Advisory Commission on Childhood Vaccines

March 5, 2015

95th Meeting

Members Present

Kirsten Feemster, M.D. ('15)
Charlene Douglas, Ph.D. ('15)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('15)
David King, ('15)
Luisita dela Rosa, Ph.D. ('15)
Jason Smith, J.D. ('15)
Sylvia Fernandez Villarreal, M.D. ('15)
Michelle Williams, J.D. ('15)

Division of Vaccine Injury Compensation

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

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

Dr. Feemster called the 95th meeting of the Advisory Commission on Childhood Vaccines to order and, after roll call and after introductions requested approval of the December 2014 meeting minutes. On motion duly made and seconded the minutes were unanimously approved.

Dr. Feemster invited the report from the DICP.

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

Dr. Houston welcomed those present on the teleconference and briefly reviewed the meeting agenda. The agenda includes an update from the Department of Justice (DOJ), reports from the chairs of the Process and Adult Immunization Workgroups, a review of Vaccine Information Statements, and finally updates from the ex officio members from the Food and Drug Administration (FDA), Centers for Disease Control (CDC), National Institutes of Health (NIH) and the National Vaccine Program Office (NVPO).

Looking at petitions and adjudications, Dr. Houston noted that the number of petitions filed thus far in FY 2015 is on track with the cases filed in 2014 for the same period, and the

projection of total cases that will be filed for the full fiscal year is 696. The 160 cases adjudicated as of February 2, 2015. In FY 2014 480 cases were adjudicated, of which 357 were compensated and 123 were dismissed. Breaking that number down, it is anticipated that 69 cases will be conceded by HHS, 15 will require a court decision, and 297 will be resolved through settlement (78%, which is in line with the last few years). Concerning awards ($83 million to date), it is expected that total awards for FY 2015 will be about $250 million, with about $21 million for attorneys' fees and costs. The balance in the Vaccine Injury Compensation Trust fund was $3.5 billion as of December 31, 2014.

Dr. Houston reported that the several regulations related to the Vaccine Injury Table (Table) continue to be reviewed by the Department of Health and Human Services (HHS) under the standard clearance process. The National Vaccine Advisory Committee met on February 10-11, and the Advisory Committee on Immunization Practices held an abbreviated meeting, because of inclement weather, on February 26. Finally, the VICP has responded to several inquiries regarding the measles outbreaks in various parts of the country, providing information about the program's activities. Dr. Houston provided contact information for anyone interested in reaching the program through e-mail or telephone.

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

Mr. Matanoski reported that 154 petitions were filed in the U.S. Court of Federal Claims (CFC), adult claims dominating with 131 petitions. Petitions filed by minors, most filed by parents, totaled 23. That number is slightly less than last year for the same period (mid-November 2014 to mid-April 2015), but the projection for the year is about 700 petitions, which is driven by a seasonality in the cases filed. Far more petitions are filed in the flu season, fall to early winter, which is consistent with the dramatic increase in flu immunizations at that time of year. There were 142 adjudications, which compares favorably with petitions filed in terms of keeping up with the workload. Of the cases adjudicated, 117 were compensated, 92 through settlement. Twenty-five were not compensated, usually the result of a court decision. Only two petitions were withdrawn.

Turning to active cases, two cases were decided in the Court of Appeals for the Federal Circuit (CAFC), both involving the HPV vaccine, both affirmed. Both cases had already been heard in the CFC. In Flores v. HHS, the petitioner claimed that a blood clot caused by the HPV vaccination resulted in a stroke, but the Special Master determined that respondent's experts were more convincing, arguing against that premise. The appellate courts affirmed that finding. In Koehn v. HHS, the petitioner's attorney claimed that the vaccine was causative in onset of juvenile neuropathic diabetes and again the CAFC affirmed the Special Master's decision that the vaccine was not involved.

Mr. Matanoski reported on a new case, not previously discussed with the ACCV. In Hermiz v. HHS, a child who received an influenza vaccine experienced degeneration of motor control; the petitioner claimed the vaccine was responsible for the condition. The Special Master felt the respondent's experts were more persuasive and ruled against the petitioner. The case was affirmed by the CFC and now is on the CAFC docket.

In the CFC, five cases were decided during the last quarter.

- In Moriarty v. HHS, involved MMR vaccine and a petitioner's claim that the vaccine caused onset of seizures and impaired cognitive functions. The Special Master found against the petitioner's claim that MMR can cause an epileptic encephalopathy. That decision was affirmed by the CFC.
- In Lerwick v. HHS, a damages claim, the petitioner disagreed with the Special Master's decision about the skill level of care that should be provided for the injured party. That decision was affirmed on appeal by the CFC.
- In Mosley v. HHS, concerning transverse myelitis claimed to have been caused by tetanus toxoid vaccine, the Special Master's decision in favor of respondent was vacated and remanded for rehearing based on a legal error by the Special Master, who failed to discuss the testimony of four treating physicians in the final ruling.
- In Castaldi v. HHS, a statute of limitations case, the respondent's position was affirmed, that the first symptoms of loss of speech and motor control actually occurred well before the three-year statute for filing a claim.

Mr. Matanoski briefly reviewed several new cases pending before the CFC:

- Barclay v. HHS, is a DTaP vaccine case that involves a claim of Dravet syndrome. In a number of prior claims the condition has been ruled to be unrelated to any vaccine injury.
- Santini v. HHS is a case similar to Barclay in history and outcome at the Special Master level.
- In Rowan v. HHS, the claim is based on the inclusion of an adjuvant in the HPV vaccine received by the injured party. Adjuvants enhance the positive effects of vaccines and the claim is that in this case it caused autoimmune syndrome induced by adjuvants (ASIA). The Special Master noted that the theory related to the causation of ASIA has been put forward by only one physician, and the prior ruling was that the theory was not reliable.
- In Milik v. HHS, in a claim related to MMR vaccine, the Special Master determined that the petitioner failed to meet any of the Althen causation criteria.
- Somosot v. HHS, an attorney's fees and costs case, was appealed by the petitioner because the Special Master disallowed the claim as untimely. The case was filed five years after the onset of symptoms

Finally, Mr. Matanoski reported that cases are tracked by injury, vaccine and time to settle. Of the 92 cases settled during the last period the average settlement was reached one year, nine months after filing. With regard to the cumulative record, 28% of cases were settled within a year, an additional 45% within two years, and an additional 9% within three years – a total of 82% of cases settled within three years. Mr. Matanoski commented that, of the 92 cases settled, 84 were claims by adults, and 72 of the 92 were flu cases. Looking at cases conceded by HHS (through acceptance of petitioner's proffer), the majority involved claims for flu and SIRVA (shoulder injury related to vaccine administration). Those claims are on the rise. SIRVA is among the injuries being reviewed by the HHS in the current Table clearance process. In anticipation that the injury will be added to the Table, decisions are being made that reflect that

outcome. Because of that more liberal policy, when the decision is finalized to add SIRVA to the Table, there should not be a dramatic change in the outcomes of SIRVA claims.

During discussion it was noted that SIRVA is related to the mechanical process of injection and not an allergic or physiological reaction to the vaccine being administered. Therefore it might be appropriate for the Commission to address reduction of that injury through proper training of vaccinators. Similarly, syncope, also not related to an allergic or physiological reaction of a vaccine, might be reduced by increased vigilance at the time of vaccination. Dr. Shimabukuro commented that there is significant guidance available concerning safe administration of vaccines through CDC and professional societies. It was noted that CDC has a web site entitled "Call the Shots," that provides such information. Dr. Pron added that nursing training programs provide a significant level of training in administering injections. There was a suggestion that a background report on the issue of injection technique, risks and precautions, be included in a future ACCV agenda. Mr. Matanoski offered the comment that the majority of SIRVA-type claims involved mainly flu vaccines that were administered outside of a medical facility, such as in "alternative" sites -- pharmacy chains, and pharmacies within supermarkets. But there is no data on training level of those giving the shots.

After the discussion, there was agreement that an agenda item should be added for the next meeting that would include background information about vaccine administration from CDC and the professional society. Dr. Houston agreed to provide assistance in developing that presentation.

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

Ms. dela Rosa reported that Dr. Houston provided an update on how recommendations to the Secretary of HHS are handled. She noted that, since the Secretary has just come on board, the process may or may not change. She added that senior HHS administrators had met with the Secretary to provide some background on the various advisory groups within HHS but that there was no written protocol for the process by which the Secretary reviews recommendations provided.

The Workgroup reviewed the information-gathering activities of the ACCV. An example is the proposed survey of petitioners' attorneys. It was noted that the National Childhood Vaccine Injury Act provides for a waiver of the requirements of the Paperwork Reduction Act if the information gathering is related to implementation of the Act. If that exemption applies, a proposal to collect information can be developed.

With regard to resources for identifying candidates as Commission members, an announcement is made in the Federal Register, public media is relied on to publicize the vacancies, and the Commission members are invited to submit nominations. The program welcomes any suggestions to improve the recruitment process. Finally, Ms. dela Rosa noted that, with regard to in-person meetings of the Commission, two are authorized for the year (June and September meetings are available), to be determined by the Commission. She added that HRSA prefers reliance on the virtual meetings via teleconference or webcast.

Asked about the selection process for new Commission members, Dr. Houston stated that the nominations have been submitted for approval. HHS has indicated that the process takes 6-9 months, but there has been no clarification of that process. The Federal Register notice for replacement of members leaving in December will be published and the Commission will be informed of the date of publication.

There was a brief discussion about the lack of response to recommendations submitted to the Secretary. The result was an expression of concern by several commissioners about the lack of communication with the Secretary's office. Dr. Feemster stated that a specific request should be resubmitted to the Secretary for a definitive clarification of the role of the Commission with regard to recommendations made to the Secretary's office. Dr. Houston clarified the specific request of the Commission: that the Secretary provides a description of the vetting process for recommendations received from the ACCV; and an update on the status of recommendations already submitted to the Secretary. Dr. Houston stated that she would convey the request to HRSA leadership. She observed, however, that some recommendations require legislative action by Congress, which may take a longer time to process.

Asked for clarification of the Paperwork Reduction Act exemption, Ms. Overby noted that the question of the exemption came up when the Commission was considering a survey of petitioners' attorneys. She added that if the information gathering relates to fulfilling the implementing the Act, then the exemption would apply. She further clarified that the funds for the administrative requirements of the VICP, including conducting such surveys and/or other collection of information are appropriated by Congress.

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

Dr. Villarreal expressed appreciation for the Workgroup members who participated in the teleconference which focused on making a recommendation to the Secretary regarding inclusion of Pneumococcal (PPSV23) and the zoster (shingles) vaccines, which are recommended for adults as additional vaccines covered under the National Vaccine Injury Compensation Program (VICP) and therefore subject to the excise tax. Dr. Shimabukuro has agreed to look at the PPSV23 vaccine and obtain the perspective of the CDC working group concerned with universal recommendation of the vaccine. Several Workgroup members will be looking at the legislative history of the VICP to determine if adult immunizations and immunizations for pregnant women have ever been addressed. They will also look at CMS Medicare/Medicaid payment recommendations for the two vaccines. Ms. Herzog will invite vaccine manufacturers to present concerns and recommendations to the working group. Ms. Davey will look at the effect of the tax code.

Dr. Villarreal stated that the Workgroup will meet every second Thursday of each month for six months, when a recommendation should be prepared for the Commission. She added that the pneumococcal vaccine was also administered to a limited population of children with specific disorders (sickle cell, asplenia, profound pulmonary disorders) and Dr. Shimabukuro would be looking at that issue as it is discussed in a separate CDC working group. The Adult Immunization Workgroup would also be amenable to looking at other vaccines that may be recommended by the ACIP for select subgroups. Dr. Shimabukuro observed that including

children for PPV23 vaccine in the Program would require a legislative change, and without that a change in recommendations by ACIP or CDC would probably not have an effect. There was a brief discussion about whether there was precedent to reinterpret legislation to accommodate some of the issues under discussion.

Dr. Feemster stated that she had to leave the meeting and requested that Mr. Smith act as chair. Mr. Smith announced that the next agenda item was review of Vaccine Information Statements related to human papillomavirus vaccine (HPV), pneumococcal conjugate vaccine (PCV13), and pneumococcal polysaccharide vaccine. He stated that he would recuse himself from the discussion related to the PCV 13 vaccine. Dr. Pron also recused herself from the discussions of the PCV13 and HPV vaccines. Mr. Smith noted that anyone recused from a discussion could remain in the meeting, but would not participate.

Review of Vaccine Information Statements (VIS), Mr. Skip Wolfe and Ms. Suzanne Johnson-DeLeon, CDC

HPV (Human Papillomavirus Vaccine)

Mr. Wolfe invited Ms. Suzanne Johnson-DeLeon to participate in the discussion and began review of the first paragraph, Why Get Vaccinated. Mr. Kraus expressed concern that the wording may suggest a broader prevention of cancers than is actually the case. Acknowledging that Gardasil 9 is effective against 70% of HPV that causes cancer, he agreed with the suggestion that a less rigid description of the benefits of the vaccine would be appropriate, *Gardasil 9, prevents <u>many</u> cancers caused by human papillomavirus, including: cervical cancer in females; vaginal and vulvar cancers in females; and anal cancer in females and males.* There was an observation that Section 1 includes statistics for cervical cancer, but none for the other cancers listed. Mr. Wolfe commented that such statistics could be included.

Turning to Section 2, Ms. Johnson-DeLeon noted that ACIP had voted to extend the age range for HPV vaccine to 21. Mr. Kraus mentioned that the duration of the Gardasil might indicate a booster dose, and Mr. Wolfe agreed that a two-dose schedule might have to be considered in the future. In Section 3, following a comment about the termination of pregnancy being unnecessary if an individual was not aware of the pregnancy when vaccinated, Dr. Shimabukuro suggested stating there is no medical intervention needed. There were no recommendations for Section 4, except that Mr. Wolfe noted that previous recommendation to remove the reference to temporary pain (second bullet under "Problems that could happen after any vaccine,") was inadvertently not corrected. He said it would be changed. There were no recommendations pertaining to Section 5. In Section 6, Mr. King suggested emphasizing the sentence concerning the time limit to file a claim for compensation, perhaps with an italic or bold typeface. There was a comment that in many cases individuals actually fail to file a claim within the 36-month time limit. Mr. Kraus added that the ACCV had considered a recommendation to extend that time limit. He recommended including the alert and the added emphasis. There were no recommendations related to Section 7.

Pneumococcal Conjugate Vaccine (PCV13)

It was noted that Mr. Smith and Dr. Pron had recused themselves from the discussion of this VIS. It was also noted that PPSV23 was originally on the agenda but was removed since it is not a covered VICP vaccine. Mr. Smith commented that he would give the Commission an opportunity to comment on the vaccine, even though it was not on the agenda.

Dr. Villarreal commented that the original indications for use of PCV13 included otitis media, which is not included in the VIS. Dr. Shimabukuro suggested that it might have been deleted because it was not very effective against that disorder. It was noted that the condition was listed in the statistics section stating that, before the vaccine was available, there were 5 million such infections in children. The Commission agreed that the statements should be investigated.

There was an observation that when Inactivated Influenza Vaccine and PCV13 are taken together there is a risk of febrile seizure, which should be noted on the VIS. Finally, there was the same comment about emphasizing the time limit for filing a claim that was made for the previous VIS.

Pneumococcal Polysaccharide Vaccine (PPSV23)

Although comment was invited concerning the vaccine, several Commissioners suggested that, since it was an adult vaccine, not covered by the Program, that discussing it would be inappropriate. Mr. Wolfe commented that, even if the Commissioners did not discuss the vaccine specifically, comments made about other vaccine would be taken into consideration in developing a VIS for PPSV23.

Mr. Smith thanked Mr. Wolfe and Ms. Johnson-DeLeon for their help in reviewing the two Vaccine Information Statements. Referring to the next presentation by Dr. Shimabukuro, Mr. Smith stated that he would recuse himself from any discussion related to the meningococcal B vaccine.

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

Dr. Shimabukuro reported that the Vaccine Adverse Event Reporting System (VAERS) form 2.0 was posted in the Federal Register for a 60-day public comment period, which ended on January 23. Nineteen comments were received and review of those comments is in progress, which may result in some revisions to the form. In regards to ongoing Clinical Immunization Safety Assessment (CISA) project, Dr. Shimabukuro stated that currently there are eight studies in progress. A complete list of activities can be found at https://clinicaltrials.gov/.

Noting that the February 2015 Advisory Committee on Immunization Practices (ACIP) was shortened because of weather, Dr. Shimabukuro reported that, for meningococcal B vaccine a recommendation was made for administration to children 10 years of age and older who are considered at increased risk. Those risk groups include persons with complement deficiency, asplenia, certain lab workers or persons exposed during an outbreak. It does not include college students in general.

There was an ACIP vote to reaffirm the existing recommendation for influenza vaccinations for everyone 6 months of age or older. The preference for live attenuated influenza vaccine (LAIV) over inactivated influenza vaccine (IIV) in persons aged 2-8 years was removed and either product is acceptable. This was based on several effectiveness studies that did not support the superior effectiveness of LAIV over IIV. The HPV session focused on the newly licensed HPV9 vaccine, and the recommendation was to administer HPV 9, 4 or 2 to females aged 9 to 26; HPV 9 or 4 for males 9 to 21. HPV 9 was approved for use in boys 9 to 15, so that use in older adolescents and young adults is an off label use.

The ACIP recommended that a single dose of yellow fever vaccine (YFV) provides long-lasting protection and is adequate for most travelers. Additional doses were recommended for: certain travelers (e.g., women pregnant when they received their initial dose, hematopoietic stem cell transplantation recipients [once they are immunocompetent] and HIV infected individuals), certain individuals in high risk settings (i.e., travelers who received last YFV dose at least 10 years prior and who will be in high risk settings [e.g., rural W. Africa]), and laboratory workers who routinely handle wild type YF virus. International Health Regulations requiring travelers to show a YFV dose within 10 years for entry is being discontinued effective June 2016.

Dr. Shimabukuro reviewed several recent published papers:

- Klein et al. Safety of Measles-Containing Vaccines in 1-Year-Old Children. Pediatrics. 2015 Jan 5. pii: peds.2014-1822. This study did not identify any new safety concerns comparing MMRV with MMR + V or after either the MMRV or the MMR + V vaccine; outcomes included anaphylaxis, ITP, ataxia, arthritis, meningitis/encephalitis, acute disseminated encephalomyelitis, Kawasaki disease, seizure, and fever. Risks for the 7 main outcomes were not significantly different. Several outcomes had few or zero postvaccination events. This study provides reassurance that these outcomes are unlikely after either vaccine.
- Abrams et al. Childhood vaccines and Kawasaki disease, Vaccine Safety Datalink, 1996-2006. Vaccine. 2015 Jan 3;33(2):382-7. Childhood vaccinations studied did not increase the risk of Kawasaki disease; conversely, vaccination was associated with a transient decrease in Kawasaki disease incidence. Verifying and understanding this potential protective effect could yield clues to the underlying etiology of Kawasaki disease.
- Sukumaran et al. Adverse events following measles, mumps, and rubella vaccine in adults reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013. Clin Infect Dis. 2015 Jan 30. pii: civ061. [Epub ahead of print]. In this review of VAERS data, there were no new or unexpected safety concerns detected for MMR vaccination in adults. There were reports identified of pregnant women exposed to MMR which is a group in whom the vaccine is contraindicated, suggesting the need for continued provider education on vaccine recommendations and screening.
- Moro et al. Adverse Events following Haemophilus influenzae Type b Vaccines in the Vaccine Adverse Event Reporting System, 1990-2013. J Pediatr. 2015 Jan 15. pii: S0022-3476(14)01163-9. This review of VAERS reports did not identify any new or unexpected safety concerns for Hib vaccines.

- Moro et al. Safety of quadrivalent human papillomavirus vaccine (Gardasil®) in pregnancy: Adverse events among non-manufacturer reports in the Vaccine Adverse Event Reporting System, 2006-2013. Vaccine. 2015 Jan 15;33(4):519-22. This review of VAERS non-manufacturer reports following vaccination with HPV4 in pregnancy did not find any unexpected patterns in maternal or fetal outcomes.

During discussion, Dr. Pron asked if there were any current reports on the measles outbreak. Dr. Shimabukuro noted that that area was covered by the National Center for Immunization and Respiratory Diseases, and he stated that he would request that an update be provided to the Commission.

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

Ms. Schuster reported that a large Ebola clinical trial opened in Liberia, sponsored by NIAID, to assess the safety and efficacy of two experimental vaccines to prevent Ebola virus infection is now open to volunteers in Liberia. The study, known as PREVAIL, the Partnership for Research on Ebola Vaccines in Liberia, a Phase 2/3 study and is designed to enroll approximately 27,000 healthy men and women aged 18 years and older.

Ms. Schuster recalled that she had described a series of consultations on pregnant women in clinical trials related to antimicrobials and vaccines. Participants in those meetings prepared a series of papers, which appeared in a recent supplement to the journal, Clinical Infectious Diseases. The papers looked at global and national initiatives to facilitate studies of pregnant women, recruitment and retention of women in clinical studies, maternal immunization, and the design of drug trials.

Referring to a new feature on the NIAID web site, Ms. Schuster described the NIAID Showcase that highlights notable scientific advances made by NIAID labs and NIAID-funded researchers during FY 2014. Finally, Ms. Schuster commented on the Precision Medicine Initiative, announced by President Obama in the State of the Union speech. Precision medicine focuses on the individual patient, including a genetic component.

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

LCDR Marshall reported that FDA approved Trumenba in October 2014, a vaccine to prevent invasive meningococcal disease caused by Neisseria meningitides serogroup B, for individuals 10 to 25. In January 2015, FDA approved Bexsero, the second vaccine to prevent invasive meningococcal disease caused by Neisseria meningitides serogroup B, for individuals 10 to 25. Both were granted Breakthrough Therapy status, which allowed approval to be expedited. In January 2015 FDA approved HPV-9 vaccine for prevention of cervical, vulvar, vaginal and anal cancers caused by seven HPV types, and for prevention of genital warts caused by two HPV types. The HPV-9 is for females age 9 through 25 and males 9 through 15. In January 2015, the Office of Vaccine Research and Review (OVRR) approved a supplement to

the BLA for Pneumococcal 13-valent conjugate vaccine (Prevnar 13), to include package insert language regarding the effect of fever-reducing medications given with routine pediatric vaccinations in healthy infants. Non-medication (prophylactic) use may reduce the response to some vaccine serotypes following PCV13 immunization. Finally, in December, FDA approved a Biologic License Application supplement to Pneumovax 23 to add a 2D barcode on single dose units that contains product identification information (including lot number and expiration date).

In December 2014, FDA published new requirements for pregnancy and lactation labeling. The Pregnancy and Lactation Labeling Rule removes pregnancy letter labels, and requires that package labels be updated when new information becomes available. The new labeling will include information on pregnancy, labor and delivery, lactation including nursing mothers, and information for males and females of reproductive potential.

Finally, LCDR Marshall noted that the Vaccine and Related Biological Products Advisory Committee met on March 4 to discuss the selection of influenza strains to be included in the vaccines for the 2015-2016 flu season.

During discussion, Dr. Houston clarified an issue related to meningococcal vaccines, since there was apparently some confusion about its coverage under the Program. She stated that all meningococcal vaccines are covered.

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

Dr. Bok reported that the National Vaccine Safety Research Plan launched in January and includes a cooperative agreement to look at research, monitoring and outcomes definitions for vaccine safety. The objective is to conduct research in vaccine safety that: determines the safety profile of new vaccines during the early development stage; develops or modifies existing vaccines to improve their safety; directly impacts the current vaccine safety monitoring system; and produces consensus definitions of vaccine safety outcomes that could be utilized to collect consensus data in clinical research conducted globally. Of particular interest are projects related to researching, establishing or testing the vaccine safety profile of vaccines that are either currently recommended for, or are expected to be, routinely administered to pregnant women or newborns. Topics of research may cover, establishing the safety of a vaccine in the pregnant woman, her newborn or both, at any stage of the vaccine development, test and pre-clinical or clinical research and monitoring of vaccine safety.

There is now a Vaccine Safety Scientific Agenda, drafted by the Immunization Safety Task Force, to support a broad collaboration of federal partners that have any involvement in vaccines. A list of the leading institutions, safety systems and objectives can be found at http://www.hhs.gov/nvpo/vacc_plan/vaccine-safety-scientific-agenda.html that includes current and future research projects.

The National Vaccine Advisory Committee (NVAC) met on February 10th & 11th. Dr. Bok stated that the National Adult Immunization Plan has been released and is out for public comment and that NVPO expects to launch the Plan at the June NVAC meeting.

During discussion, Mr. Kraus asked about any plans for a study of vaccinated/unvaccinated children. Dr. Shimabukuro stated that CDC had addressed that issue through the Vaccine Safety Datalink, which had been identified as a system to look at outcomes in child with different levels of vaccination. The Institute of Medicine study concluded that conducting a randomized controlled trial would not be feasible.

Public Comment

Mr. Smith invited public comment. There were no requests for public comment.

Future Agenda Items/New Business

Mr. Smith invited recommendations for future agenda items. He noted that Dr. Villarreal had mentioned discussing available guidance with respect to vaccine administration as a potential future agenda item. The discussion would include background information about vaccine administration from CDC and the professional society. He added that the issue of clarifying the relationship between the Secretary's office and the ACCV, in terms of recommendation submitted to the Department, should also be discussed.

Mr. King noted that a topic mentioned at the last meeting was not included in the agenda for the meeting, a discussion of a recommendation to increase funding for the Program to enhance processing of the increased number of claims filed. He requested that the discussion be scheduled for the June meeting. He also noted that the public comment opportunity, previously scheduled at the beginning of the meeting and related specifically to the agenda, was not included on the agenda for this meeting. He recommended including it in the June meeting agenda.

Adjournment

There being no further business, Mr. Smith invited a motion to adjourn. On motion duly made and seconded, the Commission unanimously approved adjournment.