Advisory Commission on Childhood Vaccines

March 5, 2009

Day One

Minutes

Members Present

Jeffrey M. Sconyers, J.D., Chair
Tawny Buck, Vice Chair (via telephone)
Margaret Fisher. M.D.
Charlene Gallagher, J.D.
Magdalena Castro-Lewis
Sherry K. Drew, J.D.
Thomas Herr, M.D.
Sarah Hoiberg
Tamara Tempfer, RN-C, MSN, PNP

Executive Secretary

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

Staff Liaison

Michelle Herzog, Principal Staff Liaison

Welcome and Approval of Minutes

Mr. Sconyers called the meeting to order and expressed appreciation to Michelle Herzog for her outstanding support in coordinating the meeting logistics and preparing the meeting materials. He noted that Ms. Buck, vice chair, was attending the meeting via teleconference.

Mr. Sconyers invited a motion to approve the September and November 2008 minutes, adding that a sentence had been inserted on page 10 of the minutes, to wit: *Mr. Sconyers requested that in the future the Commission be informed of such action before final publication.* Dr. Evans explained that the Interim Final Rule effective November 10, 2008 had removed rotavirus from the Vaccine Injury Table and that the removal would not affect anyone's rights. He added that the Secretary would insure that future proposed changes to the Table are referred to the Commission for review and comment. Dr. Fisher proposed correction of two minor typographical errors.

On motion duly made and seconded, the minutes of the November 18, 2008 meeting as corrected were unanimously approved.

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

Dr. Evans welcomed those in attendance and, after reviewing the two-day agenda, noted that Commission members received materials including the written text of presentations, articles, and other commentaries about the vaccine programs, and White House press release that announced the President's appointment of Dr. Mary Wakefield as HSRA Administrator.

Turning to the Vaccine Injury Compensation Program (VICP) statistics, Dr. Evans reported that there had been a recent increase in non-autism claims, mainly because of the inclusion of influenza vaccines. The 104 claims filed in the first five months of the fiscal year, mainly by older adults, suggest that the year-end total estimated at more than 200 claims will significantly exceed the average annual claims rate over the last six years of 167 claims. Autism claims continue to decline.

Although awards have averaged about $65 million annually over the past seven years, the amount increased in 2007 and 2008 to an average of almost $90 million, and awards through February FY 2009 have been about $60 million. The 2009 amount was influenced by the largest award in VICP history, $13.4 million in the Solano case. The balance in the trust fund is nearly $3 billion and, partly because of the increase in influenza vaccines, the income for FY 2009 should be about $300 million, about two-thirds of which is derived from vaccine excise tax and one-third from interest on income. Since outlays should be in the $120 million range, the net trust fund balance increase for the year is expected to be almost $150 million.

Dr. Evans outlined activities since the last meeting. He attended the February 2 Institute of Medicine meeting of the Committee to Review Priorities in the National Vaccine Plan. The focus of that meeting was communications. On February 4 he attended the National Vaccine Advisory Committee (NVAC) Working Group on Vaccine Safety on which Ms. Buck serves. That working group is providing scientific review of the CDC Immunization Office's scientific agenda, and an overall review of the vaccine safety system. Dr. Evan noted that he attended the full NVAC meeting which followed on February 5-6 and as an ex officio member provided an update of the VICP and introduced Ms Castro-Lewis, who also attended the meeting. Finally, he added that he attended the Advisory Committee on Immunization Practices (ACIP) as an ex officio representative of HRSA and provided an update on the VICP.

Dr. Evans announced that on February 12 the U.S. Court of Federal Claims had issued its decisions in the three test cases (Cedillo, Hazelhurst and Snyder). Finally, he congratulated Cheryl Lee, who had been promoted to GS-13 Management and Program Analyst

Report from the Department of Justice
Catharine Reeves, J.D., Acting Deputy Director, Torts Branch
Lynn Ricciardella, J.D., Trial Attorney, Torts Branch

Mr. Reeves reported that she is serving as Acting Deputy Director for the Civil Division, Torts Branch, vaccine section at the Department of Justice (DOJ) as Mr. Vincent Matanoski was called to active duty for the U.S. Navy in the Congo, and Mr. Mark Rogers remains deployed to Iraq where he is serving with the U.S. Marine Corps.

Personnel
There were no staffing changes since the last meeting.

Power Point Presentation Summary
Ms. Reeves introduced her Power Point materials, entitled March 5, 2009, Department of Justice Power Point Presentation (DOJ PP), as part of her presentation.

Statistics
Ms. Reeves reiterated the statistics provided by Dr. Geoff Evans, Division of Vaccine Injury Compensation (DVIC) and advised that there were 90 cases filed since the last ACCV meeting. Of those, 39 were autism cases and 51 were non-autism. Of the 51 non-autism cases, 39 were on behalf of adults. There were 45 cases adjudicated since the last meeting. Of those, 37 were found compensable, and of those, 7 were conceded by HHS and 20 were not conceded. Of the 20 cases that were not conceded, 18 were settled and 2 were resolved by a decision from the Office of Special Masters. The remaining 18 cases were found to be not compensable. (DOJ PP, pp. 3-5)

Referencing the DOJ PP, Ms. Reeves reiterated the glossary of terms, which are contained in the presentation materials, and which, at the suggestion of Jeff Sconyers, will continue to be provided as part of the DOJ presentation at each ACCV meeting. DOJ PP, pp. 5-6.

* Petitions adjudicated means that final judgment has been entered on the petition and it is ready for payment.
* Final judgment means that the U.S. Court of Claims enters a decision on the petition awarding or denying compensation.
* Compensable means that a petitioner's claim is found to be compensable and can be achieved several different ways. A claim can be conceded by the Secretary, Department of Health and Human Services (HHS) as meeting the Table requirements or the standards for actual causation, or the petition can be heard by the Office of Special Masters and a decision awarding compensation is issued, or the case can be settled and compensation is awarded that way.
* Concession means that HHS has determined that the petitioner has met the standards for a Table claim or petitioner has proven causation-in-fact.
* Settlement means that the petition has been resolved by the mutual agreement of both parties.
* Decision means that a decision is entered after a Special Master hears the evidence (or rules on the record without a hearing) and issues a decision on the merits of the petition.
* Non-compensable or Dismissed means that the petition has been dismissed by the Court.

Ms. Buck asked about the 18 non-compensable petitions and whether those were final judgments. Following brief clarification, Ms. Reeves responded that the 18 non-compensable petitions listed all reflect final judgments. In further clarifying the flow chart (DOJ PP, p 7), Ms. Reeves observed that while looking at conceded and non-conceded cases, the cases that are conceded go directly to damages but many of those cases are settled by the parties or they are resolved by a proffer on an award of compensation by the respondent to which the petitioner agrees (which is not reflected in the current flow chart). Ms. Reeves responded to Ms. Buck's further question on clarifying the terms by explaining that a "proffer" can result after a conceded case, which moves directly to damages, is resolved. Once the case is in damages, the Special Master may convene a hearing to determine a level of compensation, but, more often than not, cases are resolved either by a negotiated settlement between the parties, or via a "proffer" on the award of compensation filed by respondent. Essentially, the respondent "proffers" to the Special Master the evidence that it feels supports a compensation award in a pleading, to which the petitioner agrees. The Special Master then issues a decision awarding compensation to petitioner based on that "proffer."

Ms. Reeves acknowledged that the term "proffer" should be placed into the glossary for future reference. Ms. Buck asked how many of the conceded cases - percentage-wise- are resolved by proffer. Ms. Reeves estimated that most conceded cases were resolved by proffer or settlement. Ms. Buck observed that a line should be placed from settled to compensated because settled means compensated. (DOJ PP, p. 7).

Autism

Ms. Reeves turned to the Autism section of the Power Point presentation, noting the recently issued autism decisions on February 12, 2009, would be covered in more detail by Ms. Ricciardella, lead counsel on the autism cases. (DOJ PP, p. 8). In short, in all three "Theory 3 One" autism cases, compensation was denied. Those three decisions, which are lengthy, are all available on the website for the U.S. Court of Federal Claims (CFC). Decisions on "Theory Two" have not been issued. Theory Two is that thimerosal-containing vaccines alone can cause autism, while Theory One involved whether measles-mumps-rubella (MMR) vaccines and thimerosal-containing vaccines can combine to cause autism. "Theory Three" is that MMR

vaccine alone can cause autism; however, no test cases have been scheduled for hearing in Theory Three. (DOJ PP, pp. 9-10).

Appeals
Ms. Reeves turned to pending appeals. (DOJ PP, p. 11). First, she noted that DOJ has prepared and provided the ACCV with a separate copy of a summary of recent precedent-setting cases from the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). This was at the ACCV's request and will be updated for each meeting. (Cases for this reporting period are listed at DOJ PP, pp. 12-13, and are available as listed on the Court's website).

Ms. Reeves noted that two separate cases involving jurisdictional issues are before the U.S. Supreme Court. Petitioners in Kay v. HHS and Mojica v. HHS have each sought writs of certiorari. At that level, the Government's interests are represented by the Office of the Solicitor General and not the Office of Vaccine Litigation. Currently pending before the Federal Circuit is the case Nordwall v. HHS. In that case, petitioner's attorney failed to properly withdraw the appeal from the Federal Circuit and the claim was dismissed for failure to prosecute; however, petitioner's counsel recently requested an opportunity to voluntarily withdraw the appeal, which is the only reason the appeal remains pending. Andreu v. HHS is scheduled for oral argument before the Federal Circuit on April 1, 2009.

The last two slides (DOJ PP, pp. 12-13) reflect the number of pending cases before the CFC. The cases of Sabella v. HHS and Carrington v. HHS both involve attorneys' fees and costs. Ms. Reeves observed that five of the cases listed as pending before the CFC involve the same issue, that is, whether hepatitis B vaccine caused the alleged injury of autoimmune hepatitis. The cases are identified as Hager, Porter, Rotoli Myers and Torbett, were all assigned to the same judge, and are all represented by the same petitioners' law firm.

Questions/Comments on Ms. Reeves' Presentation
Dr. Herr asked whether DOJ could identify the specific vaccine(s) involved in the adjudicated cases. While Ms. Reeves was unable to provide the answer at that time, it was noted that DOJ could provide that information at the next meeting.

Ms. Ricciardella's Presentation on the Autism Decisions Issued February 12, 2009
Ms. Ricciardella reiterated that the three decisions issued on February 12, 2009 by three separate Special Masters related to the three test cases presented in Theory One, which was whether thimerosal containing vaccines combined with the MMR vaccine to cause autism spectrum disorders. The Court in each of the three test cases ruled that thimerosal containing vaccines combined with the MMR vaccine cannot cause autism and did not cause it in the individual test cases that were before the Court. Recalling the background of the autism proceedings, Ms. Ricciardella noted that there are 5,000 pending claims in the Program that were grouped into an Omnibus Autism Proceeding (OAP). Three theories of causation were offered by the Petitioners' Steering Committee (PSC). Theory Two is whether thimerosal containing vaccines alone can cause autism. That theory was tried in three separate test cases last year with two hearings in May and one in July. The parties are still in the post-hearing briefing process with petitioners' brief due April 3, 2009 and the Government's post-hearing brief due June 2, 2009. A decision in the Theory Two cases is not expected for quite a while.

Regarding Theory One, the three decisions are very complex and, when combined, exceed 650 pages. For purposes of a summary, the decisions held that thimerosal containing vaccines cannot dis-regulate an infant's immune systems or cause some sort of immune dysfunction. Second, the decisions held that the measles component of the MMR vaccine cannot cause autism or gastrointestinal inflammation. If petitioners intend to appeal the decisions issued on Theory One, those appeals are due to the CFC on March 16, 2009. Thereafter, parties can appeal as of right to the Federal Circuit, and if further, appeal is sought to the U.S. Supreme Court, such review is discretionary.

Ms. Buck wondered whether the approximately 5,000 pending cases in the OAP cases can still proceed regardless of these three recent decisions. Ms. Ricciardella confirmed that each petitioner has the right to proceed individually. Ms. Buck questioned the significance of the three decisions while 5,000 more remain. Ms. Ricciardella explained that the Court will need to address the posture of those cases. The theory behind the OAP was to adduce a body of evidence, which would be used by the Court to make findings of fact and conclusions of law, and then apply those findings to the remaining 5,000 cases. The course of those 5,000 cases depends upon how each of those petitioners chooses to proceed. Ms. Buck asked whether or not each case in the Program is reviewed individually and questioned the design of an Omnibus Proceeding used in the Program. Ms. Ricciardella emphasized that each case is individual and the Court will decide how to apply the body of law and factual findings concerning the science and medicine that was presented in the three test cases on the first theory. Ms. Buck cautioned that the three decisions were issued by the Court and not scientists and questioned how criteria would be used from those decisions to dismiss or not review each case.

Ms. Ricciardella discussed the applications for interim fees and costs in the OAP. The Court received an application for interim fees and costs in the Cedillo v. HHS and Hazlehurst v. HHS cases, which were the test cases for Theory One. DOJ also received the application submitted by the PSC in the King v. HHS case, which is one of the test cases for Theory Two. That application encompasses work done in the King case, as well as all work done by the PSC since the inception of the OAP in 2002. No applications have been received in the Snyder v. HHS case, which is the third test case in Theory One, or in the Dwyer v. HHS case, which is one of the test cases in Theory Two. The Hazlehurst interim fee application has been resolved by the parties and is awaiting decision by the Court. Respondent filed its response to the Cedillo interim fee application in November, 2008, the parties were able to reach an understanding as to an amount of interim fees in the Cedillo case. DOJ filed its response to the PSC interim fee application on February 6, 2009.

Ms. Tempfer asked for clarification about the application of the theories to the remaining 5,000 cases. Ms. Ricciardella explained that the theories derived from petitioners and their counsel and they would decide how, if at all, to categorize their cases into the proposed omnibus theories. Further clarifying, Ms. Ricciardella explained that the PSC informed the Court last summer that the evidence for Theory Three would be subsumed into Theory One and that there would be no further evidence submitted for Theory Three. Thus, we are awaiting decisions only in Theory Two. Responding to Ms. Tempfer, Ms. Ricciardella emphasized that the 5,000 individual cases were being reviewed individually; several cases have been voluntarily dismissed by petitioners while others are deciding further options.

Ms. Ricciardella discussed the “short form” autism petitions, which were previously discussed. She reiterated that early on in the autism proceedings, the Court allowed petitioners to file short form autism petitions essentially indicating that they wanted their case to proceed in the OAP. No records were filed with those cases. Currently, the Court has ordered the monthly activation of approximately 200 pending OAP cases to obtain and file medical records in support of their petitions. Once the complete records are filed, respondent has been ordered to review the records to determine whether or not the claim was timely filed within the three year statute of limitations.

Ms. Buck asked about the processing of interim fees applications. Regarding the OAP, Ms. Ricciardella explained that interim fees were very recently resolved between the parties in the Cedillo and Hazlehurst interim fee application, and payment should issue shortly. Regarding the other pending interim fee applications arising from the OAP, Ms. Ricciardella emphasized that the applications were very voluminous and DOJ very recently filed its opposition. Ms. Ricciardella emphasized that DOJ intends to try and negotiate; however, there are approximately 13 law

firms, with an unknown amount of attorneys, involved in the PSC's fee application, in King. Ms. Buck raised concerns that the process is moving as quickly and smoothly as possible. Acknowledging those concerns, Ms. Ricciardella advised that the process is moving as quickly as reasonably can be done given the magnitude of the fee applications in the OAP.

Ms. Hoiberg expressed frustration that the attorneys in the OAP have worked seven years without pay. Ms. Ricciardella emphasized under the Program, fees and costs must be reasonable. Presently, a determination on the amount of fees awarded is pending before the Court for decision.

Mr. Salmon asked whether Ms. Ricciardella could estimate the number of cases that have left the Program and gone to state courts since the three test cases were decided. Ms. Ricciardella was unaware of a specific number. Since the February 12, 2009 decisions, seven claims have been voluntarily dismissed. Of those seven, she was unaware whether any were pursuing civil actions. Ms. Ricciardella explained that before a petitioner can file a civil action, a final judgment would be needed consistent with the terms of the Vaccine Act. Voluntary dismissals do not result in final judgments. Ms. Drew commented that attorneys could request a ruling on the record, which would result in a final judgment enabling petitioner to file in civil court, however, given that the decisions were issued less than a month ago, petitioners likely have not considered that option yet.

Petitioners Steering Committee Omnibus Autism Proceeding Update
Tom Powers, J.D., Williams, O'Leary, Love, and Powers, PC

Referring to the previous discussion about the theory one decision by the Special Masters, Mr. Powers commented that the Court did not find that thimerosol cannot possibly suppress the immune system or that MMR cannot possibly trigger autistic regression, but that the evidence presented by the petitioners was insufficient to prove their claims by a preponderance of the evidence, which is the burden of proof placed on the petitioners. He felt some petitioners and their attorneys were looking at whether to pursue the same claims with different and perhaps better evidence (e.g., new evidence based on peer-reviewed scientific studies published since the decision came down). They are also contemplating motions for review, which must be submitted by March 15th. Probably all three cases will petition for review.

Concerning the theory two cases, the petitioners' attorneys are in the process of preparing the briefs for the Court, which should be filed during the summer. Nearly every petitioner in the omnibus autism proceedings has elected to continue and not seek individual litigation. During the past few months the Court has activated a significant number of cases, which requires petitioners to file medical records to support their claims. The Department of Justice will first review each case for timelines of filing and one of three decisions can result -- first, that the claim was timely filed; second, that there is insufficient material in the medical file to determine timeliness such that addition information must be submitted; and third, that the claim clearly was filed too late for consideration. Enough cases have been activated that every attorney working on omnibus cases is involved in the process.

Mr. Powers commented on the interim payments issue. The expenses in the King v. HHS case involved 13 attorneys who agreed at the behest of the Court and the Department of Justice to consolidate their expenses under one filing. Mr. Powers noted that his firm was coordinating that process. He expressed a hope that issues of contention might be resolved well before the Court becomes involved, perhaps even by an outside arbitrator.

Finally Mr. Powers described the recent Supreme Court ruling in Levine v. Wyeth Pharmaceuticals, in which an individual was seriously injured after an injection of a drug caused gangrene and loss of an arm. The State Court awarded damages. Wyeth pursued appeal to the Supreme Court based on the premise that approval of the drug by FDA and Wyeth's conformance to FDA labeling and licensing requirements preempted such a claim. The Supreme

Court rejected the premise, which may have a significant effect on vaccine claims in the civil courts. In an earlier case, Sykes v. Bayer, the plaintiff maintained that vaccine manufacturers failed to warn vaccine recipients of potential harm. The Court of the Eastern District of Pennsylvania dismissed the claim based on preemption. The Supreme Court decision essentially repudiated that decision and will probably be a significant development in civil pharmaceutical litigation. Asked about whether the same principle would apply to cases involving medical devices, Mr. Powers noted that the Medical Device Modernization Act specifically provides for such preemption, whereas there is no mention of preemption in the Food and Drug Modernization Act.

During discussion, asked about the timeline for the theory two cases, Mr. Powers stated that no one knows when the decisions will be issued, but the fact that the theory only involves thimerosol-containing vaccines acting alone may make it easier to consider the issues, which may reduce the time required for the Court to review the briefs. .

Discussion of Decisions in the Omnibus Autism Proceeding
Jeffrey Sconyers, J.D., Chair

Mr. Sconyers invited Commission member comments on the Courts decision in the three cases based on the first theory of causation. Ms. Buck opened the discussion by asserting that the omnibus process was at variance with the spirit of the VICP, and that every parent enrolled in the omnibus proceedings should be able to rely on a careful consideration of his or her particular claim. She added that the program and its procedures should reflect the benefits to injured individuals intended in the original program.

Ms. Hoiberg added that she felt the omnibus proceeding would actually hurt the families involved and not help them. Dr. Fisher stated the opinion that the Court had heard clear scientific evidence and decided that it was insufficient to support the three claims, and that it was time to accept the Court's decision in those cases. She added that if an individual's claim is not significantly different from the three test case claims, that processing the 5,000 similar claims would have a serious negative effect on the Court's ability to hear other claims that would be filed.

Asked about the science of the decision, Mr. Sconyers commented that there were opposing views. One is that the petitioners did not present scientific evidence to prove injury; another is that such scientific evidence does not exist. Dr. Herr added that the scientific evidence provided to the Court was extensive, even more than the ordinary claim procedure since the limits of discovery were expanded so that more data could be submitted than is allowed in the normal claims process. He added that the injuries associated with the claims are tragic, but may not be related to a vaccine, and that is the focus of the Commission's responsibility -- taking care of children who have been demonstrably injured by vaccines.

Ms. Hoiberg pointed out that, aside from a primary injury directly caused by some aspect of a vaccine, it has been shown (as in the Hannah Poling case) that a vaccine might exacerbate a pre-existing condition -- low birth weight, an inherent autoimmune condition, or even just being sick at the time of the vaccination. Therefore, each case is potentially unique and should be addressed individually. Ms. Buck commented that so much importance might be attached to the three cases, that there may be the tendency to conclude that other similar claims are not valid, an attitude that may deprive some families of a fair opportunity.

Ms. Gallagher expressed the opinion that the charge to the Commission is to make recommendations to the Secretary of HHS about the program as it relates to valid vaccine injuries, and that it is important that individual Commission members focus attention on children affected by those injuries with the understanding that it is not feasible to reach out to all afflicted children, many of whom may not have been injured by a vaccine. Concerning the decision of the Court, she felt that parents and their attorneys would have to assess their own individual cases

and determine whether to proceed with new evidence, if it exists, that does not duplicate the evidence submitted in the three test cases.

Ms. Drew commented that, as in other omnibus proceedings, once a decision is handed down, petitioners' attorneys carefully review their cases against that decision and determine whether a case can be made that is sufficiently different from the omnibus cases to warrant a renewed effort to prevail. She felt that if attorneys in this instance felt that was appropriate, they would move to separate their claims and go forward.

DVIC Outreach Plan
Kay Cook, Chief, Policy Analysis Branch, DVIC

Ms. Cook described the DVIC Outreach Plan, which has two objectives -- to increase knowledge about the program, and to increase public awareness of the benefits of the VICP. That is being done through the DVIC web site, printed materials, compliance with the CDC-mandated Vaccine Information Statements program, and by attendance at legal and professional conferences. The program has a call center which responded to 532 calls and 174 e-mails requesting specific information, and distributed more than 2,500 pamphlets and brochures. Work is ongoing with HRSA's Communications Office to explore additional opportunities, including exhibits at medical conferences and possibly working with an outside media consultant. Ms. Cook invited suggestions for the program.

Asked about the brochures and pamphlets, Ms. Cook stated that they are mailed in response to telephone, e-mail or mail requests. Ms. Castro-Lewis observed that the conferences mentioned were mainly professional level meetings and that it might be appropriate to consider becoming involved at the community level, through churches, health fairs and so on. Ms. Buck suggested that there are organizations that are at least peripherally involved with the vaccine programs -- NGOs, state immunization programs, state and local non-profit organizations, associations (such as the Association of State and Territorial Health Officials (ASTHO)) which might be appropriate points of contact for outreach efforts. Ms. Hoiberg added that individuals within the program might be interested in participating at the local level. There were a number of additional suggestions regarding resources that could contribute to the outreach effort -- public health nurses who often provide the immunizations at the local level, state programs that target parents of young children to encourage them to take advantage of vaccination programs, local pediatricians and even mayors' offices. Finally Ms. Castro-Lewis noted that CDC has a number of grants to provide health education at the community level, and information about the VICP could be integrated into those programs.

Asked about the survey that the Commission had been briefed on previously, Mr. Sconyers suggested that discussion be deferred until the next meeting, when the results of the survey would be the subject of an agenda item.

Ms. Buck commented that the 2008 public involvement was not especially impressive -- about 1.5 phone calls a day, an e-mail inquiry every other day on average. She suggested that a more aggressive plan would be helpful. Ms. Cook agreed, saying that suggestions concerning such a plan would be appreciated. Ms. Gallagher suggested that the Commission set up a subcommittee to address the issue.

Dr. Evans commented that publicizing the program is important but that there have been issues that put some impediments in the way of progress. There have been budget limitations and there has been a HRSA policy that required centralization of all outreach activities. The new leadership and the new administration may change some of those policies. Also he noted that, having personally manned exhibit booths at medical meetings, he could attest to limitations to that approach. He noted that there is a subtle barrier to promoting the VICP program as part of other vaccine-promoting programs because it suggests the risks involved in vaccines. Ms. Hoiberg observed that pharmaceutical manufacturers have to append a list of adverse effects to all ads,

but that people still take their drugs. Finally, Dr. Evans pointed out that the February 12 decision concerning the three test cases garnered an immense amount of publicity about the vaccine program.

Mr. Sconyers suggested that the Commission members contemplate the outreach program and, with support from the subcommittee, be prepared to provide guidance to Ms. Cook at the next meeting. Inviting volunteers for the subcommittee, he appointed Ms. Castro-Lewis, Ms. Drew, Dr. Herr and Ms. Hoiberg.

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

Dr. Salmon described the goals of the NVAC Safety Working Group. The first is to review the Immunization Safety Office's research agenda with an eye to its content, prioritization of research, and possible barriers to that research agenda and how to overcome them. Second, to produce a white paper on the Federal vaccine safety system, including infrastructure needs, reduction of adverse events and enhancement of public confidence in vaccines. The Working Group's 17 members represent a wide range of vaccine-related disciplines and include two consumer representatives, Ms. Buck, who has a vaccine-injured child, and a mother of a child with an infectious disease.

The ISO research agenda derives from a recommendation by the Institute of Medicine that included a call for open public meetings, the first of which was held in April 2008. In the fall of 2008, adding a private sector company, Keystone, a steering committee was set up to consider how best to engage the public in the review process. The steering committee included Keystone, offices from HHS and two associations (ASTHO and National Association of City and County Health Officials).

The steering committee developed a plan to hold pubic meetings in three locations -- Birmingham (AL), Ashland (OR) and Indianapolis (IN). There will also be a stakeholders meeting on March 16th, which will consider materials created by a writing group that met in late February. With the output of the three public meetings and the stakeholders meeting, the Working Group will prepare a recommendation to NVAC concerning the ISO research agenda, which NVAC will review and ultimately develop into a recommendation for the CDC.

The public meetings were specifically designed as listening sessions and, except for a very brief 15-minute orientation about the benefits and risks of vaccines, not as an opportunity to provide any significant education about vaccine programs or issues. The Federal representatives who attended were there to listen. After a similarly brief presentation of the meeting's scientific agenda, the attendees broke into smaller groups to carry out the agenda, coming together at the end for a general open discussion, a polling exercise, and a wrap-up session.

The individuals who attended were invited to comment on a wide range of vaccine-related issues. The attendees were selected because they lived in the vicinity of the meeting and because they had some affiliation or contact with health-related groups in the community. Birmingham and Indianapolis were geographically separated and had similar relatively high levels of acceptance of the local vaccine programs. Ashland was a city that showed some skepticism about vaccines, with about 25% of the population rejecting vaccination.

Dr. Salmon emphasized that the three meetings did not represent a random sample of the local populations or of the country as a whole. Selection criteria in the three cities was not uniform and there were a number of areas of recruitment (which Keystone managed) -- state and local health departments, various community resources like PTAs, minority organizations and medical practices, as well as ads in newspapers and on radio. There were 46 to 70 public participants at the meetings, most of whom had children. Over half had some college or a degree, with Ashland having the highest level of education (almost 50% of the attendees had advanced degrees).

The small group discussion agendas were not specific and allowed the groups to develop topics that were considered important to them. The topics included diseases (especially autism, autoimmune disorders), vaccine ingredients (especially mercury, thimerosal, and other additives), specific vaccines (MMR, Gardasil and flu vaccines) and the subject of mandatory vaccination. The open discussion generated a wide range of interests, including vaccines in combination, effectiveness, supply, surveillance, special populations (e.g., vulnerable populations such as children, pregnant women, elderly and susceptible populations such as those genetically at risk), and issues of trust and who was in charge. There was also a recurring question about whether there had been studies of vaccinated and unvaccinated populations.

Five scenarios were described after which discussion about alternative values held by the participants. For example, one vaccine given to a pediatric population caused mild fever in 1 in 20 and caused a more serious brain swelling in 2 in a million. Asked about which side effect caused greater concern, 90% of participants chose brain swelling as a greater concern. Participants were also polled to elicit quantitative responses. The combination of scenarios and polling revealed that people in these three cohorts were more concerned about severe adverse events than mild ones, more concerned about benefits and risks to children than adults, more concerned about public versus scientific issues, and were concerned about vulnerable and susceptible populations, especially with regard to risk of autism.

Dr. Salmon noted that there were some limitations that would be addressed differently if another series of meeting was held, including a more sophisticated screening questionnaire for attendees, better reporting of the small group discussions, and refinements in the scenarios and polling questions. A post-meeting survey indicated that most participants felt that the discussions were fair to all and that the scenario/polling process was effective in identifying values. Ms. Buck, who was involved in the town meetings, stated that Keystone was very effective and that the participants felt the meeting sponsors listened to them more than they talked to them.

Referring to the writing group that met in February, about 20 people gathered and worked intensively for two days to create a document for consideration at the stakeholders meeting to be held on March 16th. The group included professionals in medicine and public health as well as advocates interested in the issues related to autism and mercury in vaccines. Also a participant in the writing group, Ms. Buck said that the meeting was designed to solicit a variety of points of view from people in both the vaccine field and the child health field. Finally she said that the NVPO, which was represented at every meeting and the writing group, had developed an excellent model of public engagement and transparency. She suggested that the Commission develop a written statement of endorsement and support for the process, perhaps encouraging additional similar meetings.

Asked about whether additional meetings were possible, Dr. Salmon mentioned that there was some resistance to the concept, some groups that intended to attend cancelled at the last minutes, some expressed the opinion that only scientists should provide input to the NVAC review. The effort also required significant time and resources. He indicated that the jury was still out as to whether there should be additional similar projects, but that the Working Group would appreciate the Commission recommendations. Sconyers invited Ms. Buck to draft a statement of support that the Commission could review the following day.

Finally, asked about how to make such a process truly representative of the country, Dr. Salmon commented that elucidating statistically valid representative values might be a challenge. He felt the product of these three meetings should be considered a single data point, and that a mechanism such as the random-sample-based National Immunization Survey would be more likely to provide information on which to base policies. Mr. Sconyers commented that the Commission may be amenable to expressing support for a continuing process of engaging the public to provide input for NVAC to consider in its execution of its charge concerning the ISO research agenda.

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

Dr. Broder began with a brief overview of the MMRV vaccine, a combination live attenuated vaccine that protects against measles, mumps, rubella and varicella (chicken pox). In 2005 the FDA licensed the vaccine for children 12 months to 12 years and the following year ACIP recommended the use of MMRV vaccine and preferred use of MMRV over administration of the two separate vaccines, measles, mumps, and rubella (MMR) and varicella (V) vaccines. Pre-licensure research showed that MMRV or MMR+V vaccinations were equally effective in preventing the four diseases. Data from clinical trials showed that within a short time after vaccination, the MMRV vaccine had a higher rate of fever (usually in the 5-12 day period after vaccination) than the separate MMR and varicella vaccines. The Vaccine Safety Datalink and Merck Pharmaceuticals-sponsored researchers conducted studies around the same time looking at risk of febrile seizures. Preliminary findings from both both showed a higher rate of febrile seizures in the first to second week after vaccination with MMRV, compared with MMR+V. In 2008, ACIP considered the data and removed its preference for MMRV vaccine use over separate vaccinations, allowing providers and parents to choose which mode of administration their children and patients would receive. It was somewhat moot because there was a scarcity of the MMRV vaccine because of manufacturing problems unrelated to safety or efficacy, which continues today. MMRV is currently not being manufactured.

The ACIP also recommended forming a working group to look at MMRV issues. The MMRV working group has two co-leads from CDC, one representing risk assessment (safety) and the other representing vaccine policy related to measles, mumps, rubella and varicella. In addition to ACIP, four federal agencies are represented on the working group -- CDC, HRSA, FDA and NVPO -- and there are 14 non-federal members, mainly from academia, representing a wide variety of disciplines.

Dr. Broder discussed the primary vaccine safety concern related to the combination MMRV vaccine -- febrile seizures, which usually occur in the general population between ages 6 months and 60 months. Febrile seizures are defined as seizures that occur in febrile children who do not have an intracranial infection, metabolic disturbance, or history of afebrile seizures. The peak age of risk for febrile seizures, between 14 and 18 months, overlaps age at which the first dose of protection against measles, mumps, rubella and varicella is recommended. Less than 5% of children experience febrile seizures and there is little risk of epilepsy developing in those children with febrile seizures who are not in specific risk categories (e.g., children who have underlying neurologic conditions or prolonged febrile seizures).

Dr. Broder stated that data has shown that there is an increased risk of febrile seizure related to DTP and MMR vaccines (although any vaccine-induced fever could trigger a seizure). The Working Group is developing an evidence-based framework to assess risk based on three areas -- the clinical importance of an event (both the medical and the social impacts), the population-based risk (epidemiology), and the biological plausibility (scientific basis for the event). The process will include review of published and unpublished data, discussion with experts, and a survey of the Working Group members to elicit experiences and opinions.

There are two important studies that provide data for the assessment, a study by the Vaccine Safety Datalink (VSD) and one sponsored by the manufacturer, Merck Pharmaceuticals. The VSD study (led by Dr. Klein) looked at children 12 to 23 months of age in a window 7 to 10 days after vaccination. The study suggested that the risk of seizure after MMRV was twice that of MMR+V (about 9 per 10,000 for MMRV versus 4 per 100,000 for MMR+V). The Merck-sponsored study (led by Dr. Jacobsen) looked at a 30-day window, included a chart review, and the study showed a similar twofold increase in the period 5-12 days after vaccination. The study also suggested that three to four weeks after vaccination there appeared to be a reversal of seizure risk pattern, such that the MMR+V group showed a slightly higher rate of seizures

(although not statistically significant). In the Merck-sponsored study no overall risk for febrile seizures was observed in the month after MMRV vaccination, compared with MMR+V. The VSD is reviewing charts of children who had seizures within one month after vaccination, other than the 7-10 day period, to learn more about the risk in the month after vaccination.

In addition to the risk, the Working Group is considering social impact, the burden of disease and the immunogenicity/effectiveness of the vaccines, program implementation, equity and access, and the recommendations of leading professional organizations, like the American Academy of Pediatrics. The final policy recommendation will be one of the following: no preference for MMRV versus MMR+V (current recommendation), preference for MMRV versus MMR+V, preference for MMR+V versus MMRV, or a recommendation to use only MMR+V.

Dr. Broder described a survey conducted by Dr. Kempe and colleagues to assess physician perspectives. In brief, the survey revealed that physicians do not believe that febrile seizures are serious adverse events but are very sensitive to the fact that parents perceive them as serious adverse events. After receiving the latest risk information, most physicians agreed that in the future they would recommend MMR+V rather than MMRV.

Finally, Dr. Broder mentioned that the Working Group would present the following at the June 2009 ACIP meeting: results of the expanded VSD study, a final safety evidence assessment, a summary of the evidence for the elements of the policy framework on which policy options would be based, and the Working Groups recommendations for policy options for MMRV. She expressed appreciation for the work of the Working Group members, particularly Drs. Marin and Temte, who participated in the discussion.

During discussion, Ms. Hoiberg expressed the opinion that regardless of the discussion about minimal risk, a seizure always carries with it some risk of brain damage. Dr. Herr commented that the majority of children who have seizures with fever have a concomitant illness. Children who have classic febrile seizures are neurologically normal, experience very brief seizures with no risk of brain damage. There is a small percentage of these children (about 3%) who subsequently develop a seizure disorder for reasons other than the initial febrile seizure. Dr. Temte agreed that febrile seizures were a generally benign event, but that policy related to this issue may rely more on perception than fact. Ms. Buck agreed that public concerns are as valid as scientific concerns in developing policy. She added that parents' perceptions must be considered.

Dr. Broder commented that the results of a parental perception survey would also be presented at the June 2009 ACIP meeting. She added that although the higher risk of seizure related to MMRV exists, there is still a risk of seizure with the MMR vaccine.

Dr. Fisher recalled that the move to combination vaccines was in part a response to parent requests to reduce the number of needle sticks their children had to undergo. That group of parents still exists, but there is another group emerging that is recommending reversion to the previous multiple needle stick process, something that might be a challenge to do. Ms. Drew observed that parents accepted the conversion from oral polio vaccine to inactivated polio vaccine administered by injection, mainly to avoid the small risk of developing poliomyelitis from OPV.

Finally Dr. Evans expressed appreciation to Dr. Broder and the ACIP Working Group for developing a large amount of data and information in a short amount of time.

Update on Vaccine Activities
Jessica Bernstein, M.P.H., National Institute of Allergy and Infectious Diseases

Ms. Bernstein reported that the Interagency Autism Coordinating Committee had just released the Federal Strategic Plan on Autism Spectrum Disorder Research, details of which are available on the Committees web site -- www.iacc.hhs.gov.

She announced that CDC and NIH had released a program announcement on vaccine safety research, and applications received were being reviewed by study sections.

Finally, the National Children's Study (NCS), sponsored by NICHD, was beginning to recruit at two locations, one in Queens (NY) and one in a rural area of North Carolina (Duplin County). The study which will eventually recruit over 100,000 subjects at birth and will collect data through age 21 on a variety of health issues, including genetics and environmental effects on health. Dr. Herr suggested that the NCS might be a good vehicle for a sub-study on vaccinated versus unvaccinated children. Dr. Salmon added that there are no exclusion criteria for unvaccinated children. However, the data on vaccinations is basically self-reported via parent-submitted shot cards, which have dubious reliability.

Update on Vaccine Activities
Marion Gruber, Ph.D., Center for Biologics and Evaluation Research (CBER), Food Drug Administration (FDA)

Dr. Gruber reported that there have been no new vaccine approvals since the last ACCV meeting. FDA is currently reviewing license applications for several vaccines -- a human papillomavirus virus vaccine, a Japanese encephalitis vaccine, an adenovirus vaccine, a thimerosal-free influenza vaccine, and a meningococcal vaccine. Additional license applications are expected in 2009.

She discussed the Vaccines and Related Blood Products Advisory Committee (VRBPAC) meeting on February 18-19. The Committee reviewed the composition of the influenza vaccine for 2009-2010, which will continue to be a trivalent vaccine containing the same two A strains as in the previous influenza season, but a different B strain. The VRBPAC formally approved the trivalent combination, which is the same formulation as that recommended by the World Health Organization.

VRBPAC also discussed the implications of adding a second B strain to the current trivalent seasonal influenza vaccine. A model presented by the CDC predicted a modest impact on public health, i.e., an additional 300 influenza related deaths could be prevented by adding a second B strain and there would be fever hospitalizations. The VRBPAC was in favor of including a second B strain to seasonal influenza vaccine. Manufacturers present at the meeting indicated that current manufacturing capacity would make adding a second B strain to trivalent vaccines possible. FDA will need to map the regulatory pathway supporting licensure of a quadrivalent inactivated influenza vaccine.

VRBPAC also discussed conducting clinical trials in children with pandemic influenza vaccine candidates. Pandemic preparedness may necessitate that such studies be done in the prepandemic period to provide a scientific basis for dose and scheduling recommendations for the peditaric population in the event of a pandemic. Regulations (subpart D of Title 45 of the Code of Federal Regulations) that govern clinical studies in children in order to minimize risk will need to be considered. Companies present at the meeting provided an overview of the clinical development of pandemic influenza vaccine candidates and results of studies in pediatric populations conducted so far. The committee was not asked to formally vote but the overwhelming majority of committee members stated that pediatric trials with pandemic influenza vaccine candidates should be conducted.

Finally, Dr. Gruber explained that many vaccines are formulated with additives called adjuvants, which enhance the vaccine's immune response. Currently there is one approved adjuvant in the U.S., an aluminum compound. Novel adjuvants are being developed. FDA/CBER, in cooperation with the National Institutes of Health (NIH), conducted a workshop on adjuvants and adjuvanted vaccines on December 2 & 3, 2008, to assess current scientific knowledge regarding vaccine adjuvants and to facilitate the development of a research agenda to improve the safety and efficacy assessments of adjuvanted vaccines for the treatment and prevention of disease.

Public Comment and Adjournment

There were no requests by the public to comment. The meeting recessed at 5:05 p.m., to reconvene the following morning, March 6, at 9:00 a.m.

Advisory Commission on Childhood Vaccines

March 6, 2009

Day Two

Minutes

Members Present

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

Executive Secretary

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

Staff Liaison

Michelle Herzog, Principal Staff Liaison

Unfinished Business from Day One
Jeffrey Sconyers, J.D., Chair

Mr. Sconyers welcomed the members and guests to the second day of the ACCV meeting. He announced the only unfinished business was review of the statement drafted by Ms. Buck concerning the public engagement strategy. There was agreement that the statement reflected the sentiments of the Commission members. There was a motion to accept the statement and, during discussion, Ms. Castro-Lewis suggested that the audience be expanded to include other interested populations. The Commission agreed on the following addition to the statement: *We encourage the use of the process to include stakeholders in other populations*. Dr. Salmon requested that NVAC should be included in the federal groups involved, especially since the initial request for the program originated in NVAC. There was a motion to include those amendments and the amended motion was unanimously approved.

Review of Vaccine Information Statements
Skip Wolfe, Centers for Disease Control and Prevention

Mr. Sconyers announced that Drs. Fisher and Herr and Ms. Tempfer had agreed to review the vaccine information statements (VIS), especially from the clinical standpoint, but that all Commission members were invited to comment. The objective is to insure that the statements are scientifically and factually correct and that they communicate the message effectively.

There were a number of suggestions during the discussion that applied to all vaccine information statements: Ms. Gallagher noted that the header at the top of every statement (that the

statement is available in Spanish) be printed in both English and Spanish and that the typeface be bold since the type size is small.

Mr. Wolfe commented that his office was considering conducting some focus groups to elicit consumer and provider opinions of the structure and content of the statements.

Ms. Castro-Lewis commented that the box containing the statement about the NVICP should be consistent on all statements. Dr. Herr suggested that for consistency the words compensation and pay, meaning the same thing, should be avoided in the same sentence or section. Ms. Gallagher suggested that the first sentence describing the program should be, "A federal program has been created to help pay for the care of people who may have been harmed by a vaccine." Ms. Hoiberg encouraged adding a sentence to encourage people who believe they have been injured to promptly contact the program. Mr. Sconyers suggested the wording, "You should contact the VCIP immediately in case of a serious reaction to a vaccine."

Mr. Sconyers, noting that some statements that apply to all VISs are written better than others and that the CDC should evaluate the best versions and include them in all statements. For example, the sentence in the rotavirus statement that reads, "Like all vaccines, rotavirus vaccine will continue to be monitored for unusual or severe problems," would be appropriate for all VISs. He also felt that the description of mild, moderate and serious side effects found in some of the VISs would be appropriate to all and that if there were no known moderate or serious side effects, that fact should be noted. There was also a comment that some of the descriptions of very rare side effects should be more clearly discussed

Mr. Sconyers observed that the complex vaccination schedule presented in some of the VISs might confuse parents, especially considering how many vaccines are involved. Ms. Gallagher agreed, noting that there was a simpler chart presentation on the CDC web site.

Beginning with the review with the rotavirus statement, Dr. Fisher noted that the statement recommended avoiding children with rotavirus diarrhea is not accurate; in fact exposure may exist in people (not just children) who are asymptomatic. He added that under section 6, since only babies will receive the rotavirus vaccine, the wording should be "get the baby to a doctor right away." He also suggested that listing some symptoms of adverse reactions in both section 5 and 6 was redundant. Concerning the caveat in Section 4 about giving a baby who has a mild illness the vaccine, Dr. Fisher noted that, since the vaccine is only licensed for babies if they receive the first dose by age 14 weeks, that caveat provides more flexibility to the provider who must decide whether or not to vaccinate. Mr. Sconyers suggested that, in Section 3, the wording should be "given no later than 14 weeks 6 days."

Mr. Sconyers invited comments on the hepatitis B VIS. Dr. Fisher suggested deleting the words "on the job" in the last risk factor for hepatitis B in Section 1, since any used needle carries the risk on or off the job. Mr. Sconyers observed that the phrase one in a million adverse events was well-expressed and could serve as a template for similar risk levels on other VISs. Ms. Buck added that, in the same paragraph, the last sentence noting that 100 million had received hep B vaccine tends to prompt the question, how many adverse events occurred in that number. She felt that the sentence added nothing and should be left out. There was a brief discussion about Section 4 and the warning to advise a provider if the recipient has a serious allergy to any component in the vaccine. Ms. Buck felt it could be difficult for a parent to know what components were in the vaccine and whether the child had an allergy before a first dose administration. She felt there should be some kind of screening procedure. Mr. Wolfe suggested that the provider should be responsible for asking about a child's or adult's allergies before administering a vaccine. He added that it would not be practical to list the components on the VIS, but they are listed on the package insert. Mr. Wolfe added that CDC is working on developing a one-page information sheet for providers, written at a higher technical level. The sheet would include ingredients, contraindications, etc., to give doctors a more convenient source of information about individual vaccines.

The final discussion concerned the Multiple Vaccines Information Sheet. Dr. Fisher commented that there were inaccuracies in the specific disease descriptions on the second page. One does not get tetanus from a cut or wound, but from contamination introduced by the cut or wound. Haemophilus influenza type B can be contracted from asymptomatic individuals, and the claim in the section on polio that there may be no symptoms may be true of some of the other diseases listed on the page. Rotavirus may be transmitted from any person, not just a child. Finally, in the section "How Vaccines Work," in the case of HIB in children under two and for tetanus there may be no immune response, so the word "usually" should be inserted as a modifier. And vaccines are not made from the bacteria, but from products of the bacteria. Mr. Wolfe agreed, adding that there was an effort to simplify a highly technical discussion in order to communicate the basic information about the mechanism of action of vaccines. Dr. Fisher suggested adding a few words, such as, "vaccines are made from the products of germs that cause the disease, but they have been changed, weakened or killed to make them safe." Dr. Salmon added that, in the same section, a child's immune system responds in a similar way, not the same way, it would if the child was actually sick from the bacteria.

There was a brief discussion about the brevity of the Multiple Vaccine Information Sheet. Ms. Gallagher felt there was too little information to be fully helpful. Mr. Wolfe observed that the regulation requires that the sheets provide information on risks and benefits and information on the VICP, which the sheet does. Ms. Buck felt that the format of the Multiple Vaccine Information Sheet could be improved, but that even so the information was sketchy compared to the individual VISs.

On another subject, Ms. Buck asked about the risk of giving vaccines to children who are ill or who may be in vulnerable populations. Ms. Gallagher explained that there had been clinical trials that included both as well as immunocompromised children. Generally the conclusion has been that vaccinations for mildly ill children do not increase risk of adverse events. Ms. Buck felt that the issue should be more clearly discussed in the VISs and Mr. Wolfe agreed that it would be an appropriate topic for the focus groups.

Finally looking at the adolescent multi-vaccine information sheet, Dr. Herr offered the opinion that the section on side effects was poorly written and difficult to understand. Other comments included a suggestion to clarify the difference between risk and precaution with regard to syncope within a short time after vaccination, to improve the explanation of reported paralysis related to HPV vaccine, and a suggestion that an adolescent who experiences a serious adverse event should have someone else get him to a doctor, rather than suggest that he get himself to a doctor. There was a criticism of the artwork on the first page (faceless adolescents).

Mr. Wolfe stated that the influenza VIS had been significantly revised, combining the statements for inactivated influenza vaccine and live activated influenza vaccine into one statement to deemphasize the difference between the two and to provide simpler language.
There was a brief discussion about the influenza VIS that included consensus that it was appropriate to combine the TIV and LAIV vaccines into a single VIS.

Mr. Wolfe expressed appreciation for the comments and invited Commission member to submit any additional comments through Ms. Herzog.

National Vaccine Plan
Ray Strikas, M.D., National Vaccine Program Office (NVPO)

Dr. Strikas presented an overview of the National Vaccine Plan, briefly describing the chapters in the plan, which includes an executive summary, and chapters on the purpose, perspective and scope of the plan; the approach to developing the plan; the framework; the National Vaccine Plan structure; and the process of monitoring and evaluation. There are five goals -- to develop new and improved vaccines; to enhance vaccine safety; to improve communications and education to support decision-making by stakeholders (consumers, providers and policy makers); to insure a

stable supply of effectively deployed recommended vaccine in the U.S., and to increase global prevention of death and disease through better use of vaccines. Finally, there are several appendices that contain background information.

There was a Federal Register Notice published on January 14th inviting public comment on the plan, pursuant to which 40 responses from individuals and organizations were received. The deadline for response was extended to allow responses until March 31. The timeline for the process involves activities by federal agencies (HHS, NVPO, DoD, USAID), an active role for NVPO and NVAC, the Institute of Medicine's Expert Committee on Review of Priorities for the National Vaccine Plan, and the NVPO's public engagement program. Subject to the limitation that the IOM final report will not released until November, the goal is to complete the Plan by late 2009 or early 2010.

The IOM's Expert Committee is clearly an important resource. It has already had meetings looking at research, scientific innovation, regulatory issues and public needs and priorities. There will be a meeting on April 14th to consider vaccine safety -- to identify vaccine safety concerns, to look at basic science and research, and to examine policy issues related to vaccine safety and vaccine injury compensation.

With regard to public engagement, there will be public meetings held in March and April in St. Louis, Columbus and Syracuse that will discuss 12 topic areas derived from the five main goals discussed above. The participants in the public meeting will first develop a set of values against which they can discuss the 12 topic areas. The values that emerged from previous focus groups were that children matter most and communications, safety, access and affordability are important.

The NVAC met on February 6 and the summaries of various breakout sessions at which the goals were discussed will be posted on the web. Ultimately the NVAC will review all of the output of the various participants and provide recommendations to the NVPO which will develop a draft National Vaccine Plan. The ACCV will review the draft plan and submit comments and recommendations to NVAC.

Mr. Sconyers expressed appreciation for the presentation and invited ACCV members to attend the April 14 IOM meeting in Washington, DC.

ACCV Recommendations Workgroup Report
Jeffrey Sconyers, J.D., Chair

Mr. Sconyers reported that the work group had developed a final draft of recommendations to be submitted to the Secretary of Health and Human Services, which would hopefully lead to new legislation to amend the Act. Before describing the recommendations, he expressed appreciation to the work group members -- Ms. Buck, Ms. Hoiberg, Ms. Castro-Lewis, Dr. Herr and Ms. Gallagher -- and to Dr. Evans and Ms. Herzog.

Mr. Sconyers described the recommendations:

- Adjust the benefit caps for pain and suffering to account for inflation since 1988 when they were first established, and to adjust for inflation into the future;
- Extend the statute of limitation to eight years for both death and injury, corresponding to the eight-year retroactive coverage on a new vaccine as provided under the Act, with exclusive jurisdiction under the Act for claims added as a result of changing the statute of limitations;
- Provide compensation for family counseling expenses and for the expenses incurred when a trust, guardianship or conservatorship must be established on behalf of an injured minor;

- Permit the appointment to the Commission of an adult who has been injured by a vaccine (or his or her representative), expanding the current limitation of appointment only of a parent of an injured child;
- Amend the Act to allow compensation for death *and* injury, not *either* death or injury;
- Permit parents or legal guardians to seek compensation for their damages related to companionship, loss of earnings, and medical expenses incurred related to an injured child;
- Amend the Act to provide for interim payment of attorneys' fees;
- Modify the definitions in the Act to recognize that components that are incorporated into vaccines manufactured in accordance with the FDA-approved formulation constitute part of the vaccine, and are not considered adulterants or contaminants;
- Permit payment to attorneys when the petitioner cannot be located for receipt of payment (currently the payment must be made to both parties).

Dr. Fisher suggested that there be no dollar amount attached to the recommendation regarding the caps for pain and suffering, a provision that was accepted before the motion to approve was made. On motion duly made and seconded, the letter to the Secretary containing the recommendations was unanimously approved. The Commissioners, by consensus, agreed that Mr. Sconyers and Ms. Buck should be signatories to the letter.

Election of Chair and Vice Chair

Mr. Sconyers noted that, in recognition of her exceptional service during her term as vice-chair, Ms. Buck served as the nominating committee. Ms. Buck announced that, in consultation with Mr. Sconyers and Dr. Evans, the following slate was established for the Commission's consideration:

Chair - Magdalena Castro Lewis
Vice Chair - Sherry Drew

Mr. Sconyers, noting that additional nominations from the floor were welcome, suggested a short recess so that members could contemplate the nomination process.

(Brief recess)

After the recess, in the form of a motion, Ms. Tempfer offered the name of Charlene Gallagher to serve as chair. The motion was seconded.

Ms. Gallagher made a motion, duly seconded, to nominate Thomas Herr to serve as vice chair.

Closing the nominations for chair, Mr. Sconyers invited the nominees for chair to comment. Ms. Castro-Lewis made a short statement, affirming that she was able to fulfill the duties of chair. She agreed that it would be positive to have a member of the public as either chair or vice chair. Ms. Gallagher expressed appreciation for the nomination and stated that she felt she would be able to fulfill the responsibilities of the position of chair.

Mr. Sconyers invited comments from Commission members. Ms. Hoiberg expressed an endorsement of Ms. Castro-Lewis, and Ms. Tempfer offered an endorsement of Ms. Gallagher.

Mr. Sconyers invited a secret ballot and, after receiving the hand-written votes, announced that Ms. Castro-Lewis was elected chair for the next term. Noting that the results of the election for chair might impact the nominating process, he invited additional nominations for vice chair. Dr. Fisher made a motion, duly seconded, to nominate Ms. Gallagher for vice chair.

After brief comments by the nominees, Mr. Sconyers invited a secret ballot and accepted handwritten ballots. He announced that Ms. Drew was elected vice chair.

Dr. Herr suggested that at the end of the next term that the nominating committee be composed of outgoing members.

Public Comment

Mr. Moody stated that the compensation program was an important aspect of the confidence that the public has in the national vaccine program. He felt that the three decisions of the Special Masters would be affected by a long appeal process, part of which would be based on developing science in the autism area. He recommended that the Commission advocate that the Vaccine Safety Datalink release data to the public either voluntarily or by direction of the Court. Finally, there must be baseline data to compare vaccinated and non-vaccinated individuals to sort out issues of disease and adverse events among these two populations. He urged the Commission to support an aggressive "safety first" research agenda.

Future Agenda Items and Adjournment

Dr. Evans announced that Michelle Herzog would be leaving the DVIC shortly. He expressed appreciation for her exceptional service to the Commission and to the Commission members, each of whom relied on her for logistical support.

Mr. Sconyers invited suggestions for future agenda items, noting that at the next meeting there would be a report on the petitioners survey, and a report by the work group appointed to work on outreach recommendations. Dr. Evans commented that the IOM would initiate a HRSA-funded project to assess four vaccines and his office would keep the Commissioners informed. Ms. Buck noted that the NVAC Vaccine Safety Working Group would hold a stakeholder meeting to invite comments on the ISO scientific agenda on March 16 in Washington, DC.

On motion duly made and seconded, there was unanimous agreement to adjourn. The meeting adjourned at 11:37 a.m.

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Jeffrey Sconyers, J.D.
ACCV Chair

Tawny Buck
ACCV Vice-Chair

_____ _____

Geoffrey Evans, M.D.
Executive Secretary, ACCV

Date