Advisory Commission on Childhood Vaccines

June 4, 2009

Day One

Minutes

Members Present
Magdalena Castro-Lewis, Chair
Sherry K. Drew, J.D., Vice Chair
Tawny Buck
Margaret Fisher. M.D.
Charlene Gallagher, J.D.
Thomas Herr, MD
Elizabeth Saindon
Jeffrey M. Sconyers, J.D,
Tamara Tempfer, RN-C, MSN, PNP

Executive Secretary

Geoffrey S. Evans, M.D., Director, DVIC

Staff Liaison

Michelle Herzog, Principal Staff Liaison

Welcome, Report of the Chair and Approval of Minutes

Ms. Castro-Lewis called the meeting to order and, after introductions, provided a brief report. She noted that the Outreach Workgroup had met twice since the last meeting, and that the letter, which was reviewed and approved at the last meeting, had been sent to the Secretary. She announced that she and Dr. Evans had attended the recent NVAC meeting, and one of the interesting agenda items was a report on the self-evaluation the Committee had completed, adding that such an internal evaluation of performance and effectiveness might be appropriate for the Commission to undertake.

Since Mr. Sconyers had attended the April meeting of the Institute of Medicine stakeholders meeting, she invited him to comment. He stated that this meeting, the fourth in series, concerned issues of vaccine development, testing and safety. He explained that there were four panels, three devoted to the science of the issues and one, on which he participated, that examined issues of policy and specifically the National Vaccine Injury Compensation Program.

Ms. Castro-Lewis invited approval of the minutes of the March 5-6, 2009 meeting and, with minor corrections the minutes were unanimously approved.

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

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Dr. Evans welcomed those in attendance to the 72nd meeting of the ACCV and, after reviewing the two-day agenda, described two pieces of legislation recently introduced. The first, H.R. 2459, introduced by Congressman Dan Burton, includes amendments to the National Childhood Vaccine Injury Compensation Act that reflect some of the recommendations approved by the ACCV in March, and is consistent with previous bills introduced by Congressman Burton. A second bill, H.R. 3617, was introduced by

Congresswoman Karen Maloney and contains amendments to the Food, Drug and Cosmetic Act aimed at reducing mercury exposure.

Turning to the Program statistics, Dr. Evans noted that the filing of non-autism claims continue to increase. Influenza vaccines are responsible for most of this increase. At the same time, the number of autism claims has declined, possibly because of the decisions in the three test cases for the combined theory. With few exceptions, dismissed claims have exceeded compensated claims each year. However, the trend changed in 2008 when there was an increase in total claims. This was due to a surge of influenza claims filed in 2007 in order to meet the 2-year filing deadline whenever a new vaccine is added to the VICP. The decline is cases dismissed in 2008, and thus far in 2009, reflects the increased number of settlements. In 2007, the percentage of cases deemed non-compensable was 51%; in 2009 it was 36% and through June 1, was only 19%. Of the compensable cases, 62% were settled in 2007 versus 85% that have settled thus far in 2009. Dr. Evans noted that concessions by the Department are usually based on proof of a Table injury.

In terms of compensation, although the long-term average is $69 million annually, the past few years have been significantly higher, and the trend so far in 2009 indicates a record year. The compensation for the first five months of the year is over $61 million. Attorney's fees have averaged about $5 million annually, but already have reached $4.5 million through June 1, 2009.

Currently, the trust fund stands at almost $3 billion. The income projection for FY 2009 is $300 million, about a third of which is from interest income on the corpus of the trust.

Dr. Evans briefly described his official activities since the last meeting, which included attending the March 18-19 Vaccine Safety Datalink meeting in Atlanta; being a subject expert at the National Vaccine Plan Public Participation Workshop in Columbus, Ohio on March 28; providing a Program update at the April 1 National Immunization Conference in Dallas; attending the April 14 IOM meeting of the Committee on the National Vaccine Plan (Mr. Sconyers also attended as a panel member); attending the April 20 IOM Committee to Review Adverse Effects of Vaccines; participation in the May 7-8 Clinical Immunization Safety Assessment meeting in Atlanta; and finally participation in the NVAC meeting on June 2-3 (at which the Ms. Castro-Lewis commented on behalf of the ACCV).

When asked about the current program to develop an H1N1 vaccine, Dr. Evans explained that compensation for any swine flu vaccine-related injuries would be handled by the Preparedness Countermeasures Injury Compensation, which was established by the 2005 Public Readiness and Emergency Preparedness Act. The PCICP is modeled after the Smallpox Vaccine Injury Compensation Program, both of which are administered by HRSA. The VICP covers the trivalent (three virus) seasonal influenza vaccine. Neither the monovalent (single virus) vaccine under development for the novel H1N1 swine flu, nor a possible future quadrivalent (four virus) seasonal vaccine can be covered by the VICP without meeting the requirements for coverage under the Act (recommendation for routine administration to children, and a tax imposed by Congress).

Ms. Buck suggested that it would be helpful to know what vaccines are causing what specific injuries, if that data can be teased out of the VICP database. In addition, she indicated that it would be helpful to understand the criteria relied on to determine whether to pursue the litigative risk process. Dr. Evans noted that analysis of vaccines versus injuries was complicated by the fact that some vaccines alleged to cause injury are not the ones actually identified in the compensation or settlement that decisions are on a case by case basis, often with many factors going into a settlement decision. Ms. Buck also stated that the Commission should know what criteria were provided to the IOM for the vaccines to be considered by the IOM committee. Dr. Evans explained that the IOM was only provided broad information about the vaccines and injuries that are encountered by the Program. No specific criteria were invited by IOM nor offered by the Program.

Report from the Department of Justice
Mark W. Rogers, J.D.
Deputy Director, Torts Branch
Civil Division, Department of Justice

Personnel

The office hired one attorney to replace one who had departed.

Power Point Presentation Summary

Mr. Rogers referenced the Power Point materials, entitled June 4, 2009, Department of Justice Power Point Presentation (DOJ PP), as part of his presentation.

Statistics

Mr. Rogers began his presentation with statistical information noting that DOJ offers a slightly different snapshot of the statistics than the Department of Health & Human Services (HHS). DOJ uses the time reference of the last meeting, and focuses more on litigation. Since the last meeting, 99 claims were filed. Of those, 24 were autism petitions and 75 were non-autism petitions. (DOJ PP, p. 3). The ages of the claimants was evenly split between adult (18 and over) and minors (under 18). (DOJ PP, p. 3). In that same time period there were 61 adjudications. Of those, 28 were compensable (the method of disposition was by settlement, not a Special Master's decision), and 33 were not compensable. (DOJ PP, p. 4). Of the 33 found not compensable, 25 were autism petitions, most of which were voluntarily withdrawn, while 8 were non-autism claims. (DOJ PP, p 4). Regarding autism petition dismissals, Mr. Rogers commented that there has been an uptake in those dismissals since the February, 2009 decisions came out on Theory I (whether measles-mumps-rubella vaccines and thimerosal-containing vaccines can combine to cause autism), and he predicted that the increase in the autism dismissals (approximately 140 more) would be reflected in the statistics at the next meeting.

Turning to the statistics materials, there is a breakdown on compensable cases that were conceded. For this time-period, HHS did not concede any claims. (DOJ PP, p. 4). Mr. Rogers cautioned that the statistic for compensable cases (DOJ PP, p. 4), includes two types of compensable cases: litigative risk settlement and settlements following a Special Master's decision awarding causation (entitlement) and then the parties settle damages. Here, of those cases not conceded by HHS, the path to compensability included a settlement.

If HHS does not concede a case, and the Special Master formally determines that causation has been shown, there has been a settlement on damages. Mr. Rogers emphasized that there are two kinds of settlement: one encompasses the whole case including causation and damages, and the other is when the Special Master decides causation for petitioners and then the case is settled on damages. Both types of settlement result in a judgment awarding compensation. The statistics for this time-period show a zero for decisions that determine the level of damages in a litigative context. (DOJ PP, p. 4). Dr. Fisher asked about the 28 cases that were settled, and whether they involved the Special Master. Responding, Mr. Rogers said that the 28 cases listed as "compensable" (DOJ PP, p. 4) are comprised of two types of settlement categories: cases where the Special Master has made a decision that there is evidence of vaccination causation and then what was settled on damages, and litigative risk settlements (without the Special Master's decision on causation). Mr. Rogers explained that the definition of a petition resolved by a negotiated settlement may encompass a contested causation issue but the last act in the case is a settlement of the level of damages.

Turning to the flow-chart slide (DOJ PP, p. 7), Mr. Rogers went through the petition process. Common to all cases, HHS reviews all petitions. There are two paths following HHS's review. If HHS concedes the case, we go down the right side of the flow-chart (DOJ PP, p. 7). Using the right side of the flow-chart, Mr. Rogers explained that once the case is conceded, it moves to "damages." On the issue of "damages" (in a conceded case), the Special Master can decide to convene a "hearing" on the amount of damages.

During this time-period, there were no hearings on damages. The middle box represents "settlement on damages," meaning that the parties settle the amount of damages and file a stipulation, which results in judgment entered on the level of damages. The third box is a "proffer," which occurs when both sides agree to use a single life care planner to determine the amount of damages to which the parties agree. The "proffer" does not need to go through the formal DOJ settlement approval process. It is submitted to the Special Master, who approves it. Ms. Castro-Lewis asked about the difference between the "proffer" and the "settlement." Mr. Rogers explained that "proffers" are very similar to "settlements" but in a settlement, there is fundamental disagreement between the parties over the level of damages that is resolved by a formal agreement to compromise the parties' positions. A proffer indicates there is fundamental agreement of the parties as to the level of damages that should be awarded – no compromise is needed. Unlike proffers, DOJ must get formal approval for settlements.

Turning to the left side of the flow-chart, Mr. Rogers explained that this side represents the flow of petitions that are not conceded by HHS. (DOJ PP, p. 7). There are two things that can happen with non-conceded cases. Looking at the far left column, the parties can comprehensively settle their differences – "settlement." That means that HHS believes petitioner has not proven causation, however, we will settle the case for "x" amount and the parties negotiate to reach an amount. That "settlement" is submitted to the Special Master, who almost always approves it. That is known as a litigative risk settlement. Responding to Dr. Herr's question on damages amounts, Mr. Rogers acknowledged that it is fair to say that damages resolved under a litigative risk settlement would be less than if HHS had conceded the claim.

Regarding the "settlement" (litigative risk) column, Ms. Buck expressed significant interest in the criteria used to reach litigative risk settlements. In particular, she expressed interest in what vaccines and injuries were being alleged and how decisions on litigative risk settlements are made. Acknowledging Ms. Buck's questions, Mr. Rogers explained that unlike the transparency available through a Special Master's decision, which, by design, is meant to be very exhaustive in explaining how he/she arrives at the decision to compensate a petitioner, settlements offer a very different means to resolve a case. By its nature, a settlement is not transparent. Recalling the intent of the Vaccine Act, Mr. Rogers offered that resolution of petitions was intended to be expeditious. In his view, parties gravitate towards settlement because it is fast. Mr. Rogers appreciated the interest in seeking information but predicted that opening the settlement process to public view would likely lead to posturing by the parties and reluctance to settle claims on either side. He recognizes the tension between a need for information and resolving cases quickly by settlement. Ms. Buck felt that the lack of transparency has contributed to a deterioration of public confidence in the Program. Ms. Gallagher suggested that perhaps release of the pleadings only, and not the settlement process, might be a compromise, since the pleadings would include the vaccines and the injuries involved. Mr. Rogers acknowledged the point and added that often the pleadings include a broad range of vaccines and injuries that are then winnowed down during the settlement process so only one or two vaccines and injuries might be involved in the final settlement. In addition, the settlement process is "free-wheeling" so to speak. The factors that go into any given settlement are wide-ranging. Offering examples, Mr. Rogers explained that one factor in a given case could be that an expert got sick and could not continue in the case. That becomes a factor in settling a case because you have worked with that particular expert throughout the case, and now you need to start again. That factor has nothing to do with causation, but HHS decides that in the interest of expeditiously trying to resolve these cases, it will settle that case. Other factors that could be considered in a settlement include the Special Master assigned to the case – he/she may hold a particular view of petitioner's expert, which may tilt in favor of settlement. We also consider a litigative risk ratio. For instance, if the Government's chances of losing are 20%, we still may settle the case for 10 or 15% because of the cost of litigation. Ms. Buck commented that because the Program is based on policy and science, [DOJ/HHS] is weighing those two elements in the process of settling but unlike a decision issuing from the Special Master, the settlement process is not transparent and creates the public perception that there is a conflict within the Program itself. Acknowledging the frustration, Mr. Rogers explained that to the extent there is a desire for more transparency, it could be met through the open hearing and Special Masters' decision process, which, by definition, is explanatory given their obligation to explain their decisions. Mr. Rogers acknowledged that the main concern surrounds causation decisions, not the actual amount of the damages and noted that while there were 28 settlements, not all of them shield the Special Master's decision on causation. He

offered that is a substantial amount of published decisions by the Special Masters, U.S. Court of Federal Claims (Court of Federal Claims), and U.S. Court of Appeals for the Federal Circuit (Federal Circuit), which drives the settlement process by virtue of the law on causation.

Responding to Ms. Castro-Lewis' question on whether there are specific vaccines that constitute more settlements, Mr. Rogers deferred that there is a considerable body of law that examines the available evidence on causation and render a finding. Mr. Rogers urged caution in trying to use decisions issued in a legal forum as the basis for driving the medical side of the public policy equation. Further on the disclosure side, Mr. Rogers explained that a Special Master is involved early on. Special Masters freely express their views of particular case, based on their accumulated experience, to petitioners at the initial Rule 4 conference. Responding to Ms. Buck's question about the criteria being used in litigative risk settlements, Mr. Rogers explained that they [DOJ/HHS] look very carefully at the litigative risk in deciding whether or not to settle a case.

Ms. Buck asked whether or not DOJ was contributing in any way to the funding of the IOM contract - the HRSA/IOM contract, to which Mr. Rogers said no. Traditionally, DOJ has had additional or excess funds, which in the past have been transferred to HHS. To his knowledge, such funds have never had any strings attached so to speak. Mr. Rogers confirmed that DOJ is not contributing in any way to the IOM's study of vaccine adverse events and does not direct how HHS uses any transferred funds.

Responding to Dr. Fisher's question regarding the level of involvement of a Special Master in the settlement process, Mr. Rogers expressed that Special Masters are obliged to conduct an initial Rule 4 conference. Thereafter, the Special Master, who is also interested in resolving cases, will continue to oversee the settlement process and may be more or less active depending on how well the parties are working together towards the settlement.

Mr. Sconyers commented that there appeared to be a conflict in the approach to resolution of claims between HHS, which relies on science, and by DOJ, which appears to be driven by the legal aspects of the claims process. Mr. Sconyers felt that one of the basic problems with the Program is the public perception surrounding those two areas, and that claims are being compensated using a lower standard as far as science is concerned. Consequently, the public is unaware that the Program seeks to compensate people who might be able to demonstrate a connection between a vaccine and alleged injury. Mr. Rogers acknowledged the point. He emphasized that while DOJ views the cases through a legal prism and HHS leans toward science, they work together to reach a settlement policy. He indicated that trying to resolve the issue so that it tilts back towards a more public, transparent decisional framework may be something that the Commission would want to explore further.

Autism

Mr. Rogers reiterated that the three test cases (for Theory One, which was whether thimerosal containing vaccines combined with the MMR vaccine to cause autism spectrum disorders), Hazelhurst v. HHS, Cedillo v. HHS, and Snyder v. HHS, have been scheduled for oral arguments in the Court of Federal claims. (DOJ PP, p. 8-9). Hazelhurst is scheduled for June 11, 2009, Cedillo is scheduled for July 7, 2009, and Snyder is scheduled for July 29, 2009. For Theory Two (whether thimerosal containing vaccines alone can cause autism), DOJ has filed post-hearing briefs in the cases Mead v. HHS, King v. HHS, and Dwyer v. HHS. Those cases are currently pending before the three Special Masters for decision.

Appeals

The U.S. Supreme Court has denied certiorari in Mojica v. HHS and Kay v. HHS, both jurisdictional cases. (DOJ PP, p. 10). In the Federal Circuit, the case of Nordwall v. HHS, which involved a standard causation issue that petitioner lost at the Court of Federal Claims, was withdrawn by petitioner. (DOJ PP, p. 10). Finally, there are several cases (17) pending in the Court of Federal Claims, all filed by petitioners. (DOJ PP, p. 11-12). Mr. Rogers noted that the bulk of the appeals involved causation, and that DOJ typically does not pursue appeals.

Further Comment

Responding to Ms. Buck's question about the budget for autism cases, Mr. Rogers offered that while the office does not track the comparative cost between autism and non-autism cases, three-four attorneys were working on autism. About one-third of the office is involved, which in Mr. Rogers' view is a global effort.

Ms. Gallagher welcomed Mr. Rogers back and thanked him for the DOJ's laudable settlement effort, as opposed to pushing claims towards hearing, which would slow down the process. Notwithstanding the good point's rose surrounding the public's perception of settlements, Ms. Gallagher complimented DOJ for settling cases.

Dr. Fisher clarified that the last five appeals (identified at DOJ PP, p. 12) were concluded and asked for the definition of "remanded." Mr. Rogers clarified that the affirmed (Doe 11 v. HHS) means that the Court of Federal Claims agreed with the Special Master. Remanded means that the Court of Federal Claims had concerns and sent the case back to the Special Master for additional fact-finding. Depending on the result, either party could again move for review by the Court of Federal Claims.

Omnibus Autism Proceeding Update
Gary Golkiewicz, J.D.
Chief Special Master, U.S. Court of Federal Claims

Mr. Golkiewicz agreed to discuss three issues -- the Masias case, which involved the issue of irreducible minimum, that amount that no reasonable litigant would deny was owed to the moving party; the Miyake case which involved annuity experts and brokers; and the Omnibus Autism Proceeding.

The Masias case was concerned about interim fees and the importance of preventing undue financial hardship because a proceeding is protracted, involves costly experts who must be paid in a timely manner, and the importance of preserving the appropriate legal team for the petitioner. The appearance of interim fees has introduced a layer of litigation in addition to the issues of entitlement, damages and attorneys' fees. Fortunately, most of the issues regarding interim fees have been settled by the parties to each case.

Since interim fees involve reimbursement submissions by attorneys, there can be disagreement as to what is reasonable. Masias awards what is essentially not in dispute, the irreducible minimum, and amount that are sufficiently reasonable that all parties can agree. Disputed amounts are then deferred until there is time to address them or until the final award of coats and fees is resolved.

The Miyake case involved the question of the federal government funding an annuity through a commercial broker, something that was not considered appropriate by the special master who originally interpreted the Act in 1988. In 1989 Congress amended the Act so that special master could pay awards in a lump sum or fund an annuity, which had the advantage of transferring the investment risk and the risk of interest rate fluctuations and the need to establish a specific life expectancy for the claimant. Finally, if the government bought and owned the annuity, certain taxes benefits would accrue to the beneficiary. The legislation did not mandate that the government be the buyer and owner; it made that an option for the claimant. However, the tax benefits to the claimant made it obvious that the government should buy and own the contract.

The petition in Miyake challenged that premise, claiming that the annuity broker was acting as respondent's expert and therefore not representing the best interests of the claimant. Mr. Golkiewicz likened the arrangement to the typical real estate transaction in which the seller's agent purports to represent the buyer as well, an ethical dilemma.

In any event, the special master's decision in Miyake was that the claimant was entitled to choose his or her own financial experts. In fact, in the past, petitioners have been able to employ their own financial advisers and, for the most part, respondent agreed those advisers could be paid by the Program. Mr. Golkiewicz noted that this decision could have a financial impact on the program if the practice of hiring financial experts at the discretion of the petitioner becomes common practice.

Turning to the Omnibus Autism Proceeding, Mr. Golkiewicz commented that the Department's briefing at the last ACCV meeting was accurate and timely. He conceded that the question that is now on the table, what the impact of the decisions in the test cases will be, cannot be answered until the Federal Circuit and, if the case goes that far, the Supreme Court, hand down decisions in the case. He added that the review process can be a very long process, citing examples of appeals that have gone on for many years, including a specific example of Whitecotton v. HHS that was initially decided by the special master in 1990. For more than six years it moved through the appeals system during which ten decisions were handed down. Partly because of the government's inclination not to appeal, it was finally settled.

Mr. Golkiewicz explained that an omnibus proceeding is not unique and in fact courts often hear common cases without calling them omnibus proceedings. He offered an example that early in the Program the Court grouped over 200 cases involving polio vaccine which was based on the claim that the vaccine could contain live virus as a result of manufacturing practices. It would have been impractical to hold over 200 hearings, especially since the one qualified expert witness would certainly not agree to provide the same testimony 200 times. Therefore, the Court would try one case, decide it, and then invite attorneys in all the other cases to show that their particular case was different and should be considered separately. In fact, although the single case never came to court for various reasons, no additional claims were filed on the basis that there was something different about them.

Mr. Golkiewicz commented that the Autism Omnibus Proceeding was actually different from most omnibus-like proceedings because of the number of potential claims that could be filed, and because the Internet enabled a much higher level of awareness about the issues.

During discussion, asked about litigated risk settlement and the criteria that apply, Mr. Golkiewicz commented that the Court's web site contains the decisions on all cases, including settlements, and that there are key words included to make search easier. Concerning the focus on settlement, he recalled that at the outset of the program the government's position was not to settle and to take all cases to a judicial decision. He felt the current emphasis on settlement was appropriate in spite of the moderate conflict between the science and the legal issues. Mr. Golkiewicz noted the importance of moving cases through the system, an objective fully endorsed by the new Chief Judge of the Court. He felt that a facilitator in the early stages of the filing process who could help get the case ready for a more efficient resolution would be a helpful addition to the process. In addition, alternative dispute resolution should be a part of the whole process. Finally, there should be a proactive effort to ensure that petitioners are treated equally.

Petitioners Satisfaction Survey
Namratha Swamy, Ph.D., Altarum Institute

Dr. Swamy explained that the Altarum Institute was asked to evaluate whether the VICP was organized in such a way that a valid evaluation could be made of consumer attitudes -- was there a set of goals, processes and measureable outcomes within the VICP? Could successes and challenges be identified? Was there data that could support the development of the survey questions. An Evaluation Feasibility Study Report was submitted to DVIC in March 2007 and the survey was authorized in June 2007. The project was named Petitioners Satisfaction Survey.

The objectives of the Survey included an assessment of the petitioner's satisfaction with the overall claims process, whether navigating the legal process was difficult or easy, whether the time line was acceptable and whether the resolution of the claims was timely, and whether the award, if any, was satisfactory. The final survey was developed in cooperation with DVIC and ACCV.

As a matter of privacy the Survey (available in English and Spanish) was sent to petitioners through their attorneys and Altarum had no contact with the petitioners. The data collection process was challenging and the survey response was somewhat disappointing. The initial target audience was 716 petitioners represented by 265 individual attorneys. Over half of the attorneys (142) did not respond, responding attorneys reported 35 non-deliverable petitioner addresses, leaving only 448 petitioners who received the survey. Only 107 of those returned the survey, resulting in a response rate of 23%. For the results to be statistically significant the return rate must have been at least 35%.

Although there was no personal information on the respondents, there was limited demographic data available from those who returned the surveys. About 58% were completed by a parent or guardian and 40% of the surveys were self-reported. Only a few were completed by a spouse or partner. About 60% were age 36 to 49, with 11% younger and 28% older. Half of the inured parties were five years old or younger, 25% were under six months of age. The other half were distributed evenly from age 6 to about 60. Ninety percent self-reported that they were non-Hispanic white. Over half had college degrees and over half had family incomes over $60,000 a year.

With regard to the survey results, for many of the questions there was a relatively even distribution among the three basic options -- very positive/fairly positive, neutral, and fairly negative/very negative. Dr. Swamy indicated the following responses:

- Most (about 75%) found out about the VICP from the Internet, parents and friends, health care providers or their attorneys.
- On ease of obtaining information, 35% came down on the easy side, 32 percent on the hard side. Asked about suggestions for improvement, health care providers and parents/friends were mentioned, a few suggested more advertising and outreach.
- Over half stated there were two life care consultants, one selected by the petitioner, one by the Program, about 20% could not remember and a few had either a single Program-appointed or personally selected planner. Those satisfied with their life care consultant(s) stated they were sensitive to their needs and responsive; those dissatisfied usually pointed to lack of understanding of current and future needs.
- About a 17% of respondents said finding an attorney was very easy, about 26% said it was very difficult. There were suggestions that a list of attorneys who specialize in vaccine compensation cases should be published.
- About a third found the claim filing process more or less easy; about 40% found it more or less difficult; the rest were neutral.
- About a third were satisfied with the hearing process, slightly more than a third were dissatisfied.
- About 40% received a financial award, 60% did not. Interestingly only 19% appealed the negative decision and 28% “couldn’t remember” if they took any action.
- Contrary to the usual proportion of good to bad outcomes, VICP got high marks on helping with Medicaid liens -- about half agreed VICP was helpful and only a quarter felt that VICP was “unhelpful.”
- However, that ratio was reversed when asked about adequacy of compensation -- 51% said compensation was more or less inadequate, while 30 percent agreed it was more or less adequate.
- Concerning the length of the claims process, most (64%) thought it was too long, about 20% felt it was acceptable.
- Finally, over half said the method of payment of the compensation was more or less satisfactory.

There was a statistically significant correlation between receiving an award and overall satisfaction with the claim filing process, the hearing process and the length of the process.

The more substantive recommendations that were derived from participant comments were:

- Continue to survey petitioners about the VICP process,
- Conduct future evaluations that will elicit a greater diversity of perspectives (e.g., include DOJ, petitioners' attorneys, DVIC staff, and others).
- Continue outreach to enhance public awareness of the VICP,
- Consider options to streamline the claims process.

During discussion, Dr. Swamy explained that there was follow-up with attorneys in some cases, but typically there was no improvement in response and some attorneys said outright that they did not want to participate. Mr. Sconyers commented that, whether or not future surveys included respondents other than petitioners, the objective of the surveys should always be to elicit what is best for the petitioners. Dr. Swamy agreed, but added that the expanded surveys might offer some insights as to how to improve the overall process.

Dr. Evans made the point that, once a petitioner files a claim, neither the Program nor the Department of Justice is allowed by regulation to be involved with the petitioner in any aspect of the claims process. That is the role of the petitioners' attorneys and other consultants. Ms. Drew noted that there was a suggestion by someone who did not participate in the survey to appoint an ombudsman to provide some counsel for petitioners and petitioners' attorneys concerning the claims process.

Noting that the number of respondents for each question varied, there was some concern about the validity of the responses or perhaps the bias that might be introduced when respondents were allowed to choose which questions they would answer. Dr. Swamy noted that some questions did not apply to some respondents and, as part of the introduction to the survey, similar to a consent form, the respondent was assured of privacy and the right to provide only information each respondent felt comfortable providing.

Ms. Gallagher stated that the survey showed a significant satisfaction with the program, and that the VICP should be gratified with that response.

Developing Vaccine Recommendations and Policy
Advisory Committee on Immunization Practices (ACIP)
Jean Clare Smith, M.D., M.P.H., CDC

The ACIP was established in 1964, following the passage of the Vaccine Assistance Act, which authorized the federal government to purchase vaccines and support state efforts to develop effective immunization programs. The charge to the ACIP was to develop recommendations for the Secretary HHS and for the Director of CDC regarding the use of licensed vaccines in the civilian population of the United States. Specifically, the ACIP shall make recommendations for vaccines that have been licensed by the FDA for commercial distribution.

In 1972, the passage of the Federal Advisory Committee Act (FACA) established the existence of Federal Advisory Committees, and required that such committees hold open meetings except under certain limited circumstances. In 1972 ACIP was designated a FACA committee and began holding open meetings. In October 1994, the Vaccines for Children Program was established to provide certain vaccines to children who are Medicaid-eligible, uninsured, American Indian and Alaskan Native, or under-insured children. The ACIP is charged with specifying which vaccines will be provided by the program. The Program currently spends $3 billion per year to provide those vaccines, distributed through public and private sectors.

The process by which a vaccine is recommended begins with commercial vaccine development and testing. It continues with submission by the manufacturer of a biologics license application (BLA), FDA review that culminates in licensure of the vaccine, at which point two parallel processes occur. The first process is government, in which the CDC must determine whether to include the vaccine on a list of recommended vaccines for use in the U.S. That process is facilitated by the review by the ACIP of the vaccine (which actually begins well before FDA licensure. When the ACIP issues its recommendation the

CDC considers the recommendation and, once the recommendation is approved, publishes the recommendation in the MMWR (Morbidity and Mortality Weekly Report).

Then states can develop their own regulations and process, while the uptake and financing mechanisms are put in place for distribution of the vaccine.

The ACIP is composed of 15 voting members, including the chair and one consumer representative, who are not associated with the federal government. They come from a wide variety of disciplines associated with medicine, health care, public health and consumers. Each member serves four years and the terms overlap to ensure continuity. New members are recommended by the ACIP Steering Committee and approved by the Secretary HHS. There are eight non-voting *ex officio* members from various federal agencies (CMS, DoD, DVA, FDA, HRSA, IHS, NIH and NVPO). In addition, there are 26 liaison representatives from associations and professional societies who may be considered stakeholders in the national vaccine program.

The ACIP meets three times annually, in February, June and October. The meeting agenda is developed from recommendations by ACIP members, federal agencies and others. The meetings are open to the public, include time for public comment, minutes are published and formal recommendations are published in the MMWR after approval by the Secretary HHS and Director CDC. ACIP is supported by a number of work groups that conduct extensive background work, which is finally reviewed at the Committee level. Currently there are 15 task-oriented work groups (which continue until their tasks are completed) and four permanent work groups (adult immunization, general recommendations, childhood/adolescent immunization schedule, and influenza vaccines). The task-oriented work groups are concerned with much more specific issues (such as HPV vaccines, pertussis vaccines, MMRV vaccine safety, etc.).

In considering a vaccine, the ACIP first looks at the FDA licensed indications and schedule, and then considers other factors including overall disease burden in the U.S., vulnerable high risk populations, the feasibility of distribution and implementation based on the way the vaccine is moved from manufacture to actual administration in an individual, cost effectiveness and recommendations of other professional organizations (like the AAP and ACP).

The ACIP may consider two types of recommendations. First, vaccines intended for universal use are usually age-based with regard to administration and must offer a benefit to the general population. A risk-based recommendation is targeted at a specific population (e.g., anthrax for lab workers).

Dr. Smith concluded her presentation by discussing the ACIP management structure, including the members of the ACIP Steering Committee, who are all associated with a federal office within the HHS. The Steering Committee develops the meeting agenda, recommends candidates for membership, and recommends changes in or new procedures for the ACIP.

Report from the ACIP Workgroup on MMRV Vaccine
Karen Broder, M.D., ISO, CDC

Dr. Broder stated that in March 2009 she had presented an update to ACCV which informed the Commission that two post-licensure studies indicated that children 12-23 months who received an initial dose of MMRV had increased risk of febrile seizure within the first two weeks of vaccination compared to same age children who received MMR and varicella vaccines administered separately (two injections). In considering the ultimate recommendation on MMRV, the ACIP working group will also look at data from a study by Alan Janssen about mothers' perceptions of the MMRV vaccine and febrile seizures. By teleconference Mr. Janssen agreed to present his findings.

Mr. Janssen recapped the findings of the study mentioned by Dr. Broder, adding that the increased risk for febrile seizures after the MMRV combination vaccine was twofold. He explained that his study was based on 16 focus groups, each consisting of about six mothers who had not been advised

in advance about the discussion topic (they were, however, fully consented on arrival and so understood who was conducting the study and why). Before providing any information about MMRV versus MMR and varicella separately (MMR + V), they were asked about their perceptions of risks and benefits of combination vaccines in general. For the combination vaccine they cited fewer shots, less pain, greater convenience and lower costs. Disadvantages of combination vaccines might be more side effects that the combination might make identification of the specific cause of adverse events more difficult, and the impact on the child's immune system might be greater than administering the shots separately.

With regard to whether each mother would allow her child to receive the combination MMRV, 25 were more or less negative, 23 were neutral, and 33 were more or less positive. There were a few minority opinions -- that neither the combination MMRV nor the separate vaccines (MMR+V) were appealing . Even when the mother admitted there was no scientific evidence, that MMR causes autism a few stated a preference for administering MMR separately (three shots) (note - monovalent measles, mumps and rubella vaccines are not currently being distributed in the United States) . Before receiving information about febrile seizures the mothers were generally less concerned about that side effect, although there was a general concern about the side effect of post-immunization fever.

Mothers were provided information about risks and benefits MMRV and MMR+V in both a narrative text and comparison table format. The majority of mothers appreciated the table that compared the MMRV and MMR+V in terms of: protection, number of shots, fever risk and febrile seizure risk. Mothers reported that the increased risk of side effects with the MMRV was easier to grasp in the table format than in the text format. After receiving the risk information, the number of mother highly resistant to the combination MMRV increased to about one-third (in the first survey it had been about 20%). There was also an indication that, in spite of the risks, many of the mothers indicated that they would rely on the recommendations of their child's pediatrician in making the decision between MMRV and MMR+V

During discussion, asked about the final decision on MMRV, Dr. Broder stated that the ACIP would consider four alternatives at their next meeting in June 2009 and would probably arrive at a final recommendation. The four alternatives are: a preference for MMRV over MMR and varicella vaccines administered separately (MMR+V); allowing a choice between the two without either being preferred; a preference for the separate MMR+V vaccines; and recommending only the separate vaccines (that is, removing the current recommendation for MMRV).

It was noted that the second MMRV immunization did not result in the increased risk of febrile seizure seen in the first dose. Dr. Broder explained that, because of the lack of time with the mothers, that issue was not included in the discussion. In a separate part of the study, the issue was discussed with physicians.

Update on the Immunization Safety Office (ISO)
Cindy Weinbaum, M.D., ISO, CDC

Dr. Weinbaum briefly noted that the ISO had recently released two studies on the safety of the DTaP vaccine, both of which were negative (no neurological side effects were associated with the vaccine). Another study of influenza vaccine in children ages two months to two years also showed no adverse events related to the vaccine. In light of a new vaccine that may be introduced for novel flu strains, the ISO is gearing up for active adverse events surveillance with HMOs and for a program of enhanced voluntary reporting.

As Acting Director of ISO, Dr. Weinbaum stated that the search for a permanent director is underway and should be completed soon. There have also been recent organizational changes that moved ISO from CDC's Office of the Chief Science Officer to its new home in the Division of Healthcare Quality Promotion. Finally, the ISO has completed a draft five-year agenda, a project that was recommended in a 2005 IOM study, which was recently reviewed by the IOM.

Update on the National Vaccine Program Office (NVPO)
Dan Salmon, Ph.D., NVPO

Dr. Salmon commented that the NVPO Safety Working Group had completed work on the research agenda that was the subject of a recommendation in the 2005 IOM report. The research agenda was formally approved and forwarded to the Assistant Secretary for Health at HHS, who would then forward it on to CDC. The Working Group is now beginning work on its second task, a review of the vaccine safety system. That will require slight modification in the Working Group membership to broaden the expertise needed to consider the issues. That process is well under way. The Working Group will have representation from the major vaccine-related advisory groups, including ACCV (Ms. Buck is a co-chair of the Working Group), NVAC (Trish Parnell is a consumer representative on that committee), ACIP (Robert Beck) and VRBPAC (Vicki DeBolt).

The Working Group will have its first meeting on July 15-16, an information-gathering effort that will involve several panels. One panel will look at basic policy issues that that would guide the safety system. Another panel will consider innovative ways to overcome gaps in the safety science infrastructure, while a third will consider a system to support the needs of the public, public health and the professional community to enhance confidence in vaccine safety. A fourth panel will review lessons learned from other safety systems not related to vaccines (e.g., transportation, chemical industry, drug safety, etc.). Finally a panel will begin to develop a strategy for enhancing the adoption and implementation of the white paper that will be the eventual product of the Working Group.

Asked about whether the meeting would be open to the public, Dr. Salmon explained that there was concern that a fully open meeting, which would allow media coverage, might inhibit free and open discussion of the issues. Therefore, the meeting is closed to the public, but he added that there will be broad participation on the various panels by representatives of most stakeholders interested in the issues.

Update on National Institute of Allergy and Infectious Diseases (NIAID/NIH) Vaccine Activities. Barbara Mulach, Ph.D., NIAID

Dr. Mulach explained that NIAID was preparing to support the current effort to develop an effective vaccine for the 2009 H1N1 vaccines. To that end NIH will have evaluation units in place to do clinical studies and to develop studies, in cooperation with FDA, that are needed but will not be done by the manufacturers. For, example, there will be a need to look at special populations (e.g., pregnant women, children, individuals with special health problems and needs). There will also be a need to consider dosage -- single or multiple doses, timing between doses, use of adjuvants and other additives, like thimerosal.

Dr. Fisher commented on the emergency authorization to use Oseltamovir off-label in children and asked if there would be similar authorization in this case? Dr. Mulach suggested it was a question for FDA, but added that such a decision would be affected by whether or not the vaccine contained an adjuvant. In response to a question, she explained that an adjuvant was an additive that helps the immune system mount an effective vaccine response to a viral assault on the system.

Finally, Dr. Mulach briefly discussed the National Children's Study, which is now under way and recruiting pregnant and soon-to-be-pregnant women. The Study will gather data on 100,000 subjects over a period of 20 years. Asked about whether the Study would be able to compare children who were vaccinated versus those who were not, Dr. Mulach explained that the study was observational and therefore data would be collected on both. The ramifications of vaccination will be part of the data collected.

Public Comment and Adjournment

Ms. Castro-Lewis invited public comment. Mr. James Moody, representing Safe Minds, commented. Mr. Moody stated that the NVAC Safety Working Group had recommended a study of first-time vaccinations in children. Aside from immediate and obvious serious adverse events, there may be long-term chronic adverse events that are more difficult to recognize. A comparison study between

vaccinated and non-vaccinated children should provide data useful in identifying such long-term adverse events. Mr. Moody urged that such a study be undertaken in a timely manner.

He added that Dr. Wayne Alexander, NICHD Director, had stated that the Children's Study should include as many as 10,000 children who would not be vaccinated. That number should provide the statistical power to develop an analysis of the long-term effects of vaccination versus non-vaccination. However, that data will take years to accumulate and other studies should be considered in the shorter term.

The meeting recessed at 5:15 p.m., to reconvene the following morning, March 6, at 9:00 a.m.

Advisory Commission on Childhood Vaccines

June 5, 2009

Day Two

Minutes

Members Present
Magdalena Castro-Lewis, Chair
Sherry K. Drew, J.D., Vice Chair
Tawny Buck
Margaret Fisher. M.D.
Charlene Gallagher, J.D.
Thomas Herr, MD
Elizabeth Saindon
Jeffrey M. Sconyers, J.D,
Tamara Tempfer, RN-C, MSN, PNP

Executive Secretary

Geoffrey S. Evans, M.D., Director, DVIC

Staff Liaison

Michelle Herzog, Principal Staff Liaison

Ms. Castro-Lewis called the meeting to order and invited Mr. Malone to discuss the process by which vaccine information statements are developed.

Vaccine Information Statement Process Presentation
Kevin Malone and Skip Wolfe, CDC

Mr. Malone described the immunization situation in the seventies, at which time the CDC was purchasing large amounts of vaccine from manufacturers for use in clinics around the country that provided mass vaccinations for children. These shots were typically given by nurses or other non-physician clinicians. In a 1974 case before the Fifth Circuit, Reyes v. Wyeth, the Court ruled that, in a mass immunization setting in which a "learned intermediary" (typically a physician) does not examine a patient before vaccination, the vaccine manufacturer retains responsibility for informing the parents of the risks related to a vaccine. In response, the manufacturers threatened to stop providing vaccines for mass vaccination unless the government would assume the duty to warn responsibility to provide that information. The CDC negotiated an agreement to either provide such an examination by a physician or to provide written information about the vaccine to patients/parents of children prior to immunization.

The CDC prepared "Important Information Statements" (IIS) that were included with every dose of vaccine purchased by CDC and distributed through grant programs at the state level. The National Childhood Vaccine Injury Act (1986), which established the VICP, the NVPO, and the ACCV, required record-keeping for all vaccinations, and set up VAERS, also included a requirement to develop vaccine information materials. Unlike the IIS, which were required only with CDC-purchased vaccine doses, the new Vaccine Information Statements (VIS) were required to be distributed to every person receiving any VICP covered vaccine administered in the United States, whether publicly or privately purchased. CDC has also prepared VIS's for voluntary use with other vaccines.

The law required that the information statements be subject to the Administrative Procedures Act's rulemaking requirements, which meant that each statement would be published in the Federal Register, after which there would be a time for public comment (90 days), after which the new or revised information statement could be added to regulations and distributed. In the initial round CDC provided for 180 days for comment including a public hearing. The process took almost three years. In those early days the CDC consulted with the ACCV, with FDA and with numerous non-governmental groups, including the American Academy of Pediatrics and the predecessor of the parent advocacy group now called the National Vaccine Information Center. There was also a three-day workshop in Atlanta to discuss the development of the vaccine information materials, which a representative of ACCV attended.

The law required a significant amount of information to be included in the vaccine information statements: a discussion of the disease the vaccine would prevent; symptoms of potential reactions to the vaccine; precautions to reduce the risk of serious adverse events; symptoms or early warning signs of possible adverse reactions; how to monitor and report adverse reactions; contraindications to taking the vaccine; identification of groups of individuals who might at higher risk of adverse reaction; a summary of state and federal laws related to the vaccine and other information the Secretary may deem appropriate. The resulting document was ten pages long.

The first information pamphlet completed the rulemaking process in early 1992. There was immediate reaction -- the pamphlets were too long, took too much time to read, contained technical terms that had to be defined (thereby adding to the length of the document),some of the discussion was too technical, and there was too much information. In 1993, CDC's request to Congress to amend the requirements resulted in legislation that considerably reduced the required verbiage. The new document would discuss the benefits and risks of the vaccine, include information about the VICP and any other information the Secretary deemed appropriate. Illustrations could be included for clarification.

The new law also required distribution to anyone receiving a vaccination, not just parents of children. It also rescinded an option in the previous law that providers could develop and distribute their own materials in lieu of the CDC information materials. Finally, the new law provided for a shorter public comment period after publication in the Federal Register (60 days) and eliminated the requirement for a public hearing. CDC continues to consult with ACCV, FDA , health care providers and parent advocacy groups.

Initially the information was translated into four foreign languages (Spanish, French, Vietnamese and Chinese); now there are versions in about 25 foreign languages.

Mr. Wolfe explained the process of developing what are now called Vaccine Information Statements (VIS). A first draft is developed and reviewed by several experts at CDC, followed by ACCV and FDA review. The VIS is then published in the Federal Register for comment (now 60 days). CDC incorporates appropriate comments and recommendations and the VIS goes through the formal CDC clearance process for publication. The final version is then published as a notice in the Federal Register. The Federal Register notice includes a mandatory use date (not later than 6 months after publication) and the new or revised VIS is then released.

Concerning the distribution, initially CDC printed one copy of the document for every dose purchased, sending the copies to the manufacturer for inclusion in shipments to users. States and others would also receive camera-ready copy. As the Internet became more widely used, providers could download the VIS and print their own copies. Some began to request permission to provide a laminated "office copy" for patients to read on site. CDC approved the request as long as the provider was able to also give the patient a hard copy to take home. Now CDC is working on a system that will allow patients to download the VIS to any Internet-capable device (Blackberry, iPhone, etc.).

During discussion, it was asked if the ACCV would be able to re-review the VIS after the public comment changes had been made, Mr. Wolfe responded that the schedule is not amenable to a second review by the reviewing bodies, but that the ACCV could be informed when the second Federal Register

notice is published. It was also suggested that the ACCV, in its review, consider providing specific language for any recommendations made.

There was a brief discussion about the accuracy and cultural reliability of the translations, and how the CDC insures quality in each language. Mr. Wolf conceded that the translations are provided by two universities and there is no specific mechanism to check the reliability of the translations.

Asked about whether health care providers are actually distributing the VIS's, Mr. Malone stated that there is a statutory requirement to do so, but no enforcement mechanism. There is also a requirement that providers note distribution of the VIS in the patient's medical record. Various ideas to remind providers of mandatory use have been considered – (e.g., announcements in JAMA, approaching medical boards to send out announcements.

Update on the Center for Biologics and Evaluation Research (CBER)
Marion Gruber, Ph.D., CBER, FDA

Dr, Gruber announced that one vaccine had been approved since the last ACCV meeting. IXIARO was approved on March 30th. It is a vaccine indicated to protect against Japanese encephalitis, a mosquito-transmitted virus. Other vaccines in the pipeline include those for human papillomavirus, a thimerosal-free flu vaccine, a meningococcal conjugate and a new pneumococcal conjugate vaccine.

CBER's H1N1 activities in the Office of Vaccines include working to facilitate the availability of a safe and effective vaccine, and the office is engaged in engineering and growing a reference strain for the 2009 H1N1 virus. Discussions are under way with BARDA and NIH concerning the initiation of clinical trials to evaluate immune response of new vaccines that are predicated to be available from manufacturers in the summer of 2009. It is assumed that the vaccine will be an inactivated monovalent H1N1 2009 influenza strain. The clinical trials will also look at vaccine dosage for the general population and for special populations.

ACCV Outreach Workgroup Report
Sarah Hoiberg, ACCV

Ms. Hoiberg reported that the Outreach Workgroup had met three times since the last ACCV meeting. Although it had been determined that some projects, like public service announcements, were not cost effective, there was agreement that an Internet aspect might be feasible, such as a WebMD connection or perhaps an improved search effectiveness through Google or Yahoo. Dr. Herr mentioned that the Workgroup talked about educating pediatricians, especially to recognize possible side effects of vaccinations (as opposed to simply treating conditions without regard to causation). He suggested submitting an article, perhaps on a periodic basis, to the American Academy of Pediatrics news publication. Ms. Hoiberg added that there was a possibility to piggyback on CDC's regular mass mailings. She also thought investigating the possibility of obtaining support from Pharma might be fruitful.

Dr. Fisher, noting that perhaps half of the pediatrician in the country are AAP members, outreach should also be directed at other professional groups, such as the American Academy of Family Physicians and other groups that are involved with mothers or children. These other groups might include nurses, pharmacists, and emergency medicine professionals. She added that ACIP could include a blurb in vaccine recommendations identifying the VCIP program, and licensure bodies could be approached to mention VICP when licenses are distributed. Dr. Weinberg mentioned that whenever VAERS is promoted there could be a link to the VICP, perhaps just a URL added to whatever announcements are made.

Asked about funding, Dr. Evans stated that $10,000 had been designated for outreach in the administrative budget, although there is the possibility of moving some funding around within the agency, and using end-of-year monies if available. He added that approval had been received to continue the outreach program involving attendance at various professional society meetings. He explained that the activity was primarily maintaining a booth in the exhibit area, but there were also opportunities to make

short presentations. Concerning materials that can be distributed, Dr. Evans explained that a colorful poster has been designed, as well as a baby-oriented booklet. In addition, materials could be developed economically from existing materials, which obviates the need for design expenses and for obtaining clearance for release since clearance has already been approved for existing materials.

Dr. Evans commented that, in large federal organizations, anything involving contracts, contractors, review and approval processes will take time and requires significant planning.

Ms. Buck commented that outreach should be a very high priority and that when monies become available, such as the funding spent on the IOM study, the Commission should have an opportunity to discuss how the funds would be used.

Institute of Medicine Project on Vaccines and Adverse Events
Kathleen Stratton, Ph.D., IOM
Rosemary Johann-Liang, MD, DVIC

Ms. Castro-Lewis introduced the topic of the IOM study by noting that a letter was prepared by the previous ACCV leadership about concerns expressed by individual Commission members. That letter had three points -- how the guiding principles were considered in developing the IOM contract; the use of trust fund monies in financing the IOM contract; and the consistent objection by the ACCV to use trust fund money for vaccine safety research.

Dr. Evans discussed the origins of the issue, noting that Dr. Stratton had presented basic information about the project at the November 2008 ACCV meeting, and that he announcement of the contract in April by the IOM may have surprised some Commission members. In retrospect, the project should have been discussed in detail at the March meeting and Dr. Evans expressed regret for any confusion or concern that occurred as a result.

By way of background, the National Childhood Vaccine Injury Act called for the IOM to conduct two evaluations; one on pertussis and rubella vaccines (under Section 312) and one on remaining vaccines (under Section 313). The Act also called on the Secretary of HHS to propose modification to the Vaccine Injury Table based on the results of these evaluations . The first report was published in 1991 after which the Department developed a set of proposed changes to the Table (and Aids to Interpretation) and initiated an extensive review and public comment process, including a notice of proposed rulemaking, two public comment periods, a public hearing, which eventually resulted in publication of a final rule in 1995. The ACCV was consulted twice during this process.

The second evaluation of the remaining Program vaccines (including hepatitis B and Haemophilus vaccines) was completed in 1994, and the same process resulted in publishing a final rule in 1997. In both of those evaluations, because of the well-established independence of the Institute of Medicine, the government had little interaction with the IOM contractor. Both studies conducted multiple public workshops and heard extensive testimony from experts in the field.

By 2004, five more vaccines had been added to the Program. In an attempt to update the Table, the Program briefed the ACCV on possible injuries that might be added to the Table for several of theses vaccines. After consideration, the ACCV voted in favor of them all. However, approval by the Department stalled because of the lack of an independent IOM evaluation. The ACCV noting the lack of progress, established a workgroup which recommended the Secretary establish a standing scientific panel of experts to review the Table and recommend changes, and approved a set of guiding principles to guide future ACCV decisions concerning the application of science to Table modifications. The IOM was not specifically mentioned in the scientific panel recommendation because of concerns by some workgroup members over the 2004 IOM report on vaccines and autism. On the other hand, the independence of the panel could be called into question if the Secretary appointed panel members. The panel would also be required to consult the ACCV about which adverse events to study and which sources of data should be used in the studies, the latter request again inconsistent with an independent scientific body performing the evaluation.

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Concerning the funding for the IOM study, Dr. Evans stated that HRSA funded all but $100,000 of the $1,698,000 IOM contract. The remainder came from National Vaccine Program Office discretionary funds. Asked about the Omnibus Autism Proceeding funds for expert witnesses, Dr. Evans acknowledged that unexpected monies became available when the number of theories to be heard was reduced from three to two. In response to another question, Dr. Evans noted that the alternative use of the funds was cleared through congressional committee staff of both houses and both parties. Nor was it possible to include the funding in the HRSA budget request, since they are now working on 2011 and this study would have begun well before that time period. He added that additional funds have now become available through the stimulus funding that will allow the IOM contract to be expanded to include additional vaccines and adverse events. The additional vaccines are hepatitis A vaccine, meningococcal vaccine, and MMR and DTAP vaccines in various combinations.

Dr. Evans briefly addressed the concerns of some of the Commission members with regard to the role of the Commission in the process, noting that the Commission is charged with providing advice to the Secretary and is not an arbiter on whether or not HRSA enters into contracts with outside contractors, like the IOM. The Commissions advice and counsel is important and appropriately considered and it is understandable that when that advice is not accepted that the Commissioners might express concern. It is a situation common to many federal advisory committees.

Ms. Buck made a statement that expressed her concern that the process that accompanied the IOM contract was less than transparent, and that a full and free discussion would be appropriate. She expressed concern that the present proposed composition of the IOM panel was heavily weighted with pediatricians and epidemiologists, neither of whom would be considered experts in the legal proceedings of the VICP.

Dr. Johann-Liang, HRSA's project officer for the IOM contract, presented a rationale for the IOM evaluation, and the primary outcome of the effort is to update the Table. The first step is to obtain current scientific data that will support the deliberations of the ACCV and the Secretary in making decisions with regard to the Table, including a new look at the time interval related to each adverse event of interest. The last IOM-based revisions to the Table were in 1997 when only seven vaccines were covered. One major change over time has been an increase in adult claims, which now exceed the number of claims for those below age 18. The objective of the IOM study is to review the biological mechanisms and theories on adverse events associated with vaccines and to develop a framework for categorizing the strength of the scientific evidence on causality. IOM will review those adverse events that VICP requests, but retains the right to add adverse events if IOM thinks it is necessary. As in the past, the IOM will not be making recommendations on changes to the Table. Rather, the IOM's scientific information and conclusions will assist the Secretary in developing future proposals to modify the Table, which will then go through rulemaking and public comment.

There was a brief discussion about the charge to the IOM. Dr. Johann-Liang stated that the objectives of the Committee is to develop a framework for assessing the evidence regarding biological mechanisms supporting or refuting theories regarding adverse events associated with vaccines and a comprehensive literature review of relevant epidemiological and clinical studies bearing on the causal relationships between specific vaccines and adverse events in question. To that end the IOM will conduct public workshops with invited speakers and the opportunity for public comment, and will issue a report that summarizes the epidemiological, clinical and biological knowledge related to adverse events associated with vaccines. The IOM committee will focus on the science, and not the Program needs or requirements.

Noting the time remaining for the meeting, Ms. Castro-Lewis noted that Dr. Stratton had not been able to make her presentation. Dr. Stratton agreed to return to discuss the IOM study. Turning to the last agenda item, Ms. Castro-Lewis invited public comment.

Public Comment

Ms. Vicki DeBolt, representing the National Vaccine Information Center, asked how the IOM Committee would deal with the fact that many vaccines are given in combination with others at the same time and the issue of adverse events could be complicated by the multiple injections. Dr. Stratton stated that the issue had not yet been addressed by the IOM, but it was an important point that the Committee would certainly address.

Mr. James Moody, representing Safe Minds, commented that the IOM study should keep in mind that the legislated purpose of the VICP is to protect those who may be injured by vaccines. So the Committee should rely on the evidentiary standard intended by Congress and suggested by the courts in cases such as Capizzano v. HHS -- and that is biological plausibility. The charge to the IOM suggests evidence of biological mechanism, which is a much higher scientific standard than biological plausibility. Secondly, the IOM Committee should include autism in its considerations, particularly since the Program has been compensating certain autism injuries and there are 5,000 autism cases pending in the vaccine court.

Future Agenda Items and Adjournment

Ms. Castro-Lewis noted that the presentation by the IOM would be included in the next meeting agenda.

On motion duly made and seconded, there was unanimous agreement to adjourn. The meeting adjourned at 12:00 p.m.

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Magdalena Castro-Lewis
ACCV Chair

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Sherry K. Drew
ACCV Vice-Chair

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Geoffrey Evans, M.D.
Executive Secretary, ACCV

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Date