

Advisory Commission on Childhood Vaccines

September 20, 2016

101st Meeting

Members Present

Kristen A. Feemster, M.D., Chair ('16)

Jason Smith, J.D., Vice Chair. ('16)

Charlene Douglas, Ph.D. ('16)

Edward Kraus, J.D., ('16)

Luisita dela Rosa, Ph.D. ('16)

Karlen E. Luthy, D.N.P., ('18)

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., Acting Director, DICP

Andrea Herzog, Principal Staff Liaison, ACCV

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 to confirm those in attendance.

Public Comment on Agenda Items

Dr. Feemster invited public comment specifically related to the agenda. There was none.

Approval of June 2016 ACCV Meeting Minutes

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

Report from the Division of Injury Compensation Programs, Dr. Narayan Nair, Acting Director, DICP

Dr. Nair briefly reviewed the meeting agenda, which would include an update from the Department of Justice Vaccine Litigation Office, a report from the ACCV Process Workgroup, and the regular updates from the ex officio members representing the various Department of Health and Human Services (HHS) agencies. Noting that the DICP is on a fiscal year (FY) ending September 30, 2016, Dr. Nair reported that as of September 2, 2016, the division had received 986 petitions. The average number of petitions filed annually for the 5-year period beginning FY 2011 was 546. There has been an increase in petitions filed each fiscal year since then.

The number of compensable adjudications has increased annually from 266 in FY 2011 to 556 through September 2, 2016 of this fiscal year. The total number of adjudicated cases in FY 2011 was 1,637, of which 1,371 were dismissed. In FY 2016, there was a total of 718 adjudications through September 2, 2016, of which 162 cases were dismissed.

A 3-year snapshot of non-autism adjudications was presented to the commissioners. There were 581 compensable non-autism claims adjudicated in FY 2016 as of September 12. The 581 non-autism claims adjudicated were broken down into three categories: concession by the HHS, 171 (29%); court decisions, 41 (7%); and the majority by settlement, 369 (64%). There were 151 claims deemed not compensable, making a total of 732 non-autism adjudications in FY 2016 as of September 12, 2016.

Through September 1, 2016, the program awarded \$191 million to petitioners, and approximately \$20 million for attorneys for fees and costs. The Vaccine Injury Compensation Trust Fund stood at \$3.6 billion as of August 31, 2016. The sources of revenue were \$221 million from excise taxes and \$50 million from interest on investments, for a total of nearly \$272 million. Interest as a percentage of income was 19%.

Dr. Nair commented that the Notice of Proposed Rulemaking (NPRM) for revising the Vaccine Injury Table was published in the Federal Register on July 29, 2015. To obtain public comments, a public hearing was held on January 14, 2016 and a 180-day public comment period ended on January 25, 2016. The public comments were reviewed and a final rule has been developed which is being reviewed by the HHS. With regard to outreach, on August 9, 2016, Dr. Nair stated that he had provided an overview of the VICP to representatives of the Association of State and Territorial Health Officials (ASTHO).

Dr. Nair concluded his prepared remarks with instructions about obtaining ACCV meeting information and about how to contact ACCV support staff.

During the discussion, Dr. Nair was asked about the estimated release date of the Final Rule revising the Vaccine Injury Table, Dr. Nair said it is expected to be published by the end of the calendar year.

Report from the Department of Justice, Catharine E. Reeves, Acting Deputy Director, Torts Branch

Ms. Reeves welcomed the commissioners. Ms. Reeves referenced the Department of Justice PowerPoint materials as part of her presentation for the 3-month period from May 15, 2016 to August 15, 2016. During this reporting period, 276 petitions were filed, which is an increase of 70 petitions compared to last period. Of those 276, 30 were filed on behalf of children (11%) and 246 were filed by adults (89%). (DOJ PP at 2).

With regard to total cases adjudicated, Ms. Reeves noted that 233 claims were adjudicated this quarter. (DOJ PP at 3). There were 180 cases compensated. Of those 180 cases, 67 were conceded cases by HHS. Of those 67 conceded cases, 65 were resolved by a decision adopting a proffer, and 2 were resolved by a decision adopting a settlement stipulation. Ms. Reeves noted that 17 more cases were adjudicated this period than last period. There were 113 cases compensated, but not conceded by HHS. Of those, all 113 cases were resolved by a decision adopting a settlement stipulation. (DOJ PP at 3). There were 53 cases dismissed. Of those, 51 non-OAP cases were resolved by decisions dismissing the petition, and 2 were

dismissed from the OAP. (DOJ PP at 3). There were 13 petitions voluntarily withdrawn, which Ms. Reeves remarked was an increase of 4 compared to last period. (DOJ PP at 4).

Turning to appeals, one case filed by petitioners was decided by the U.S. Court of Appeals for the Federal Circuit (CAFC). (DOJ PP at 5). In *Milik v. HHS*, the CAFC affirmed the dismissal of the case per curiam, and petitioner filed a combined petition for panel rehearing and en banc rehearing, which was denied. In addition to three appeals filed by petitioners that are pending, six new appeals were filed by petitioners in *Canuto v. HHS*, *R.V. v. HHS*, *Culligan v. HHS*, *Fishk is v. HHS*, *Meylor v. HHS*, and *Meylor v. HHS*. (DOJ PP at 6).

Ms. Reeves discussed appeals at the CFC, and noted that five appeals filed by petitioners were decided by the CFC. The CFC affirmed the denial of compensation in all five cases. (DOJ PP at 7). Ms. Reeves noted that petitioners filed eight new appeals to the CFC, most of which involve entitlement, but some of which involve attorneys' fees and costs. (DOJ PP at 8). Respondent filed appeals in two cases regarding attorneys' fees and costs, in *Allicock v. HHS* and *Garrison v. HHS*, and in one case involving a special master's award of interim damages. Six cases remain pending at the CFC. (DOJ PP 8).

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

Ms. Reeves noted the history of adjudicated settlements, which are listed in order of the time they took to resolve. (DOJ PP at 10-21).

Report from the ACCV Process Workgroup, Ms. Martha Toomey, ACCV Member and Workgroup Chair

Ms. Toomey summarized the recommendations proposed by the Workgroup that would address the existing inadequate funding and lack of staff support (both special masters and staff). The Workgroup felt that there were not enough special masters to properly handle the caseload, the result of increased petitions being filed (an increase of 80% in three years between 2013 and 2015, from 525 to 945). That has resulted in a backlog of cases that may eventually result in delayed compensation for vaccine-injured individuals who submit legitimate claims.

The Workgroup decided not to dilute the initial recommendation and to focus on the most important issues, lack of special masters and inadequate funding. The workgroup proposed a recommendation that would require a legislative amendment to the National Childhood Vaccine Injury Act of 1986, which contains the words the "office of special masters shall consist of not more than 8 special masters." The new wording would be: the "office of special masters shall consist of *at least* 8 special masters." A second recommendation proposed by the Workgroup was that the Secretary support an increase in the appropriations for the Office of Special Masters (OSM) to pay for additional special masters and VICP staff at HRSA, DOJ and OSM.

Ms. Toomey explained that the draft letter would be kept short and focused, but that supporting documentation, including statistics, would be attached. The final letter would be submitted to the Commission for review, revision, if deemed appropriate, and submission to the Secretary.

Ms. Jocelyn McIntosh, Senior Staff Attorney, OSM commented that Chief Special Master Dorsey had requested that a message be relayed to the Commission. Chief Special Master Dorsey, wanted the commission to know that she appreciated their interest in and consideration of her remarks when she participated in the March 2016 ACCV meeting. Ms. McIntosh, expressed the Chief Special Master's thanks for the Commission's diligent work in developing the recommendation.

Noting that the Commission had considered the recommendation, Dr. Feemster invited a motion to approve the submission of the recommendation to the Secretary of HHS.

On motion duly made and seconded, the Commission unanimously approved submitting the recommendation as written to the Secretary.

Ms. Toomey stated that the Workgroup had other items that were being discussed and recommendations related to those items (including a change in the statute of limitations and the inclusion of a vaccine-injured individual on the Commission) would be discussed by the Workgroup and included on a future meeting agenda.

Noting that the Commission had been especially efficient in conducting the first agenda items, Dr. Feemster re-ordered the agenda to accommodate those presenters who were scheduled after the lunch break. She invited LCDR Valerie Marshall to discuss FDA activities.

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

LCDR Marshall briefly reviewed her presentation, which would address recent vaccine approvals, the upcoming Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to be held on October 13, 2016, and the FDA emergency preparedness response to the Zika threat.

Regarding new approvals, LCDR Marshall discussed the approval in June 2016 of a cholera vaccine (live, oral) trade name Vaxchora. Cholera is caused by *Vibrio cholerae* serogroup 01. The vaccine is approved for adults 18 to 64 years of age who may be traveling to cholera-affected areas. Vaxchora is the only FDA-approved vaccine for cholera, and it is approved specifically for travelers to those high-risk areas. FDA granted this application fast track designation and priority review status.

In May 2016, the FDA approved a supplement to the biologics license application (BLA) for influenza vaccine, Flucelvax, manufactured by Seqirus, that adds a fourth strain to the mix, making it a quadrivalent formulation. Flucelvax quadrivalent is the first four-strain flu vaccine and it is indicated for persons four years of age and older.

In July 2016, the FDA approved a supplement to the BLA for Prevnar 13, expanding the indication to adults 18 through 49 years of age for the prevention of pneumonia. Prevnar is effective against 13 serotypes of *S. pneumoniae*. It was previously approved for children 6 through 17, and adults 50 and older. This change expanded the age indication for receipt of the vaccine.

Finally, in July 2016, the FDA approved a strain change supplements to the BLAs for licensed influenza vaccines to include the 2016-2017 seasonal influenza vaccine formulation. Flu vaccine lots released by the FDA are available for distribution by the manufacturers.

LCDR Marshall announced that one VRBPAC meeting is scheduled on October 13, 2016, to discuss the selection of strains to be included in an influenza virus vaccine for the 2017 Southern Hemisphere influenza season.

LCDR Marshall mentioned that investigational Zika virus vaccines are in the early stages of development. In June 2016, the FDA authorized the first clinical trial for an experimental Zika virus vaccine. The FDA will work with industry to clarify regulatory and data requirements necessary to move the product development forward as expeditiously as possible. During discussion, LCDR Marshall clarified that the term “early stages of development” indicates that the new vaccines have not been tested in humans and have not undergone the standard FDA

clinical trial reviews for new products. New drugs are tested in animals before beginning Phase I studies. There was a brief discussion of the potential of using existing drug development platforms for Zika virus vaccine.

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

Ms. Schuster described a large NIH-supported natural history study of Zika virus in pregnant women, which began in Puerto Rico and will expand to other countries including Brazil and Colombia. The study will enroll up to 10,000 pregnant women in their first trimester and observe them for the duration of their pregnancies with at least one-year of follow-up for their infants after birth. The National Institute of Allergy and Infectious Diseases (NIAID) began a study in August, enrolling up to 80 participants at three sites in the U.S., to evaluate a candidate Zika vaccine. The Phase I trial will assess efficacy and safety.

The journal, *Science*, reported on a study of three candidate Zika vaccines, an inactivated vaccine, a DNA-based vaccine, and an adenovirus vector-based vaccine. These vaccines protected against infection, induced immune responses, and showed no adverse side effects when tested in rhesus macaques. Another paper was published in *Nature*, that looked at two experimental Zika vaccines, a DNA-based vaccine and an inactivated virus vaccine. Both were tested in mice and a single dose of the vaccines protected against the Zika virus. Finally, the National Institute of Child Health and Development (NICHD) will sponsor a meeting in late September to look at how Zika virus affects child development.

In 2013, approximately 84,000 to 170,000 individuals worldwide were infected with yellow fever, with 29,000-60,000 deaths. The current yellow fever vaccine is in short supply and not recommended for certain populations, such as infants and pregnant women. An investigational vaccine developed by Bavarian Nordic is being evaluated in an NIAID-sponsored Phase I trial for its safety, tolerability, and potential ability to prevent yellow fever infection. The trial will enroll 90 healthy individuals who have never been infected by a flavivirus (the family of viruses that includes dengue, Zika, West Nile, among other viruses). The trial will assess the vaccine with and without an adjuvant.

NIAID continues to support influenza vaccine research, including a study that has led to the discovery of antibodies that can target multiple influenza strains. This study is discussed in a paper in the July 21 online edition of *Cell*. Additional publications of interest include a report in *Vaccine* (August 23, 2016) on a FDA/NIH workshop on respiratory syncytial virus (RSV) vaccines; and a summary of findings from an NIAID-sponsored workshop on gonorrhea vaccines in *Clinical and Vaccine Immunology* (August 5, 2016).

Although not specific to vaccines, Ms. Schuster mentioned the Cancer Moonshot initiative announced by President Obama in his State of the Union address in January. The Cancer Moonshot is led by Vice President Biden and seeks to broaden cancer diagnosis, prevention, and treatment in the U.S. Finally, on September 8, NIH announced the Antimicrobial Resistance Diagnostic Challenge which will award \$20 million in prizes for innovative point-of-care, in vitro, diagnostic tests to rapidly identify antibiotic-resistant infections. The prize is offered by NIH and the HHS Office of the Assistant Secretary for Preparedness and Response.

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

Dr. McNeil announced that he would provide an update of the recent meeting of the Advisory Committee on Immunization Practices (ACIP); and discuss several recent publications that might be of interest to the Commission. In their session on cholera, the ACIP recommended Vaxchora, previously mentioned in the FDA vaccine activities update, for travelers 18 to 64 years of age who are at increased risk of disease as described below. Although *Vibrio cholera* 01 infection can be effectively treated with timely rehydration, the disease can be fatal, if untreated. Individuals who are especially at risk include those with blood type O, pregnant women, those with immunocompromising conditions and those with cardiovascular and/or renal disease.

Dr. McNeil noted that the FDA had revised the dosing schedule for meningococcal B vaccine, Trumenba, as a 2-dose and a 3-dose schedule (the FDA noted a preference for the latter). For the meningococcal conjugate vaccine, ACIP voted unanimously to recommend meningococcal conjugate vaccine be administered routinely to HIV-infected people age two years and older. This was because it is now clear there is an increased risk in HIV-positive individuals.

Dr. McNeil commented that two new influenza vaccines are available. Flucelvax quadrivalent vaccine, licensed in May 2016, showed an immune response and evidence of safety and tolerability similar to the previous trivalent vaccine. FluLaval was licensed for persons three years and older, and the manufacturer (GSK) has submitted a supplemental BLA to revise the vaccine's age indication downward to include persons 6 month to 35 months. GSK presented safety and immunogenicity data that showed the vaccine compared favorably with Fluzone quadrivalent. An ISO report to the committee of end-of-season influenza safety monitoring revealed that analysis of the Vaccine Adverse Event Reporting System (VAERS) showed no new safety concerns regarding influenza vaccines. The CMS Medicare database did reveal an increased rate of Guillain-Barré Syndrome (GBS), 7.25 cases per million inoculations, up from 5.45 cases per million. The Vaccine Safety Datalink (VSD) identified a signal for GBS following inactivated influenza vaccine (IIV3) of 2.6 cases per million inoculations. These rates are similar to earlier surveillance figures. Asked about the discrepancy in the CMS data, Dr. McNeil explained that, historically, there has been low or no risk of GBS found in different studies and work is ongoing to better refine the risk estimate for this rare outcome.

An evaluation of vaccine effectiveness of IIV and live attenuated influenza vaccine (LAIV) against influenza A and B, revealed the latter was significantly less effective in children 2-17 years old. An AstraZeneca study released effectiveness percentages: LAIV4, 46%, and IIV, 65%. The third vote of the meeting was that ACIP recommends that the LAIV should not be used for the 2016-2017 flu season. A Vaccine for Children (VFC) program vote followed to remove LAIV from the VFC program for the 2016-2017 influenza season.

Dr. McNeil commented that there was a presentation on respiratory syncytial virus (RSV) infection that showed that children under two are most vulnerable, although there is also a significant disease burden in older adults. A formalin-activated vaccine failed in Phase I trials in the sixties, causing vaccine-enhanced disease syndrome in RSV-naïve infants. However, there are currently Phase I clinical trials of a candidate vaccine for children, and Phase I-III trials for a vaccine in pregnant women.

The ISO presented a summary at ACIP of VAERS data for pregnant women, indicating no new unexpected vaccine safety concerns; and the VSD found that Tdap during pregnancy was

not associated with an increased risk of birth defects among live offspring. The Clinical Immunization Safety Assessment (CISA) Project reported that Tdap was well tolerated in both pregnant and non-pregnant women. Moderate to severe injection site pain was more frequent among pregnant women, but did not lead to repeat medical visits for that issue. Half of the pregnant women had received a prior Tdap injection, but reactions were similar in all patients regardless of earlier Tdap injections. Both pregnant and non-pregnant women had significantly higher antibodies to all antigens after inoculation.

Finally, the human papillomavirus (HPV) vaccines show no evidence of waning protection after a 3-dose schedule, and antibody responses were maintained over time after the same vaccination schedule. Of 13 studies, 10 showed that 2 doses were not as effective as 3 doses. The ACIP is considering a proposed recommendation of two doses of HPV vaccine for children who begin inoculations before their 15th birthday (0 and 6-12 months); and a three dose schedule for those who have reached the age of 15 (0, 1-2, and 6 months).

Dr. McNeil briefly mentioned several publications that might be of interest to the Commission.

Duffy et al. looked at febrile seizure risk in children 6-23 months (*Pediatrics*. 2016; 138). Giving IIV3 and either pneumococcal conjugate vaccine or a DTaP-containing vaccine was associated with increased risk of febrile seizure.

Sawyer et al. quantified the risks associated with vaccines and febrile seizures (*Pediatrics*. 2016; 138). This review found that although the risk of febrile seizure is very small (estimated as ~1 episode in a 5-year period in pediatric office practice), the benefit of receiving the vaccine far outweighs the risk. It was noted that the study looked at febrile seizure and not later sequela.

Stockwell et al. assessed fever frequency after pediatric LAIV versus IIV vaccination. (*J Pediatric Infect Dis Soc*. 2016 Jun 14) Post vaccination fever frequency was low overall and did not differ with regard to vaccine type during the 2013-2014 flu season.

Moro et al. looked at post-marketing surveillance of human rabies diploid cell vaccine (Imovax) from 1990 to 2015 in VAERS. (*PLoS Negl Trop Dis*. 2016; 10(7)). The analysis did not identify any new or unexpected adverse events. The majority of adverse events reported were non-serious.

Lindsey et al. looked at VAERS reports following yellow fever vaccination from 2007-2013 (*J Travel Med* 2016 23(5)). The report substantiates the generally accepted safety profile of yellow fever vaccine, and encourages continued physician and traveler education.

Bardenheier et al. analyzed VAERS data on military and civilian personnel receiving the pandemic influenza A (H1N1) 2009 monovalent and seasonal flu vaccines during the 2009-2010 season (*Vaccine* 2016; 34(37)). Despite higher vaccination coverage in service personnel the rate of adverse events reported was about half that in civilians. The rate of GBS was higher in the military personnel.

Vazquez-Benitez et al. looked at the risk of small-for-gestational-age births after flu vaccination during pregnancy (*Am J Epidemiology* 2016 184(3)). Confounding factors include potential biases in outcomes that could be due to variable access to vaccines, and baseline differences between vaccinated and unvaccinated women.

Clogston et al. looked at unintentional administration of insulin instead of influenza vaccine (*Drugs Ther Perspective* Aug. 2016). The assessment revealed that deviations from recommended practices contributed to the adverse event, which would be preventable with proper training and controls.

Moro and Chen published a commentary in *Vaccine* 2016 Aug 20. The Global Alignment of Immunization Safety Assessment in pregnancy, and international collaboration associated with the Brighton Project, has developed 10 obstetric and neonatal definitions, along with tools to harmonize data collection, analysis and presentation. Vergnano et al. developed a case definition for neonatal infection immunization safety data (in *Vaccine* 2016 Aug. 1); and DeSilva et al. did the same for congenital anomalies (in *Vaccine* 2016 Jul. 16).

Dr. Feemster noting that the ex officio reports had been completed, suggested that the Commission continue to the Vaccine Information Statements.

Review of Vaccine Information Statements, Skip Wolfe, CDC

MMRV Vaccine (Measles, Mumps, Rubella and Varicella): What you need to know

Mr. Wolfe invited comment on the first section, “Why get vaccinated?” He noted that wording had been crafted to indicate that the four diseases covered by MMRV vaccine were not inherently serious diseases, and could have relatively mild symptoms, but those infected could experience serious consequences. It was noted that, per custom, words of four or more syllables are typically not used in the text of the VIS – specifically “consequences.” Mr. Wolfe felt the word should not be an obstacle to readers, but he would look for an appropriate synonym of three or fewer syllables. Mr. Wolfe also agreed that a suggestion that the words “especially among children” should be deleted. He added that there were separate VIS for MMR and varicella and the wording in those VIS had been harmonized with this MMRV version. There was a brief discussion about using the word “tiredness,” and Mr. Wolfe said that his staff would reconsider the wording. There was an observation that death could be a rare outcome of any of the four diseases, although only mentioned under measles and mumps. Mr. Wolfe agreed that death could be incorporated in the introductory sentence applying to all four (and deleted from measles and mumps).

Mr. Wolfe moved to the second section, for which there were no comments. In the third section, “Some people should not get this vaccine,” Mr. Wolfe noted that there had been some minor structural changes to the paragraphs. In the fourth section, concerning risks, Mr. Wolfe suggested that the wording of the second paragraph be revised to read, “Most children who get MMRV vaccine do not have any *serious* problems with it.” There was also a suggestion that the first sentence in that paragraph should address the fact that there is a risk of adverse reaction when being inoculated with any vaccine. The recommendation was to use a term like “less serious” rather than safer.

Mr. Wolfe commented that a sentence was added to the section entitled “Minor problems following MMRV vaccine include,” to explain that if a rash develops there is a possibility of contagion, albeit a rare event. In the paragraph on severe problems, the term “lowered consciousness” was deemed vague. There was a suggestion that it indicates a change in alertness or awareness. In the same section there was a comment that the sentence, “These reactions happen so rarely that it is difficult to tell whether they are caused by the vaccine,” might suggest that the severe, rare problems are not caused by the vaccine. That might be misleading. There was a counter argument that it is, in fact, difficult to determine causation. Mr. Wolfe commented that the thoughts expressed would be useful in reconsidering the wording.

There was a comment that the Commission had previously agreed that the term “health care provider” should be used instead of “doctor.” Mr. Wolfe agreed that there had been a significant number of opinions offered concerning the two terms. After a brief discussion about the rationale for using the terms, Mr. Wolfe said that, if the term healthcare provider is clearly understood universally, he would be amenable to using the term rather than “doctor” throughout all VIS. Mr. Wolfe explained that the rest of the document contained wording that appears in all VIS. Since that wording had been reviewed a number of times, he suggested that the review was complete.

Dr. Feemster concluded the discussion of the VIS and moved to the public comment period.

Public Comment

Ms., Theresa Wrangham, representing the National Vaccine Information Center (NVIC), expressed appreciation to staff for the timely placement of the meeting book on the ACCV website. She emphasized the importance of having that prepared information available to supplement the meeting’s verbal discussions.

Ms. Wrangham recommended that, in addition to the Process Workgroup’s recommendation for the Secretary to increase the number of special masters and support staff for the special master’s office, that a recommendation be included to increase funding for research to fill the gaps in knowledge identified by the Institute of Medicine study. That research would support the expansion of the Vaccine Injury Table when appropriate quality research is available. The NVIC requested that the Commission support the premise that research must be funded outside the bounds of the Vaccine Injury Compensation Trust Fund. The NVIC recommended that the Commission establish a mechanism by which the satisfaction of petitioners, especially in light of experiences reported by petitioners who were dissatisfied with the awards made by the program. The Commission should review the comments in the 2009 Altarum report, the 2010 Banyan report and the 2014 GAO report.

Ms. Wrangham renewed her prior request that, since vaccines carry the risk of injury or death, the ACCV should support the right of every parent to make voluntary vaccine decisions for themselves and their children. They should be able to make those decisions without the threat of sanctions, such as being removed from a doctor’s practice.

Lastly, with regard to the MMRV VIS, it should be noted that these infections usually resolve without complication. Unfortunately, there is insufficient information about the diseases and the effects of vaccination to allow individuals to make informed decisions about the use of vaccines.

Future Agenda Items/New Business

Dr. Feemster invited suggestions for agenda items. She noted that the Process Workgroup would provide additional information about their recommendations beyond those approved at this meeting. She also suggested that there would be follow-up on the legislation that was in part a result of the ACCV Maternal Immunization Workgroup’s activities.

The format of the December meeting, teleconference or in person, will depend on a number of considerations, such as whether there will be new Commission member on board at that time.

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