Advisory Commission on Childhood Vaccines
December 4, 2014
94th Meeting

Members Present

Kirsten Feemster, Chair ('14)
Jason Smith, J.D., Vice Chair ('14)
Charlene Douglas, Ph.D. ('14)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('13)
Luisita dela Rosa, Ph.D. ('15)
Sylvia Fernandez Villareal, M.D. ('15)

Division of Injury Compensation Programs

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

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

Dr. Feemster called the 94th meeting of the Advisory Commission on Childhood Vaccines (ACCV or Commission) to order and, after roll call and introductions, noted that the Commission had participated in a Government Accountability Office (GAO) study in 2014 and that report has been released and published on the GAO web site. The report was developed through interviews with stakeholders interested in vaccines, vaccine safety and the National Vaccine Injury Compensation Program (VICP).

Dr. Feemster requested approval of the September 2014 meeting minutes. Ms. Herzog noted that the letter from the National Vaccine Information Center (NVIC) that was to be incorporated into the minutes was inadvertently omitted from the draft minutes provided to the members of the ACCV, but she stated it would be incorporated in the version that will be posted on the HRSA web site. With that revision, on motion duly made and seconded, the minutes of the September 4-5, 2014 meeting were unanimously approved.

Update on the 27th Annual Judicial Conference, Chief Special Master Denise K. Vowel

Chief Special Master Vowel of the U.S. Court of Federal Claims (CFC) commented that the vaccine areas covered at the Judicial Conference included recent damage awards, settlements in progress, and her update on the activities of the Office of Special Masters, including a review of the current caseload. One focus was on the effort to reduce the number of outstanding claims filed more than ten years ago (about 3% of the total claims), and most of those should be resolved in 2015.

The conference included a panel to provide a venue for discussing attorney's fees, and two panels led by special masters. Special Master Tom Gowen focused on life care plans, and Special Master Christian Moran looked at emerging issues related to vaccine damage claims.

Chief Special Master Vowel explained that her office had addressed the increased level of claims that has occurred in the last few years. Based on calendar year claims, there were 680 cases in 2014, which was up from 525 in 2013 and above the average of 400 that were filed in the prior four years. She added that her office is capped at eight special masters and a limited staff of attorneys, but that in July a Special Processing Unit (SPU) had been approved with authority to hire permanent staff attorneys. That action followed consultation with the petitioner's and respondent's bars, and there was agreement that the SPU would focus on table injuries or "quasi table injuries", such as Shoulder Injury Related to Vaccine Administration (SIRVA), Guillain-Barrè Syndrome (GBS), and intussusception following rotavirus. These claims are typically processed expeditiously. The program so far appears to be working well.

Chief Special Master Vowel noted that the information on the conference, including the audio recording of the conference sessions, is available on the web. Asked about future increases in the number of special masters, Chief Special Master Vowel stated that she had proposed a increase the number of special masters from 8 to 12. She added that staff attorneys help support the day-to-day management of cases. There are now four such staff attorneys, and there may be increased funding in 2016 that would support more. Dr. Villarreal observed that, as discussed in the GAO report, the Commission should remain aware that adding injuries to the Vaccine Injury Table is an important part of moving claims through the system more quickly and more easily. Chief Special Master Vowel suggested that an increase in Department of Health and Human Services (HHS) staff would also be helpful, since the information required to make decisions about case settlements in part depends on the submission recommendations from HHS.

Dr. Feemster invited the report from the DICP.

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

Dr. Houston welcomed those present on the teleconference and briefly reviewed the meeting agenda. Following Chief Special Master Vowel's discussion of the 27th Annual Judicial Conference and her own report of DICP activities, the agenda includes an update from the Department of Justice (DOJ), reports from the chairs of the Process Workgroup and the Adult Immunization Workgroup, a review of Vaccine Information Statements, and finally updates from the ex officio members from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the National Vaccine Program Office (NVPO).

Dr. Houston commented that her report would reflect the first month of Fiscal Year (FY) 2015, during which 73 claims were filed (projected to be 876 for the fiscal year). There were 19 adjudications (projected to be 228), of which 12 were compensable and 7 were dismissed. She commented that the projected 876 claims for the year was a number considerably larger than any previous year. Concerning awards, petitioners were awarded $17.5 million and attorney's fees totaled $2.3 million. Those amounts are estimated to be $210 million and $27 million

respectively, by the end of FY 2015. Dr. Houston reported that the Vaccine Injury Compensation Trust Fund balance was $3.5 billion as of September 30, 2014.

With regard to significant activities, Dr. Houston noted that there are several VICP regulations going through the clearance process. She also stated that the GAO report was published and can be reviewed on the GAO web site. The National Vaccine Advisory Committee (NVAC) met on September 9-10, 2014, and a summary of that meeting will be included in the NVPO report later in the meeting, and on October 29-30, the Advisory Committee on Immunization Practices (ACIP) met and the summary of that meeting is on the ACIP web site. Finally, the Vaccine Safety Datalink met on November 4-5, and a report is available on their web site.

Dr. Houston announced that the next solicitation will request that an obstetrics-gynecology doctor (preferably a specialist in prenatal health) to serve as a new member of the ACCV. She encouraged ACCV members to submit nominations for that new vacancy. She added that staff would provide a link when the Federal Register Notice is posted. Finally, the Health Insurance Marketplace open enrollment period is November 15, 2014 through February 15, 2015.

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

Mr. Matanoski referenced the Department of Justice PowerPoint materials (DOJ PP), dated December 4, 2014, as part of his presentation. Mr. Matanoski reported that 249 petitions were filed since the last report to the Commission (DOJ PP at 2). Of the 249 petitions, 42 were minor petitioners and 207 were adult petitioners. Although there are seasonal fluctuations in large part because of the effect of influenza claims, the total for the year should exceed that of the previous year. Petitions alleging SIRVA are also increasing. With regard to adjudications, 180 cases were completed during the reporting period, also a new high (DOJ PP at 3). Because of the dramatic increase in claims filed, the gap between claims filed and adjudications is widening. The number of claims voluntarily withdrawn remains at three, a relatively insignificant factor in the statistical snapshot (DOJ PP at 4).

Turning to appeals, Mr. Matanoski reported that *Graves v. HHS* was affirmed by the Court of Appeals for the Federal Circuit (CAFC) (DOJ PP at 5). This case involved a question about the statute of limitations – not only for the late filing of the claim itself, but a late filing of the appeal as well. The CAFC's affirmance supports the original decision by the special master. Of the seven pending cases before the CAFC, three are new and all are entitlement cases filed by petitioners. (DOJ PP at 6). In *Griffin v. HHS*, the issue is whether a contractor working outside the U.S. for the federal government is entitled to file a vaccine injury claim. A federal employee in the same situation is covered, but this contractor's agreement with the federal government clearly stated that the individual involved was not a federal employee, so the special master denied the claim. The CFC affirmed the special master's dismissal. In *Crutchfield v. HHS*, the special master denied petitioner's claim that the measles-mumps-rubella (MMR) vaccine caused type 1 diabetes, which was affirmed by the CFC. Petitioner appealed. In *Stillwell v. HHS*, the special master denied petitioners claim that a flu vaccine caused acute disseminated encephalomyelitis (ADEM) noting that the diagnosis was questioned. The CFC affirmed dismissal.

Turning to the CFC, Mr. Matanoski noted that five cases were recently decided. (DOJ PP at 7). Three of these cases were already discussed (*Griffin*, *Crutchfield*, and *Stillwell*). Of the remaining two, *Harris v. HHS* arose out of a claim that human papillomavirus (HPV) vaccine caused systemic lupus erythematosus, but the special master ruled that there was insufficient evidence to establish a logical sequence of events that would support the development of the disease. In *Somosot v. HHS*, the special master denied a claim that a vaccine caused cerebral palsy because the claim was not filed within the statute of limitations. Evidence showed that the symptoms of the disease predated the time of the diagnosis by three years, which would mean the claim was filed six years after the onset of the disease, outside the timeframe for filing a claim.

There are currently nine cases pending at the CFC, all filed by petitioners (DOJ PP at 8). Of those, five were not previously discussed at prior ACCV meetings. In *Spahn v. HHS*, the special master denied a claim that tetanus vaccine significantly aggravated a preexisting obsessive compulsive disorder. In *Guerrero v. HHS*, the special master reduced petitioner's request for over $66,000 in attorneys' fees and costs to $49,000. In *Hirmiz v. HHS*, the special master decided that respondent's expert's testimony outweighed the testimony by petitioner's experts. In *Moriarty v. HHS*, the special master found that there was insufficient evidence to support petitioner's claim that the MMR vaccine caused seizures through an autoimmune disorder. In *Lerwick v. HHS*, petitioner appealed the special master's damages award, claiming that it provided insufficient funds for attendant care needs.

Two oral arguments were scheduled. (DOJ PP at 9). In a case already discussed at a previous ACCV meeting, *Flores v. HHS*, the oral argument was scheduled for the same timeframe as the ACCV meeting, December 4, 2014. The other, *Lerwick v. HHS*, is scheduled for January 28, 2015.

Turning to settlements, Mr. Matanoski discussed the compilation of adjudicated settlements (by stipulation) during the preceding quarter (DOJ PP at 10-20). There were 106 settlements finalized in the last period: 98 adult cases, and 8 minor child cases. Eighty-one of the cases were flu claims, either flu vaccine alone or in combination with other vaccines. The average processing time was 20 months, about the same as reported at the last ACCV meeting. Cases resolved within a year accounted for 34% of all cases, within the second year 42%, and within the third year 17% -- so a total of 93% of the cases were resolved in three years or less. However, Mr. Matanoski suggested that the settlements may not be as timely in the future because of the rapidly rising number of claims filed, which in combination with a fixed budget for staffing, translates into a larger number of pending cases.

In conclusion, Mr. Matanoski addressed the increasing number of vaccine cases and personnel limitations within his office. He commented that the Office of Special Masters has shifted some of their burden to staff attorneys in effort to more quickly adjudicate cases. He explained that, in spite of efficiencies that have been achieved, the respondent still was faced with a substantially increased workload and limited resources. Proposed changes to the Vaccine Injury Table may help to resolve cases more rapidly, which should alleviate some of the pending case strain. Cases have been conceded at an increasing rate over the past year.

Responding to questions about statutory limitations on DOJ staffing, Mr. Matanoski stated that there are no statutory limitations on the number of people DOJ could use for Vaccine Act work, and added that HHS also is not limited by legislation. Mr. Kraus commented that while petitioners' attorneys may be responsible for some of the delays in case processing, HHS might consider improving efficiencies similar to the efforts of the Office of Special Masters. Dr. Houston indicated that DOJ has 90 days to respond to a claim and rarely violates that deadline, attesting to the fact that HHS is also responsive in the preparation of case documentation. She offered that funding streams are very distinct between HHS and DOJ, making it impractical for the two agencies to develop joint funding proposals. Finally, she assured the ACCV that all three agencies were cognizant of the need for increased funding and all are taking steps to address the issue. Mr. Matanoski reiterated that Congress controls budget approvals, and that DOJ could be reaching the limits of utility of certain new process efficiencies, like the SPU, because of increasing case volume. He noted that the marked increases in caseload must be handled by a DOJ staff that cannot be increased because of a static budget. With fixed staffing levels, pushing DOJ resources to address SPU cases to move them along rapidly, necessarily means that other cases are receiving less resources and focus.

Dr. Feemster expressed appreciation for the presentation, reiterating her previous request for recommendations from the ACCV that might support the efforts of the agencies to expedite claims processing. Mr. Matanoski commented that DOJ's funding requests have been finalized; however, he was open to the ACCV's input for the next funding cycle.

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

Ms. dela Rosa reported that the workgroup met on November 21 and discussed the status of appointments to the ACCV (continues to be a pending issue), reviewed past and future activities, and discussed the May 2009 ACCV Process Workgroup recommendations. Three continue to be of interest to the workgroup -- the statute of limitations, the increase in the benefits cap, and the appointment of a vaccine-injured adult to serve as a member of the ACCV. The remaining eight are less timely now than they were when originally put forth, and the workgroup agreed that further action on those recommendations could be deferred. Ms. dela Rosa stated that the workgroup had requested that Dr. Houston provide information about what transpires after the Secretary receives a formal recommendation from the ACCV.

A representative of the National Association of Pediatric Nurse Practitioners explained that the association supports appropriate immunization of all infants, children, adolescents and adults; and supports assistance for families who have experienced debilitating vaccine injury of a family member.

Another issue discussed by the workgroup was how to gather information through surveys in face of regulations that require extensive and time-consuming review and approval of surveys. Ms. Overby explained that there is an exemption in the Vaccine Act if the survey seeks information that would be required to implement the Vaccine Act. Former ACCV chair Dave King, had suggested establishing a workgroup that could address issues related to that exemption.

During discussion, asked about the progress toward approval of new members of the ACCV, Dr. Houston stated that inquiry was made of the Secretary and it has been clarified that

there is a 6-9 month process to select nominees (which began in September 2014). Three nominees were put forward for approval. That could mean that current members might be asked to extend their terms.

Dr. Feemster commented on the prior discussion of seeking more resources, suggesting that the Process Workgroup could add that issue to its agenda. Mr. Kraus suggested that, although the workgroup's role is not clear, the issue could be placed on the agenda for the next meeting.

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

Dr. Villarreal reported that the workgroup would meet via teleconference as required. Dr. Feemster, Ms. Williams, Mr. Kraus and Mr. Smith agreed to participate on the workgroup. She stated that Ms. Herzog would provide a table identifying child and adult vaccines not covered by the Vaccine Injury Table. She defined adult as being at least 18 years of age. One of the issues to be addressed will be including adult immunizations in the VICP, which is not the case under the current legislation. Dr. Villarreal stated that she would submit a more formal proposal for the objectives of the workgroup.

Review of Vaccine Information Statements (VIS), Mr. Skip Wolfe, CDC

Mr. Wolfe stated that there would be two influenza VIS's to review, neither of which has been significantly changed. The last time there was a revision was in 2013 and that VIS pertained to the current 2013-2014 flu season. In the past, the VIS was revised annually to include information about the specific ensuing flu season. However the objective now is to make the VIS more general, without customizing it to the specific flu season, therefore making it a more lasting document that could be used for several years. He noted that the title of the VIS included the terms "inactivated" and "recombinant." The latter word was suggested by the subject matter experts, even though only one vaccine (Flublok) is a recombinant vaccine. Whether the vaccine is inactivated or recombinant should not be of concern to the recipient. Of concern is whether a vaccine contains live virus, and none do, and that fact is clearly stated in the VIS. During the discussion there was a suggestion that a phrase used in other VIS that pertain to recombinant vaccines might be easier to understand – vaccines made with parts of the virus.

Asked about whether a discussion should be included about infants under six months of age who cannot receive the vaccine and are therefore vulnerable, Mr. Wolfe commented that, since only prospective vaccine recipients receive the VIS, the parents of a very young infant would not. There was a suggestion that the term "infants" should be include in the sentence that begins, "Flu is more dangerous for some people."

Mr. Wolfe commented that in the second section an introductory sentence emphasizes the importance of receiving the vaccine annually and reminds parents that children may need two doses. He also stated that a suggestion by Mr. Kraus to change the wording in a sentence about thimerosal was inadvertently overlooked, but the changed wording would be included in this revision: Studies have not shown that thimerosal is harmful (instead of studies have shown that thimerosal is not harmful). Mr. Smith noted that in the VIS for live attenuated influenza vaccine (LAIV), which can be given to individuals two through nine, there is a statement that it may be given safely at the same time as other vaccines. That is not included in the VIS under review.

Mr. Wolfe agreed, noting that administering such vaccines in combination is an issue that parents are concerned about.

Dr. Shimabukuro suggested that, to clarify that inactivated or recombinant vaccines are not the same thing, the second sentence in the section be clarified to read: Inactivated and recombinant flu vaccines are given by injection (or shot) and do not contain live influenza virus. There was agreement that the revised wording was easier to understand, and further agreement that the term "recombinant" is a technical term that might be eliminated.

In Section 3, Mr. Wolfe noted that specific allergens, which were identified in the current VIS, had been removed since it was revealed that lay readers were confused about whether the list was complete. Mr. Wolfe stated that there were no substantive changes in either Section 4 or Section 5. Dr. Shimabukuro pointed out that, in Section 4, the statement that shoulder pain being rare is true, but in fact the condition may become chronic. He suggested removing the words "and is temporary."

Under Section 4, there was a brief discussion about moderate problems, and there was agreement that the latest data indicate that receiving flu vaccine in combination with pneumococcal vaccine and/or vaccines containing Dtap, may increase the risk of febrile seizures. Therefore, there was agreement that "Dtap-containing vaccines" should be added to the first sentence.

Mr. Wolfe stated that Sections 5, 6 and 7 were standard for most VIS, and there had been extensive discussion in the past to arrive at the wording in those sections.

Moving to the intranasal, live attenuated influenza vaccine (LAIV) information statement, Mr. Wolfe noted that Section 1 was identical to the VIS just reviewed. Section 2 had been revised to include a definition of "attenuated," and provide the age range for receiving the vaccine. It was noted that the statement that the viruses in the vaccine were weakened to prevent causing flu is repeated. There was agreement that the second duplicative statement should be removed, but that for emphasis the remaining statement should be in boldface type.

In Section 3, a rationale was added to the statement about waiting four weeks between receiving a second live vaccine – that is, vaccines may be less effective if given too close together in time. Also in the same section, there was a recommendation to clarify giving the flu shot instead of the nasal flu vaccine to children with asthma or wheezing problems, since that applies only to children age 2 to 4. Dr. Shimabukuro suggested that a risk warning concerning asthma/wheezing should go in Section 4. Finally, Mr. Wolfe stated that the VIS must include the wording regarding the risk of death, but he welcomed any rewording that would make the statement less threatening. As before, Sections 5, 6 and 7 are pro forma for all VIS.

Mr. Wolfe expressed appreciation for the Commission's comments and recommendations.

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

Dr. Shimabukuro noted that he would summarize the October 2014 ACIP meeting, outline Clinical Immunization Safety Assessment (CISA) research studies, and discuss recent publications germane to vaccines. Currently there is a published Federal Register Notice inviting public comment on the revised Vaccine Adverse Event Reporting System (VAERS) reporting form that will allow public comment through January 23. Then final revisions will be made and the new form 2.0 will be incorporated into the information technology platform. Once implemented, and after a reasonable period of reporting under the new form, there will be a review of the results comparing the old form with the new form.

Dr. Shimabukuro commented that the ACIP meeting also included a summary of the U.S. Flu Vaccine Effectiveness Network. The highlights of that presentation showed that, during the last two flu seasons the relative effectiveness favored the live attenuated influenza vaccine (LAIV) versus inactivated vaccine (IIV) in young children. There is a recommendation that LAIV be used in young children if available, but vaccination should not be delayed, so IIV could be used if there is a scarcity of LAIV. In the last flu season (2013-2014) relative effectiveness favored IIV. Finally, data showed that H1N1 was the predominant virus in 2013-2014. Medimmune reported a post-licensure study showing significant vaccine effectiveness for LAIV4 against the B-Yamagata flu, but not the H1N1 strain.

Dr. Shimabukuro commented that the PharmaJet (PJ) Stratis Needle-Free Injection System was approved in August 2014 (an informational item at the September ACCV meeting). Apparently as effective as standard needle injection, its use in the current season has been limited because most of the product was already distributed. Although injection site reactions were more frequent with the PJ system, other reactions were comparable with standard needle injection. Finally, patients and health care providers appear to be satisfied with the needle-free process.

Dr. Shimabukuro stated that the ACIP update also included an announcement that Novartis submitted a biologic vaccine application for persons 10 to 25 years to receive Bexsero, a meningococcal serogroup B vaccine, in two doses. It is the same vaccine used under an Investigational New Drug (IND) protocol in the Princeton-University of California at Santa Barbara outbreak. He reiterated the announcement that Trumenba was approved in October, also for individuals 10 to 25 years of age, as a three-dose series.

Finally, Dr. Shimabukuro stated that a clinical trial of a 9-valent HPV vaccine showed that it was well tolerated in young men and women, and switching to that vaccine could prove cost effective. Approval is expected in 2015.

Concerning the CISA studies, CISA is a collaboration between CDC and seven medical research centers that conduct vaccine safety studies. Dr. Shimabukuro noted that the studies can be reviewed on the web at clinicaltrials.gov.

Dr. Shimabukuro mentioned six publications of interest, including:

- Haber et al, looking at post-licensure analysis of VAERS surveillance of trivalent live attenuated influenza vaccines in adults, suggested there was little concern, except for a higher than expected incidence of GBS;

- Haber et al, is a follow on to the Haber study concerning reports of expired LAIV vaccine being used (although LAIV has a relatively short expiration date from season to season, which is a mitigating circumstance);
- Kharbanda et al, described a study of the association of maternal pertussis vaccination with obstetric events, showing that Tdap did not appear to be a risk for increased risk of hypertensive disorder or preterm or small for gestational age at birth;
- Duffy et al, described a study showing that influenza vaccines containing A(H1N1)pdm09 virus strain were not associated with an increased risk of narcolepsy;
- Tartof et al, discussed a study of inpatient admissions for febrile seizure that showed no difference in children with vaccine-associated febrile seizure and non-vaccine febrile seizure;
- Kharbanda et al, analyzed increased uptake in Tdap coverage in pregnant women following the California Department of Public Health recommendations.

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

Ms. Schuster explained that NIAID continues to support and conduct research on diagnostics, therapeutics and vaccines for Ebola. NIAID support includes work in West Africa, participation in World Health Organization and United Nations policy meetings, collaborations with pharmaceutical companies and vaccine manufacturers, support for Commissioned Corps officers assigned to provide clinical care, provision of expert advice to federal agencies, and interactions with Congress and the public.

NIAID is supporting clinical trials on candidate vaccines for Ebola, including one co-developed by NIAID and GlaxoSmithKline. Clinical testing began in September 2014. The vaccine was well-tolerated and produced immune responses in the 20 adults who participated in this trial. Additional details are available on the NIAID web site.

NIH is collaborating with Department of Defense in supporting NewLink Genetics Corp. in the conduct of Phase I investigational studies of the recombinant vesicular stomatitis Ebola vaccine, VSV-ZEBOV. This candidate vaccine was developed by researchers at the Public Health Agency of Canada. Clinical trials began in October at Walter Reed Army Institute of Research and at NIH, evaluating the vaccine for safety and efficacy.

NIAID recently sponsored a Phase II clinical trial to look at a candidate vaccine for H7N9 avian influenza, which prompted immune responses when the vaccine was mixed with an adjuvant. The trial enrolled 700 healthy adults at four sites in the U.S. The experimental vaccine is made from inactivated H7N9 virus. The results of the study were published in the Journal of the American Medical Association in October 2014. Finally, NIAID has awarded seven contracts to medical research institutions to discover and characterize new adjuvants. Total funding for the contracts could be as much a $70 million over five years.

Collaborating with the Bill and Melinda Gates Foundation, NIAID co-sponsored a conference on clinical research in pregnant women on September 29-30, 2014. The objective, in the context of pregnancy research, was to identify knowledge gaps in the context of global health vaccines and antimicrobials; and to develop research tools to support the design and implementation of clinical trials to respond to those gaps.

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

LCDR Marshall reported that in September 2014, the package insert for Menactra was revised to include safety and immunogenicity data to support Menactra re-vaccination in individuals 15 through 55 years of age who are at continued risk for meningococcal disease if at least four years have elapsed since the prior dose.

In October 2014, the FDA approved Trumenba, the first vaccine licensed in the United States to prevent invasive meningococcal disease caused by *Neisseria meningitides* serogroup B in individuals 10 through 25 years of age.

In December 2014, a public workshop, "Immunology of Protection from Ebola Virus Infection," was jointly sponsored by FDA, NIAID, Department of Defense, CDC, and the Biomedical Advanced Research and Development Authority (BARDA). The purpose of the workshop is to discuss the Ebola virus and vaccine immunology to help inform future clinical, scientific and regulatory decision-making related to development of vaccines to protect against Ebola.

Finally, in March 2015, the Vaccines and Related Biological Products Committee (VRBPAC) will meet to consider recommendations for the selection of strains to be included in the 2015-2016 influenza season vaccine.

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

Dr. Bok reported that NVPO is working with the Adult Immunization Task Force (under the direction of the HHS Assistant Secretary for Health), to develop a plan to promote a higher uptake of vaccines by adults. Adults significantly lag children in compliance with immunization recommendations. That plan is going through clearance and should be launched in early 2015.

Dr. Bok noted that the September 2014 NVAC meeting included a session on maternal immunization, and NVAC has created a Maternal Immunization Working Group to identify barriers and opportunities to overcome those barriers and for developing vaccines for pregnant women. The new working group follows on a previous working group that was focused on access to existing vaccines by pregnant women.

Public Comment

Dr. Feemster invited public comment.

Ms. Theresa Wrangham, representing the NVIC, expressed appreciation for the Commission's correction of the September 2014 minutes by including the NVIC's letter submitted at that meeting. However, a second correction was not considered, that of clarifying the participation of the NVIC in the Process Workgroup. That request was sent to ACCV staff and Ms. Wrangham asked that the e-mail request be distributed to the full Commission and that the submission of the request be included in the corrections to the September minutes.

Ms. Wrangham stated that the law provides for the information submitted by NVIC be made available to the public. The information would lessen any "new efforts" to implement existing legal reporting requirements. However, if such implementation is necessary, it should not be constrained by budgetary limitations or by defining the implementation as optional. The public should be able to access information easily.

With regard to the GAO report, the ACCV can make recommendations for adequate funding to handle the increased caseload. However, the ACCV should consider the GAO finding that increased caseloads are related to increases in off table injury petitions, which is linked to adding vaccines without adding related vaccine injuries. Ms. Wrangham recommended providing adequate funding for independent research to identify who is at risk for vaccine injury, properly compensating those injured, and developing information on prevention of such injuries in the future. Further, the ACCV should consider the limitations of reliance on the epidemiological data used by surveillance systems such as the Vaccine Safety Datalink (VSD), which do not include the biological data considerations. The ACCV should also be concerned about the limited access to VSD data by independent researchers, which hampers independent replicability studies.

Ms. Wrangham stated that the NVIC is opposed to the opening statement in the Vaccine Information Statements, titled "Why get vaccinated?" The VIS should provide factual information on vaccine risks and benefits, and that statement appears to be a bias in terms of "selling" immunizations. The length of the VIS is also too short to provide complete information about the vaccination decision. The vaccine product insert should also be made available as an attachment to the VIS. Concerning the meeting discussion of the flu VIS and the claim that there are many flu deaths, Ms. Wrangham felt there should be clarification that the flu deaths are actually the result of flu diagnosis and not flu-like illness, since the latter could inflate the number of deaths and be misleading.

There were no further requests to comment.

Future Agenda Items/New Business, Dr. Kristen Feemster, Chair, ACCV

For clarification, Dr. Houston stated that the current nominee cohort of three prospective members was forwarded to the Secretary in September 2014, making it possible that those nominations could be approved by the next ACCV meeting. An invitation for nominations for the second 2014 cohort will be published in the Federal Register in the next few weeks.

Dr. Feemster suggested that consideration of a recommendation to increase funding for the program, to enhance processing the increased number of claims files, be included in the March meeting agenda. The Commission agreed that would be an appropriate topic for discussion.

Adjournment

On motion duly made and seconded, the Commission unanimously approved adjournment.