Advisory Commission on Childhood Vaccines

(ACCV)

March 7, 2013

87th Meeting

Teleconference Minutes

ACCV Members Present

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

Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Department of Health & Human Services

Vito Caserta, MD., Director
Andrea Herzog, Staff Liaison

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

Mr. King called the meeting to order and, after introductions, invited public comment concerning any agenda item. Theresa Wrangham, representing the National Vaccine Information Center, commented that when the Vaccine Injury Statements are addressed the Commission should also discuss the recent Institute of Medicine report on adverse events, and the report's mention of the lack of science related to adverse events. She also commented that the Commission should discuss whether or not the recent recommended changes to the Vaccine Injury Table will be included in the information on the VIS. James Moody, representing the National Autism Association, commented that there is no data available to develop a baseline for unvaccinated children. Concerning the data that currently exists in the Vaccine Safety Datalink, he expressed interest in that data, specifically how many unvaccinated children are in the VSD, whether or not exemption status for children can be verified through VSD, and whether or not CDC will support dissemination of VSD data to the public for comparative studies of vaccinated and unvaccinated children.

There being no further comments from the public, Mr. King invited approval of the December 16, 2012 ACCV meeting minutes. It was noted that there was a public comment that was not reflected in the minutes, which was answered by Mr. Matanoski during the subsequent Department of Justice presentation. Ms. Herzog agreed to review the recording of the meeting and revise the minutes as appropriate. On motion duly made and seconded, the minutes were unanimously approved in anticipation of that revision being added to the minutes.

Mr. King invited Dr. Caserta to provide a report on the Division of Vaccine Injury Compensation.

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

Dr. Caserta briefly reviewed the agenda for the meeting, noting especially that certain Vaccine Information Statements would be reviewed by the Commission. Reviewing the recent history of petitions filed, Dr. Caserta stated that there were no petitions filed under the Omnibus Autism Proceeding in 2013; there were only five during the preceding two years. Non-autism petitions have increased significantly since 2006, when there were 168; those filings have averaged around 400 since 2010. Similarly, non-autism adjudications have steadily increased during the past several years. With regard to adjudication categories, in the recent past, concessions by Department of Health and Human Services have been 5% or less, U.S. Court of Federal Claims decisions between 14% and 20% -- settlements predominate at an average level of 80% of cases. Petitioner awards have been generally increasing in the last five years and, awards are on track to be about $338 million for this fiscal year. Increased adjudications for flu injury, mainly filed by adults, accounts in part for the increase. Attorney's fees should end up at about $21 million, which is also consistent with the upward trend in that category. At the end of December 2012 the Trust Fund stood at nearly $3.5 billion – net income was $56.5 million, made up of $42 million from excise taxes (73%) and $15.6 million from accrued interest (27%).

Dr. Caserta notified the Commission that, in the future, adjudications would be reported as a single number, rather than the previously reported categories of autism and non-autism. Since there are no more autism petitions being filed, this simplifies the reporting procedure. The Commission agreed that this reporting procedure would be appropriate in the future. In addition, Dr. Caserta noted that DHHS has never compensated a claim based on autism alone, but has compensated claims filed on the basis of injury theories other than autism, e.g., encephalopathy. In those cases typically the child was vaccinated, developed symptoms of encephalopathy, and later in time might exhibit symptoms that are medically diagnosed as autism, reflecting the brain damage that might have been caused by the original encephalopathy.

It was noted that in the PowerPoint on Adjudications, as of March 1, 2013, there was an indication that an autism case was filed in 2012. Dr. Caserta subsequently explained that the 2012 case was encephalopathy but not part of the OAP; of the four cases reported in 2011, three were in fact OAP cases but the other was not.

Finally, Dr. Caserta provided information about contacting the DVIC – on the Internet www.hrsa.gov/vaccinecompensation and by telephone 800-338-2382 (Andrea Herzog).

During discussion, Mr. Kraus noted the increase in the rate of case adjudication through settlements, which he suggested were good for petitioners – there is a more rapid resolution, more certainty with regard to the outcome – but the information available to the public after a settlement is significantly limited. The only information on the record is the statement of injury, the denial by DHHS that the injury was caused by a vaccine, a general description of the terms of settlement, i.e., the gross amount of the agreed on award but no rationale, no information on claim evidence submitted by the petitioner and no record of testimony. Therefore, Mr. Kraus suggested that the settlement lacks transparency. There is insufficient information available to develop an understanding of the rationale that resulted in the decision to settle. Mr. Kraus recommended establishing a working group to deal with how data and statistics are put together for the benefit of the public. He felt that the working group should have representation from the Commission, Health Resources and Services Administration, Department of Justice, and interested members of the public.

Ms. Herzog reminded the Commission that the establishment of committees, subcommittees and working groups is addressed in the ACCV charter, adding that there is no specific prohibition against including non-Commission members. There was agreement by the Commission that staff should look into establishing the work group as recommended by Mr. Kraus. There was a brief discussion about whether the purpose of the working group is to data mine past cases, in which case there would be no need to include non-Commission members in the membership, or whether the purpose is more development of a methodological proposal or recommendation, in which case some input from other stakeholders would be appropriate.

There was further discussion that resulted in agreement on the objective of the working group, to recommend a process by which information that resides in the records of the various settled cases can be made available to the public and that the settlement process be as transparent as possible. Mr. King suggested an e-mail to Commission members to elicit indications of interest in participating on the working group, and to for any Commission member to offer suggestions that might refine the general objective as described above.

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

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

Mr. Matanoski began with DOJ's statistical report for the time period of November 16, 2012 – February 15, 2013 (DOJ PP at 2-4). During this reporting period, 95 new petitions were filed. No petitions for autism were filed. Mr. Matanoski reminded the Commission that DOJ's reporting period does not coincide with DVIC's reporting period. Of the 95 new petitions, 76 were adult claims and 19 were minor claims. By comparison, during the previous reporting period (August 16, 2012 – November 15, 2012), 149 petitions were filed, including 124 adult claims and 25 minor claims. Mr. Matanoski projected approximately 400 new petitions for fiscal year 2013. Mr. Matanoski reported that 287 petitions were adjudicated with 93 compensated and 194 not compensated/dismissed. By comparison, during the previous reporting period, 361 were adjudicated with 88 compensated and 273 not compensated/dismissed. Mr. Matanoski attributed this trend to a decline in the OAP cases. Of the 93 claims compensated, six were conceded by HHS (five were by decision adopting a proffer and one by decision adopting a settlement). Of the 87 cases compensated but not conceded by HHS, 10 were by decision adopting a proffer and 77 were by decision adopting a stipulation. Ms. Pron asked about the percentage of settlements involving adults versus minors and whether DOJ could break down compensated versus non- compensated cases by adults and minors. Mr. Matanoski opined that most of the settlements involved adults. He said he would look into further breakdowns of settlements but cautioned that it may be time-intensive to review each case. Of the 194 petitions dismissed this quarter, 29 were non-autism and 165 were autism cases (DOJ PP at 3).

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). He reiterated that none of these illustrations has changed since they were presented at the last meeting, and explained the level of appeals beginning with a decision by the special master, appeal to the U.S. Court of Federal Claims (CFC), and a second appeal to the U.S. Court of Appeals for the Federal Circuit (CAFC). Finally, a party could petition the U.S. Supreme Court to hear the case as a final appeal (DOJ PP at 9-10). Of interest to the ACCV, Mr. Matanoski noted that the case *Sebelius (HHS) v. Cloer* will be argued at the Supreme Court on March 19, 2013 (DOJ PP at 11). As discussed at the last ACCV meeting, the case involves an *en banc* decision of the CAFC regarding attorney's fees and costs in time-barred cases.

Turning to appellate activity in the CAFC and CFC, Mr. Matanoski highlighted two cases that were decided by the CAFC since the last meeting. *Hibbard v. HHS* involved petitioner's *en banc* request for review by all of the CAFC judges following a CAFC decision by a three judge panel affirming the petition's dismissal. The CAFC rejected petitioner's *en banc* request. In *W.C. v. HHS*, petitioner challenged the special master's fact-finding and denial of compensation, which was affirmed by the CFC. The CAFC affirmed the decision below. *Tembenis v. HHS* is a new appeal to the CAFC filed by respondent. In that case, the CFC affirmed an award by the special master of future lost wages in addition to the statutory $250,000.00 death benefit to the estate of a minor

child.

Turning to appeals at the CFC, Mr. Matanoski reported that six cases were decided by the CFC since the last meeting – all six involved fact finding determinations by a special master (DOJ PP at 14). Of those, Mr. Matanoski discussed two cases of interest to the ACCV. *Wax v. HHS* was originally filed in federal district court alleging illness related to the vaccine preservative thimerosal. That court dismissed the action and petitioner then filed in the Program. The special master concluded the claim was filed after the statute of limitations had expired. Petitioner appealed to the CFC asserting equitable tolling based on ambiguity and misunderstanding of the law. The CFC found that mistake of law was insufficient to trigger equitable tolling and denied petitioner's appeal. *Silva v. HHS* involved a decision on attorneys' fees and costs. In *Silva*, petitioner's attorneys sought fees after the special master denied entitlement to compensation. Prior to an entitlement decision, petitioner's attorneys tried to withdraw from the case. The special master found that the petition was filed without a reasonable basis where counsel failed to review the medical records, which did not support filing a vaccine petition. In denying attorneys' fees, the Special Master noted that there was no statute of limitations deadline or other reason that would have precluded counsel's review of the medical records and operative facts prior to filing the petition. The CFC affirmed the special master's decision as within his discretion and supported by the record.

There were five new appeals to the CFC, all filed by petitioners (DOJ PP at 15). Of those, two involved procedural anomalies. In *Eisler v. HHS*, petitioner appealed the special master's decision denying a request to redact petitioner's name from the decision. In *Palluck v. HHS*, petitioners sought review by the CFC claiming that the special master's time-frame to issue a decision on remand has expired. In *Bast v. HHS*, petitioners appealed the special master's decision denying entitlement in a mitochondrial-oxidative stress claim. The special master found that the child suffered from a genetic mutation, which was the sole cause of injury. *Caves v. HHS* involved an attorneys' fees request of $185,000.00, which the special master reduced to approximately $110,000.00 based on duplicative and excessive billing by petitioner's attorneys.

Turning to the slide entitled Scheduled Oral Arguments (DOJ PP at 16); Mr. Matanoski briefly reviewed the calendars for the Supreme Court, the CAFC and the CFC. He noted that *Shapiro v. HHS* was being rescheduled because there were three cases scheduled at the CAFC for April 5, 2013. Turning to the slides entitled Adjudicated Settlements (DOJ PP at 17-25); Mr. Matanoski noted that 78 cases were settled during the current reporting period. Although there was one very involved hepatitis B case that took over seven years, most cases (84%) were resolved in three years or fewer. Using the data for this reporting period, Mr. Matanoski made the following observations: 16 cases were resolved in one year or less; an additional 35 before the end of the second year; 14 in the two-to-three- year period, and 11 between the third and fourth year. Only two took more than four years, including the hepatitis B case mentioned previously.

Mr. Matanoski concluded his remarks by addressing the issue of the obtaining data from the settlements for the purpose of gleaning information about vaccine safety discussed by the Commission during DVIC's presentation. Mr. Matanoski did not believe that information other than that which is currently reported could be provided. Mr. Matanoski cited confidentiality concerns and noted that under the Act, information provided in a case is confidential absent consent from both parties to the proceeding for its release. Mr. Matanoski emphasized that of the 78 settlements identified in the slides, he had no information as to what prompted the parties to settle. He reiterated points made from prior meetings on the subject of settlements, explaining that there are a number of possible reasons why cases settle. Examples included that petitioner has no expert, has unpersuasive evidence, or desires to get money now rather than wait for possibly more money in the future after a trial on their claim has concluded. There are a variety of factors that induce settlement and oftentimes these factors are completely unrelated to vaccine safety and science. Settlements are made based on the best interests of a petitioner with the advice of counsel. Respondent may also be influenced by issues that are not related to the science of the case. He urged caution in trying to extrapolate conclusions about vaccine safety from settlements. He urged similar caution be applied when considering court decisions. Cases are presented and litigated by advocates, and evaluated using legal precepts rather than scientific

ones. Mr. Matanoski considered it a mistake to use judicial proceedings as a surrogate for science. Mr. Matanoski noted that data and information generated during a trial that is concluded by a decision of the court would provide more reliable scientific information because of the expert testimony, but even that information is subject to the confidentiality rights of the parties. He observed that the Vaccine Act addressed methods to assess vaccine safety, establishing a mechanism where medical and scientific bodies conduct research on vaccine safety issues. This has been done in the past with the Institute of Medicine (IOM). Mr. Kraus commented that that confidentiality could be a non-starter in trying to obtain more information from settlements. He noted that facts in the stipulation are taken from the petition, and also that DOJ usually engages in settlements. Mr. Matanoski observed that the Office of Special Masters publishes all decisions adopting stipulations of settlement.

Responding to the point about facts from the petitions, Mr. Matanoski observed that the facts from the petition may not necessarily match information in the records, and oftentimes petitions do not even allege a particular injury, or the injury is determined to be different as described in the medical records. Stipulations adopting settlements could be fraught with misinformation and are not appropriate to extrapolate vaccine- safety issues. Ms. Pron observed that just because a case is settled, one cannot draw a conclusion about causation. Mr. Matanoski maintained that a more reliable and valuable source of information about vaccine safety and vaccine injury comes from scientific studies mounted by independent entities, such as the IOM. Dr. Caserta agreed with Mr. Matanoski and added that DVIC often initiates research prompted by publicly available information that may emerge from the vaccine program cases. For example, DVIC undertook a study of shoulder injuries related to vaccine administration (SIRVA) based on claims filed by petitioners. The IOM used DVIC's paper on SIRVA in its recent 2011 review.

Mr. King invited comment with regard to DOJ's presentation. There being none, he invited Dr. Feemster to report on the Maternal Immunization Workgroup activities.

Report from the ACCV Maternal Immunization Workgroup
Kristen Feemster, Chair

Dr. Feemster reported that the workgroup requires additional time to finalize a report for the Commission. Since the last meeting the workgroup has met twice via teleconference, the first of which addressed maternal Group B Streptococcus vaccine that, once approved, would be recommended for pregnant women. During the second teleconference the workgroup began to develop draft recommendations, finalizing a draft in response to the workgroup's first charge regarding vaccines not currently covered by the Program. Specifically this relates to vaccines that pregnant women may receive that are not recommended for routine administration in children and would therefore not be covered by the Program. At the next meeting the workgroup will deal with the remaining charges in anticipation of developing a report to be presented at the next meeting in June.

Report from the ACCV Process Workgroup
Luisita dela Rosa, Chair

Ms. dela Rosa reported that the workgroup had met twice since the last Commission meeting, and at the last meeting the Commission approved making a recommendation to the Secretary to add to the Commission membership a vaccine-injured adult or an individual qualified to represent a vaccine-injured adult. The workgroup agreed that the letter should be prepared by the full Commission. It was noted that in the past staff had drafted those letters, and the letter concerning the additional member was prepared by staff and sent to the Secretary. The workgroup also addressed the issue of statute of limitations, which is now 36 months after initial diagnosis of a qualified injury, or 24 months after a death resulting from a vaccine-related event. This excludes some claims because of circumstances beyond the control of the injured person, such as a diagnosis that is unavoidably delayed. The workgroup agreed to recommend to the Commission reconsideration of the May 2009 ACCV recommendation of changes to the statute of limitation. The workgroup agreed that the eight-year statute of limitation in that

recommendation is appropriate, but further agreed that any change should allow a statute of limitation of not less than six years.

This change would be consistent with the intention of the original National Childhood Vaccine Injury Act of 1986 to protect vaccine manufacturers and health care providers. The workgroup understands that the change involves legislation and that the recommendation to the Secretary is an intermediary step to such legislative change. The effect of the change would make the Vaccine Program the exclusive remedy for any vaccine injury diagnosed up to eight years after the original vaccination, and petitioners would not be able to opt out of the Vaccine Program process to pursue a claim in any other court during that period of time.

There was a motion and second that the Commission consider and approve the recommendation.

During discussion of the motion, Ms. Pron suggested that the eight-year recommendation versus the Commission's accession to a six-year statute of limitation should be clarified in any letter to the Secretary. Asked whether there was any response or action that followed the 2009 recommendation to the Secretary, staff confirmed that, other than an acknowledgment of receipt of the recommendation by the Secretary, there was no action. Ms. Overby offered her recollection that, although there was some legislation activity in that timeframe concerning the statute of limitations, the Department was not involved in the process. The recommendations for action apparently came from entities outside the DHHS. It was noted that the legislation was not passed. Ms. Overby indicated that the legislation, in fact, was not reported out of committee, nor was the Secretary asked to testify or make any other statement concerning the legislation.

Ms. dela Rosa commented that the 6-year limit was based on 42 USC Sec 300aa-16 for claims filed with the CAFC. Mr. Smith commented that the 6-year proposal failed in 2009, which would suggest that an 8-year proposal would need a strong rationale to be considered. Although it was observed that there is an 8-year exception to the statute of limitation when a vaccine injury is added to the Injury Table, the rationale for that seems to be that the proposal to add to the Table begins when there is a tacit recognition that the injury is probably caused by the vaccine, and the 8-year look-back provides fair treatment for petitions that would have been timely filed were the process more rapid, but were not because of the natural delays that occur in the process to finally approve an Injury Table addition.

Asked about any negative effect of extending the statute of limitations, Dr. Caserta noted that the Trust Fund would become vulnerable to additional claims not anticipated in the original legislation. Mr. Smith commented that, regardless of the issues related to the 6- or 8-year revision, the workgroup reached consensus that an extension of any length would be beneficial to the Vaccine Program. After discussion, the Commission agreed that the recommendation should propose an undefined extension of the statute of limitations. A brief discussion would be added to indicate the Commission's preference for an extension of 6 to 8 years.

Concerning the rationale, there was a suggestion that the petitioners' bar be polled to determine whether or not an approximate number of potential claims are not pursued because of the statute of limitations. There was a brief discussion about the mechanics of conducting such a survey and there was agreement that the survey should be an official ACCV survey and that an official of the petitioners' bar should be contacted to make arrangements for the survey. Ms. Overby reminded the Commission that the survey would probably be subject to OMB regulations and clearance if the survey was directed at more than nine respondents. Dr. Caserta suggested that ACCV not specify the detailed questions for the survey, but communicate the general inquiry to the petitioners' bar, which might then be able to respond without the need of a formal survey. Ms. Overby recommended the proposal be reviewed by the HRSA Office of Planning and Evaluation for a determination of next steps, which might include consultation with OMB. Mr. King commented that there should be no delays that would postpone final consideration by the Commission until the next meeting.

Mr. Kraus spoke in opposition to the open-ended extension of the statute of limitations, preferring to either specify the 6 to 8 year period or to table the motion until more information can be gathered by

the workgroup and more discussion can be undertaken by the Commission, probably at the next regular meeting. After further discussion, there was ultimate agreement to abide by the original motion that would include the recommendation of the workgroup to extend the statute of limitations to 6 to 8 years. There was also agreement that the letter of recommendation to the Secretary should include a rationale for the time period, which would additionally mention the fact that at least two previous panels had recommended a similar course of action. The motion was unanimously carried by voice vote of 8 for, none opposed.

Ms. Herzog agreed to prepare a draft letter of recommendation to the Secretary, which could be reviewed by the Commission as soon as available.

Review of Vaccine Information Statement (VIS)
Mr. Skip Wolfe, Centers for Disease Control

Mr. Wolfe announced that the Commission would review three VIS's – 1) Influenza Vaccine, Live Intranasal; 2) Influenza Vaccine, Inactivated; and 3) Pneumococcal Conjugate Vaccine. He added that there has been an effort to simplify the format of all VIS's. Information that does not apply specifically to the actual vaccination process has been eliminated or minimized; language has been simplified; and a standard seven-section format has been adopted.

1) Review of VIS for Influenza Vaccine, Live Intranasal (LAIV)

Because many flu shots are administered in commercial, not medical sites (Wal-Mart, CVS, Walgreen's, etc.), the introductory sentence that precedes Section 1 reads, "Your doctor recommends that you get a dose of PCV13 vaccine today," could be inaccurate. The Commission recommended a more generic phrasing, such as, "You are considering getting a flu shot today." Mr. Wolfe agreed that the sentence could be revised, but added that the same wording (Your doctor) appears on all VIS's, and in those cases it is probably a valid statement. However, there were several comments that the sentence may not be required at all and should be eliminated, since the first section is a rationale for receiving the vaccine.

Section 1- Why Get Vaccinated.

Mr. Wolfe noted that *Section 1 – Why Get Vaccinated* is identical to the first section in the *Influenza Vaccine, Inactivated,* so that any changes made will be made identically to both.

There was a suggestion that a paragraph in Section 2 should be relocated to Section 1. The paragraph: "Flu vaccination is especially important for people more likely to get a severe case of flu, such as younger children, older people, and people with certain health problems. It is also important for anyone in close contact with these people." Mr. Wolfe agreed to look at a way to incorporate the sense of the sentence, whether taken in whole or in part.

There was a comment that, since there is no solid evidence that the flu vaccine is the "best way to protect against flu," the wording might be revised to be less exclusive – perhaps it is an "important way to protect against flu." Mr. Wolfe added that the word "yourself" could be removed to make the statement less specific to an individual; who might get the flu in spite of the vaccination. There was also a suggestion that the word "flu" could be expanded to be "flu and its complications."

Section 2 – Live, Attenuated Influenza Vaccine – LAIV, Nasal Spray

Mr. Kraus commented that, since not everyone should get a flu shot every year, the phrase "You should get a dose of flu vaccine every year," is not accurate. Mr. Wolfe commented that the "you" was specifically included to make the recommendation more personal. Dr. Caserta commented that the sentence suggesting that the vaccine lasts a year may be contrary to recent published research that

indicated that some immunizations may not last a full year. Mr. Wolfe suggested revising the sentence to read "up to a year."

Section 3 – Precautions

Ms. Pron suggested that the word "precautions" might not be understood by all readers, and may not convey the serious nature of the discussion under the heading. Dr. Wolfe stated that the heading used in earlier VIS's might be appropriate – "Some people should not get the vaccine."

It was noted that an individual with severe allergies should check with his/her doctor, and not simply "not get it," since some allergies would not be triggered by the flu vaccine. It might also be helpful to advise an individual with severe allergies who may be obtaining the vaccine from a commercial site to check with the doctor in advance. Ms. Pron also suggested that the warning should be more prominently displayed, perhaps on the first page of the VIS.

There was an observation that individuals may be informed by a physician that they have Guillain-Barre syndrome (GBS) or Miller Fisher syndrome, which is a closely related disorder. It was recommended that both terms be used in the reference to GBS.

Under the bullet concerning a contraindication for LAIV in various categories of people, it was noted that the term LAIV might not be understood, so that a revision to the fourth bullet would be appropriate. For example, LAIV is a nasal spray and the alternative in this precaution is a flu shot (injection). It was suggested that the term "nasal spray" be used instead of LAIV. There was also concern that recommending informing "your doctor" might be a logistical challenge to an individual getting a flu shot in a commercial site – it might be better to use a more general term that would include the individual administering the shot.

Section 4 – Risks

Under the paragraph dealing with mild problems, the indication that "some children and adolescents 2-17 years of age have reported" should either specify how the reports were made or the wording should be revised. Dr. Shimabukuro suggested that confirming the side effects with, for example, FDA might be helpful, since some of the side effects may have been taken from drug trial reports or package inserts. Mr. Wolfe confirmed that the Advisory Committee on Immunization Practices recommendations use the term "have reported." He added that he would check with the flu subject matter experts and with Immunization Safety Office.

Section 5 through 7

Mr. Wolfe noted that these three sections are identical on all VIS's, and the wording has been discussed extensively in the past. Nonetheless he invited comments. Mr. Kraus recommended expanding the wording in Section 6 by substituting the following for the first sentence: The federal government created the National Vaccine Injury Compensation Program (VICP) in 1986 in order to provide compensation to certain individuals who may have been injured by a vaccine, including the flu vaccine. Mr. Wolfe agreed that the wording was appropriate. Since Congress actually created the program, there was a suggestion that the first part of the sentence state that the VICP is a federal program, rather than a program created by the federal government

2) Review of VIS for Influenza Vaccine (Inactivated)

Section 1- Why Get Vaccinated

Mr. Wolfe noted that Section 1 was the same as the wording in the VIS for Live, Attenuated Influenza Vaccine – LAIV, Nasal Spray. He noted that the term "inactivated" should be considered synonymous with "killed" or "not live."

Section 2 – Inactivated Flu Vaccine

It was noted that flu vaccines do not necessarily, but usually change, every year. There was also a recommendation to replace "flu vaccine is changed each year" to "flu vaccine is made each year." Mr. Kraus suggested that a flu vaccination is not necessarily 100% effective. Mr. Wolfe noted that the paragraph stating that "it will not prevent all cases of flu" and the statement that there are flu-like illnesses that are not prevented by flu vaccines should explain that efficacy issue.

There was a comment that, for individuals over 65, offering an "optional" high dose vaccine might be confusing, and the wording might be revised to read, "you may want to consider 'high dose' vaccine, which you may discuss with your doctor."

Section 3 – Precautions

Mr. Wolfe stated that the changes made for the LAIV nasal spray would also apply to the inactivated vaccine. There was a comment that the term "killed virus" should be replaced with "does not contain live flu virus."

Section 4 – Risks

Dr. Caserta commented that the Institute of Medicine (IOM) report identified a number of risks that pertain to most vaccines, including syncope and SIRVA (shoulder injury related to vaccine administration) and bursitis, and it might be appropriate to include these conditions under risks. The conditions actually apply to all injectable vaccines. Mr. Wolfe stated that language dealing with these issues has been developed for other VIS's and that wording could be imported into the flu VIS. Dr. Shimabukuro recommended the term "shoulder injury" because it might be more easily understood. He agreed to help formulate a statement that would reflect the issues noted in the IOM report.

Dr. Caserta commented that the statement that there is no link of flu vaccine to GBS may be inaccurate, since there have been studies published that indicate the 2009 H1N1 vaccine might be linked to GBS. There was a brief discussion of the research results that have indicated that the risk is about one to two additional cases of GBS per million vaccinations. Mr. Wolfe stated that he would harmonize the VIS with the ACIP report. Dr. Caserta suggested clarifying the sentence in the same paragraph concerning lower risk of severe flu, which is actually unrelated to GBS.

Section 5 through 7

Mr. Wolfe indicated that, like the sections previously discussed under the LAIV nasal spray, the provisions of these three sections are identical and the one significant change to the LAIV VIS would be incorporated in this VIS.

3) Review of VIS for Pneumococcal Conjugate Vaccine

Prior to any discussion, Mr. Smith recused himself on the basis of his employment with the manufacturer of the vaccine, Pfizer Inc. He also noted that there are disease states in patient subgroups that are not consistent with the FDA-approved labeling. In the pediatric population PCV13 is indicated for the prevention of IPV caused by the 13 serotypes in the vaccine, and non- pneumococcal pneumonia; and then for pediatric and 50-plus populations of which the vaccine is indicated. Pfizer does not have safety or effectiveness data in immune-compromised persons.

Mr. Wolfe stated that an interim VIS was just published for PCV13, different from the draft being reviewed. However, this version must be reviewed and finalized. During this review there were changes recommended only for Sections 1 and 4.

Section 1- Why Get Vaccinated

Asked about the first sentence, Mr. Wolfe stated that in most cases a health care person would, in fact, recommend this vaccine. It would be unlikely that an individual in a commercial site would make a decision on his own to get the vaccine. He also stated that the brand name is used in the VIS because there are no other brands.

There was a suggestion to clarify the phrase "before vaccine, pneumococcal infections caused many problems in children" – because there was an alternative polysaccharide vaccine available. The wording should indicate "before this pneumococcal vaccine was available." There was also a suggestion to increase the impact of the sentence concerning pediatric meningitis deaths by saying one out of ten children die.

Section 4 – Risks

Asked why there were no categories of risk (mild, moderate or severe), Mr. Wolfe stated that originally all of the risk were, in fact, mild. However, it was noted that the pneumococcal-flu vaccine given together with flu was addressed in the flu VIS as moderate risk, and the meningitis mentioned in Section 1 is a serious risk. Dr. Shimabukuro commented that, after 2010, febrile seizure risk was added to the package insert for Prevnar. He recommended consulting with the pneumococcal experts on the issue.

Update on the Immunization Safety Office Vaccine Activities
Tom Shimabukuro, CDC

Dr. Shimabukuro reported on the ACIP meeting held February 2013. During the meeting ACIP recommended that children 6-18 years of age with immunocompromising conditions, functional or anatomic asplenia (abnormal spleen function that increases risk of infection), cerebrospinal fluid leaks or cochlear implants, and who have not previously received a 13-valent pneumococcal conjugate vaccine (PCV13), receive a single dose of PCV13, whether or not they have received either PCV7 or PPSV23. The recommendation is provisional until published in the MMWR.

There was an extensive discussion of the newly approved influenza vaccines that should be available for the 2013-2014 flu season. The new vaccines include Flumist Quadrivalent from Medimmune for healthy non-pregnant persons 2 to 49 years of age; Fluarix Quadrivalent from GSK for persons 3 years of age and older; Flucelavax from Novartis, a cell culture-based trivalent inactivated vaccine for persons 18 and older; and FluBlok from Protein Sciences, an egg-free recombinant vaccine for persons 18 to 49.

Dr. Shimabukuro described several publications, one by Nordin et al, on trivalent inactivated flu vaccine for pregnant women, and another by Tseng et al, on the safety of a tetanus-diphtheria-acellular pertussis vaccine in the elderly. Both studies support the safety these vaccines in these age/risk groups. A third study by Jackson et al, confirmed lower risk of injection site reactions when DTaP is administered in the thigh in children 12 to 36 months of age. Finally, a paper by Zheteyeva et al reviewed VAERS reports of Menactra (a meningitis vaccine) in pregnant women, which showed no concerning patterns in maternal, infant or fetal outcomes.

Dr. Shimabukuro addressed a paper by Glanz et al, on a Vaccine Safety Datalink study looking at undervaccination in eight managed care organizations. The paper was included in the IOM review of the safety of the childhood immunization schedule. Dr. Shimabukuro noted that the paper concluded that under vaccination in children 2 to 24 months increased over time, which was to be expected. There were different health care utilization patterns between under vaccinated children and those who were age appropriately vaccinated. Under vaccinated children had less outpatient visits but increased inpatient admissions compared to age appropriately vaccinated children.

Dr. Shimabukuro noted that there is a data-sharing program for the VSD, administered by the National Center for Health Statistics' Research Data Center. Interested individuals can access the Center on www.cdc.gov/vaccinesafety/activities/VSD/datasharing.html.

Dr. Shimabukuro stated that CDC has reviewed the IOM report and considers the VSD to be a key national resource for monitoring vaccine safety. Dr. Shimabukuro indicated that the IOM stated in its report that it is not ethically feasible to do a randomized controlled study of vaccinated versus unvaccinated children. The IOM did recommend that CDC explore options that might result in an alternative study design that would meet ethical guidelines.

Update from the National Vaccine Program Office
Dr. Steven Bende

Dr. Steven Bende reported that NVPO through CDC had requested an IOM study of the vaccine schedule for children and the report had endorsed the current schedule. The report also noted there was little evidence concerning under-vaccinated children and there were valid reasons not to mount randomized controlled studies comparing vaccinated and un-vaccinated children. Mainly the IOM felt it would not be ethical to conduct studies in which children would be deprived of vaccine protection for research purposes. In addition, the IOM report urged that CDC set priorities for research based on solid epidemiological evidence. There was also a recommendation that NVPO develop more effective communications with providers to support a stronger public awareness program to encourage parents to vaccinate their children.

Dr. Bende reported that NVPO convened a meeting in Bethesda to look into the increasing rate of pertussis infection. There was some discussion about whether new vaccines should be developed, especially since there are emerging strains that may be more resistant to current vaccines. The discussions are preliminary at the moment. Dr. Bende said he would provide the agenda for the meeting for Commission review.

Update on the Center for Biologics Evaluation and Research
LCDR Valerie Marshall

LCDR Marshall reported that on December 14, the FDA approved the supplement for GSK's influenza vaccine to include a quadrivalent formulation for persons three years of age and older. On January 16th the FDA approved Flublok, a trivalent seasonal vaccine indicated for active immunization against disease caused by influenza virus subtypes A and B. This was approved for persons 18 to 49 years of age. It is the first vaccine manufactured using an insect virus expression system and recombinant DNA technology.

In February, the Vaccine and Related Biological Products Advisory Committee held an open meeting to make recommendations concerning the flu strains to be included in the 2013-2014 seasonal flu vaccine. The vaccine formulation will include two influenza virus A strains, H1N1 and H3N2, and one strain of influenza B, and a formulation for new quadrivalent vaccine that will include two strains of influenza A and two strains of influenza B.

Public Comment

Ms. Theresa Wrangham, representing the National Vaccine Information Center, which represents vaccine-injured individuals, and has been a strong advocate for a number of years, commented that the recent IOM report found little evidence of research to assess the efficacy of the current vaccine schedule, and little evidence to support the allegation that the most commonly reported vaccine injuries are in fact caused by vaccines. Much of the public is unaware of the ACCV and the VICP and there are questions about information available. Ms. Wrangham noted that the Commission members had earlier questioned whether members of the public can be voting members of ACCV working groups. The answer should be yes, since NVIC members have participated on NVAC working groups. The NVIC would be pleased to participate in the review of VIS's.

Ms. Wrangham added that parents would like more comprehensive information about the immunization schedule, which could be considered in the VIS review process. To be more transparent, agencies should articulate the limitations on data provided to the public. An ACCV workgroup should be

sensitive to the need for transparency with regard to release of new data. NVIC supports appropriate release of new data with regard to vaccine safety and efficacy, and participation by public and private stakeholders in the ACCV process. In terms of the recommendation to the Secretary concerning the statute of limitations, NVIC believes the Secretary should be informed of the apparent limited awareness by the public of the ACCV and the Vaccine Program.

James Moody, representing the National Autism Association, encouraged full transparency in terms of data residing in the records of adjudications, whether by settlement or court decision. The data available should include the determination of the claim, and the award broken down by category. Mr. Moody also stated that Dr. Caserta's concession that an early vaccine injury, such as encephalopathy, can lead to a later diagnosis of autism, which attests to a clear link that should be considered in future claims. He felt that to maintain the position that there is no relationship between vaccines and autism is less than forthright. The Commission should strongly support research to answer this question.

Wayne Rhode, parent of a vaccine-injured child who was later diagnosed with severe regressive autism, and a member of several national advocacy organizations, encouraged the Commission to allow members of the public who cannot attend the meeting to submit comments for the record. In addition, Mr. Rhode stated that he was disappointed in the lack of activity related to promoting public outreach since the Commission's first effort in 2009-2010. He expressed concern about reports that physicians have not supported parents of children who may have been injured by a vaccine by denying the likelihood that an injury was vaccine-related, and/or by failing to assist parents in their efforts to submit Vaccine Adverse Event Reporting System reports. Also, with the growth of large storefront vaccine services, he recommended a more aggressive effort to make those who obtain vaccines from those new sources aware of the Vaccine Program.

Old Business/New Business:

Ms. Herzog commented that there were two public comments regarding the agenda at the last meeting that were not included in the minutes of the meeting. Comments by Mr. Louis Conti and Ms. Theresa Wrangham made at that meeting will be incorporated in the minutes of the December 16th meeting. Mr. King agreed that the corrected minutes should be sent to all members and, if there are no exceptions, the minutes will be assumed to be approved.

Dr. Caserta announced that the next meeting will probably be by teleconference. Ms. Herzog stated that she was working on teleconference systems that would allow better access to meeting materials in real time.

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

_____ _____

Dave King, ACCV Chair Date

_____ _____

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