administration to children. See section 2114(e)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included as covered vaccines in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines (42 CFR 100.3(c)(5)).

By way of background, trivalent influenza vaccines (meaning they each contain three vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season) are routinely given to millions of individuals in the United States each year. Trivalent influenza vaccines include an inactivated (killed) virus vaccine administered using a syringe as well as a live, attenuated product administered in a nasal spray. All trivalent vaccines have been covered under the VICP since July 1, 2005. On April 12, 2005, the Health Resources and Services Administration (HRSA) published a notice in the **Federal Register** announcing that such vaccines were covered under the category for new vaccines on the Table. See 70 FR 19092. Subsequently, the Secretary engaged in rulemaking to add trivalent influenza vaccines as a separate category on the Table (category XIV on the Table). See 76 FR 36367.

Since that time, quadrivalent influenza vaccines (meaning that they contain four vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season) have been approved by the Food and Drug Administration (FDA), and such vaccines are expected to be administered as an alternative to trivalent influenza vaccines during the upcoming and future flu seasons. On June 25, 2013, Public Law 113–15 was enacted, extending the applicable excise tax on trivalent influenza vaccines to also include any other vaccines against seasonal influenza. See Public Law 113–15 (amending 26 U.S.C. § 4132(a)(1)(N)).

The amendment included in Public Law 113–15 ensures that all FDA-approved seasonal influenza vaccines, including quadrivalent influenza vaccines, and other new seasonal influenza vaccines are covered under the VICP. Under the regulations governing the VICP, Category XVII of the Table specifies that "[a]ny new vaccine recommended by CDC for routine administration to children, after publication by the Secretary of a notice of coverage" is a covered vaccine under the Table (42 CFR 100.3(a), Item XVII). As explained in HRSA's notice of coverage with respect to the coverage of trivalent influenza vaccines, the CDC recommended in its May 28, 2004, issue of the Morbidity and Mortality Weekly Report (MMWR) that influenza vaccines be routinely administered to children between 6 and 23 months of age because children in this age group are at an increased risk for complications from influenza. That recommendation extends to seasonal influenza vaccines beyond trivalent vaccines. The latest CDC update of its annual influenza vaccination recommendation was published in the MMWR on September 20, 2013. MMWR 2013;62, No. 7. This report updated the 2012 recommendations by the CDC and its Advisory Committee on Immunization Practices regarding the use of influenza vaccines for the prevention and control of seasonal influenza. Routine annual influenza vaccination is recommended for all persons aged 6 months and older. For the 2013–14 influenza season, it is expected that trivalent live attenuated influenza vaccine (LAIV3) will be replaced by a quadrivalent LAIV formulation (LAIV4). Inactivated influenza vaccines (IIVs) will be available in both trivalent (IIV3) and quadrivalent (IIV4) formulations. No preferential recommendation was made for one influenza vaccine product over another for persons for whom more than one product is otherwise appropriate.

This notice serves to satisfy the regulation's publication requirement. Through this notice, all vaccines against seasonal influenza (beyond trivalent influenza vaccines, which are already covered under Category XIV on the Table) are included as covered vaccines under Category XVII of the Table (new vaccines).

Under section 2114(e) of the PHS Act, as amended by section 13632(a) of the Omnibus Budget Reconciliation Act of 1993, coverage for a vaccine recommended by the CDC for routine administration to children shall take effect upon the effective date of the tax enacted to provide funds for compensation with respect to the vaccine included as a covered vaccine in the Table. Under Public Law 113–15, the excise tax for vaccines against seasonal influenza (beyond trivalent influenza vaccines) "shall apply to sales and uses on or after the later of: (A) The first day of the first month which begins more than 4 weeks after the date of the enactment of this Act [i.e., Pub. L. 113–

15]; or (B) the date on which the Secretary of Health and Human Services lists any vaccines against seasonal influenza (other than any vaccine against seasonal influenza listed by the Secretary prior to the date of the enactment of this Act) for purposes of compensation for any vaccine-related injury or death through the Vaccine Injury Compensation Trust Fund." Public Law 113–15, § 1. The law further provides that if the vaccines were sold before or on the effective date of the excise tax, but delivered after this date, the delivery date of such vaccines shall be considered the sale date. *Id.*

Under this statutory language, the effective date of the excise tax for seasonal influenza vaccines other than trivalent influenza vaccines is the later of August 1, 2013 (which is the first day of the first month beginning more than 4 weeks after the effective date of Public Law 113–15, which was June 25, 2013), or the date on which the Secretary publishes a notice of coverage under the VICP for seasonal influenza vaccines not previously covered under the VICP. This publication is the notice referred to in the latter requirement. Because this publication is made after August 1, 2013, the effective date of coverage for all vaccines against seasonal influenza (beyond trivalent influenza vaccines, which are already covered by the VICP) is the effective date of this publication, November 12, 2013.

Petitions filed concerning vaccine-related injuries or deaths associated with all vaccines against seasonal influenza vaccines must be filed within the applicable statute of limitations. The filing limitations applicable to petitions filed with the VICP are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)). In addition, section 2116(b) of the PHS Act lays out specific exceptions to these statutes of limitations that apply when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this provision, persons who may be eligible to file petitions based on the addition of a new category of vaccines under Category XVII of the Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)). Thus, persons whose petitions may not be timely under the limitations periods described in section 2116(a) of the PHS Act, may still file petitions concerning vaccine-related injuries or deaths associated with seasonal influenza vaccines (with the exception of trivalent influenza vaccines that are already covered under the VICP) until November 12, 2015, as long as the vaccine-related injury or death occurred on or before November 12, 2021 (8 years prior to the effective date of the addition of non-trivalent seasonal influenza vaccines as covered vaccines).

The Table will be amended through subsequent rulemaking to include all vaccines against seasonal influenza in place of only trivalent influenza vaccines under Category XIV of the Table. Once that is done, the Table's coverage provisions (codified at 42 CFR 100.3(c)) will explain that trivalent influenza vaccines are included on the Table as of July 1, 2005, and that other seasonal influenza vaccines are included on the Table as of November 12, 2013.

Dated: November 5, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–26992 Filed 11–8–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Virology—A Study Section, October 03, 2013, 08:30 a.m. to October 04, 2013, 05:30 p.m., Embassy Suites Baltimore—Downtown, 222 St. Paul Place, Baltimore, MD which was published in the **Federal Register** on September 17, 2013, 78 FR 180 Pgs. 57169–57170.

The meeting will start on December 16, 2013 at 9:00 a.m. and end December 17, 2013 at 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: *November 5, 2013.*

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26894 Filed 11–8–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel, October 10, 2013, 09:00 a.m. to October 10, 2013, 03:00 p.m., National Institutes of Health, 6700 B Rockledge Drive, 3137, Bethesda, MD, 20892 which was published in the **Federal Register** on September 16, 2013, 78 FR 56904.

The meeting notice is amended to change the date of the meeting from October 10, 2013 to December 5, 2013. The meeting is closed to the public.

Dated: November 5, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26906 Filed 11–8–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: December 6, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeffrey H Hurst, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7208, Bethesda,

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U. S. Court of Federal Claims

717 Madison Place, NW
Washington, DC 20439
202-357-6400

Denise K. Vowell

Denise Vowell was appointed as Special Master on February 1, 2006. She was designated Chief Special Master by the court to succeed Patricia E. Campbell-Smith, effective September 19, 2013.

Ms. Vowell is an honors graduate of Illinois State University (B.S. in Political Science and Philosophy in 1974) and the University of Texas School of Law (J.D. 1981), and a distinguished graduate of the Industrial College of the Armed Forces (M.S. in National Resource Strategy in 1998). She enlisted in the Army in 1973 while an undergraduate at Illinois State, and received a direct commission in the Women's Army Corps (WAC) in 1974. After serving as a Military Police officer, she was selected for the Army's funded legal education program. While an Army officer, she served as a tort litigation attorney, prosecutor, defense counsel, chief legal officer, and as both a trial and appellate judge. She retired from the Army as the Chief Trial Judge in January, 2006.

Her publications include: The Fourth Amendment Warrant Requirement and Courts-Martial: Military Justice versus Military Readiness, 8 American Journal of Criminal Law 281 (Nov. 1980); To Determine an Appropriate Sentence: Sentencing in the Military Justice System,114 Military Law Review 87 (Fall 1986); Using Operations and Maintenance Funds in Contingency Operations, Military Review, Vol. LXXX, p. 38, (Mar-Apr. 2000). In addition, she authored numerous published and unpublished opinions as an Associate Judge, U.S. Army Court of Criminal Appeals. She was a frequent guest lecturer on trial advocacy, evidence, and procedure at the Army's Judge Advocate General's Legal Center and School.

She is a member of the National Association of Women Judges, and currently chairs the Military Courts committee. In her spare time, she advises a Senior Girl Scout troop and an all-girl Boy Scout Venturing Crew in the Bailey's Crossroads area of Northern Virginia where she resides. She is an avid backpacker and someday hopes to thru-hike the Appalachian Trail.