

## **Advisory Commission on Childhood Vaccines**

**June 3, 2016  
100th Meeting**

### **Members Present**

Kristen A. Feemster, M.D., Chair ('16)  
Charlene Douglas, Ph.D. ('16)  
Edward Kraus, J.D. ('16)  
Karlen E. Luthy, ('18)  
Luisita dela Rosa, Ph.D. ('16)  
Jason Smith, J.D. ('16)  
Martha Toomey ('18)  
Alexandra Stewart, ('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., Acting Director, DICP  
Andrea Herzog, Staff Liaison

### **Welcome, Report of the Chair and Approval of Minutes Kristen Feemster, ACCV Chair**

Dr. Feemster called the meeting to order and completed a roll call, reflected above, for the record and briefly reviewed the agenda..

### **Public Comment on Agenda Items**

Dr. Feemster invited public comment on the agenda. Ms. Theresa Wrangham, Executive Director, National Vaccine Information Center commented regarding the petition to add injuries for seasonal influenza vaccine to the Vaccine Injury Table (Table), and the presentation available online from the DICP stating there is insufficient medical research to support adding many of the items in the petition to the Table.

The National Childhood Vaccine Injury Act of 1986 that established the Advisory Commission on Childhood Vaccines (ACCV or Commission) spelled out a broad range of responsibilities for the Secretary of HHS to continually monitor and improve vaccines for children, which should include support for research. The Commission has recommended that Congress provide sufficient funds to underwrite that charge. There have been four successful petitions with regard to vaccine-induced multiple sclerosis related to influenza vaccine, which must have generated sufficient medical evidence to support the petitions, despite the indication that there is likely insufficient research-based evidence in the scientific literature. Ms. Wrangham suggested that the data provided by the petitioners in those four cases could be

helpful in the deliberations that will occur under the agenda item, although she doubted that it would be included in the DICP presentation.

Dr. Feemster noted that there were no other comments concerning the agenda.

### **Approval of March 3, 2016 minutes**

Dr. Feemster invited approval of the March 3, 2016 meeting minutes. On motion duly made and seconded, the minutes were unanimously approved.

### **Report from the DICP, Dr. Narayan Nair, Acting Director, DICP**

Dr. Nair welcomed all present and on the teleconference line, and expressed appreciation for their participation. Reviewing the agenda, he noted that the Department of Justice (DOJ) would provide an update, and that DICP would provide information about the petition to add injuries from seasonal influenza vaccines to the Vaccine Injury Table (VIT), and the Commission would hear updates from the ex-officio members (Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and National Vaccine Program Office (NVPO).)

Dr. Nair noted that, with four months remaining in the fiscal year, 707 petitions have been filed, continuing the consistent trend since 2011 of annual increases in petitions filed. As of June 1, 2016, there have been 346 compensable claims and two dismissed claims. Adjudications for non-autism claims totaled 346, made up of 96 (28%) compensable; 32 (9%) court decisions; and 218 (63%) by settlement. There were two claims dismissed. Asked about why the latter number was significantly lower than in previous years, Dr. Nair stated that no analysis of the dismissals had been made to explain the decrease.

Monetary awards for petitioners as of June 1, 2016, were over \$140 million, and attorneys' fees were about \$13 million. The Trust Fund stands at \$3.6 billion as of March 31, 2016, with excise tax revenue of \$130 million, interest income of \$27 million, for a net income of \$157 million.

Dr. Nair commented that the Notice of Proposed Rulemaking for the revisions to the Table was published in July 2015, the required public hearing was held on January 14, 2016 and the public comment period closed ten days later, on January 25, 2016. The Department is reviewing those comments in order to develop the final rule.

Recalling that a private citizen exercised the right to request the addition of injuries related to adding food allergies to the VIT, Dr. Nair commented that the Commission had reviewed that request and agreed not to make a recommendation regarding the petition. That citizen subsequently submitted additional information about the request, but after further consideration a decision was made to abide by the Commission's original determination.

Finally, Dr. Nair mentioned the DICP outreach activities. The revised VICEP web site was launched on February 19, 2016. DICP also participated in two major meetings in April --

the National Hispanic Medical Association Annual Meeting (in collaboration with FDA's Office of Women's Health), and a presentation to pharmacy students and pharmacists at Howard University.

In closing, Dr. Nair mentioned that the Senate had introduced a bill that would provide VICP coverage for pregnant women and in utero injuries related to maternal immunizations.

### **Report from the Department of Justice, Ms. Catharine Reeves, Acting Deputy Director, Torts Branch**

Ms. Reeves welcomed the commissioners and reported that Vince Matanoski has retired and that she is serving as the Acting Deputy Director. Ms. Reeves referenced the Department of Justice Power Point materials as part of her presentation for the three-month period from February 16, 2016 to May 15, 2016. As noted after the meeting, the DOJ statistics inadvertently included cases for which judgment had not entered, so these notes reference the amended presentation circulated on June 15, 2016 (Amended DOJ PP). During this reporting period, 206 petitions were filed. Of those, 38 were filed on behalf of children (18%) and 168 were filed by adults (82%). (Amended DOJ PP at 2). The number of new filings is slightly lower than in the previous reporting period.

With regard to total cases adjudicated, Ms. Reeves noted that 216 claims were adjudicated this quarter. (Amended DOJ PP at 3). There were 167 cases compensated. Of those 167 cases, 61 were conceded cases by HHS. Of those 61 conceded cases, 1 was resolved by a decision awarding damages, 59 were resolved by a decision adopting a proffer, and 1 was resolved by a decision adopting a settlement stipulation. Ms. Reeves noted that the number of cases adjudicated this period was similar to the number last period. There were 106 cases compensated but not conceded by HHS. Of those, all 106 cases were resolved by a decision adopting a settlement stipulation. (Amended DOJ PP at 3). There were 49 cases dismissed. Of those, 46 non-OAP cases were resolved by decisions dismissing the petition, and 3 were dismissed from the OAP. (Amended DOJ PP at 3). Ms. Reeves noted that it was not clear why there was a discrepancy between the 49 cases DOJ reported as having been dismissed and the 2 cases that DICP reported. There were 9 petitions voluntarily withdrawn, which Ms. Reeves remarked was an increase compared to last period. (Amended DOJ PP at 4).

Turning to appeals, six cases filed by petitioners were decided by the U.S. Court of Appeals for the Federal Circuit (CAFC). (Amended DOJ PP at 5). In *Padmanabhan v. HHS*, which was discussed at the last meeting, the CAFC affirmed the dismissal of the case per curiam, and petitioner filed a combined petition for panel rehearing and en banc rehearing. In *Moriarty v. HHS*, the CAFC vacated the decision by the U.S. Court of Federal Claims (CFC) and remanded the case. The CAFC affirmed in *D'Angiolini v. HHS* and *Milik v. HHS*, and affirmed per curiam in *Greenberg v. HHS* and *Nuttall v. HHS*. An affirmative appeal in *Guerrero v. HHS* was voluntarily dismissed by respondent. In addition to four appeals filed by petitioners that are pending, two new appeals were filed by petitioners in *R.K. v. HHS* and *Canuto v. HHS*, with the latter having been filed between the reporting period and this meeting. (Amended DOJ PP at 6).

Ms. Reeves discussed appeals at the CFC, and noted that six appeals filed by petitioners were decided by the CFC. Of those six, four were affirmed, one motion for review was denied with the prior decision dismissing the case for failure to prosecute being affirmed, and one motion for review was denied with the prior remand decision being affirmed. (Amended DOJ PP at 7). In addition, in

one appeal filed by respondent regarding attorney's fees and costs, the special master's decision was affirmed. Ms. Reeves noted that petitioners filed seven new appeals to the CFC, three of which were filed since submitting the initial DOJ PP. Those three are *Valle v. HHS*, *Murphy v. HHS*, and *Lasnetski v. HHS*. (Amended DOJ PP at 8). Respondent filed appeals in two cases regarding attorney's fees and costs, in *Simmons v. HHS* and *Garrison v. HHS*, with the latter having been filed between the reporting period and this meeting. Four cases remain pending at the CFC. (Amended DOJ PP 8).

No cases are scheduled for oral argument at the CAFC or CFC. (Amended DOJ PP at 9).

Ms. Reeves noted the history of adjudicated settlements, which are listed in order of the time they took to resolve. (Amended DOJ PP at 10-20).

Ms. Toomey asked whether it is quicker for a petitioner to proceed to hearing or settle. Ms. Reeves responded that settlements tend to proceed through the system quickly, but there are many reasons why cases can take longer to resolve. Ms. Reeves noted that one of the settlements that took years to resolve involved delays in obtaining medical records, significant pre-hearing procedural history, and an entitlement hearing, and the case settled after the hearing while the parties were waiting for a decision. Ms. Reeves commented that the VICP process still remains far quicker than the normal tort system.

Mr. Kraus commented on the discrepancy in the reported cases dismissed by DOJ and DICP, and requested that there be follow-up regarding the numbers. Ms. Overby commented that there may be a lag between when HHS receives the judgment from the court or DOJ. Ms. Reeves noted that the numbers will be confirmed and reported to the ACCV.

### **Petition to Add Injuries for Seasonal Influenza Vaccine to the Table, Terry Dalle-Tezze, Pediatric Team Lead, DICP**

Dr. Dalle-Tezze explained that the National Childhood Vaccine Injury Act of 1986 (the Act), authorized the Secretary of HHS to maintain the Table, and provided a way for the Secretary to modify the Table through the federal rulemaking process. The Act also allows any person to petition the Secretary to modify the Table and, unless frivolous, the petition is referred to the Commission for review and comment or recommendations. Once a comment has been submitted, the Commission has 180 days to submit a recommendation to the Secretary, who then either initiates the rulemaking process by publishing notice of proposed rulemaking in the Federal Register proposing changes to the Table, or publishes a statement in the Federal Register explaining the rationale for not conducting the rulemaking process.

Although most claims do not fit the parameters of the Table, a petitioner may seek compensation for an alleged injury by providing proof of causation, and/or proof of significant aggravation of an existing condition. The standard of proof is preponderance of evidence. The petitioner must show that the injury lasted more than six months, or resulted in an inpatient hospitalization and surgical intervention, or death. The ACCV has established and published guidance, "Guiding Principles for Recommending Changes to the Vaccine Injury Table." The Guiding Principles include two tenets: the Table revisions should be scientifically and medically credible; and any change should, whenever possible, be made to the benefit of the petitioner.

Dr. Dalle-Tezze provided an overview of his presentation which discussed a review of the medical and scientific literature regarding of neurological injuries and influenza vaccines; a discussion of the purpose of the DOJ quarterly report (which is reviewed at each Commission meeting), the role of the Vaccine Adverse Event Reporting System (VAERS), and a review of the medical literature related to multiple sclerosis and transverse myelitis as they relate to influenza vaccines. The discussion also considered two questions posed in the petition:

1. “There appears to be sufficient evidence to amend the VIT [Table] to include a "catch all" phrase with respect to adverse health conditions/injuries associated with the flu vaccine. The "catch all" phrase may read as follows: "any adverse neurological disorder or condition." This would preclude having to list each neurological condition separately. The timeline could be set at an appropriately agreed upon time post flu vaccination (e.g., 90 days).” This would cover all neurologic injuries and conditions that might pertain to influenza vaccine
2. “Should a "catch all" phrase not be used, at a minimum, the Table should list anaphylaxis, shoulder injury related to vaccine administration (SIRVA), vasovagal syncope, multiple sclerosis (MS), Guillain-Barrè Syndrome (GBS), transverse myelitis (TM), and myelitis as being associated with the flu vaccine.” It was noted that anaphylaxis is already covered by the Table for most vaccines.

Dr. Dalle-Tezze summarized the questions in the petition.

- First, should any or all neurologic disorders be added to the Table as an injury for influenza vaccine?
- Second, should multiple sclerosis and myelitis/transverse myelitis be added to the Table as injuries for the influenza vaccine?

The petition also cited the DOJ Quarterly Reports and the VAERS Reports as “sufficient evidence to amend the VIT,” because both specifically identify those injuries as being related to influenza vaccine. Dr. Dalle-Tezze suggested that the Commission is familiar with the DOJ Quarterly Reports since they are discussed at each ACCV meeting. The reports primarily provide statistical information about claims files, adjudications and final settlements. However, he stated that the settlement of a claim does not imply vaccine causation. There are many reasons to settle a case and the settlement does not provide a reliable rationale for any vaccine injury. That caveat is explained in detail on the VICP web site.

The value of the VAERS reports lies in the fact that over 30,000 reports are collected annually and although about 85% are mild reactions, the remaining reports include serious adverse events. VAERS is a voluntary passive reporting system that may include descriptive errors, incomplete information, underreporting, and VAERS provides no proof that the vaccine was a causative factor (only that the event occurred following vaccination). Nonetheless, it is a helpful tool in detecting new or rare events, monitoring any increases in adverse events,

identifying risk factors, and assessing the safety of new vaccines. Neither the DOJ Quarterly Reports nor the VAERS reports ascribe injury causality to any vaccine.

Dr. Dalle-Tezze discussed the response to question #1 in the petition stating that the medical and scientific literature does not support that any neurological disorder or condition is caused by influenza vaccines. The 2012 Institute of Medicine report, “Adverse Effects of Vaccines: Evidence and Causality”, which looked at a number of specific possible neurological conditions, concluded that there was inadequate evidence to accept or reject a causal relationship. With regard to the proposal to add any neurological disorder or condition to the Table, the proposal was too broad in scope to justify including any neurological injury, and the ACCV guideline that “the Table should be scientifically and medically credible” would not be met.

Concerning question #2, the list of specific conditions, one on the list, anaphylaxis, is currently on the Table for most vaccines, and is proposed as an addition for varicella, influenza, meningococcal and HPV vaccines. GBS, SIRVA and vasovagal syncope are also proposed as injuries for influenza vaccine. Question #2 also requested addition of MS, myelitis and TM, and the Department added acute disseminated encephalomyelitis (ADEM), although the latter was not in the petition request. There was a conclusion in the 2012 IOM report that the epidemiological data was insufficient to suggest a causal relationship between influenza vaccine and MS, and the report concluded that the evidence is inadequate to accept or reject a causal relationship. Other studies cited and found in the scientific literature do not support the theory that influenza vaccine causes MS, and that adding the injury to the Table would not comply with the guideline that the Table should be scientifically and medically credible. The 2012 IOM report also looked at myelitis and flu vaccine and came to a similar conclusion. Finally, although not in the petition, the IOM report also found that evidence in the medical and scientific literature does not support a causal link between ADEM and influenza vaccine.

Dr. Dalle-Tezze explained that the Commission has four options to consider for the addition of injuries for the influenza vaccine:

1. add all neurologic injuries to the Table;
2. add multiple sclerosis to the Table;
3. add myelitis/transverse myelitis to the Table; and/or
4. add none of the above to the Table.

Dr. Feemster invited questions and comments. Mr. Smith asked for comments from the physicians on the Commission and Dr. Feemster observed that, from Dr. Dalle-Tezze’s presentation, it appears clear that there is no reliable causal relationship between the flu vaccine and the injuries discussed. Dr. Nair added that, even without the additions to the Table, claimants can still pursue compensation. There was a concern that the term “all neurologic injuries” was too broad. It would include autism spectrum disorder, which may not be appropriate. There was also a comment that the Commission had not heard conclusive evidence that MS and myelitis have a clear flu vaccine-related causal relationship. Finally, opting for the fourth proposal (add nothing discussed to the Table) does not preclude revisiting the issues in the future.

On motion duly made and seconded, the Commission unanimously approved the fourth option, “Do not add any of the above to the Table” for influenza vaccines.

Dr. Feemster invited reports from the ex officio members.

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

Dr. Cano provided an update of the February 2016 Advisory Committee on Immunization Practices (ACIP), addressing selected sessions beginning with the session on human papillomavirus (HPV) vaccines. The U.S. administers a three-dose schedule for 4-valent, 9-valent and 2-valent HPV injections. Merck is conducting a clinical trial of a two-dose 9-valent vaccine that appears to compare favorably with the present 3-dose regimen. The FDA is reviewing that clinical trial. Merck is also looking at a 2-dose schedule for a 4-valent vaccine, but does not intend to submit the data to FDA. The transition to the 9-valent vaccine should be completed by the end of 2016.

With regard to meningococcal disease, there have been outbreaks of the disease in men who have sex with men (MSM), and HIV infection increases the risk of infection. During the outbreaks, MenACWY vaccine was recommended for MSM and there is a consideration for recommending the vaccine for HIV-infected individuals as well as MSM. Further studies are needed to better understand the epidemiology. Next steps include continued vaccination with MenACWY and enhanced surveillance of the populations at risk, cost effectiveness and GRADE analyses are in progress.

Dr. Cano explained that Ixiaro (Valneva) is the only vaccine available in the U.S. for Japanese encephalitis. It was licensed in 2009 for adults. In 2012 ACIP recommended a booster dose, and in 2013 the age range recommendation was extended to children 2 months old or older. ACIP will probably update its original 2010 recommendation; FDA is reviewing safety and efficacy data that might justify a booster dose for children.

Dr. Cano discussed influenza vaccine effectiveness, noting that for the 2015-2016 flu season an interim assessment of effectiveness against medically-attended flu was 59%, higher than the previous year's flu season when effectiveness was measured at 30% (when a different vaccine was administered). That number might change for post-season results. The manufacturer of the flu vaccines, Protein Sciences Corporation, released data from an analysis comparing quadrivalent recombinant-IIV (RIV4) with IIV4 and PCR confirmed that incidence of flu-like illness was lower with the recombinant version (2.2% versus 3.3%). Both vaccines had similar safety profiles. Injection site pain and tenderness were lower with the RIV4 formulation.

A review of the scientific literature reveals that in egg-allergic recipients there was a low rate of minor adverse reactions. Rare serious adverse events, and immediate hypersensitivity reactions were similar in both egg-allergic recipients and in recipients who were not egg-allergic. In studies of live attenuated influenza vaccine (LAIV) there were no systemic reactions observed (both LAIV and IIV have very low amounts of egg protein).

Dr. Cano stated that the ACIP formally voted on the following recommendations:

- Annual influenza immunization continues to be recommended for all individuals aged 6 months or older.
- Vaccine should be offered by the end of October, and as long as the virus is circulating and vaccine is available.
- Remove the 30-minute post-inoculation observation, except for a 15-minute period for syncope.
- Persons with egg allergies who have required epinephrine therapy for adverse reactions may receive any licensed flu vaccine.
- Wording requiring a consult for individuals suspected of having an egg allergy, with or without history of allergic reaction to eggs, will be removed. And the algorithm on egg allergy will be removed.

Dr. Cano briefly referred to a number of recent publications:

- Haber et al reported on post-licensure surveillance data from VAERS that indicated that quadrivalent inactivated flu vaccine had a similar safety profile to trivalent inactivated flu vaccine, and most reactions were non-serious. The data were similar to pre-licensure studies. (Vaccine Mar 23, 2016)
- Miller et al, in a similar study of VAERS data on 23-valent pneumococcal polysaccharide vaccine, showed no new or unexpected safety concerns and the data were similar to pre-licensure studies. (Vaccine Apr 14, 2016)
- Baxter et al reported data on various vaccines and risk of optic neuritis that showed no association between any vaccine and the disorder. (Clin Infect Dis. April 10, 2016)
- Li et al, using data from the Vaccine Safety Datalink, showed no increased risk from flu vaccine during the flu seasons from fall 2013 through the 2014-2015 flu seasons. The exception was febrile seizures that were reported previously. (Pharmacoepidemiol Drug Saf, April 1, 2016)
- Gee et al looked at quadrivalent HPV vaccine and confirmed that pre-licensure and post-licensure 4vHPV safety data has been reassuring as to safety. (Hum Vaccine Immunother, Mar 30, 2016)
- Baxter et al analyzed a large database and found no association between influenza vaccine or any other vaccine and sudden-onset sensorineural hearing loss. (Otolaryngol Head Neck Surg. Mar 29, 2016)
- Moro et al relying on VAERS data, found no unexpected adverse events in pregnant women who received Tdap. (Vaccine Mar 22, 2016)
- Schiffer et al described recent developments in the understanding and use of anthrax vaccine adsorbed (BioThrax is the only FDA-approved vaccine for prevention of anthrax in humans). (Expert Rev Vaccines, Mar 25, 2016)
- Su et al reviewed an MMWR article describing a VAERS report of inappropriate administration of the meningococcal conjugate vaccine, Menveo, when providers administered only one of two required vaccine components. (MMWR Morb Mortal Wkly Rep, Feb 19, 2016)

Dr. Cano concluded her presentation.

**Update from the National Institute of Allergy and Infectious Diseases (NIAID, NIH),  
Vaccine Activities, Dr. Barbara Mulach, NIAID, NIH**

Dr. Mulach began her presentation with background about the Zika virus. As of May 2016, Zika was present in 60 countries and territories, 14 of which have reported infections contracted between 2007 and 2014. Also as of May 2016, there were 591 travel-associated cases in the U.S., but no locally acquired infections. However, in U.S. territories there have been 939 cases reported, 935 of which were locally acquired. NIH has an existing screening program to identify potential therapeutics for flaviviruses, and Zika virus was added to that program. Research has been initiated to look at the biology/structure/evolution of the virus and the nature of the mosquito vectors. NIH will also build on existing research programs to develop vaccines, diagnostics and therapeutics, and to better understand the mechanism of the pathogenesis involved. For example, there is DNA vaccine research built on a platform that developed such a vaccine for West Nile virus, and work on a live attenuated Zika chimera vaccine relying on previous research on a dengue vaccine.

Dr. Mulach explained that the research involves collaboration with other institutions in the U.S. and abroad, looking at the epidemiology and natural history of Zika virus infection, and there is a focus on the incidence and adverse outcomes in infected pregnant women, including a collaboration with NICHD.

Recalling an earlier briefing on dengue fever research, Dr. Mulach commented that a Phase III clinical trial is soon to be initiated in Brazil, and the Commission will be regularly informed of its progress. Finally, Dr. Mulach described a collaboration between NIAID and the manufacturer of a malaria vaccine, PfSPZ, which showed efficacy in a Phase I trial of 101 healthy adults. The vaccine seems to show long-term protection that would be beneficial to travelers and military personnel, and durable protection for populations residing in malaria-endemic regions.

Dr. Mulach announced that NIH had awarded six grants to support research on combination adjuvants to improve vaccine response and effectiveness. There is also research being supported to look at influenza vaccine efficacy. Finally, a large clinical trial (5,400 participants) looking at a combination of two HIV vaccines is expected to begin in South Africa in November 2016.

**Update from the Center for Biologics, Evaluation and Research (CBER), FDA,  
Vaccine Activities, LCDR Valerie Marshall, CBER, FDA**

LCDR Marshall addressed FDA vaccine supplement approvals, and emergency preparedness. In April, 2016, the FDA approved a supplement to the biologics license application (BLA) for Trumenba, a meningococcal Group B vaccine for individuals age 10 to 25. The approval included a two-dose schedule (modifying the previous 3-dose schedule) for administration of the vaccine at 1-2 months and at 6 months. Also in April, the FDA approved

several BLA supplements to change product labeling for 14 vaccines. The change involved informing users that the product or product container is not made with natural rubber latex.”

In March, 2016, the FDA approved a supplement to the BLA for Afluria, an influenza virus vaccine, to include non-seasonal updates to the package insert, including updates to the post-marketing adverse event terms; and information related to Afluria exposure and surveillance information related to pregnant women. Also in March, the FDA approved a supplement to the BLA for Fluzone quadrivalent vaccine to include the 2016 Southern Hemisphere formulation (recommended by WHO).

LCDR Marshall commented on several issues related to emergency preparedness. In late March, FDA participated in the WHO consultation on a rationale for a vaccine efficacy trial during public health emergencies (integrating infectious disease modeling). In early May, FDA participated in the second WHO consultation on regulatory considerations for the evaluation of Ebola vaccines intended for emergency use. And in early June, FDA will participate in a WHO consultation on potential regulatory approval pathways for Zika vaccine in emergency situations. There are no FDA-approved vaccines for Zika.

LCDR Marshall concluded her report.

**Update from the National Vaccine Program Office (NVPO)  
Dr. Cristina Herrera, NVPO**

Dr. Herrera explained that the vaccine prioritization tool software, SMART Vaccines 2.0, will conduct a stakeholders meeting at the end of June 2016. The tool was developed by the Institute of Medicine and there is collaboration between NVPO and the Fogarty International Center to continue its development.

Dr. Herrera commented that NVPO coordinates and leads the Immunization Safety Task Force (ISTF). The Task Force ensures that all federal efforts relevant to immunization safety are coordinated and integrated and that opportunities to enhance synergies across the federal government in immunization safety are identified. The Task Force has held two meetings, one on chimeric yellow fever dengue vaccines, and one on surveillance of Guillain-Barre syndrome in the U.S as it relates to the Zika virus epidemic.

Dr. Herrera noted that NVPO supported a vaccine safety publication submission for a paper entitled, “Unique Safety Issues Associated with Virus-vectored Vaccines: Potential for and Theoretical Consequences of Recombination with Wild Type Virus Strains.”

Finally, Dr. Herrera stated that NVPO is re-establishing the Vaccine Safety Fellowship program, which she will be supervising. NVPO has committed additional funding of \$500,000 to support vaccine safety through the NVPO 2017 Cooperative Agreement. The NVPO awards for vaccine safety research will be introduced at the June NVAC meeting, to be awarded in September.

**Public Comment**

Dr. Feemster invited public comment.

Ms. **Theresa** Wrangham, **Executive Director, National Vaccine Information Center (NVIC)**, clarified her earlier comment about the value of evidence available in the petitions and claims filed and settled. She felt that such information would be helpful to the Commission's deliberations.

Regarding the adequacy of awards, noting the case of the petitioner who requested review of what was considered an insufficient award, Ms. Wrangham commented that there is no mechanism to assess the satisfaction/dissatisfaction of petitioners who receive awards. There has been no such survey since the 2009 Altarum Report. The announcement of the improved number of settlements and the improved speed with which the cases are being resolved was welcome, but information about the quality of those settlements is lacking. The NVIC request that the Commission revisit the 2009 Altarum Report, the 2010 Banyan report, and the 2014 General Accountability Office (GAO) report and prepare a report on progress made and what is needed to improve awareness of and satisfaction with the VICP.

The NVIC also renews its request that the ACCV issue a statement that the use of vaccines carries a risk of injury and, because of that risk, the ACCV supports the right of every parent to provide informed consent and to make choices about administering vaccines to their children.

Finally, a process should be in place to include the opportunity for those who petition for addition/revision to the Table to provide evidence to clarify the request in the petition.

Dr. Feemster stated that there were no other requests to participate in public comment.

#### **Future agenda items and New Business, Dr. Kristen Feemster, Chair**

Dr. Feemster invited suggestions for future agenda items. There was a suggestion that the Commission address the public comment issue on informed consent; and that working group meetings be scheduled. Although not firm, the tentative date for the next meeting is September 20, 2016.

#### **Adjournment**

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