Advisory Commission on Childhood Vaccines

June 14, 2012

Minutes

Members Present

David King, Chair
Charlene Douglas, Ph.D.
Kristen Feemster, M.D.
Edward Kraus, J.D.
Ann Linguiti Pron, MSN, CRNP, RN (via telephone)
Luisita dela Rosa, Ph.D.
Jason Smith, J.D.
Sylvia Fernandez Villareal, M.D.
Michelle Williams, JD

Division of Vaccine Injury Compensation

Geoffrey Evans, M.D., Director, DVIC

Welcome, Report of the Chair and Approval of Minutes
David King, ACCV Chair

Mr. King called the meeting to order and, after introductions, discussed a proposal developed by the Agenda Committee to establish working groups to consider an overarching question: What would a perfect vaccine compensation program look like and what existing barriers would impede development of such a program? To that end the first three working groups would look at vaccines and pregnancy (chaired by Dr. Feemster), attorney's fees (co-chaired by Mr. Kraus and Mr. Smith), and Commission process (chaired by Ms. Dela Rosa). The first meetings of the working groups would be held immediately following the ACCV meeting, and future meetings might be scheduled via teleconference, none simultaneously so that members would have the option of attending any or all the working group meetings.

Mr. King also said that the Agenda Committee discussed the concept of themed Commission meetings, so that one or two major areas of interest could be more thoroughly reviewed. In addition he expressed the opinion that meetings should be less reactive than in the past, when the Commission mainly hears reports, and more proactive and interactive.

Turning to approval of the March minutes, Mr. King invited comments, and there was a suggestion that, on page 6, when Dr. Johann-Liang recommended three ways to consider each Table revision, that the last sentence be amended to read: There was general agreement among ACCV members to follow this *three-step* approach (change in italics). With that change, on motion duly made and seconded, the Commission unanimously approved the minutes of the March 8-9, 2012 meeting minutes.

Report from the Division of Vaccine Injury Compensation,
Geoffrey Evans, Director, DVIC

Dr. Evans welcomed Commission members and guests to the 84th meeting of the Advisory Commission on Childhood Vaccines, and briefly reviewed the agenda. Turning to the numbers, Dr. Evans reported that total claims filed this fiscal year should be about 350 claims, down from a 2010 high of 448 claims. Approximately half thus far are for influenza and the majority has been filed on behalf of adults. In terms of adjudications, a large number are attorneys' fees and costs decisions in Omnibus

Autism Proceeding claims. Most final judgments for non-autism claims are through settlement (about 80%) and four cases were conceded for entitlement to compensation by DVIC. Total awards, including attorney's fees and costs, will probably be about $192 million, down from the high of $234 million in 2011. Finally, Dr. Evans stated that the Trust Fund balance is $3.4 billion at mid-year. By the end of the year tax revenues and accrued interest should be about $240 million, which should exceed outlays. The proportion of that amount that is interest is less than in the past, reflecting current low interest rates.

Under Significant Activities Dr. Evans updated the National Vaccine Advisory Committee on the VICP at its meeting on June 5-6. VICP background, process, significant events and current activities were covered during the 30-minute session. In the discussion that followed, he explained that the decrease in concessions over the past several years is because of the significant increase in influenza claims. Trivalent influenza vaccines are listed on the Vaccine Injury Table but currently do not have any injuries listed. Therefore, petitioners must prove causation in order to receive compensation.

There was a brief discussion about the issue of so few concessions, and Dr. Evans reminded the Commission that the reason was that most of the current claims are "off-Table" meaning that they allege conditions not listed on the Vaccine Injury Table. The last Commission meeting was devoted to consideration of proposed revisions to the Table, which if the changes are approved, would increase the number of injuries listed for influenza and other VICP-covered vaccines. One member noted that claims compensated through settlement typically do not contain much evidentiary information; usually only the claimed injury and vaccine alleged to have caused the injury, the settlement terms and the award are published. Other information, which would be helpful to those filing subsequent claims, is not released. That means that most plaintiffs' attorneys must start from scratch in building their cases, especially for the basis for awards. Dr. Evans commented that the Department of Justice has been routinely providing settlement information during their ACCV presentation, and that Mr. Matanoski could better address the issue during his update.

Report from the Department of Justice,
Vincent Matanoski, Assistant Director, Torts Branch, Department of Justice

Mr. Matanoski referenced the DOJ Power Point materials, dated June 14, 2012, (DOJ PP) as part of his presentation.

After greeting the Commission, Mr. Matanoski expressed that DOJ provides a quarterly snapshot of statistics that are reported at ACCV meetings. (DOJ PP, p. 2 "Reporting Period 2/16/12-5/15/12"). Looking at non-autism claims, Mr. Matanoski observed that nearly 100 non-autism claims were filed. Seventy percent of those claims were filed by adults. This is because there is a cohort for the influenza vaccination that includes the entire population and not just the birth cohort. During this reporting period, 96 non-autism and 0 autism petitions were filed. Of those 96 new petitions, 70 were adults and 26 were children. (DOJ PP, p. 2).

Turning to the next slide, there were 731 cases adjudicated, the majority of which (609) were dismissed autism cases. (DOJ PP, p. 3). There were 68 non-autism cases dismissed without compensation. There were 54 cases compensated. Of those 54, five were conceded by HHS. Mr. Matanoski noted that the numbers in this slide reflect cases that have gone to judgment, and thus these cases may have been filed years ago. In contrast, the statistics provided by Dr. Evans for HHS are considered "real time" in terms of providing statistics when the cases were filed (pre-judgment). Of the 5 conceded cases, damages were resolved in those by a decision adopting a proffer in 4 cases, and 1 case was resolved by a decision adopting a stipulation. There were 49 cases not conceded by HHS but nevertheless were compensated. Of those, 1 case was decided on damages by a Special Master, 5 were resolved by a decision adopting a proffer, and 43 were resolved by a decision adopting a stipulation, known as lititgative risk type settlement. (DOJ PP, p. 3).

At this point, Mr. Matanoski paused his slide presentation to address questions raised earlier in the meeting during Dr. Evans' presentation. As summarized by Mr. Matanoski, Mr. Kraus asked about

the nature of settlements versus concessions, and if there were cases in the Program that ought to be conceded, but instead were being settled. Further, does that mean that people are reinventing their case each time? Finally, he asked if settlements publicly available.

Addressing the last question first, Mr. Matanoski explained that the information should be publically available. When a case is settled, the court issues a decision, which includes the stipulation. The decision and stipulation, which includes the terms of settlement, are filed and available to the public. Under the Vaccine Act, petitioners have an option to redact certain personally identifying information from the decision, such as the name of a minor child, although the decisions remain intact. All decisions including those adopting stipulations, are publically available.

Addressing the broader question as to how settlements fit in to the picture, Mr. Matanoski explained that settlements were useful tools for resolving cases in the Program. Illustrating his point, Mr. Matanoski noted that a settlement constitutes an agreement between the two parties. As such, the relative strengths of a case are evaluated and likely affect the amount of settlement. Mr. Matanoski did not think that settlements were causing petitioners to "re-invent the wheel" with each new case. He noted that the Court has issued guidelines to assist practitioners in the settlement process, and he believed that those were being updated. Speaking from his experience, Mr. Matanoski found that many of the vaccine practitioners are experienced in the Program and he has not seen cases slowing down in the settlement process. Mr. Matanoski noted that a concern could be that people may not realize that they had a viable claim if many similar cases settled and settlement information were not publically available. That is, would one realize that he/she had a viable case if many of those cases settled? Parenthetically, Mr. Matanoski noted a decline in claims being filed untimely, which he attributed to awareness of the Program, availability of information on the internet, and an informed petitioners' bar. Many law firms now represent petitioners from all over the country, so cases are brought nationally, as opposed to locally.

Mr. Kraus asked about the specific information in the settlement agreement. Citing a lititgative risk settlement, Mr. Matanoski replied that settlement stipulations contain the vaccine involved, alleged injury, date of vaccination, and the amount of the settlement.

In follow-up, Mr. Kraus commented that while that information has some use, what is missing is any discussion of the medical, scientific literature, and/or medical expert—nothing that builds "public knowledge about sort of the mechanistic evidence that is out there [connecting] a vaccine with a particular vaccine injury." Mr. Kraus noted that there should be a distinction between awareness of the Program versus awareness of the broader science and/or mechanistic evidence. Mr. Kraus acknowledged Mr. Matanoski's point that attorneys who handled petitioners' claims were experienced and well-connected in the vaccine community, but questioned whether such knowledge extends beyond that community. Mr. Kraus also responded to Mr. Matanoski's comment about a decrease in untimely cases filed, stating that he attributed it to practitioners unwilling to file untimely or arguably untimely claims because there is no likelihood of getting attorneys' fees. He acknowledged that could change depending upon the Federal Circuit's decision in *Cloer v. HHS*. Mr. Matanoski agreed with Mr. Kraus that settlement stipulations do not contain actual medical evidence; however, they do include the name of vaccine and alleged injury, along with contact information for the petitioner's attorney who handled the claim. As a practical matter, one interested in pursuing a similar claim could call the attorney. Mr. Matanoski cautioned that settlements between parties occur for many different reasons, and factors such as the strength of a case may both affect the amount of the settlement and each party's underlying decision to settle.

Dr. Shimabukuro commented that he had read some decisions and wondered whether in a concession more detail, similar to what Mr. Kraus had referenced, was included.

Dr. Shimaburkuro added that settlements, which are agreements, would contain fewer facts than a decision. Mr. Matanoski replied that decisions awarding compensation in a conceded case typically would not contain lengthy detail about facts or evidence because it has been conceded and the Special Master is not deciding entitlement. On the other hand, when a case is contested on entitlement, and there is a decision in petitioner's favor, it would include a discussion on the medical evidence. Likewise, a decision denying entitlement to compensation would contain substantial detail on the evidence. More

discussion about the evidence would also be expected in decisions following a hearing. Mr. Matanoski reiterated that all cases are subject to a final decision, i.e., settlements still need to be approved by the Court, and a decision adopting a stipulation of settlement terms would be issued.

Mr. Kraus added that in a concession, the government agrees that the vaccine caused the injury, which is significant. In a settlement, respondent disagrees that the vaccine caused the alleged injury but will nevertheless resolve the case by settlement. As an attorney who represents vaccine injured clients, Mr. Kraus echoed that the speed of resolving a case by settlement is an important factor for seriously injured clients. If there is an offer to resolve the claim now, as opposed to waiting two or three years later and risking an unfavorable decision, one could understand why many of the vaccine injury cases are being settled. Mr. Matanoski added that in an actual causation cases, the Secretary could agree that the vaccine caused the injury and concede. In contrast, in a presumptive Table claim, the Secretary would state that the vaccine fit the Table criteria for presumptive injury and that the case should be compensated.

Dr. dela Rosa asked about the process of settlements, life care plans, and proffers and the stages involved in those. Responding, Mr. Matanoski referred to slide 8 in his presentation as a visual guide. (DOJ PP, p. 8). As an example, Mr. Matanoski explained that if a case was conceded by HHS, it moves to damages, which may include life care planners to determine the type of damages, as well as costs associated with services. Some claims do not need life care planners, although more complex cases would likely use life care planners. If the parties disagree about the damages, the Special Master may issue a decision, if they do agree upon what the evidence shows on damages, and then a claim could be resolved by proffer. If the parties disagree upon the level of damages, they can still settle the case using life care planners. Life care planners are also used in settlements involving complex medical cases where a decision on entitlement has not been issued by the special master. Determining a settlement amount can still be somewhat complicated in any given case. Essentially, the complexity of the injury in any given case drives the amount of evaluation needed to determine damages. In a lititgative risk context, the parties gauge their respective levels of exposure and make choices about how to resolve a claim based on the complexity of the specific facts and injury, including speed of resolution.

Dr. dela Rosa asked whether the Special Master issues a decision finding or denying compensation in settled cases. Mr. Matanoski replied that in a litigative risk settlement, the parties decide to settle before the Special Master decides entitlement in the case. However, there could still be a settlement after a Special Master issued a decision finding entitlement. In that instance, the settlement would be about the damages.

Mr. King asked if conceded cases can be broken down by presumptive versus causal, and whether that information would be helpful to the ACCV. Mr. Matanoski did not know the breakdown. Dr. Evans contributed that ninety percent or more concessions were presumptive. Mr. King clarified that presumptive meant “on the Table” and that if it was on the Table, it was conceded. If the injury was not on the Table, the cases are settled, which Mr. King noted appears to be a trend. Referencing off-Table cases, Mr. King summarized that the parties fight over what caused the injury and determine to settle. Mr. Matanoski agreed.

Dr. Feemster commented that it is not required that an injury be on the Table to be conceded. Rather, it is about weighing the available evidence to decide whether or not there is causation. Even if an injury is not on the Table, based on the evidence of a causal relationship, the claim could be conceded. Likewise, if there is not enough evidence to meet the bar of causation, it can be settled. In sum, Dr. Feemster noted that a claim is conceded if there is causation or the injury is on the Table. Mr. Matanoski agreed and added that conceptually, most cases that are conceded should be conceded because the injuries are presumptive. If there is good scientific evidence supporting causation, one would want to see that move to the Table as a presumptive injury. But there is also the ability for a concession on actual causation based on the evidence.

Mr. King observed that the Table could be viewed as a lagging indicator of injuries because it takes time for the science to develop, and time for injuries to be added to the Table. The process can take

years. Mr. Matanoski agreed, and noted that with good science, one might see cases conceded under actual causation standard and then later move to the Table. This "lag time" affords a safety net for the DVIC agency to concede cases where the evidence is strong while an injury is moved to the Table. In response, Mr. King questioned whether or not this issue lends itself to a working group noting that the issue of presumptive versus casual seems to turn on the interpretation of the science, which can be interpreted differently by the different parties. Mr. Matanoski considered that assessment to be fair. Mr. King further added that in trying to do what is best for the Vaccine Injury Compensation Program, one question is what is the best way for this issue to move forward, and suggested a working group. He also added that another component to explore would be timeliness, and whether or not claims are being filed timely, and attorneys' fees in that regard. Mr. Kraus said that as a petitioners' attorney, he was in favor of expanding the statute of limitations from the three years, noting that there have been legislative efforts to expand the statute of limitations beyond 36 months from the onset of injury. Mr. Kraus added that he has received calls from people who may have potential vaccine claims that cannot be filed because the injury manifested over four years ago. Mr. Kraus questioned if that issue should be addressed by a working group. Dr. dela Rosa asked whether it were true that the statute of limitations is triggered by the first symptom of the injury, not the date of the vaccination, which Mr. Matanoski confirmed. Mr. Kraus clarified that it was unlikely that the first symptom would, for example, manifest four or more years after vaccination, and even if it did, it would be extremely difficult to prove a temporal association in that instance. While theoretically possible to prove causation if you had a vaccine in 2008 and your first symptom started in 2012, as a practical matter proving causation would require looking into that gap of time. Mr. Kraus added that the autism litigation showed that people did not realize a vaccine may have caused their injury until after the statute of limitations expired.

Returning to his presentation, Mr. Matanoski identified slides 5 through 8, which showed the glossary of terms and wire diagram of petition processing. (DOJ PP, pp. 5-8). There were no questions. Focusing on slides 9 and 10, Mr. Matanoski explained that these slides were new and were included in response to questions raised at the last meeting about what happens on appeal. (DOJ PP, pp. 9-10). Mr. Matanoski first addressed the levels or tiers of appeal. A decision by the Office of Special Masters can be appealed to the U.S. Court of Federal Claims (CFC), which is an appeal of right, and is the first level of appeal. The next tier of appellate review is the U.S. Court of Appeals for the Federal Circuit (CAFC or Federal Circuit), where a panel of three judges hears the appeal. At this level, there is the opportunity to request to have your case heard by the entire Federal Circuit, *en banc.* The next level of appeal from the Federal Circuit is the U.S. Supreme Court, which is discretionary. (DOJ PP, p. 9).

Mr. Matanoski next referenced the "wire diagram" illustrating the appeals process. (DOJ PP, p. 10). A decision by the Office of Special Masters awarding or not awarding compensation may or may not be appealed. If is not appealed, then judgment enters. If it is appealed, then it moves on the wire diagram to the Court of Federal Claims. The Court can either affirm or reverse the decision. The CFC judge may also enter his/her own findings. The CFC may also identify a problem with the case and send it back to the Special Master for further proceedings, which is called a remand. Upon remand, the Special Master may enter another decision, with another appeal opportunity to the CFC. Ultimately, a decision by the CFC can be appealed to the Federal Circuit. The Federal Circuit can affirm or reverse the CFC decision. The Federal Circuit can also reverse and enter its own decision, or remand the case back to the CFC for further proceedings. In that instance, the case could end up back to the Special Master for further proceedings if the Federal Circuit decides that the Special Master erred and the CFC affirmed that error. At the final tier, a case could be heard by the Supreme Court, if the Court accepts the appeal.

Mr. Matanoski next discussed appellate activity beginning with the Federal Circuit. (DOJ PP, p. 11-12). *Hammitt v. HHS* and *Stone v. HHS*, both involved Dravet's Syndrome and were appealed by petitioners to the Federal Circuit and affirmed. (DOJ PP. p. 11). The Federal Circuit affirmed the decisions by the Special Master and CFC, which found that the Dravet's Syndrome was caused by the SCN1A genetic mutation, and that was responsible for the injury alleged to be caused by vaccination. Another case, *Simanski v. HHS*, turned on a legal issue and was reversed. (DOJ PP, p. 11). In *Simanski*, the Special Master dismissed petitioners' case because they did not follow an Order to supplement their expert report with further information. On appeal by petitioners, the Federal Circuit reversed because, technically, the Special Master used a summary judgment process, that had not

evaluated the evidence in the light most favorable to the non-moving party as required in summary judgment. The Federal Circuit remanded and instructed the Special Master to either apply the summary judgment standard and determine if the case should be dismissed, or take more evidence. *Hager v. HHS*, appealed by respondent, was a companion case to *Rotoli v. HHS* and *Porter v. HHS*, which had previously been decided in respondent's favor. (DOJ PP, p. 11). In *Rotoli-Porter*, which was reported at the last ACCV meeting, the Federal Circuit reversed the CFC, finding that credibility determinations by a Special Master are entitled to deference. As in *Rotoli-Porter*, the Federal Circuit in *Hager* reversed the CFC and reinstated the Special Master's decision denying compensation.

As has been discussed at prior meetings, *Cloer v. HHS*, originally involved a statute of limitations issue where the Federal Circuit found that the statute of limitations runs from the onset of the first symptom of the vaccine injury. (DOJ PP, p. 11). Certain exceptions can be made to the statute of limitations in extraordinary and extremely rare circumstances. *Cloer* also raised a question of recovering attorneys' fees in untimely claims. In the recent 7-6 *en banc* decision, a majority of the Federal Circuit found that petitioner's attorneys in *Cloer* could receive fees, even though their claim was time-barred, because it was not frivolous when it was filed. The dissent disagreed, and looked at the text of the statute to say that if a petition is untimely, it may not be filed; thus, Congress could not have intended that attorneys' fees be provided when such a barred petition is filed. Mr. Matanoski explained that we will wait to see how this develops, but predicted increased transactional costs to litigate whether or not the case was untimely and if attorneys' fees should be paid. He added that this may become important in resolving autism claims as a number of those petitions were untimely when filed. Attorneys may, nevertheless, now be seeking to demonstrate good faith and reasonable basis when filing the petition to obtain attorneys' fees for untimely claims. Mr. Matanoski predicted increased litigation and diversion of litigation resources to address those claims. Identifying a potential litigation resources issue involving attorneys' fees versus other areas, Mr. King asked if there was any way to add resources to DOJ to address the fees problem as opposed to removing resources from other areas that the Program focuses on. Mr. Matanoski felt that it was a budget issue, noting that currently DOJ has staff fully engaged in working cases, and has reduced processing time over the years. He attributed that to the hard work of all parties including the Court and petitioners, as well as willingness and cooperation to engage in other tools such as settlements to move the cases. He further noted a government hiring freeze. Mr. King acknowledged Mr. Matanoski's point that these issues might occur in the future. Mr. Matanoski predicted that these issues will likely continue in the future if the decision in C*loer* remains. Mr. Matanoski commented that he was unaware of the number of cases that may be considered eligible for equitable tolling, but based on past experience, he felt that there were few. In cases that are deemed eligible for equitable tolling and thus, timely, attorneys' fees would be available regardless of the recent *Cloer* decision.

Mr. Matanoski then turned to slide 12, showing cases pending at the Federal Circuit. (DOJ PP, p. 12). *Viscontini v. HHS*, is a recent appeal by petitioner, involving a hepatitis B vaccine and Crohn's disease. The Special Master found that petitioner was not entitled to compensation, and the CFC affirmed. In *Doe 21 v. HHS*, a new appeal by respondent, the Special Master found respondent's experts more credible on the scientific issues. (DOJ PP, p. 12). It was appealed to the CFC, which disagreed with the Special Master's credibility determinations. Respondent has appealed the CFC decision to the Federal Circuit because we believe that the issue is similar to *Rotoli-Porter* in that the CFC should afford deference to the Special Master in making factual and credibility determinations.

Turning to the CFC, Mr. Matanoski noted that several cases were recently decided by the CFC. (DOJ PP, p. 13). *Paluck v. HHS*, involved a mitochondrial disorder where the Special Master found that petitioner did not establish causation. The CFC reversed and remanded to the Special Master for further proceedings. *Phillips-Deloatch v. HHS* involved a writ of mandamus, which is an unusual issue in a Vaccine case. Petitioners sought a writ of mandamus to force the Special Master to issue a subpoena to a non-party drug company to obtain certain information about the Gardasil vaccine. Because the Special Master denied petitioners' request, finding that they had not established the need for this extraordinary discovery, they sought to use the writ authority at the CFC to order the Special Master to issue the subpoena. The CFC denied the writ. The case remains with the Special Master to decide the merits of the entitlement claim. *Deribeaux v. HHS* is another Dravet's Syndrome (SCN1A) case with similar issues

to *Stone* and *Hammitt*. It was recently affirmed by the CFC. *McKellar v. HHS* and *Woods v. HHS* involved interim attorneys' fees and costs awards. The Secretary appealed these cases because of concerns about whether interim fees were permitted under *Avera* given the posture of the cases, and whether or not a reasonable basis was established. In each instance, the CFC reversed the finding of interim fees and costs and the cases were remanded to the respective Special Masters.

Several new cases were filed at the CFC. (DOJ PP, p. 14). *Graves v. HHS*, involves a $60,000.00 award in pain and suffering in addition to the $250,000.00 statutory death benefit based on the Federal Circuit *Zatuchni* decision. Petitioner appealed the award contending that the amount was insufficient. *Castaldi v. HHS*, involves a statute of limitations issue, where the Special Master issued findings of fact but not a final decision. Petitioner appealed and the case presents an interesting question about whether such an appeal, also called an interlocutory appeal, can be heard by the CFC before a final decision issues. *Contreras v. HHS* involves a potential fact issue. *Davis v. HHS*, appealed by petitioner, involves attorneys' fees and costs. The Special Master denied attorneys' fees for petitioner's appeal (of a decision denying compensation) to the Federal Circuit. The Special Master awarded some attorneys' fees for petitioner's CFC appeal but denied all fees associated with the Federal Circuit appeal finding that petitioner's Federal Circuit appeal lacked a reasonable basis in light of existing case law that was neither examined nor cited by petitioner in bringing the appeal.

Mr. Matanoski next discussed settlements and offered a broad overview. (DOJ PP, pp. 16-20). He touched on the three oldest cases, two of which were twelve years old. They were both hepatitis B cases that were part of the hepatitis B omnibus, and sat idle for a number of years during omnibus proceedings. Additionally, there was one settlement that took six years to process, with five years spent waiting for petitioner to provide an expert report. In 2010, an expert report was produced and the case moved forward to a hearing. It was settled thereafter. Turning to the three shortest settlement time-frames, those cases either had the medical records filed at the time the petition was filed, or shortly thereafter. Mr. Matanoski observed that there were 44 cases listed as settlements during this quarterly period. Of those, 29 claims, or about two-thirds, were resolved within two years. Eighty percent of the cases were resolved within three years. Mr. Matanoski commented that the settlement process continues to move cases quickly.

Ms. Williams thanked Mr. Matanoski for his presentation. She observed that there appears to be an ongoing trend that more cases are filed "off-Table," and asked whether those cases take longer to process. Mr. Matanoski answered that off-Table claims do not necessarily take more time. Off-Table cases may not have strong enough evidence to meet a presumption standard, but they may be strong enough nevertheless to move through settlement by the Special Master or settlement by another process. Additionally, conceded cases may have very complex damages issues, and damages settlements can be a lengthy process. Mr. Matanoski offered that conceptually, presumptive cases would move faster than off-Table cases. Ms. Williams asked whether it would be useful to provide data on processing times for Table versus off-Table cases. Mr. Matanoski acknowledged that intuitively one would expect presumptive cases to move faster because the claim moves directly to damages. Ms. Williams asked whether or not DOJ had that type of information. Mr. Matanoski said DOJ would see if it could provide the data. Acknowledging that the Program is not doing anything differently, Ms. Williams questioned whether it should. Replying, Mr. Matanoski cautioned against trying to draw conclusions from that type of data given the uncertainty of damages and that some cases present complex damages in a conceded case, as opposed to a non-conceded case. The sample size of conceded cases will be fairly small, while the sample size of non-conceded cases will also include many cases that are settled by lititgative risk, which also bypasses entitlement. Those cases tend to move quickly through the process because they do not necessarily have a hearing. Damages may be less complex for an individual who, for example, brings a case and moves into settlement with an overall number in mind so damages processing may be reduced.

Dr. Villarreal asked if the rotavirus vaccine on slide 21, which reflected an adjudicated settlement in nine months, was the original rotavirus vaccine that came off the market, or a newer one. Mr. Matanoski replied that it was the newer vaccine.

Update from the National Institute of Allergy and Infectious Diseases,
Barbara Mulach, NIAID, NIH

Dr. Mulach reported that NVAC conducted a session to discuss current outbreaks of pertussis and an apparent waning of immunity in the general public. There is a recommendation for pregnant women to receive the Tdap vaccine. NIAID is supporting a current Phase I study which will vaccinate pregnant women with Tdap and then looking at safety and immune response in the woman and in her baby when the woman is vaccinated and a second study getting ready to start a study in postpartum women, including an assessment of immune response in their babies. One goal of the study is to determine whether there is a declining immune response and whether there is a need to re-vaccinate the mother when a subsequent pregnancy occurs 2 or more years after the first child is born.

Dr. Mulach reminded the Commission that the Jordan Report is available from NIAID. It is a report of the status of vaccine research and it includes a number of expert articles on immunization. Finally, she noted that the director of NIMH, Dr. Thomas Insel, has started a blog on the NIMH web site about autism in the U.S. and globally. The blogs discuss research and the relationship of genetics and environment on current knowledge of autism causes and effects.

http://www.nimh.nih.gov/about/director/index.shtml

Update on the Center for Biologics, Evaluation and Research Vaccine Activities,
LT Valerie Marshall, CBER, FDA

LT Marshall announced that Dr. Marion Gruber had been appointed permanent director of the Office of Vaccines Research and Review (OVRR). She had been serving in an acting capacity for some time. The OVRR has not approved any new vaccines since the last Commission meeting, but there are several under review at the present time.

During discussion, Dr. Evans asked about a quadrivalent flu vaccine that might be appropriate for the seasonal influenza immunization program. He explained that, if approved for that program, it would not be covered under the VICP until the excise tax was in place. In addition, since current legislation specifically includes only a trivalent vaccine, there would have to be an amendment to the Act to include a quadrivalent vaccine. Nonetheless, because of the provision in the Act that allows an eight-year retroactive window for filing injury claims, individuals who receive the vaccine and may be injured would have recourse to the benefits of the VICP from the outset. Asked about the negative impact of such a delay by an injured individual who may need financial support during the delay period, Ms. Levine added that there would be immediate recourse to legal action against the manufacturer. Dr. Evans added that historically there have been no such delays for vaccines that were introduced and widely used. Although the Secretary does not request the excise tax, the manufacturers usually assume responsibility for requesting the tax since they have an incentive to be covered by VICP for the liability of injury.

Update on the Immunization Safety Office Vaccine Activities,
Tom Shimabukuro, ISO, CDC

Dr. Shimabukuro announced that the National Immunization Conference Online (NICO) meeting was held in March and presentations are available on the web. The vaccine safety session included an HPV vaccine safety review, a presentation on the IOM recommendations concerning revision of the Vaccine Injury Table and a presentation on immunization errors reported through the Vaccine Adverse Event Reporting System (VAERS). He added that the immunization errors presentation included examples of administration errors that did not result in adverse health events (pregnant women who inadvertently receive a live vaccine with no subsequent medical issue), and errors in vaccine administration that may result in adverse events (injections too high on the shoulder that may result in shoulder injury related to vaccine administration -- SIRVA).

Dr. Shimabukuro stated that the Advisory Committee on Immunization Practices (ACIP) would meet shortly after the ACCV meeting, and the agenda will include an update on influenza vaccine safety

monitoring, a discussion of GRADE – Grading of Recommendations, Assessment, Development and Evaluation – the program that ACIP is moving toward to guide vaccine recommendations, and an update from the IOM committee looking at identifying and prioritizing new vaccines for development. There will also be two votes, one for a recommendation about PCV13 use among immune compromised adults; and an annually recurring vote on influenza vaccines for the 2012-2013 flu season.

Listing publications of interest, Dr. Shimabukuro noted that there were three recent publications assessing risk of Guillain–Barré syndrome (GBS) following 2009 monovalent H1N1 vaccine. Taken collectively, the results of the studies indicate a small increased risk of GBS following H1N1 vaccine, similar to what has been observed in some past influenza seasons with seasonal trivalent inactivated influenza vaccine (TIV). He added that the risk was much less that that following the 1976 swine influenza vaccine. Another paper by Klein et al. concluded that the combination measles-mumps-rubella-varicella (MMRV) vaccine and the combination measles-mumps-rubella (MMR) + varicella vaccines were not associated with increased risk of febrile seizures among 4- to 6-year-olds. A final paper by Moro et al. indicated no serious safety concerns following high dose TIV in its first season of use.

National Vaccine Advisory Committee White Paper on the U.S. Vaccine Safety System, Dan Salmon, NVPO, DHHS

Dr. Salmon briefly discussed a question that has been mentioned at a number of ACCV meetings, the issue of comparative research of children fully vaccinated, unvaccinated, and those who may only receive selected vaccines. He stated that NVPO and CDC contracted with the Institute of Medicine to look at the feasibility of research related to those three groups of children. The assessment being done by the IOM is not focused on the efficacy of vaccination programs, but only the feasibility of conducting studies that look at health outcomes associated with different immunization schedules. What would the study produce in terms of conclusions, how would it be designed, how much would it cost, what were the ethics of the study, would confounding and biases affect the study plan, and what would the barriers be? The IOM established the committee of experts which has commissioned a paper on the subject, held three public meetings, invited experts to speak to the committee, and published information on the IOM website inviting public comment.

Dr. Salmon also announced that a metaanalysis was under way to look at the possible association of GBS with 2009 H1N1 vaccinations. The study will combine data from six surveillance systems, capturing more than 20 million immunized individuals. The six programs provide a broad diversity of those receiving the vaccine – the general population (Emerging Infections Program, Vaccine Safety Datalink, PRISM), the elderly (CMS data from Medicare/Medicaid), a co-morbid population (Veterans Administration) and an unusually healthy population (Department of Defense). This has been a very comprehensive safety monitoring program under the aegis of the HHS Assistant Secretary or Health through the Federal Immunization Task Force, which has representatives of a number of federal agencies (acronyms include FDA, NIH, CDC, HRSA, CMS, AHRQ, HIS, DoD and Veterans Affairs).

Turning to the main topic of his presentation, Dr. Salmon referred to a handout, the Draft White Paper on the United States Vaccine Safety System (also available on the NVAC website). Because of the length of the white paper, 54 pages, he indicated he would only highlight some important aspects. He began with the charge to the NVAC: *To review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.*

To that end the NVAC formed a working group of 18 members, nine of whom were current or former NVAC members, and public members, including Tawny Buck, co-chair of the working group and former chair of ACCV. There was broad expertise represented on the working group -- pediatric and adult infectious disease, genomics, immunology, epidemiology, public health, maternal and child health, pharmaco-epidemiology and biostatistics. The working group held a number of public meetings, soliciting input from partners in health issues, interest groups, advocacy groups, and the general public.

Dr. Salmon pointed to a busy organization chart on page nine of the report, noting that it illustrated the very complex nature of the national vaccine safety activities, including a number of federal agencies, as well as non-federal partners (industry, academia, professional organizations, advocacy groups). On page 25 of the report, the working group presents its overarching conclusion: *"as reflected in this review of the current system, the NVAC finds that the United States Vaccine Safety System is a fundamentally sound system for monitoring vaccine safety that has functioned well since the enactment of the National Childhood Vaccine Act of 1986, and believes the current system components should be maintained even in times of federal funding and uncertainty."*

Dr. Salmon commented that, although that statement was a positive affirmation of the system, the working group did develop a number of recommendations to make a good system better. He very briefly pointed out the key recommendations:

Leadership Recommendations

- 1.1 – reaffirmation of the system structure
- 1.2 – structural organizational changes Include AHRQ and HIS as Program participants
- 1.3 – enhancing the status of the NVAC

Coordination Recommendation

Expanded roles for task force and working groups

Assurance and Accountability Recommendations

- 3.1 -- Expanded role for NVAC in the NVP
- 3.2 -- Enhance the role of the task force and other coordinating bodies, including more interaction with NVAC at its regular meetings
- 3.3 -- Develop a mechanism to evaluate selected vaccine adverse events, including external evaluation on the IOM model
- 3.4 -- Monitor progress in enhancing the vaccine safety program.

Research Findings and Recommendations

- 4.1 -- Development of a vaccine safety research agenda
- 4.2 -- Support development of the vaccine safety research community
- 4.3 -- Support funding for research and investigator training
- 4.4 -- Identify public concerns and perceptions
- 4.5 -- Support research directed at clinical practice
- 4.6 -- Improve data access
- 4.7 -- Support a national biospecimen repository

Dr. Salmon interjected that the research agenda was a principal goal of the Department, mentioned in this report, in the National Vaccine Plan and by the IOM in its recommendations. To that end AHRQ is funding an extensive literature search of vaccine safety science that, when completed, will serve as the foundation for developing the national vaccine safety research agenda. Dr. Salmon also commented on the biospecimen repository, explaining that because adverse events are so rare the collection of enough specimens to complete effective research in the typical research project timeline is very difficult. By establishing a repository, sufficient biological specimens can be accumulated to design a proper study.

Post-licensure Surveillance Recommendations

- Proactive plans for post-licensure vaccines
- Expand and coordinate data collection
- Develop implementation programs for national agenda surveillance goals

Dr. Salmon noted that the FDA had been charged with developing an active surveillance system of 100 million individuals. The basis of the system in the FDA's Mini Sentinel Program that, when

combined with the other surveillance systems already mention, totals a very large number of people under active surveillance.

Clinical Practice Recommendations

- 6.1 – Improved guidance for clinicians in reporting adverse events
- 6.2 – Practices that can reduce administration errors, including barcoding vaccines

Finally, ßDr. Salmon commented that the report covers recommendations for improving communications (such as Vaccine Information Statements and package inserts), improving stakeholder and public engagement in vaccine safety, and the conduct of cost evaluations for the program across federal departments involved.

During discussion, asked about ACCV involvement, Dr. Salmon mentioned the importance of maternal health with regard to vaccine safety, an area of specific interest of the ACCV. He added that NVAC had established a maternal immunization working group that will look at new vaccines specifically for pregnant women, vaccine benefits for neonates, the importance of protection from pertussis in the mother that can be transmitted to the fetus. Dr. Salmon also mentioned the current interest in linking meaningful use data, electronic health records and vaccine safety surveillance data.

Concluding his remarks, Dr. Salmon announced that he was leaving federal service for a position in the academia. Dr. Shimabukuro commented that his contributions to vaccine safety and the NVPO had been invaluable.

Public Comment

Mr. King invited public comment.

Ms. Theresa Wrangham, representing the National Vaccine Information Center, explained that NVIC was the oldest and largest parent-led nonprofit organization representing public vaccine safety concerns. It is an independent clearinghouse for information and does not advocate for or against the use of vaccines. Ms. Wrangham recalled discussion at the last ACCV meeting about the increased use of vaccines in pregnant women and whether or not unborn babies should be covered by the VICP. Since it was her impression that there was no coverage available, she recommended that the Commission consider supporting legislation that would include compensation for a neonate who sustained vaccine injury as a result of its mother's pre-delivery inoculation.

Ms. Wrangham commended the Commission for its efforts to revise the Vaccine Injury Table, but expressed concern that the IOM conceded that 85% of the adverse events in its review lacked sufficient scientific data to make an informed judgment about the connection between the adverse event and H1N1 vaccine. She requested that the ACCV consider recommending steps to close that kind of research gap. She added that the Commission had discussed the issue at the past meeting but ended consideration because of the probable lack of funding to support such research. Ms. Wrangham contended that such budgetary considerations are beyond the purview of the ACCV and that the Commission should consider developing recommendations regardless of funding.

Finally she suggested that meeting presentations be available on the web or through some other mechanism before the meeting so that guests on the phone could follow the discussion more effectively.

Dr. Evans commented on the issue of compensation for neonates, noting that the VICP had received a few claims during its history but none had been compensated. He indicated the sticking point is the language in the legislation that specifically states that the vaccine recipient is eligible for compensation, which would preclude the eligibility of the baby.

Asked about the availability of the meeting materials, Ms. Herzog stated that all of the PowerPoint presentations and other supporting documentation is posted on the web before the meeting is held.

Adjournment

Mr. King invited a motion for adjournment, which was duly made and seconded and unanimously approved. The meeting adjourned at 11:55 a.m.