Advisory Commission on Childhood Vaccines

December 5, 2013

90th Meeting

Teleconference Minutes

Members Present

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

Division of Vaccine Injury Compensation

Vito Caserta, M.D., Acting Director, DVIC
Tamara Overby, Acting Deputy Director, DVIC
Avril Melissa Houston, Chief Medical Officer, DVIC
Andrea Herzog, Staff Liaison

Office of the General Counsel
Andrea Davey, J.D.

Department of Justice
Vince Matanowski, J.D.
Julia McInerny, J.D.

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

Noting a quorum present, Mr. King called the meeting to order and, after introductions, reminded the members that in its deliberations the Commissioners should keep in mind, in an empathetic way, the significant challenges that an individual or family faces when a sudden, unexpected and serious vaccine injury occurs. It is a whole new experience with health care issues, insurance and treatment financing challenges, dealing with the provisions of the Vaccine Injury Compensation Program (VICP). The decisions of the Commissioners should be made in favor of supporting those individuals and families in what is a significant ordeal in their lives.

Public Comment on Agenda

Mr. King invited public comment specifically on the agenda.

Theresa Wrangham, Executive Director of the National Vaccine Information Center, spoke to the agenda item entitled, Discussion regarding in-person meetings. She noted that the other federal committees responsible for vaccine-related issues usually meet in a face-to-face environment, and for the ACCV that venue would be more appropriate with regard to the objective of outreach and informing parents of the benefits of the VICP.

Approval of June 2013 ACCV Meeting Minutes

Noting no further comment from the public, Mr. King invited approval of the minutes of the September 5, 2013 meeting. Ms. Herzog stated that the minutes would be corrected to reflect that the meeting was the 89th, and not the 88th ACCV meeting,

Mr. King noted that on page 8, his name was preceded by the title Dr. and not Mr., which should be corrected in the final version.

Ms. dela Rosa stated that she had not received the meeting documents in advance. Ms. Herzog agreed to e-mail the material to her and Mr. King decided that the approval of the minutes would be delayed until later in the meeting to allow Ms. dela Rosa time to review those minutes.

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

Dr. Caserta briefly reviewed the day's agenda, noting that the Commission would participate in a discussion about making the ACCV more effective, followed by a discussion about holding in-person meetings, after which the usual agenda items would be addressed – a report from the Process Workgroup, the report from the Department of Justice, a review of selected Vaccine Information Statements, and reports from the National Institute of Allergy and Infectious Diseases (NIAID), the Immunization Safety Office (ISO), and the National Vaccine Program Office (NVPO).

Dr. Caserta reported that in the first 37 days of FY 2014, 54 petitions had been filed. That would extrapolate to about 530 for the full year, which would follow the increasing number of petitions filed annually over the past several years. However, the impact of the federal shutdown has not been assessed. In terms of adjudications, there has been a slow start with 15 adjudicated cases that, if also extrapolated, would suggest only 150 cases, a number which is probably low. The same is true of actual awards for petitioners (about $7 million) and attorney's fees (about $3 million) – it is too early to project final amounts. Finally, the Vaccine Injury Compensation Trust Fund (Trust Fund) balance is about $3.4 billion, and in the past fiscal year net income was $266 million. In that year, awards to petitioners and attorney's fees slightly exceeded the net income. In previous years income exceeded what was paid from the Trust Fund.

In terms of significant activities, the public hearing on the rotavirus notice of proposed rulemaking (NPRM) will be in December, specific date to be announced. A notice about adding seasonal quadrivalent flu vaccine to the Vaccine Injury Table was published in the Federal Register. The effective date for coverage of this vaccine is November 12, which is the date that starts the 8-year look-back period. Petitions must be filed within two years of that date. The effective date for trivalent vaccine remains July 1, 2005. Finally, the federal shutdown delayed the progress of the Vaccine Injury Table NPRM, but it is back on track and should be sent to the Department for clearance within a month.

Dr. Caserta explained that an outbreak of serogroup B meningococcal disease occurred at Princeton University and to a lesser extent at UC Santa Barbara, and Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) worked with university officials and health departments to obtain authorization to distribute a vaccine under a formal protocol as an investigational new drug (IND). The vaccine is unlicensed in the U.S. because group B disease is relatively rare compared to the other serogroups in the US licensed vaccine, but used widely in Europe with a good safety record. It is a dangerous disease with serious morbidity. The Secretary confirmed that the vaccine would be covered by the VICP since all types of meningococcal vaccines are covered.

Dr. Shimabukuro added that the vaccination program will begin at Princeton the week after the ACCV meeting, with an initial vaccination, followed by a second vaccination in February. The CDC is the IND sponsor, which is approved by the FDA and includes a safety monitoring plan and a detailed consent process. The European vaccine was only recently licensed. He added, for clarification, that the outbreak at UC Santa Barbara involved a different strain and was not caused by exposure to Princeton students.

Dr. Caserta continued with his report, announcing that VICP and the Department of Justice (DOJ) separately briefed the staff of Congressman Issa (R-CA) and Congressman Cummings (D-MD) to familiarize them with the VICP. Mr. Matanoski commented that his Office of Legislative Affairs had advised him of a request by the Health Government Oversight Committee for a briefing, and it was held with congressional staff on November 7. Mr. King requested that staff provide the names of congressional staff who may have attended the briefings. There was a brief discussion about an information item in the meeting book referring to a video entitled “The Injustice of the Vaccine Injury Program” by the Canary Party. A congressional hearing that was mentioned in that video has not been scheduled.

Dr. Caserta noted that there had been a discussion at the last meeting about adding Guillain-Barre Syndrome (GBS) to the Vaccine Injury Table (Table) for influenza, which was approved by the Commission at that meeting. Final language for the Table was provided to the Commission for review and comment. Mr. Kraus questioned why chronic inflammatory demyelinating polyneuropathy (CIDP) was considered an exclusion criteria when the symptoms are very similar to GBS. Dr. Caserta explained that the Secretary based the determination on the fact that there is consensus in the neurology community that the two conditions respond to different therapies, demonstrate different pathologies and have different disease courses. He added that that determination does not prevent a petition from being filed as a non-Table injury . He also explained that the Qualifications and Aids to Interpretation go through a number of

federal departments, including OMB, which may consult other departments (like Defense and Justice) before the final regulation is written into an NPRM. Dr. Caserta finally stated that the Commission should reach a consensus on the language of the NPRM. Although the Commission had reached consensus on the language, Mr. Kraus recommended reaching out to non-federal health experts, such as medical societies concerned with neurological issues, to proactively invite them to comment on the NPRM.

Dr. Caserta noted that nothing of significance to the VICP was discussed at either the National Vaccine Advisory Committee meeting in late September or the Advisory Committee on Immunization Practices in late October.

Dr. Caserta closed with the announcement that Amber Berrian, who was introduced at the last meeting, had moved on to another federal position within the agency and that Ms. Herzog would continue as staff liaison to the Commission.

Presentation: Making the ACCV Most Effective, Dr. Vito Caserta, DVIC; Mr. Vince Matanoski, DOJ; Chief Special Master Denise Vowell

Chief Special Master Vowell introduced the presentation with an announcement that Chief Special Master Campbell Smith had been appointed to the U.S. Court of Federal Claims on September 19th, and shortly thereafter President Obama had appointed her chief judge of that court. That loss and the retirement of one of the special masters had put the Office of Special Masters (OSM) below the legislated allotment by 25%. Those vacancies will shortly be filled by two new appointees now undergoing clearance and approval.

Chief Special Master Vowell commented that the upward trend of filings continues, about 20% higher than last year, partly because of new vaccines added to the Vaccine Injury Table. She commended the efforts to examine the most effective way for the Commission to fulfill its mission, adding that focusing on moving the proposed changes to the Vaccine Injury Table is an appropriate agenda. Although the GBS claims have been efficiently processed on the basis of causation, adding GBS as a factor in flu vaccines will expedite the process to the damage phase, which should reduce the workload on the court and speed up the resolution of the claims.

Chief Special Master Vowell noted that, in contested cases, the special masters hear expert testimony and thoroughly review relevant medical literature and, although not scientists, that experience is very valuable in reaching conclusions about claims. She encouraged the Commission to consider the resolution of such contested claims with an eye toward improving the value of the Vaccine Injury Table and advocating further research.

Although the funding for the OSM operations comes from the Trust Fund, there are financial issues that impact operations, such as the limitations of sequestration (even though the funds come from the Trust Fund, use of the funds must be approved by Congress). OSM has restricted travel because of that and hopes to ease that restriction in early 2014 so that special masters may travel to venues more convenient to petitioners.

Another issue has been the loss at HHS of an individual who worked with the state Medicaid agencies to resolve lien issues that would delay final payments. Those liens would have to be resolved before the program could make payment. Since the individual is no longer at HHS to guide that resolution, the challenges of defining the lien amount and negotiating a resolution is left to the parties of the claim.

Chief Special Master Vowell encouraged the Commissioners to review decisions on the OSM web site, visit the office when convenient, attend the upcoming Judicial Conference (February 25), and attend an entitlement hearing when possible. In conclusion, she expressed appreciation for the Commission's dedication.

Dr. Caserta reviewed the Commission responsibilities contained in the ACCV charter:

* Advise the Secretary on the implementation of the Program
* Advise the Secretary on making changes to the Vaccine Injury Table
* Advise the Secretary regarding the need for childhood vaccination products that result in fewer significant adverse reactions
* Survey programs that gather vaccine adverse event information
* Advise the Secretary on the means to obtain, compile, publish and use credible data related to the frequency and severity of childhood vaccine adverse reactions
* Recommend vaccine injury research to the NVPO Director
* Consult on the development and revision of Vaccine Information Statements

Based on this charge, Dr. Caserta indicated that he and Mr. Matanoski had reviewed the current literature to recommend strategies to help the ACCV achieve its mission and support development of more effective responses to that mission. He suggested the following:

* To request, on an annual basis, that the Secretary define the highest priority public health issues related to the Vaccine Program and the provisions of the ACCV charter. That information would serve to guide the Commission towards activities that the Department considers most important and that would therefore be more valuable in terms of ACCV effectiveness.
* Request that the Secretary apprise the Commission of new priorities that might emerge during the year. Perhaps the DVIC staff could work with the Assistant Secretary for Health, under whose aegis the NVPO operates, to ensure that those new issues are addressed by the Commission (as well as to continue addressing current priorities that include adult immunizations, immunizations for pregnant women and their unborn or newly born children, and focusing on vaccine safety research). This should make the Commission's policy recommendations more relevant to the Department's needs.

This should help ACCV provide policy input where HHS needs it most. Then ACCV should request that the Department provide feedback, perhaps at the first calendar year ACCV meeting, on actions taken with regard to ACCV recommendations, including a rationale for

either accepting or rejecting those recommendations. The Commission should consider how to communicate with interested audiences and stakeholders about what the ACCV is doing. Dr. Caserta suggested that the Commission should focus on a small number of higher priority objectives, and provide information to stakeholders on how to support those objectives. ACCV has a diverse representation among its membership and with interested stakeholders, and that should serve to promote consensus support for the Commission's goals. Part of that would be improving coordination with other federal groups, such as Advisory Committee on Immunization Practices (ACIP), National Vaccine Advisory Committee (NVAC), etc.

Dr. Caserta recommended that the Commission develop recommendations with regard to what actions are needed and why they are needed, and who should take action and when, including the degree of support needed from each interest group or stakeholder. In addition, issues that affect the program, if adopted, should be identified --cost implications, improving processing time, casting a wider net for compensation, and streamlining the program. Dr. Caserta invited discussion.

Asked about the relationship with the other federal groups that were mentioned, Dr. Caserta stated that ACCV is represented on NVAC, and provides updates to ACIP. NVAC provides an insight into the priorities of the Department and Dr. Douglas, as the Commission representative to NVAC, could bring back that information to the Commission. Dr. Bende commented that all of the meeting information, the meeting book and presentations, are available on the NVPO web site shortly after the meeting. Dr. Douglas suggested that Commission members should be provided with the NVPO web link. Dr. Feemster agreed that the Commission could identify topics of common interest with NVAC and perhaps provide space on the Commission agenda for a brief discussion or presentation.

Mr. King suggested suspending the discussion until the afternoon session in order to recess for lunch.

(Recess for lunch)

Report from the Process Workgroup, Luisita dela Rosa

Mr. King called the meeting back to order and stated that, in deference to the guest speaker, Cheryl Dammons, who would join the discussion about in-person Commission meetings, Ms. dela Rosa, chair of the Process Working Group, would report on that segment of the meeting and complete her report after the discussion.

This summary pertained to the Process Working Group meeting held on November 20, 2013.

Ms. dela Rosa commented that one face-to-face meeting per year had been authorized, presuming that the matters to be discussed at the meeting justified the expense of that meeting format. Dr. Caserta suggested requesting approval from the Secretary to hold the March meeting in that manner, with the proviso that there could be no additional in-person meetings in FY 2014. Mr. King requested a rationale

from the Secretary as to why the NVAC continued to hold in-person meetings, since both ACCV and NVAC were created by the same legislation. Dr. Caserta noted that a representative from the Secretary's office or HRSA should attend the December meeting, where the issue could be discussed. He agreed that the issue of travel could also be discussed at the December meeting.

Dr. Caserta introduced Cheryl Dammons, HRSA Associate Administrator and head of the Healthcare Systems Bureau. She expressed her appreciation for being able to speak to the ACCV. Concerning the ability of NVAC to hold in person meetings, while ACCV is restricted in that area, Ms. Dammons explained that appropriations are different for each Department of Health and Human (DHHS) activity and that she could not address the funding decisions of the Office of the Assistant Secretary for Health (OASH), under which NVAC falls. There was a brief discussion about the mechanics of funding the ACCV, in light of the fact that the ACCV receives its funding from the Trust Fund, although HRSA must approve how the funds are used. HRSAestablished a limited travel policy during FY 2013. Mr. King made the point that there is a logical disconnect between the facts that funds for ACCV come from the Trust Fund, which is unrelated to HRSA appropriations. Ms. Dammons announced that during FY 2014 the ACCV is authorized to hold two in-person meetings, with the caveat that one would be held in conjunction with new member orientation.

Mr. King invited Ms. dela Rosa to continue her report. She reported that the working group had approved three recommendations at the last meeting. The first, already submitted to the Secretary, recommended adding a vaccine-injured individual to the Commission; the second, to extend the statute of limitations for filing claims; and the third, to increase the cap for pain and suffering. Those two would be forwarded to the Secretary after the December meeting and a copy of each would be sent to each Commissioner. Ms. dela Rosa stated that the working group had approved a recommendation that the third attorney on the Commission represent vaccine-injured individuals and be familiar with the mechanics of the VICP. Then there would be two attorneys who represent vaccine injury petitions and one who represents vaccine manufacturers. Since there is a vacancy in the near future, the Vaccine Injured Petitioners Bar indicated that it would submit a proposal for that appointment.

Considering the agenda for future working group meetings, there was agreement to focus on support for the three recommendations already approved. However, there could still be consideration of the fourth proposed recommendation, that affecting derivative claims. Dr. Caserta advised the working group to limit the number of recommendations to those of highest priority so as not to dilute the impact of the working group.

Mr. Kraus made a motion, duly seconded, that the ACCV recommend to the Secretary the appointment, as the third member of the legal counsel segment of the Commission, of an attorney who has experience with the Vaccine Injury Compensation Program. During discussion, Ms. Williams suggested that the motion would eliminate the position she now holds as unaffiliated lawyer, which she felt was a valuable resource person to be on the Commission. Mr. Smith agreed, noting that the unaffiliated attorney provides a different perspective than one who is dedicated to representing vaccine-injured individuals. He noted that, if approved, the

motion would dictate that Ms. Williams slot be filled by an attorney representing vaccine injured individuals, but felt that the change would not require that in perpetuity.

Mr. King noted that the charter designates the need to appoint an attorney who represents the vaccine manufacturing industry and one who represents vaccine injured individuals. The third is not specified in the charter. However, the Commission should see the vaccine-injured individuals as most important in the consideration. Dr. Caserta observed that a second attorney associated with vaccine-injured parties, although worthwhile in that obligation, does not add to the diversity of experience that is valuable in the Commission's work. Mr. Smith observed that Mr. Kraus had done an excellent job maintaining the Commission's awareness of the needs of the vaccine-injured, and he was not sure a second attorney with similar experience would make a significant difference. Although he stated his support for the motion, he felt it would be inappropriate to interpret the motion to mean that the third attorney would always be an attorney who represents petitioners. There was also an observation that the wording could be broadly interpreted to mean any attorney, even one for a vaccine manufacturer, could qualify if he or she could demonstrate experience with the Program.

A voice vote was taken and the Commission unanimously approved the motion to recommend that the third attorney on the Commission have experience with the VICP.

Concluding the Process Workgroup report, Ms. dela Rosa suggested discussing several issues, including the Chief Special Master's recommendation for the Commission to review entitlement decisions in order to identify future research. Other issues that could be included in the discussion would be the need to improve the process to resolve the burden of Medicaid obligations that must be eliminated to facilitate payment of awards, establishing a URL link on the Commission web site to NVAC, future uses of Trust Fund monies, and providing information to stakeholder groups related to ACCV recommendations that might be helpful to those groups in pursuing their own goals and objectives that are related to ACCV goals and objectives. Mr. King asked if specific topics could be included in the ACCV meeting agenda, such as increasing the cap for pain and suffering, and inviting outside witnesses to attend and comment in a public hearing type of venue.

Dr. Caserta stated that the idea would be acceptable if the Commission felt that it would promote the goal of greater effectiveness. Mr. Matanoski agreed that, in providing advice and counsel to the Secretary regarding childhood vaccines, there is value in hearing from diverse stakeholders who are part of the ACCV process, as long as the Commission is able to crystalize the information gleaned into an appropriate recommendation to the Secretary. Mr. Kraus added that the ACCV is unlike the other vaccine advisory committees, whose purview is the overall, broad vaccine arena. The ACCV focuses on vaccine-injured individuals, and the Commission's agenda should be in consonance with that difference.

Approval of June 2013 ACCV Meeting Minutes (continued)

Mr. King moved on to the deferred approval of the minutes of the June 2013 meeting and, on motion duly made and seconded, the minutes were unanimously approved by voice vote.

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

Mr. Matanoski referenced the DOJ Power Point materials (DOJ PP), dated December 5, 2013, as part of his presentation. He reported that there were 202 claims filed in the three-month reporting period, an increase in the number reported last year. (DOJ PP at 2) Adults represented 85% of the claims (up from 75% in last reporting period). Mr. Matanoski projected filings for 2014 to reach 500. This reflects a continued increase consistent with distribution of influenza vaccine. These trends are expected to continue, although there are no plans to increase the staff at DOJ. Responding to a question about the effect of potential changes to the Vaccine Injury Table on case processing, Mr. Matanoski said that while Table changes could result in more concessions by HHS, the amount of damages would still need to be resolved on a case by case basis.

With regard to adjudications, more than half of the petitions in the reporting period were compensated (75 of 139 cases), and all but one of the compensated cases were resolved by settlement. (DOJ PP at 3). Three cases were voluntarily withdrawn. (DOJ PP at 4).
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 appeals in the U.S. Court of Appeals for the Federal Circuit (CAFC), Mr. Matanoski briefly discussed three recently decided cases by the CAFC. In *Isaac v. HHS*, petitioner claimed that a tetanus toxoid vaccine caused Guillain-Barre Syndrome, and relied on a theory of challenge/rechallenge based on a single case report. The Special Master denied compensation and the CAFC affirmed that decision. (DOJ PP at 11). In *Carson v. HHS*, the special master dismissed petitioner's claim as untimely. On appeal, the CAFC affirmed dismissal finding the claim untimely and equitable tolling inapplicable. (DOJ PP at 11). *Tembenis v. HHS*, involved a question of future lost earnings available to an estate following the death of a child. The special master held that the child's estate was entitled to lost future damages based on the expected lifetime earnings of the child. The U.S. Court of Federal Claims (CFC) affirmed the special master's decision. On appeal by respondent, the CAFC reversed, finding that the estate could not recover future lost earnings, and that the estate was entitled to damages calculated up to the date of death. (DOJ PP at 11). There is one pending case filed by petitioner and three pending cases filed by respondent. (DOJ PP at 12).

Turning to the CFC, there was one case was recently decided. (DOJ PP at 13). There were four new cases filed by petitioner and none by respondent. (DOJ PP at 14). Of those, Mr. Matanoski discussed *Scanlon v. HHS.* In *Scanlon*, petitioner alleged an injury caused by the shingles vaccine (which is administered to adults) based on the vaccine's similarity to varicella vaccine. In dismissing the petition, the special master found that the shingles vaccine is not listed on the Vaccine Injury Table, and no excise tax is levied on the vaccine, which is a prerequisite to being covered under the Act. Mr. Matanoski noted three upcoming scheduled oral arguments: one at the CAFC and two at the CFC. (DOJ PP at 15). Turning to the slides entitled Adjudicated Settlements (DOJ PP at 16-24); Mr. Matanoski noted that 70 cases were settled during the current reporting period. Of those, it appeared that 60 were for adults and 10 for minors. More than half of the settlements (42 cases) involved the flu vaccine. During this reporting period, the

average time to resolve all of the cases, from filing a petition to judgment, was one year and nine months. Of the 70 cases settled, 27% settled within the first year; 44% within two years; and 20% in the third year. A total of 91% of cases were resolved within three years, an improvement over the last reporting period. Mr. Matanoski added that, for comparison, although not necessarily indicative of a trend, 84% of cases in the last reporting period were resolved in less than three years, and 40% of cases were resolved in the first year.

Finally, Mr. Matanoski commented that the budget issues have had an impact on case processing, although it is not clear whether the federal government shutdown adversely impacted case processing. He added that DOJ would work to resolve Medicaid liens in a timely manner to ensure that those who are entitled to compensation receive it without significant delays.

Review of Vaccine Information Statements, Skip Wolfe, CDC

Td (Tetanus, Diphtheria) Vaccine

Mr. Wolfe began with the Td (tetanus/diphtheria) Vaccine Information Statement (VIS), Section 1, noting that FDA had requested that information about how tetanus is acquired be placed early in the discussion. Therefore the paragraph that follows the diphtheria description (beginning "Both diseases are caused by bacteria) has been moved to the first introductory paragraph under Section 1.

In Section 2, about Td vaccine, there was a recommendation to delete the second paragraph (beginning "A similar vaccine") because Tdap is often given off label as a booster to the first tetanus vaccination, and because there is a separate VIS for Tdap. The ensuing sentence about receiving more information from your doctor would be revised to delete the words "about both vaccines."

In Section 3, there was a brief discussion about the warning to reschedule if the individual is "not feeling well." Mr. Wolfe explained that the wording previously had suggested that the individual make a judgment about the severity of the individual's health at the time of the appointment, but there was a decision to simplify the wording and rely on the caregiver's advice about rescheduling.

In Section 4, listing adverse events, Mr. Wolfe explained that, on the advice of the subject matter experts, the list was taken from the Tdap VIS because there is no separate list of adverse effects for the Td vaccine. And on the advice of FDA, under moderate problems, the last item (swelling of the entire arm) was removed because it is not a risk. However, the swelling and severe pain is a potential adverse event following Td and it is retained as the only severe problem. There was a brief discussion about whether the "bleeding" mentioned in the Severe Problems paragraph was actually bleeding or bruising, and Mr. Wolfe indicated he would ascertain the proper word to use. Finally, inadvertently, the standard warning in all VIS about syncope and deltoid was left out and will replace the second paragraph in Section 4.

Haemophilus influenza type b (Hib) Vaccine

Mr. Wolfe commented that FDA had indicated that the paragraph in Section 1 describing incidence and mortality should be revised, since it is not clear if the fatalities are among the children or could include adults. He suggested rewording the sentence to retain the total incidence of 20,000, but describe the fatalities in terms of a percentage range, perhaps 3% to 5%. Mr. King commented that, if the numbers are used, there should be citations that support the numbers. Mr. Wolfe stated that FDA also recommended changing the term "spinal cord coverings" to "spinal cord linings." There was a suggestion that the term "invasive Hib disease" may not be easily understood by the general public and that the term "severe Hib disease" or "life-threatening Hib disease" might be more appropriate.

There were no comments regarding changes in the content of Sections 2 and 3. There was an observation; however, that in the last paragraph there is no explanation of the increased benefit of the vaccination before, not after, spleen removal. Mr. Wolfe indicated he would work on the wording of that paragraph.

Finally, Mr. Wolfe referred to the combination vaccine MenHibrix (Hib and bivalent meningococcal vaccine), commenting that a VIS is not usually created for combination vaccines and perhaps a short discussion could be appended to the Hib VIS, since it can be used for Hib immunization. He invited comments from the Commission. It was noted that there is a sentence that indicates that Hib vaccine may be given as part of a combination vaccine (in Section 2). There was a brief discussion about whether or not the vaccine would be covered. Dr. Villareal felt the reference to combination vaccines in the VIS should be sufficient.

Mr. Wolfe expressed appreciation for the comments and recommendations of the commission.

Update on the National Institute of Allergy and Infectious Diseases (NIAID) Activities, Barbara Mulach, NIH

Ms. Mulach noted two recent publications that might be of interest to the Commissioners. The first was an announcement by University of Pittsburgh researchers of release of an extensive database of 56 infectious diseases going back 125 years. Development of the database was supported by the Bill and Melinda Gates Foundation and NIH, and it is a searchable database that will allow extensive data mining.

The second is a research program at NIH to investigate the potential of a vaccine for respiratory syncytial virus that affects infants, very young children, older adults and immune compromised individuals.

The third involves development of research relying on a baboon model to look at the mechanism of action of both whole cell and acellular pertussis vaccines. Recent FDA-NIH collaborative research has shown that baboons vaccinated with acellular vaccine are able to resist infection, but may transmit the infection to other animals.

The fourth study focuses on the possibility that eye contact in infant's offers a clue to subsequent autism diagnosis. Using eye-tracking equipment, some evidence has been developed

that infants between two months and three years who have reduced eye contact, also have a high probability of an autism diagnosis.

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

LCDR Marshall reported that on November 19-20, the Center for Biologics Evaluation and Research (CBER) met with the Biotechnology Industry Organization (BIO) to discuss expedited review programs, pregnancy registries, pediatric review plans and revising the IND managed review process. On November 22, 2013, the FDA approved the first adjuvanted vaccine for the prevention of H5N1 influenza, commonly known as avian or "bird flu." The vaccine, Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, is approved for use in adults 18 years of age and older who are at increased risk of exposure to the H5N1 influenza virus. The H5N1 avian influenza vaccine is not intended for commercial availability but has been purchased by DHHS for inclusion in the National Stockpile for distribution by public health officials if needed.

Update on the Immunization Safety Office, Tom Shimabukuro, CDC

Dr. Shimabukuro reviewed presentations made at the October 2013 Advisory Committee on Immunization Practices (ACIP) meeting. Meningococcal vaccine, MenACWY-CRM (Menveo) can be used for protection against serogroups A, C, W, and Y in increased risk infants aged 2 through 23 months. Infants aged 2 through 8 months who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic are recommended to receive MenACWY-CRM prior to travel to provide protection against meningococcal serogroups A and W. MenACWY-CRM may be co-administered with PCV13, including in asplenic children.

During the session on pneumococcal conjugate vaccine (PCV), the ACIP discussed a possible reduced 3-dose PCV13 schedule. The 3-dose schedule has been approved by the European Medical Agency, but not the FDA. There is evidence supporting a 3-dose PCV series as effective against invasive pneumococcal disease, pneumonia and otitis media and strong direct and indirect (herd) effects observed in countries using 3-dose PCV schedules. However, programs may not always deliver high coverage rates. Dr. Shimabukuro commented that this presentation was for information only, and no recommendations or votes on any change were proposed.

During the human papillomavirus vaccine session, the manufacturer of a 9-valent vaccine gave a presentation. The 9-valent vaccine includes 5 additional cancer-causing HPV types (compared to the current quadrivalent vaccine) and has the potential to prevent ~90% of cervical cancers and ~80% of high grade disease (CIN 2 or worse). Six Phase III trials have been completed that included more than 13,000 subjects. A preliminary report was made at a recent EUROGIN conference, and further details of the studies will be available soon.

In the Influenza session, the manufacturer of high-dose inactivated influenza vaccine discussed a randomized control trial involving 32,000 subjects over 65 years of age, who received either standard Fluzone or Fluzone High-Dose (which contains three times the amount

of antigen than the standard version). Both are approved for administration to adults 65 and over with no vaccine type preference indicated in the recommendations. The result of the trial indicated that Fluzone High-Dose was 24% more effective in preventing influenza of any strain in adults aged ≥65 relative to Fluzone.

Dr. Shimabukuro reported that the Frequently Asked Questions (FAQ's) on the CDC website had been updated concerning HPV vaccines to address the question of whether or not those vaccines are associated with ovarian failure -- there is no evidence to indicate this. There is also a CDC Expert Commentary available that discusses rotavirus and intussusception, a subject that was covered at the last ACCV meeting. The conclusion is that there is a small increased risk of intussusception after receiving rotavirus vaccine, but the benefits of the immunization continue to outweigh those risks.

Dr. Shimabukuro commented on four recent publications:

- Glanz et al., reported in the *Journal of the American Medical Association Pediatrics* that under vaccination with DTaP vaccine increases the risk of pertussis in children 3 to 36 months of age.

- Rohani-Rahbar et al., also in *JAMA Pediatrics*, reported that measles-containing vaccines are associated with a lower increased risk of seizures when administered at 12 to 15 months of age (compared to children aged >15 months).

- McCarthy et al., in *Vaccine*, looking at claims data, found no increased outcome risk (included GBS and seizures) following administration of 998,881 trivalent inactivated vaccine (TIV) and 538,257 H1N1 vaccine doses in the 2009-2010 season, and 1,158,932 TIV doses in the 2010-2011 season.

- Moro et al. reported in the *American Journal of Obstetrics and Gynecology* that rates of spontaneous abortion, preterm birth, and major birth defects in pregnant women who received live H1N1 vaccine were similar to or lower than published background rates. No concerning patterns of medical conditions in infants were identified.

Finally, Dr. Shimabukuro commented on two vaccines not on the Vaccine Injury Table. He announced that his office is working on presentations that review the safety of zoster vaccine (for adults) and 23-valent polysaccharide vaccine (for adults mainly and for some high risk children), which will be presented to the Commission at a future meeting.

Update from the National Vaccine Program Office, Dr. Steve Bende, NVPO

Dr. Bende summarized the agenda for the September NVAC meeting, noting that there was a discussion of the Healthy People 2020 immunization goals, and update on the Affordable Care Act as it relates to immunization, an update on adult immunization standards of practice (approved at the meeting), a panel on adult immunization registries, and a briefing by the CDC on the communications plan for the upcoming flu season. On the second there were several updates by the Vaccine Hesitancy Workgroup (confidence impacts parents' acceptance of

immunization), the Maternal Immunization Workgroup, and the HPV Workgroup. The Pan American Health Organization presented a discussion on challenges to sustaining immunization programs, and the NVAC Global Immunization Workgroup made a final report and recommendations, which were unanimously approved. Finally, there was a discussion about vaccine storage and handling.

Dr. Bende commented on one area of importance in adult immunizations, which are the plans to update standards and practices such that healthcare providers, and specifically providers of immunization services, increase vaccine access and coverage. There is an adult immunization task force focused on enhancing the HHS response to that objective, and Dr. Bende discussed the activities in NVPO that are under way to support the objectives of the adult immunization strategy and plan, which are a significant part of the NVPO effort.

Dr. Bende stated that the annual report on the National Vaccine Plan will be presented at the February NVAC meeting. He also noted that a contract negotiated by AHRQ with Rand Corporation to conduct a literature search of reports of safety for all vaccines not assessed by the IOM report, should be received before the end of the year. It will be an important resource to support the NVPO's charge to develop a cohesive pan-federal vaccine research agenda. Finally, Dr. Bende commented that the NVPO was working on the development of a plan for sustained maternal safety monitoring, which will be submitted to the Assistant Secretary for Health.

Public Comment

Mr. King invited comment from members of the public.

Ms. Theresa Wrangham, representing the National Vaccine Information Center

Mr. Wrangham commented on the lack of public awareness of the VICP as evidenced by the number of claims that fail because of the statute of limitations. She commended the Commission for its interest in extending the statute, but commented that greater outreach is needed to make the public more aware of the program. She noted that media announcements and press releases by other federal groups, such as ACIP, could serve as an example. Ms. Wrangham commented that face-to-face meetings, such as those held by other vaccine advisory groups, should be encouraged, since they would provide a better vehicle for outreach.

Concerning the use of Trust Fund monies, Ms. Wrangham was not in favor of the proposal by some on the Commission that the Trust Fund financially support immunization research. She requested that the Commission recommend funding sources other than the Trust Fund, which should be reserved for compensation of vaccine-injured individuals.

Ms. Wrangham commended the Commission staff for posting the Commission meeting materials on the ACCV web site in a timely manner, unlike most of the other federal vaccine advisory committees. She also recommended that correspondence from the Secretary in response to ACCV recommendations be posted, and that a spreadsheet be developed to provide a chronological presentation of ACCV recommendations and responses to those recommendations.

Mr. Louis Conte, A Parent

Mr. Conte commented that the director of the advocacy organization, Every Child by Two, published a letter that stated that "remedies to the current program can be remedied through the Advisory Commission on Childhood Vaccines." The letter stated that the outcome of the Omnibus Autism Proceeding determined that vaccines do not cause autism. However, in a paper published in 2011, "Unanswered Cases," Mr. Conte (one of the authors) stated that 83 cases of vaccine-induced brain damage were identified that could be related to autism. Mr. Conte described the specific case of Bailey Banks, who was awarded compensation through the VICP based on the Special Master's ruling that the vaccine caused acute disseminated encephalomyelitis, a neurological condition that Mr. Conte stated was associated with autism spectrum disorder. Mr. Conte recommended that the Commission recommend to the Secretary of HHS that the Vaccine Injury Table should include acute disseminated encephalomyelitis as a precursor to autism spectrum disorder and that appropriate warnings should be added to the Vaccine Injury Statements.

Future Agenda Items/New Business

There being no further comments from the public, Mr. King invited discussion on new business and proposed future agenda items.

Mr. King suggested that the Commission begin to consider the retirement of Commissioners who have reached the end of their terms, the introduction of new members, elections leading to the next chair and co-chair – all of which should be included for consideration on the March meeting agenda. Other possible agenda items could include appropriations, the Medicaid issue, continued discussion of the virtual meeting, and research funding and the Trust Find. Mr. Kraus suggested forming an ad hoc transition workgroup to develop the agenda. Ms. Williams and Dr. Pron agreed to co-chair the ad hoc workgroup and coordinate its scheduling.

Mr. King invited a motion to adjourn and, on motion duly made and seconded, there was unanimous approval to adjourn the meeting.