Advisory Commission on Childhood Vaccines

September 3, 2015
97th Meeting
In-Person meeting held in Rockville, MD

Members Present

Charlene Douglas, Ph.D. ('15)
Edward Kraus, J.D. ('15)
Luisita dela Rosa, Ph.D. ('15)
Jason Smith, J.D. ('15)
Martha Toomey ('18)
Alexandra Stewart, (18)
Karlen E. Luthy, ('18)

Division of Injury Compensation Programs (DICP)

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

Welcome, Report of the Chair, Jason Smith, ACCV Vice Chair

Mr. Smith called the meeting to order and after roll call announced that Dr. Kristen Feemster, the ACCV chair, was not able to attend. He welcomed the three new members of the Commission – Karlene Luthy, Martha Toomey, and Alexandra Stewart -- and expressed his appreciation for the service of the three outgoing commissioners, David King, Ann Linguiti Pron and Michelle Williams. Mr. Smith noted that this was the first face-to-face meeting in many months, and all agree that such meetings are important to develop personal relationships. He added that the commissioners represent a number of stakeholders in the child vaccine community, and he encouraged the new members to feel free to ask clarifying questions about any aspect of the ACCV's charge and responsibilities.

Public Comment on Agenda Items

Mr. Smith invited public comment on the agenda. There were no requests for comment.

Approval of March 2015 minutes

Mr. Smith invited approval of the June 2015 meeting minutes. On motion duly made and seconded by Mr. Smith, the minutes were unanimously approved.

Ms. Toomey requested that the minutes include a statement describing the nature of the meeting, and it was noted that this meeting was an in person meeting with the opportunity for

commissioners and ex officio members who could not attend in person to participate by telephone.

Remarks by Hon. Nora Beth Dorsey, Chief Special Master

Mr. Smith invited the newly appointed chief special master to introduce herself.

Ms. Dorsey expressed her pleasure at being able to be present for part of the Commission meeting. She noted that the Judicial Conference would take place on September 23-24, starting at the Court, with the full program taking place at the Press Club on the 24th. Vince Matanoski will be a featured speaker, and there will be a panel on settlements and current trends in the program. She encouraged the commissioners to contact her at any time during her tenure as chief special master.

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

Dr. Houston welcomed those present and briefly reviewed the agenda. The agenda includes an update from the Department of Justice (DOJ), a report from the ACCV Adult Immunization Workgroup, 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).

Looking at petitions and adjudications, Dr. Houston stated, as of August 1, 2015, the Division had received 597 petitions and the projection, based on that number is about 651 petitions may be filed before the end of this fiscal year. The total adjudications for the current report period is 455, which projects to about 496 claims to be adjudicated in Fiscal Year (FY) 2015, more than the previous fiscal year. There have been awards totaling $295 million to petitioners, and about $17.3 million to petitioners' for attorney's fees and costs. The Trust Fund stands at $3.5 billion as of June 30, 2015. Of the $181.6 million net income to the Trust Fund, 75% was from excise tax revenue and 25% from interest on investments.

Dr. Houston announced that the Revisions to the Vaccine Injury Table Notice of Proposed Rulemaking was published in the Federal Register on July 29, 2015, and the 180-day public period extends through January 25, 2016. There will also be a public hearing to provide further opportunity for public comment, and the date of that hearing will be published in the Federal Register. The commissioners will be informed when that date is known.

Ms. Toomey asked for clarification on how the actual expenditure of awards is reported, and Dr. Houston explained that once the award is finalized by the court, that award amount is reported as part of the awards discussed above. It was noted that typically an annuity or similar instrument is purchased, which requires an up-front lump sum payment for the annuity, and then the petitioner receives annual funding support derived from that source.

Dr. Houston described outreach activities that involve the VICP, one of which is a partnership with the Office of Women's Health (OWH) at FDA, which distributes VICP

materials at various meetings. For example, the OWH distributed information at the National Association of County & City Health Officials, reaching 1,300 public health department officials and public health partners who attended the meeting. In another partnership with the Indian Health Service (IHS), the IHS included information about the Vaccine Program in their July newsletter, which went to 385 IHS grantee providers. Finally, HRSA's Bureau of Primary Health Care provided program information to 5,000 health centers.

Dr. Houston noted that the National Vaccine Advisory Committee will meet on September 9-10 in Washington, D.C., and the Advisory Committee on Immunization Practices will meet in Atlanta on October 21-22. Information on ACCV meetings, including minutes and presentations, can be found on the web at http://www.hrsa.gov/vaccinecompensation/commissionchildhoodvaccines.html.

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

Mr. Matanoski expressed his pleasure at being able to visit the regular ACCV meeting in person. He reported that the statistics reported cover the three-month period from May 16 – August 15, 2015. The total petitions filed amounted to 211, 36 on behalf of children and 175 for adults (83%). That is about the same as the previous period, currently driven by the large increase in flu vaccinations for adults. Flu also causes a slight increase in the volume of petitions in the fall, when the infection is most prevalent. Based on the petition thus far the total number of petitions anticipated by the end of the fiscal year is about 750 (compared to 630 in 2014). Another contributing factor to the increase is the growing awareness of shoulder injury related to vaccine administration (SIRVA).

Asked about the effect of an injury that occurs when an individual is an adult even though the vaccination was administered when the individual was a minor, Mr. Matanoski clarified that cases are defined as adult or minor based on age at date of filing.

Mr. Matanoski stated that 156 cases were adjudicated in the reporting period, 115 of which were compensated. Twenty-nine cases were conceded by HHS (table injuries or proven causation). Eighty-six cases were not conceded, but compensated through the process of settlement (85) or proffer (1). Mr. Matanoski described the special processing unit within the Office of the Special Master that expedites cases that are deemed to be more likely to be compensated, a process that has improved the flow of cases through the system. Neither the HHS nor the DOJ has a role in determining what cases are selected for that unit. Forty-one cases were not compensated or dismissed, and 11 cases were voluntarily withdrawn by the petitioner. The latter number is not included in the total cases adjudicated. Mr. Kraus observed that two reasons are typical for withdrawing a petition: (1) petitioner is not able to secure expert testimony to support the claim, or (2) it becomes apparent that the claim was not filed within the parameters of the statute of limitations, which is a fatal flow in the process.

Mr. Matanoski briefly described the cases related to the appellate procedure in the Court of Federal Claims (CFC) and the Court of Appeals for the Federal Circuit (CAFC). The CFC, a single judge, is the first step in the appeals process. The second step is the CAFC (a panel of

three judges) that considers the ruling of the judge in the CFC appeal process, while simultaneously considering the merits of the petitioner's original claim. All of the cases discussed were filed by petitioner. In almost every case the court affirmed the underlying decision of the special master.

Recently decided CAFC cases

- Stillwell v. HHS, involving acute disseminated encephalomyelitis, in which the court decided that the respondent's experts were more persuasive than the petitioner's experts.
- Crutchfield v. HHS, a case involving MMR vaccine and measles, and the court decided the respondent's experts were more persuasive.
- Greenberg v. HHS, a pro se case (filed by the petitioner without legal counsel) that involved MMR vaccine and an alleged injury of autism spectrum disorder. The court found it ineligible because the filing was not timely. The judge also deemed the case unlikely to be proved even if it had been timely filed. An appeal must be filed with the CFC within 30 days after the decision by the special master, which was not done (the petitioner actually bypassed the CFC appeal step, filing the appeal with the CAFC first). However, even that appeal was not filed within 30 days. The CAFC decided that the error in procedure may have been lack of understanding of the procedures of the court and ruled that the claim could be reviewed by the CFC, which is now pending.

Recently decided CFC cases

- D'Agiolini v. HHS, a claim that chronic fatigue syndrome was caused by an adjuvant in hepatitis B vaccine. Adjuvants are sometimes added to vaccines to enhance efficacy. The CFC ruled that the expert testimony did not support the claim, so the case moved up to the CAFC. The mechanism of cause in such cases is called ASIA, autoimmune syndrome induced by adjuvant, and it is the basis of a number of other claims in process.
- Godfrey v. HHS, a case involving juvenile rheumatoid arthritis alleged to have been caused by HPV vaccine or meningococcal vaccine, resulted in the special master rejecting the testimony of an expert witness. Although the CFC upheld that decision, the CAFC ruled that the CFC should review its decision, paying closer attention to the expert's testimony, and remanded (returned) the claim back to the CFC for that purpose. However, the special master also found that the petitioner failed to meet prong three of Althen (the criteria by which vaccine compensation cases are proven).
- Rowan v. HHS, a case based on ASIA described above, involved acute migraines alleged to be caused by HPV vaccine, was affirmed by the CAFC.
- Santini v. HHS was based on significant aggravation of Dravet syndrome, a genetically-induced neurological condition in children. Five previous similar cases were appealed and the special master's decision that the vaccine (Dtap) was not causative in the condition were affirmed in earlier appeals, which was also the result in this case.

- Barclay v. HHS, also a case based on onset of Dravet syndrome caused by vaccine. The special master's decision that the vaccine (Dtap) was not causative was also affirmed by the CAFC.
- Padmanabhan v. HHS, involved a claim that four vaccines (MMR, haemophilis influenza, DTAP and varicella) cause autism spectrum disorder. There was also an underlying pre-existing mitochondrial condition. The special master issued several orders over a few years to provide additional medical information. Those orders were ignored by the plaintiff and the special master finally dismissed the case for failure to prosecute (move forward with) the case. The CAFC affirmed that decision.
- Mora v. HHS, a case in which the plaintiff was offered a settlement but refused it, choosing instead to withdraw and file a civil action against the drug manufacturer. When the plaintiff found that was not allowed by a prior Supreme Court decision, a motion to set aside the original judgement was filed.
- Nutall v. HHS, involving MMR case of alleged encephalitis in which conflicting opinions by radiologists concerning the outcome of an MRI scan resulted in the special master finding that the MRI was abnormal, which was a determining factor in the case. Expert testimony convinced the court that the MRI was, in fact, normal. The case was dismissed and affirmed by the CFC.
- McLeod-Hunt v. HHS, a TDAP-meningococcal-varicella vaccines case with a claim of multiple sclerosis following vaccination. However, the symptoms pre-existed the vaccination so the case came down to significant aggravation. The first symptom occurred on the same day as the vaccination, which was deemed too soon to be related to the vaccine, and the course of the disease was subsequently that which would be expected had the disease progressed as usual.
- Whitney v. HHS, involved DTAP vaccine alleged to have caused transverse myelitis. A number of medical experts testified that there could be a vaccine connection, one expert said there was no such connection and cited a possible herpes infection that could have caused the condition. The special master agreed with the latter expert. The CFC's review resulted in remanding the case for reconsideration by the special master.

Pending CAFC cases include two involving attorney's fees and costs, and five about entitlement. Two oral arguments are scheduled: Hirmiz v. HHS on October 6, and Hodge v. HHS on September 3. The Hodge case involved a claim for equitable tolling based on a mental incapacity that resulted in filing the original claim in violation of the statute of limitations (36 months). Mr. Matanoski explained the concept of equitable tolling that is a very narrow range of conditions can rectify certain inequities. He noted that the court otherwise cannot change the deadlines for filing claims, which exist to provide a reliable framework in which to pursue claims.

Mr. Krause commented that, although the explanation is consistent with the law, the limitation in this case and others is not consistent with the purpose of the vaccine compensation program. He noted that this Commission and earlier ones had formally recommended to the Secretary that the statute of limitations be extended.

In conclusion, Mr. Matanoski discussed the 86 adjudicated settlements in the reporting period. Of those, 77 involved adults, 9 children, and 56% were brought to settlement within a year of filing the claim, 88% were settled within two years.

During discussion, Mr. Matanoski noted that there were about 1,200 cases pending, an increase of 13% over last year. He also commented that changing the statute of limitations require statutory action, as does increasing the number of special masters (currently limited to 8) to address an increase in caseload.

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

Dr. Villarreal recalled the fact that 80% of vaccine compensation claims are filed by or on behalf of adults. Two years ago the Commission was briefed on two vaccines that were approved for adults – the pneumococcal 23 vaccine (PPSV23) and the herpes zoster vaccine. PPSV 23 is also approved for children with chronic lung conditions and immune disorders.

The Workgroup usually meets the second Thursday of each month on a 45-minute teleconference to discuss how to recommend that the Secretary include these two vaccines on the Vaccine Injury Table. Their absence is problematic. Mr. Smith added that input had been received from a number of outside stakeholders. So far data from surveillance systems has not been available to the ACCV, nor is there sufficient historical information and scientific data to advise the Secretary about adding the zoster vaccine to the Vaccine Injury Table. There was, however PPSV23 data presented at one of the ACCV adult immunization workgroup meetings, probably in December 2014. Dr. Villarreal recollected that children with sickle cell anemia were given the pneumococcal vaccine, for children and adults (2-64) with certain long-term health conditions, including weakened immunity. It was also recommended for adults 19 through 64 who smoked tobacco products or who have asthma.

The working group is sending notes on these two vaccines to Ms. Herzog, and a summary of the working group's progress during 2015 will be presented to the Commission at the December meeting. There will be a recommendation to submit a recommendation to the Secretary to add both vaccines to the Vaccine Injury Table.

Dr. Houston stated that the CDC did, in fact, make a presentation in 2014 regarding adult immunization. Concerning the request for data on the PPSV 23 vaccine, since it is not covered under the program the DICP does not have data regarding potential alleged injuries associated with that vaccine. Asked whether a non-covered vaccine injury report would be accepted by the Vaccine Adverse Event Reporting Systems (VAERS), Dr. Shimabukuro stated that CDC is in the process of compiling data on PPSV 23 and zoster vaccines, and the VAERS data reveal that the post-licensure safety profile is consistent with the pre-licensure clinical trials data and other post-licensure studies.

Dr. Villarreal summarized her remarks, noting that the working group was asked to look at the two adult vaccines, one of which is also recommended for children, neither of which is on the Vaccine Injury Table – PPSV 23 and Zostavax, the shingles herpes zoster vaccine. Mr. Smith commented that to recommend adding adult vaccines to the Vaccine Injury Table, which

was created to cover only children, an amendment to the legislation would be required. There would have to be a very compelling reason and rationale to do that. The Commission would have to know if moving in that direction with a formal recommendation would result in any unexpected issues. If so, what would those issues be? And there is not enough data now to make that determination. Dr. Villarreal commented that the working group is looking for data that would support the notion that there have been people injured by either of the vaccines. Mr. Kraus stated that he had received inquiries from adults who alleged injury, but any claim would not qualify under the Vaccine Compensation Act and recourse would have be through the civil tort procedures against the manufacturer or the vaccine administrator. He added that, because of the resources available to manufacturers, it is usually economically unrealistic to pursue an injury claim, unless the injury resulted in death or a severe disabling condition. To collect data on civil cases involves a search of records from all fifty states, a daunting project.

Dr. Houston commented that in addition to the hurdle of amending the legislation, the two vaccines are not subject to an excise tax, authorized by congressional legislation, which is a requirement for adding a vaccine to the Table. Mr. Smith also observed that in opening the program for legislative revision, there could be other changes not contemplated by the basic intent to add adult vaccines. That constitutes a risk to the present program.

Dr. Villarreal stated that the next meeting of the working group would be on Thursday, October 8 and all are welcome to join the call.

Discussion of Follow-up Items from the June 2015 ACCV Meeting, Specifically on VICP Administrative Funding and Prevention of SIRVA.

Mr. Smith explained that during the last meeting there was discussion about the workload burden of the program, especially at HRSA, DOJ, and the Office of Special Masters. The question asked was, are the resources sufficient to support the efforts required to accomplish the mission of the VICP. A second presentation at the last meeting concerned SIRVA and there was insufficient time to fully explore the subject. Such a discussion was suggested for this meeting. Mr. Smith invited comments from the commissioners.

Mr. Kraus suggested it would be helpful to have a brief presentation about how the Office of Special Masters (OSM) sees the situation. The handling of cases appears to be improving and that fits with the plaintiffs attorneys' desires that cases move quickly through the process. There is a sense that the cases that are processed as before, that is, not through the special processing unit, are taking longer to resolve, probably because of resource issues. Mr. Kraus suggested that it would make sense to recommend additional resources to handle the increased caseload, which now stands at about 150 cases annually for each special master.

Ms. Toomey suggested that it might be interesting to hear how other types of courts handle caseload – family courts, appellate courts, the local county municipal court, and so on. What is the caseload per judge in those courts? What was it ten or twenty years ago? There was a question about whether Trust Fund monies could be used to alleviate some of these problems and Dr. Houston explained that Congress appropriates money from for administration of the VICP. The rest of the Trust Fund must be used to fund compensation awards.

Asked about a special smallpox program, Dr. Houston explained that smallpox is covered by a separate program, the Countermeasures Injury Compensation Program, which includes coverage for a number of vaccine-related injuries for children and adults. Mr. Kraus commented on the lack of data. The working group discussed the issue and came to the conclusion that the ACCV does not have the power to demand data, nor were there ideas on how to generate the data. Ms. Stewart suggested a survey, perhaps using Survey Monkey. Ms. Toomey commented that there are people who do not access federal web information sites because they don't trust them, others who only trust the federal information. It is a very polarized situation. And there are many confounding issues, like lack of Internet access, language barriers, and so on. That situation would bias the results of any general survey.

Charlene Douglas suggested that the statute of limitations should be related to the course of the disorder, which may not fit the three-year parameter. Dr. dela Rosa, noting that a doctor is needed to file the claim, said there was also a barrier in trying to get medical personnel to respond, many claiming inexperience with the issues. Martha added that the public advocacy group that is pro or anti vaccines, can influence a physician's response. She also noted that the congressional process, needed for the changes being recommended, is a slow process and it is important that the ACCV has congressional support to back the recommendations.

Mr. Smith suggested that the ACCV could provide information about data, workload, and caseload and make recommendations to the Secretary based on that information. That would provide an evidence base for the recommendations. Mr. Kraus reminded the Commission that a rationale for the statute of limitations recommendation had been developed by Dave King in the Process Working Group. There was also a recommendation to increase the compensation cap, which has been stagnant for a number of years ($250,000 since 1988, which should have increased to about $500,000 based on increases in cost of living indices). He questioned whether the recommendation should now include the issue of additional resources for the special masters, or whether the working group should focus on the vaccine-injured parties and not the administration of the program. He suggested that perhaps the Process Working Group should be reconvened to consider these questions.

Mr. Smith agreed that looking at the prior recommendations with a fresh eye would be appropriate. He suggested an action item that would charge Dr. dela Rosa and Mr. Krause to solicit new volunteers for the Process Working Group. He also suggested that the VICP administrative funding should be addressed by a different group. An agenda item could be added to the December meeting to discuss the challenges that the medical officers at HRSA and the attorneys at DOJ face. Ms. Stewart asked whether the number of hours per week the attorneys work is available, since the proverbial 80-hour week would be self-defeating in the long term.

Mr. Krause suggested asking whether it would make a difference if the ACCV recommended increasing funding to any of the agencies working on the program, or would the effort be the equivalent of titling at windmills. Dr. Houston commented that the effort would produce additional data, which could be useful.

Mr. Smith noted that several of the special masters will be retiring, and the expectation should be that there will be a start-up learning curve for replacements. He added that the limitation of eight special masters inhibits the effectiveness of the office in handling the workload, especially with the added burden of the increased flu vaccine injury claims. He said that he heard agreement that the statute of limitations should be referred to the Process Working Group. The issues related to VICP administrative funding will be added to the December meeting agenda.

Mr. Smith stated that, in the interest of time, the SIRVA discussion should be considered. He asked the Commission what could be done to address prevention of SIRVA. Dr. Villarreal noted that the assumed cause of the injury may not apply to children and adolescents because the injection site is either in the leg (in infants) and the arm in adolescents. The recommendation may be around encouraging the CDC to insure that training takes that into consideration. Dr. Shimabukuro stated that CDC and specialty societies publish guidance on administering injections, but the training is mainly done at the clinic or institution level.

Mr. Smith commented that the discussion of SIRVA at the last meeting was somewhat truncated by time constraints, and this discussion was scheduled to provide a little more time to consider the issue. He said that it may be the case that the commissioners feel that there is nothing more to discuss nor further actions that the Commission can take at this time, and that is fine. Alexandra asked if the Vaccine Information Sheets could include something on SIRVA, and Mr. Krause stated that that issue was the precipitating factor in scheduling the discussion. Dr. Houston commented that the VIS is intended for individuals who are actually receiving the vaccine.

Concerning training, there was an observation that most vaccine administrators have been professionally trained, as nurses or PAs, and to focus on another layer of training might be redundant. Mr. Kraus asked if it would be feasible to look at SIRVA claims in the program and determine who administered the vaccines. Dr. Shimabukuro explained that there is an ongoing CDC review of SIRVA cases filed in VAERS. When that information is available it will be provided to the Commission. That study is focused on flu cases, but it would probably be generalizable to other types of IM injections.

Mr. Smith noted that the item was included on the agenda to encourage a continuing dialog. Action by the ACCV was not contemplated. He stated that the discussion was excellent.

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

Dr. Shimabukuro expressed his appreciation for being able to meet in person. He welcomed the new members. He noted that his presentation would focus on the recent June 15 Advisory Committee on Immunization Practices (ACIP) meeting, concluding with comments on recent publications.

The ACIP approved a recommendation to administer serogroup B meningococcal (MenB) vaccine to persons 16 to 23 years of age to provide short-term protection against most

strains of the disease. There are two recently licensed vaccines, one of which was approved under an Investigational New Drug (IND) in response to a recent outbreak in two academic settings. The preferred use is in adolescents 16 through 18, but the recommendation is Category B, which means that it relies on the physician's judgment on use.

There was also a vote to approve changes in the algorithm for determining which children, aged 6 months to 8 years, need two doses of influenza vaccine. New products were incorporated in this algorithm: quadrivalent intradermal inactivated flu vaccine; trivalent recombinant flu vaccine for individuals 18 and older (an expansion of the age range); and the brand AFLURIA recommended via jet injector for ages 18 to 64 years.

Dr. Shimabukuro stated that there was also a vote to endorse the selection of four flu strains for the 2015-2016 flu season. The selections were made by World Health Organization (WHO) and FDA, and included A/ California (H1N1), A/Switzerland (H3N2), and B/Phuket, and B/Brisbane (for quadrivalent formations). There was also an influenza vaccine safety presentation that covered the end-of-season update and a report on a Vaccine Safety Datalink (VSD) study. The full report on this session was distributed to the commissioners before the meeting.

During the pneumococcal vaccine session there was a vote to approve a change in the interval between administration of PCV13 and PPSV23 in adults to at least one year (previously 6 to 12 months). Finally, although not specifically applicable to ACCV, there was a vote to approve an update in smallpox vaccine recommendations, which were last updated in 2001. Dryvax has since been replaced by ACAM 2000.

Referring to the end-of-season update previously mentioned. The report noted no new safety concerns arising out of VAERS for influenza. There was an increased risk revealed in the rapid cycle analysis for seizures after receiving trivalent and quadrivalent IIV vaccines (for children 6 to 23 months). This risk was first noted in 2010-2011, and the risk was highest in the older children peaking at 16 months of age. Two vaccines were involved, PCV13 and inactivated flu vaccine, usually delivered at the same time. There was also an increased risk of spontaneous abortions in women who received trivalent IIV in the 2010-2011 timeframe. Since findings are inconsistent with other studies, another study will be undertaken to see if the findings persist.

Turning to recent publications, Dr. Shimabukuro commented that Sukumaran et al (*Vaccine* 2015 Jul 23) compared the VSD populations with the US population and found that the two groups shared significant demographic and socioeconomic characteristics, and that the VSD population was sufficiently large to fairly represent most special population groups. Miller et al, Vaccine Safety Resources of Nurses (*Am J Nurs* 2015 August), described CDC's vaccine safety monitoring system to help nurses and others access data in the system. Grohskopf et al. discussed Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices in the United States for the 2015-16 Influenza Season (*MMWR* 2015 Aug 7).

Dr. Shimabukuro said that he and others (in *Vaccine* 2015 July 22) described VAERS, explained fundamental vaccine safety concepts, and discussed the strengths and weaknesses of VAERS. Baker et all (*Clin Infect Dis* 2015 Jun 9) described development of open-source, generalizable clinical decision making support called Electronic Support for Public Health (ESP) VAERS, which could increase adverse event detection and reporting. Moro et al (*Clin Infect Dis* 2015 May 28) analyzed death reports from 1997 to 2013, and no issues of concern were noted. Causes of death reflected those most common for the U.S. population as a whole.

Haber et al (*Vaccine* 2015 Aug 11) observed a significant increased risk (1.2 to 2.8 per 100,000) of intussusception 3 to 6 days after the first dose of rotavirus, but that small risk is outweighed by the benefits of rotavirus vaccination. Iqbal et al (*The Lancet Infectious Diseases* 2015) looked at VAERS safety data related to the introduction and changeover to inactivated poliovirus vaccine (IPV). They observed few adverse events in more than 250 million IPV doses distributed between 2000 and 2012; sudden death syndrome in infants was comparable to other vaccines; and no new or unexpected vaccine safety issues arose.

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

Ms. Schuster reported that in 2013, the NIH initiated a large, long-range study, the National Children's Study, which was reviewed in 2013 by the Advisory Committee to the NIH Director. That committee found the study infeasible as designed and Dr. Francis Collins, NIH Director, ended the study. A revised study, the Environmental Influences on Child Health Outcomes (ECHO) Program was proposed. A period for public comment was published in the Federal Register. It ended recently. ECHO focuses on perinatal, prenatal and postnatal outcomes in four focus areas: obesity, birth defects and other early outcomes; neurological disorders (including ADHD and depression); and airway diseases (including allergies and allergies).

NIAID supports influenza research, including a universal flu vaccine that would provide protection for a wide variety of flu strains. This would obviate the need to identify the four or so strains most likely to dominate during each year's flu season. An experimental universal vaccine has been developed and is being tested in mice and, if successful, then tested in larger animals (like ferrets) and then in humans.

Another vaccine being studied targets the Epstein-Barr virus, which affects 9 in 10 individuals in their lifetimes, is associated with mononucleosis, and contributes to the occurrence of certain cancers in about 200,000 individuals each year. Researchers are working on an experimental nanoparticle vaccine, which has been shown to be effective in some lab animals. The innovative nanoparticle vaccine design may be helpful in developing or redesigning vaccines for other pathogens.

In another area of research, Ms. Schuster discussed Middle East respiratory syndrome (MERS), an illness identified in 2012, and named MERS coronavirus. It causes pneumonia and has been responsible for over 500 deaths. A vaccine under development has been tested in monkeys and camels (which appear to carry the virus and transmit the disease to humans).

Finally, Ms. Schuster commented on antimicrobial resistance, a phenomenon in which an antimicrobial drug will lose effectiveness. To underscore the importance of the issue, the current administration has developed a national action plan to address antimicrobial resistance. Ms. Schuster commented that, in July, Dr. Carol Heilman, Director of the NIAID Division of Microbiology and Infectious Diseases, published an editorial in *Infectious Disease News* that included several points. First, many of the resistant antimicrobials are associated with hospitals and causing small, unanticipated outbreaks that must be addressed promptly. Second, in developing vaccines, researchers must be alert to the effect that vaccines may have on beneficial human flora in the gut. Finally, there are complex regulatory and policy challenges to implementing vaccine programs. Dr. Heilman proposed prophylactic immune interventions targeted at high-risk populations, such as individuals entering the hospital environment for elective surgery.

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

Ms. Marshall reported that in May 2015, the FDA approved a supplement to the biologics license application (BLA) for Prevnar 13, pneumococcal polysaccharide conjugate vaccine, to update the package insert to include data from the Community-Acquired Pneumonia Immunization Trial in Adults, which is a confirmatory efficacy study. The study showed that Prevnar 13 prevented a first episode of community-acquired pneumonia in adults 65 and older. In June-July 2015, the FDA approved revisions to the BLA supplement for licensed seasonal influenza vaccines, based on the Vaccine and Related Biological Products Advisory Committee (VRBPAC) recommendation that the trivalent formulation for the 2015-2016 flu season contain A/California H1N1-like virus; A/Switzerland H3N2-like virus; and B/Phuket/3073/2-13-like virus. The VRBPAC also recommended that quadrivalent vaccines contain those three flu strains plus B/Brisbane/60/2008-like vaccine.

VRBPAC will meet on September 15 to address the safety and immunogenicity of seasonal trivalent influenza vaccine, surface antigen, inactivated with the addition of an adjuvant MF59 (FLUAD), which is manufactured by Novartis.

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

Dr. Bok reported that the regular review of data published on vaccine safety, usually conducted by the Institute of Medicine, which is not a federal agency. Last year (2014) the survey was completed by the federal Agency for Healthcare Research and Quality. Dr. Bok stated that she would share that report with the Commission when it becomes available.

Dr. Bok described two studies in progress at the NVPO. The first is collaboration with CDC to evaluate the vaccine safety systems ability to test and survey the safety of vaccines administered during pregnancy. The second study is a clinical study of the safety of simultaneous administration of Tetanus Toxoid, reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and Inactivated Influenza Vaccine (IIV) in Pregnant Women.

Finally, with regard to the Cooperative Agreement for Research, Monitoring, and Outcomes Definitions for Vaccine Safety, two grants were awarded, one for establishment of a vaccine safety pregnancy database, and the other for prevention of injection site pain and syncope associated with preteen and teen vaccinations. The latter program is being done at Oregon Kaiser Permanente.

Public Comment

Comments by Janet Cakir

Janet Cakir commented that the ability to process claims should not prevent the extension of the statute of limitations. Secondly, Ms. Cakir recommended that the ACCV resubmit the letter of recommendation to extend the statute of limitation previously sent to the Secretary of DHHS, and include a request that the Secretary, within two months, officially respond, indicating whether or not there is support in her office for pursuing the recommendation. Ms. Cakir also recommend that the ACCV request that HRSA post the notes from this meeting in HTML format, because relying only on PDF format could be interpreted as impeding word search by the public of those notes.

Ms. Cakir also explained that she had been trying to file a claim for her son for four years. At the outset, she was told to wait until the Omnibus Autism Proceeding (OAP) was resolved. After a year she again contacted HRSA and was told that she could not file a claim unless her son had died and, after pursing a further explanation, she was told by a representative of HRSA that she would be added to the OAP. In the spring of 2015 she called again and was told she could not file a claim because the statute of limitations had expired. Again following up, a HRSA representative told her a claim would be established, providing her with a with a specific claim number. After 90 days Ms. Cakir called to check on the claim and a HRSA representative explained that there was no such claim and that the number she cited was not a valid claim number. A later phone call resulted in a voicemail response that Ms. Cakir could not file a claim unless her child was dead or hospitalized. Ms. Cakir recommended that ACCV conduct a review of customer service messages by HRSA, and that the ACCV direct the Special Masters court to apply equitable tolling in cases that involved misleading information provided by HRSA representatives.

Ms. Cakir recommended that ACCV recommend that the Secretary direct HRSA to post on the web the number of cases awarded and the number that were based on autism. In addition, the ACCV should recommend to the Secretary that representative members of the Senate Subcommittee on Health, Education, Labor and Human Services, and the House Subcommittee on Energy, Commerce and Health, be appointed to represent the political concerns of those committees. Finally, physicians should not discourage parents from reporting an adverse event; and they should ask parents if they want to report an adverse event.

Comments by Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC)

Ms. Wrangham commented that the NVIC worked with Congress to pass the law that created the VICP, the purpose of which was to acknowledge that vaccine injuries were real and deserving of compensation in a no-fault environment. The law also provided that patients receiving vaccines are given information on risks and benefits. Since its enactment the process of the law has become increasingly adversarial for petitioners. The response of the medical community has been prejudicial to those who seek redress for vaccine injuries. NVIC regularly receives calls expressing concerns about financial and emotional burdens from vaccine injuries; fears that child protective services will be called in if a parent chooses not to vaccinate a child; frustration when a parent hears about the VICP too late to file a claim; fear that a vaccine-injured child will be excluded from day care or school; and concern about obtaining a medical exemption from vaccination.

Ms. Wrangham expressed the opinion that the federal government has adopted a policy that discourages exemptions. She commented that the extensive ad campaigns for various vaccines, particularly influenza vaccination, should be counterbalanced by similar ad campaigns that explain the risks of vaccination and the availability of the VICP. Ms. Wrangham recommended that the ACCV support outreach efforts to provide that education. She also recommended that ACCV actively pursue the provision of a rationale from the Secretary as to why the previous ACCV recommendations have not been acted on. Finally, she recommended that the ACCV meet in person rather than by teleconference, and that the public be invited to attend those meeting.

Future Agenda Items

Asked about the lookback period that applies to injuries added to the Vaccine Injury Table, Dr. Houston explained that when a vaccine or an injury is added, there is a two-year prospective opportunity to file a claim based on any injury that occurred within the past eight years of the date when the injury/vaccine was added to the Table.

There was a suggestion that there be follow-up on the funding/workload issues which were discussed in brief earlier in the meeting.

Mr. Krause suggested that the Commission address the general issues raised by Ms. Cakir. Dr. Houston agreed that the issue could be discussed at a future meeting, but clarified that claims are not filed with HRSA, but are filed with the U.S. Court of Federal Claims. That information is provided when individuals call HRSA and it is on the web site. A HRSA representative would have no information on the status of claims at the Court. Asked about whether there was a mechanism to redirect such calls to the Court, Dr. Houston stated that she knew of no such mechanism, and that the toll-free number is answered in her office and a standard response is provided for such inquiries.

Ms. Stewart suggested creating a position for a vaccine injury ombudsperson. It was noted that the National Vaccine Information Center perceives that the Center has that role. Mr. Krause noted that the NVIC is not a federal agency. There were comments in support of establishing that kind of service in an appropriate federal office.

Concerning in person meetings, it was noted that under the present policy two in person meetings are authorized, and the choice of which meeting dates would be in person is at the discretion of the ACCV Chair.

There was a brief discussion about replacing Commission members who will be rotating off. Dr. Houston explained that the Federal Register notice that was published earlier in the year failed to elicit nominations in all of the required categories. Noting that only the recently added members would continue on the Commission (terms ending in 2018), six new members would be needed. There are three basic categories – health care professional (two pediatricians), attorney (petitioners attorney and manufacturer attorney), and public (two - parent, and member of the general public or a representative of the ob-gyn profession), for a total of six new members. It was clarified that a vaccine-injured individual could be in the public category.

Adjournment

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