Advisory Commission on Childhood Vaccines

September 8, 2017

103rd Meeting

Members Present

Karlen E. Luthy, D.N.P., Interim Chair, (’18)
Kathleen F. Gaffney, PhD, RN (’19)
H. Cody Meissner, MD, (’19)
Tina Tan, MD, (’19)
Alexandra Stewart, J.D., (‘18)
Martha Toomey (’18)

Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)

Narayan Nair, M.D., Director, DICP
Andrea Herzog, Principal Staff Liaison, ACCV

Welcome and Report of the Interim Chair
Beth Luthy, ACCV Interim Chair

Ms. Luthy called the meeting to order and introduced the Commission members present (reflected above), ex-officio members, DICP staff and a representative from the Office of the General Counsel. She invited public comment on the meeting agenda,

Public Comment on Agenda Items

There were no requests to comment on agenda items.

Approval of December 2016 ACCV Meeting Minutes

Ms. Luthy requested approval of the December 2016 ACCV meeting minutes. The Commission unanimously approved the minutes.

Report from the DICP, Dr. Narayan Nair, Director

Dr. Nair stated that the agenda would include an update on HRSA VICP activities; a presentation on the 21st Century Cures Act (enacted in December 2016); a presentation on proposed changes to the Vaccine Injury Table (Table); an update from the Department of Justice (DOJ) Vaccine Litigation Office; and updates from ACCV ex-officio members representing the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and National Vaccine Program Office (NVPO).

Looking at the data for claims filed with the VICP during fiscal year (FY) 2017, October 1, 2016 to September 30, 2017, Dr. Nair noted that average number of petitions filed from FY 2011 to FY 2015 was 546 per year. The number of petitions began to increase significantly in 2014 (633), reaching a high in FY 2016 of 1,120. The pace of claims filed in FY 2017 is consistent with the previous fiscal year. As of August 1, 2017, 987 claims were filed. The number of claims filed in FY 2017 should exceed FY 2016.

Dr. Nair presented data for adjudicated cases by category for FYs 2015, 2016 and 2017. For FY 2017, as of August 19, 2017, 730 cases were adjudicated. Of those 730 cases -- 135 were not compensable and 595 were compensable. The compensable cases were decided as follows: 156 by concession, 40 were court decisions, and 399 by settlement. Awards have increased from $216 million in FY 2011 to $230 million in FY 2016. As of August 1, 2017, the VICP has paid $259 million in compensation with attorneys' fees accounting for $26 million of that total compensation payment.

Dr. Nair discussed the balance of the Vaccine Injury Compensation Trust Fund (Trust Fund). The Trust Fund balance was $3.6 billion as of July 31, 2017. At the end of June, which was the end of the third quarter of FY 2017, the Trust Fund had collected $181 million from excise tax payments and earned $47 million in interest, for a total income of $228 million. Interest was 20.5% of total income.

In other activities, Dr. Nair reported that Revisions to the Vaccine Injury Table Final Rule went into effect on March 21, 2017, and the implementation of maternal immunization provisions were updated on the VICP website. The ACCV will discuss additional revisions to the Table, related to maternal immunizations, as part of this meeting's agenda. Finally, with regard to outreach, the maternal immunization provisions were presented to the National Vaccine Advisory Committee (NVAC) at their February meeting, and as an informational presentation at Johns Hopkins University. Dr. Nair noted that further information can be found on the Web at: www.hsa.gov/advisorycommittees/childhoodvaccines/index.html.

During discussion, he was asked for clarification about the VICP. Dr. Nair explained that the VICP is the federal program that oversees the vaccine injury compensation authorized by the National Childhood *Vaccine Injury Act* of 1986 (Vaccine Act). Agencies involved include HRSA, DOJ and the U.S. Court of Federal Claims (Court). When the Act established the compensation program, the Advisory Commission on Childhood Vaccines was also established to advise the VICP.

Report on the 21st Century Cures Act, Dr. Narayan Nair

Dr. Nair explained that the 21st Century Cures Act (Cures Act) amends the Vaccine Act. He stated that the Cures Act was passed in December 2016, and one provision in the Act applies specifically to the VICP – adding vaccines recommended by the CDC for routine administration to pregnant women to the Table. New vaccines would also be covered as they are recommended for use in pregnant womenand subject to an excise tax. . Currently, the two vaccines recommended for pregnant women are seasonal influenza and diphtheria, tetanus and pertussis (DTaP) vaccines which are currently covered by the VICP because they are recommend for routine administration to children.

The Act clarified several issues that were previously unresolved when a claim was made under the Vaccine Act, including the fact that a single administration of a vaccine to a mother would constitute a concomitant administration to the in utero child. The Act will cover the

pregnant woman who receives the vaccine and any child in utero when the vaccine was administered, and who was born alive.

Dr. Nair clarified an issue raised by a Commission member; if a child is stillborn or the mother miscarries, although the child is not eligible for compensation under the Act, the mother could still file a claim if she could prove a vaccine-related cause. He also clarified that if a vaccine is administered in error (e.g., a vaccine not routinely recommended) it would be covered and a claim could be filed.

Presentation on Proposed Changes to the Vaccine Injury Table to Add Vaccines Recommended for Routine Administration by the CDC to Pregnant Women, Dr. Narayan Nair

Dr. Nair explained that the Cures Act amended the Vaccine Act, requiring revisions to the Table to add vaccines recommended for routine administration by the CDC to pregnant women. Since DTaP and seasonal influenza vaccines are currently recommended for routine administration by the CDC to children, they are already on the Table and covered by the VICP, but for new vaccines the Table must be changed. The process is to develop a Notice of Proposed Rulemaking (NPRM) after consultation with the ACCV. The VICP provided three options for ACCV consideration. Ultimately, the ACCV will select one and formalize the recommendation with a vote.

- Option 1 – Revise Category XVII on the Table to reflect addition of the italicized words: Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children *and/or pregnant women* after publication by the Secretary of a notice of coverage.

- Option 2 – Create a Category XVIII on the Table and adding a new paragraph: Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to pregnant women, after publication by the Secretary of a notice of coverage.

- Option 3 -- Present Options 1 and 2 in an NPRM to get public comment on the issue: During discussion, it was noted that there is a filing deadline that permits retroactive claims to be filed for aspect to newly covered vaccines. An individual would have two years to file a claim for injuries incurred within eight years prior to effective date of coverage of the new vaccine on the Table. To add a vaccine to the Table, it would have to be subject to excise tax and recommended by CDC for routine administration in pregnant women.

Dr. Nair indicated that the Commission should settle on one of the three options and formalize the recommendation with a vote. He observed that Option 1 and 2 accomplish the same thing; neither has an advantage over the other. Ms. Stewart commented that the third option, involving the Notice of Proposed Rulemaking, would afford the public an opportunity to provide input. It would be the most equitable option. There was agreement that the additional input would be helpful. Ms. Luthy invited a motion.

On motion duly made and seconded, the Commission unanimously approved the third option, to publish a Notice of Proposed Rulemaking regarding the revisions to the Injury Table.

There was a comment from a Commission member about the history of the rubella vaccine, which at the outset, created significant concern among women who were pregnant and who had received the rubella vaccine before becoming aware of their pregnancy. During that period, some women chose to terminate the pregnancy because of that concern, which later proved to be unfounded. There was an observation that the anecdote might serve as a deterrent to any similar response to new vaccines (e.g., the Zika virus vaccine) when they become available.

Dr. Bok observed that one aspect of the Cures Act was encouragement to expand the participation of pregnant and lactating women in research trials, to expand the scientific knowledge concerning the risks and benefits of various prevention programs. Dr. Shimabukuro commented that essentially the two options represent the same outcome through different approaches – one, the addition of the "either/or" wording (lumping); the other creation of a separate category (splitting). Dr. Shimabukuro observed, option 3 is not an option, just a mechanism to gather more input. The Commission briefly discussed the earlier vote and agreed, by consensus; to recommend Option 1 instead of Option 3.

Report from the Department of Justice, Ms. Sarah Duncan, Trial Attorney

Ms. Duncan welcomed the commissioners and explained that she would be presenting the report from the Department of Justice (DOJ) on behalf of Catharine Reeves, Deputy Director, Torts Branch. Ms. Duncan noted that the reporting period for DOJ is different from that of the Division of Injury Compensation Programs. Ms. Duncan referenced the DOJ Power Point materials as part of her presentation for the nine-month period from November 16, 2016 to August 15, 2017. During this reporting period, 856 petitions were filed. Of those 856, 103 were filed on behalf of children (12%) and 753 were filed by adults (88%). (DOJ PP at 2).

With regard to total cases adjudicated, Ms. Duncan noted that 593 claims were adjudicated this period. (DOJ PP at 3). There were 485 cases compensated. Of those 485 cases, 153 were conceded by HHS. Of those 153 conceded cases, all 153 were resolved by a decision adopting a proffer. There were 332 cases compensated but not conceded by HHS. Of those, all 332 cases were resolved by a decision adopting a settlement stipulation. (DOJ PP at 3). There were 108 cases dismissed. Of those, 103 non-OAP cases were resolved by decisions dismissing the petition, and 5 were dismissed from the OAP. (DOJ PP at 3). There were 45 petitions voluntarily withdrawn. (DOJ PP at 4).

Turning to appeals, eight cases were decided by the U.S. Court of Appeals for the Federal Circuit (CAFC) during the reporting period. (DOJ PP at 5). Seven of these appeals were filed by petitioners and all seven concerned entitlement. Of these seven, one was affirmed per curiam (*R.K. v. HHS*), one was affirmed (*Lasnetski v. HHS*), two were remanded (*Contreras v. HHS* and *Moriarty v. HHS*), one was voluntarily dismissed by petitioner (*Murphy v. HHS*), and two were dismissed by the Court (*G.G.M. v. HHS* and *Osele v. HHS*). The eighth case concerned attorneys' fees and costs and was filed by respondent but voluntarily dismissed (*Allicock v. HHS*). In addition to one appeal filed by petitioners that is pending, three new appeals were filed by petitioners in *Simmons v. HHS, D'Tiole v. HHS*, and *Anderson v. HHS.* (DOJ PP at 6).

Ms. Duncan discussed appeals at the Court of Federal Claims (CFC), and noted that twenty-six appeals filed by petitioners were decided by the CFC. (DOJ PP at 7-9). Eighteen of the twenty-six appeals concerned entitlement and eight concerned attorneys' fees and costs. Of the twenty-six cases, twenty were affirmed, two were affirmed in part, two were remanded, one

was dismissed as untimely, and one was voluntarily dismissed by petitioner. Ms. Duncan reported that the CFC also decided one appeal filed by respondent. (DOJ PP at 9). In *Day v. HHS*, the special master's award of interim damages to petitioner was affirmed. Ms. Duncan noted that petitioners filed five new appeals to the CFC, three of which involve entitlement, and two of which involve attorneys' fees and costs. (DOJ PP at 10). Six total cases remain pending at the CFC. (DOJ PP 10).

Two oral arguments are scheduled at the CAFC in *H.L. v. HHS* and *Simmons v. HHS*. (DOJ PP at 11). No oral arguments are scheduled at the CFC.

Ms. Duncan noted the history of adjudicated settlements, which are listed in order of the time they took to resolve. (DOJ PP at 12-42). Most of the cases involved injuries related to Guillain-Barré Syndrome and shoulder injury related to vaccine administration (SIRVA).

There was a brief discussion regarding the distinction between settlement and concession. Ms. Duncan explained that a concession by HHS requires evidence that the alleged injury was caused by a covered vaccine, whereas a settlement may occur for a variety of reasons, including litigative risk on both sides.

Ms. Toomey asked how often a petitioner passes away during the pendency of a case. Ms. Duncan indicated that she did not believe DOJ tracked that information but that DOJ would confirm.

Update on the Immunization Safety Office (ISO), CDC Vaccine Activities, Dr. Tom Shimabukuro

Vaccine Adverse Event Reporting System (VAERS) Transition to VAERS-2.0

Dr. Shimabukuro stated that he would focus the CDC agency update on the transition to the Vaccine Adverse Event Reporting System (VAERS) version 2.0 reporting process. VAERS is a passive reporting system for monitoring the safety of U.S.-licensed vaccines. CDC and FDA co-manage VAERS. Since 1990, data have been collected using the VAERS-1 form, a printable form that had to be manually filled out and submitted by mail or fax. On June 30, 2017, CDC and FDA implemented VAERS 2.0, which consists of an updated electronic VAERS reporting form with revised and expanded data elements and an updated VAERS online reporting tool. The VAERS 2.0 reporting process offers two options, an updated version of the online reporting tool; and a "writable" PDF that can be filled out using a computer, saved for later revision if need be, and submitted when completed through an electronic document upload feature on the VAERS website. The VAERS 2.0 online reporting tool still has a time out feature for security reasons.

Dr. Shimabukuro reviewed the development of the VAERS-2.0 form, which began in 2014, underwent extensive user testing, and was completed in 2016. After information technology upgrades to the VAERS website in 2017, VAERS 2.0 was ready for release. Beginning with the release and continuing through the end of 2017, CDC and FDA are implementing VAERS-2.0 and phasing out the VAERS-1 paper forms.

Dr. Shimabukuro noted that VAERS 2.0 applies to public reporters, which includes healthcare professionals, patients, caregivers, guardians and other non-manufacturer reporters. Vaccine manufacturers report through a different process using electronic data transfer. Dr. Shimbakuro illustrated the reporting process through a screenshot of the new forms. He noted that commissioners and the public can access instructions on submitting reports on the Web

(https://vaers.hhs.gov/reportevent.html) or by e-mail (info@vaers.org) or phone (1-800-822-7967).

Selected Vaccine Safety Publications

Dr. Shimabukuro discussed several recent vaccine safety-related publications:

- Stockwell et al. Feasibility of Text Message Influenza Vaccine Safety Monitoring During Pregnancy in American Journal of Preventive Medicine. This study demonstrated the feasibility of text messaging for influenza vaccine safety surveillance sustained throughout pregnancy. In these women receiving inactivated influenza vaccination during pregnancy, post-vaccination fever was infrequent and a typical pattern of maternal and neonatal health outcomes was observed. Compliance on the part of participants was high.
- Moro et al. Major Birth Defects after Vaccination Reported to the Vaccine Adverse Event Reporting System (VAERS), 1990 to 2014, in Birth Defects Research. This review of the VAERS database found that major birth defects were infrequently reported, with no particular condition reported disproportionally. Birth defects after routine maternal vaccination will continue to be monitored in VAERS for signals to prompt future studies.
- Lipkind et al. Maternal and Infant Outcomes after Human Papillomavirus Vaccination in the Periconceptional Period or During Pregnancy, a Vaccine Safety Datalink study, in Obstetrics & Gynecology. Quadrivalent HPV vaccine inadvertently administered in pregnancy or during the periconceptional period was not associated with adverse pregnancy or birth outcomes.

Dr. Shimabukuro ended his report. During the discussion after his presentation, Dr. Shimabukuro explained that the VAERS is smartphone-capable. One of the aspects of the development of the system was to ensure that the website was compatible with mobile devices or notebooks and tablets. Although it is slightly more difficult to use a mobile device for reporting, the Internet connection is designed to be compatible with mobile devices – it is not just a condensed version of the web site.

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

Ms. Schuster discussed respiratory syncytial virus (RSV), a common respiratory virus that can have serious effects on infants and older adults. Although there is no vaccine currently licensed for the illness, a monoclonal antibody is licensed for limited use in children to prevent respiratory disease. The monoclonal antibody is not available to the general population. In February 2017, NIAID announced a Phase 1 clinical trial on an investigational vaccine, developed by researchers at NIAID. Phase 1 trials evaluate safety and tolerability of new drugs and vaccines. The study is being conducted at NIH. Ms. Schuster invited commissioners to visit the ClinicalTrials.gov web site for more information on this and other trials at NIH.

NIAID is also focused on Zika infection, looking at studies that are broadly directed at the natural history of the disease, and specific research into vaccines, diagnostics, therapeutics

and vector control. In June 2017, a study in several Latin American countries was launched looking at Zika disease in infants and pregnant women.

NIAID is sponsoring a large natural history study in Guatemala. This study of infants and children will focus on those infected after birth. The study will enroll about 1,200 children, including those with dengue and/or Zika infection, and a cohort who are not infected with Zika virus. NIAID has also launched a Phase 2 Zika vaccine trial using an experimental DNA vaccine developed by scientists at NIAID. A similar vaccine was developed for West Nile virus. The trial aims to enroll 2,490 healthy participants in areas of confirmed mosquito-transmitted Zika infection. A Phase 2 trial seeks to validate efficacy and further evaluate safety.

In September 2016, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development convened a workshop to develop a research agenda to improve the evaluation, monitoring and management of neonates, infants and children affected by Zika virus. The agenda included consideration of the effects of Zika exposure on child development. Finally, in February 2017, NIAID announced the launch of a Phase 1 trial to develop a vaccine to provide broad protection against mosquito-transmitted diseases – Zika, dengue fever, malaria, and West Nile virus. The research will specifically look at triggering an immune response to the mosquito's saliva, rather than a virus or parasite carried by the mosquito.

Ms. Schuster explained that NIAID is involved in a collaborative longitudinal (5-year) study, with international partners, investigating three vaccination strategies for Ebola. More than 5,000 participants in the high-risk areas of Africa will be involved in the study. In addition, results of a study of one of the three regimens was published in the Journal of the American Medical Association. The study showed that the regimen induced a persistent immune response to Ebola that lasted one year in healthy adult volunteers.

Ms. Schuster recommended the following recently published publications:

- NG Rouphael, et al. The Safety, Immunogenicity, and Acceptability of Inactivated Influenza Vaccine Delivered by Microneedle Patch --A Randomized, Partly Blinded, Placebo-controlled, Phase 1 Trial. Lancet (2017 Aug 12). The study, sponsored by NIH, found that the use of a single, dissolvable microneedle patch was well-tolerated, resulted in robust antibody responses, and was preferred by participants over the conventional flu vaccine using syringe and needle. The vaccine was reliably selfadministered, and was stable for at least a year at 40 degrees Celsius.
- Poland GA, et al. Personalized Vaccinology: A Review. Vaccine (2017 Jul 31). Personalized vaccinology suggests the development of specific vaccines based on factors that relate to overcoming the potential for poor immunogenicity or immune response, and the potential for adverse events.
- XX Gu, et al. Waning Immunity and Microbial Vaccines Workshop of the National Institute of Allergy and Infectious Diseases. Journal of Clinical Vaccine Immunology (2017 Jul 5). This was a report on a workshop.

Finally, Ms. Schuster mentioned the *All of Us* Research Program, a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. *All of Us* will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions. By taking into account individual

differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine. Additional information is available at: https://allofus.nih.gov/

Update on the Center for Biologics, Evaluating and Research (CBER), FDA Vaccine Activities, CDR Valerie Marshall

CDR Marshall stated that no new vaccine approvals have occurred since the last ACCV meeting. She focused the update on meetings of the Vaccines and Related Biological Products Advisory Committee (VRBPAC).

On March 9, 2017, VRBPAC met in an open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2017-2018 influenza season. The update includes information on world surveillance and U.S. surveillance.

On May 17, 2017, the committee met to discuss considerations for evaluation of RSV vaccine candidates in seronegative infants. The committee discussed approaches to evaluate new RSV vaccines.

On July 28, 2017, the committee met to discuss and make recommendations on the safety and efficacy of a Hepatitis B Vaccine manufactured by Dynavax. The committee voted 12 to one, with three abstentions, to support the approval of that vaccine.

CDR Marshall stated that the next committee meeting would be held on September 13, 2017 to discuss and make recommendations on the safety and effectiveness of Zoster Vaccine Recombinant (Adjuvanted) [Shingrix], manufactured by GlaxoSmithKline Biologicals.

CDR Marshall concluded her report.

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

Dr. Bok announced a new round of Cooperative Agreements. Three were awarded:

- The first was to Cincinnati Children's Hospital, which involved validation of the Global Alignment of Immunization Safety Assessment in pregnancy (GAIA) maternal and neonatal outcome definitions to standardize the evaluation of the safety of vaccines. The study is also supported by the Bill and Melinda Gates Foundation.
- The second was to the Kaiser Foundation Hospitals, which focuses on adversomics. It aims to identify inherited, immunologic, and clinical factors that may predict the occurrence of febrile seizures after measles vaccination. Tissue samples will be collected from children who had both measles and a febrile event to look at clinical indications, genetic (familial) associations.
- The third was to Rockefeller University, to look at the role of precision medicine. NIH is a co-funder. It aims to analyze the genetic determinants of the immune response following yellow fever vaccination among individuals who experience serious adverse events.

Dr. Bok stated that the 21st Century Cures Act asked NVPO, on behalf of the Secretary, to develop a report to congress about which vaccines will be beneficial to public health and how information on recommended vaccines is disseminated to key stakeholders. NVPO was also tasked to examine and identify whether obstacles exist that inhibit the development of beneficial

vaccines. Finally, the request asked for recommendations about how best to remove any obstacles in order to promote and incentivize vaccine innovation and development. The report is expected to be sent to congress before the end of the year.

The Act also establishes a task force on research specific to pregnant women and lactating women. The task force is charged with:

1. Developing a plan to identify and address gaps in knowledge and research regarding pregnant women;
2. Considering ethical issues surrounding the inclusion of pregnant women in clinical research; develop
3. Developing effective communication strategies with health care providers and the public;
4. Identifying federal activities, including existing federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities; and
5. Provide recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

Dr. Bok announced the first Vaccine Confidence Meeting, at Emory University in Atlanta, GA. It was a gathering of researchers, government agencies and health care organizations to discuss ways to increase vaccine confidence in the U.S.

Finally, Dr. Bok announced the recipient of the Vaccine Safety Award. It was presented posthumously to Dr. Roger Baxter, who was director of the Kaiser Permanente Vaccine Study Center, for his prolific contributions to vaccine safety research**.**

Public Comment

Ms. Luthy invited public comment.

Ms. Theresa Wrangham, executive director, National Vaccine Information Center, expressed appreciation for the opportunity to comment. She noted that the meeting book was posted, as had been requested in the past, but that it did not contain the complete presentations of the DOJ or the DICP. She added that speakers often make last minute changes which should be reflected in the material on the website. The National Vaccine Information Center supports the intent of the DVIC to include public comment, such as the use of the NPRM regarding coverage of maternal vaccines, as discussed during the meeting. Ms. Wranghram concurred with what Ms. Toomey mentioned: parents are most concerned about adverse vaccine events related to their own children, vaccine injury cannot be predicted before vaccination, which relates to the informed consent ethic. The National Vaccine Information Center renews its request that the ACCV issue a statement that affirms that the use of vaccines carries with it the risk of injury or death, and because of that risk, the ACCV supports the individual's right to exercise informed consent and the right to make voluntary vaccine decisions for themselves.

Concerning the VAERS-2.0 online reporting system, Ms. Wrangham commented that, according to a CDC presentation in December 2015, VAERS received about 30,000 reports annually, 70% of which are hand-prepared, 30% are submitted in an online format. It was also

estimated at that meeting that only 1% to 10% of adverse events reported to VAERS are captured. Underreporting is widely acknowledged as a weakness of VAERS. The proposed online reporting system is likely to result in even greater underreporting. It penalizes those who are not computer literate or who have limited access to Internet services. NVIC encourages the ISO to provide information to the ACCV regarding the potential negative effects of the system will be monitored and negated.

Finally Ms. Wrangham commented, National Vaccine Information Center renews its request for the Commission to consider recommendations for a mechanism that would gauge ongoing petitioner satisfaction with the VICP. This requested is based, in part, on a report that a petitioner was dissatisfied with the amount of award. Given the number of awards and the potential for awards to be insufficient, NVIC requests that ongoing petitioner satisfaction be revisited, and that the Commission review the findings of the Altarum Report (2009) and the Banyon Report (2010), and the 2014 GAO Report.

Ms. Luthy noted that there were no other requests for comment.

Future Agenda Items/New Business, Ms. Beth Luthy, Interim Chair

Ms. Luthy noted that the next meeting will take place on December 7-8, 2017. She invited suggestions for agenda items for that meeting.

Ms. Toomey suggested reviewing the work that the previous working groups were involved in to see if any of those discussions should be revisited. She also indicated it would be helpful to define the current relationship between the ACCV and the new administration. Ms. Stewart agreed that it would be helpful if the subcommittees met before the December meeting to update the individual agendas. It was noted that none of the current members were involved with the workgroup activities, so it would be worthwhile considering how to restructure the working groups to fit the current situation. Ms. Tamara Overby, Deputy Director, DICP, suggested reviewing the recommendations made by the previous workgroups, with the expectation that the new workgroup or workgroups would have to be redefined.

Dr. Nair commented that he anticipated agenda item for the December meeting would be consideration of new petitions for additions to the Vaccine Injury Table. There was also a suggestion that a discussion of RSV and Zika vaccine clinical trials be an agenda item.

Adjournment

There being no further business, on motion duly made and seconded, the Commission unanimously approved adjournment**.**