Advisory Commission on Childhood Vaccines

November 18, 2008

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 Evans, M.D., Director, DVIC

Staff Liaison

Michelle Herzog, Principal Staff Liaison

Introduction and Approval of Minutes

Mr. Sconyers convened the 71st quarterly meeting of the Advisory Commission on Childhood Vaccines (ACCV) at 9:00 a.m. and welcomed all participants. He invited a motion to approve the minutes of the September 4 & 5, 2008 meeting. Ms. Buck requested postponement of consideration of the minutes. After reviewing the minutes and comparing them to the transcript of the September meeting, she commented that the minutes should reflect in greater detail the discussions that took place, and especially include any specific requests made by Commission members. She stated that she had a series of revisions to the minutes that should be considered by the Commission. She also noted that the Department of Justice had apparently revised the section of the minutes pertaining to Mr. Matanoski's remarks, and that she also had revisions that would apply to that section. Mr. Sconyers concurred, suggesting that Ms. Buck's revisions be circulated to the Commission members for review and approval be deferred. Ms. Drew commented that she was unaware that a transcript was available, and Ms. Hoiberg suggested that the transcript be posted on the Commission's web site.

Mr. Sconyers announced a variation from the usual reports presented at the outset of each Commission meeting, noting that Ms. Gallagher and Ms. Castro-Lewis had developed the morning's agenda, which included a series of perspectives of the Vaccine Injury Compensation Program. Ms. Buck introduced the first speaker, Barbara Loe Fisher, who represents the National Vaccine Information Center, a national non-profit educational organization dedicated to the prevention of childhood vaccine injuries and deaths through public health education.

Ms. Barbara Loe Fisher
National Vaccine Information Center (NVIC)

Ms. Fisher noted that the NVIC, whose founders included parents of vaccine-injured children, worked closely with Congress in supporting the development of the National Childhood Vaccine Injury Act of 1986 (Act), which included the Vaccine Injury Compensation Program (VICP). The VICP was important because it was the first acknowledgement that vaccine injuries to children were real and caused catastrophic effects for the children and families involved. The Act was strongly supported by pharmaceutical manufacturers who threatened to stop production of vaccines unless product liability protections were provided, and by organizations representing pediatricians who were reluctant to administer the vaccines without that protection. Ms. Fisher added that at that time of passage, the Department of Health and Human Services and the Department of Justice were opposed to the legislation.

Ms. Fisher stated that promises were made by Congress and the American Academy of Pediatrics that the legislation would provide a "fair, expedited, non-adversarial, less traumatic, less expensive, no-fault compensation alternative to civil litigation." Parents had two conditions for participating in the process: first, that there would be no bar to civil litigation if federal compensation was denied or if compensation awarded by the process was deemed by the parents to be insufficient to meet an injured child's lifetime needs (or if a manufacturer's performance was clearly inadequate to produce a safe vaccine or if criminal or negligent actions were revealed); and second, the Act must include specific provisions for improving safety of the vaccines and vaccine programs. In fact, the final Act did require doctors to fully inform parents of risks, maintain permanent vaccine records for children inoculated, and report all serious adverse events that occur within 30 days of immunization. The Act also requested the Institute of Medicine (IOM) conduct a review to assess the extent to which vaccines cause injury and or death, and subsequently detailed reports were submitted by the IOM to Congress in 1991 and 1994.

Ms. Fisher stated that, in congressional testimony in 1999, she had expressed the view that parents had become disappointed in the structure of the VICP, that opposition to forced immunization programs without concomitant evidence of vaccine safety was growing, and that parents were finding themselves unable to obtain financial assistance to care for vaccine-injured children. Her testimony included references to reports from congressional committees that the system was not working properly. She added that, in preparing her remarks she had consulted with parents and plaintiff's attorneys, and had ascertained that, in compliance with federal recommendations and some school system requirements, children must receive dozens of doses of up to a dozen vaccines in order to attend school.

The intent of the Act, Ms. Fisher said, was not only to ensure a continuity of vaccine supply by alleviating product liability risks for manufacturers, but to provide parents with a federal compensation program based on the premise that if a child was injured or died, unless a specific other cause could be determined, the injury or death would be presumed to have been caused by the vaccine(s) administered. That presumption would justify compensation even if some children compensated were not, in fact, vaccine-injured. However, the architects of the Act agreed that such presumption could not be arbitrary, but must be based on reasonable evidence that when specific signs and symptoms related to disability and/or death existed after vaccination, the presumption of cause could be considered valid. After extensive consultation with vaccine manufacturers, physicians and parents of affected children, a mechanism was devised to support that requirement. The Vaccine Injury Table (Table), was codified and intended to insure that the determination of cause would remain administrative and not a matter of litigation.

Ms. Fisher noted that the original table was significantly changed by DHHS in the 1990s, when legislation provided greater discretion to the agency to redefine the rules, which resulted in elimination of almost all adverse events that would support a presumption of causation, and changes in the administrative process which in effect turned it into a trial in the US Court of

Claims under a single individual, a special master, who would hear the evidence and issue a ruling. The DHHS was also given the authority to redefine the signs and symptoms that underlie the diagnosis of a vaccine-related injury.

Ms. Fisher suggested changes that the agencies involved could make the federal compensation process more "fair and humane for petitioner." The Department of Justice could more readily allow awards for guardianship expenses, developing a fair formula to calculate loss of future income, housing modifications, and payments for mental health counseling for parents. The Court of Federal Claims could award interim fees for plaintiff's attorneys, and become less aggressive, along with the Department of Justice, in refuting testimony by plaintiff's expert witnesses. Ms. Fisher expressed the concern of parents that there has been the development of "mean-spiritedness and a growing hostility on the part of DHHS, Justice and the US Court of Federal Claims officials toward plaintiffs…." She added that Congress' assigning responsibility for administering the Act to the two federal agencies, DHHS and Justice, both of which opposed the original legislation, might be a critical flaw.

Pointing to other issues that suggest the administration of the vaccine program is becoming more and more adversarial, Ms. Fisher noted that originally 23 doses of seven vaccines were identified in federal recommendations; since then the number of doses for girls has risen to 46 (with nine new vaccines added) and 43 for boys (with eight new vaccines added). Since all new vaccines have been federally recommended they have been added to the VICP, but no side effects have been added to the Table for any of these vaccines (except anaphylaxis for hepatitis B vaccine). In looking at the statistics, Ms. Fisher pointed out that although $1.8 billion has been awarded to 2,200 plaintiffs, over 12,000 have applied. And there are 5,000 claims in limbo because they were filed by parents whose children suffered neurological and immune system dysfunction after vaccination which was diagnosed as regressive autism, a condition not covered by the Table.

Ms. Fisher noted that parents have been forced into appeals litigation with a number of cases resulting in decisions that underline the need to make the compensation system process more expeditious, just and non-adversarial. In the 2005 Margaret Althen case, the court's decision was that the burden of proof of causation should be lessened, that plaintiffs should need only show that a vaccine was the likely cause of the injury and that expert witnesses should be allowed to present circumstantial evidence, and not be limited only to conclusive scientific evidence. Subsequently, in the 2006 Rose Capizzano case, the Federal Circuit affirmed that a plaintiff need not present peer-reviewed conclusive scientific evidence of causation, but may provide a reasonable medical theory of causation, related to the vaccine, a logical sequence of cause and effect, and a temporal relationship to the vaccination. Finally, the Georgia Supreme Court held that manufacturers were not completely immune to liability if it can be proved that, even if the company is producing an FDA-approved vaccine, the company could have made a safer vaccine. Ms. Fisher reiterated that the courts are supporting the original intentions of the Act, not only to protect the vaccine supply, but to insure that all involved are working to improve the safety and efficacy of vaccines administered to children.

Ms. Fisher expressed the opinion that little can be done to recapture the original goal of Congress to provide an efficient, non-adversarial and fair compensation program for children injured by vaccines. She add that many parents believe the Act should be repealed and claims returned to the courts where discovery is allowed and where manufacturers could be sued for product defects and failure to inform about risks, and where physicians who fail to carefully screen children for potential exclusion criteria related to vaccines could be held accountable. She closed by commenting that the NVIC would continue to provide education to the public and to legislators about the Act and about the importance of safety over liability protection in matters of vaccine policy.

During discussion, Mr. Gallagher expressed the opinion that the program should not be ended, and that specific suggestions for improvement would be appreciated by the Commission. Ms.

Fisher agreed to provide her 1999 testimony to Congress in which there were specific suggestions.

Dr. Evans introduced Jackie Noyes. In addition to her role of many years as head of the Washington office of the American Academy of Pediatrics, she was previously a member of the Commission, and served as its chair in her final year.

Ms. Jackie Noyes
American Academy of Pediatrics (AAP)

Ms. Noyes recalled that the AAP became involved in the issue of vaccine injury compensation in the mid-seventies, when there was a relatively large number of vaccine producers -- seven that manufactured DPT, three for polio and six for measles. Perhaps the earliest instance involving vaccine injury was the Anita Reyes case, in which a child contracted poliomyelitis after receiving the vaccine in 1974. The Fifth Circuit Court of Appeals held that the manufacturer, Wyeth, was responsible for informing recipients of the vaccine that such a risk existed. It was subsequently proven the case was due to a wild polio virus. A massive vaccination program for swine flu occurred in 1976 and those with adverse reactions filed liability cases against the federal government. In 1977, with the national inoculation rate at about 65%, the Secretary of Health and Human Services (then Health, Education and Welfare) called for a program to encourage a broader vaccination program at the school entry. Through an intensive educational effort, the federal government staked out a role and responsibility in childhood immunizations. The convergence of all these events, coupled with the European model of a vaccine injury compensation system, led to the Academy's push for a no-fault compensation program. A variety of issues inhibited progress, but in 1983 legislation was introduced in the Senate and in 1984 in the House, the first federal legislation to provide such compensation to vaccine-injured children. Congress adjourned without passage and the process began anew in 1985. The bill passed in 1986 without funding. Ms. Noyes pointed out that it was important at that time to insure the fiscal survivability of the program. The next Congress refined the Act by providing a source of financing, the dose surcharge, and adding liability protection for vaccine administrators.

Ms. Noyes explained that in 1989 there was an opportunity to try to pass an amendment to the original bill that included updating the Vaccine Injury Table, providing a death benefit, refining the process of setting up a life plan annuity, payments for parental pain and suffering, and interim payments for attorneys, but for various reasons, many having to do with the political process, the amendment failed to progress. Nonetheless, there are champions of the program on the Hill, including Senator Orin Hatch and Representative Henry Waxman, who continue to be interested in an effective program.

Ms. Noyes commented that public awareness of the program was apparently lower than most stakeholders believed, and she recommended that there be a focus in the future on developing a campaign to provide public education on both the vaccine safety issues and the compensation program. She commended the Chief Special Master's efforts to bring parties together in workshop settings to discuss the program and how the compensation process should work. Although not perfect, Ms. Noyes suggested that, compared with the tort process that could take over a decade to finally settle, the provisions of the Act have been effective. There is a national childhood immunization program that might not have developed without it. She added that there is an opportunity now to renew efforts to improve the program by educating the new Secretary and the new Congress. Ms. Noyes concluded with the proposition that, if the surplus in the trust fund remained above a certain amount, perhaps a billion dollars, as a stopgap measure a small percentage of the fund or new income into the fund might be used to promote and fund vaccine safety. She believes that this kind of amendment was consistent with the intent of the original bill. She did agree that should the fund fall to a level where it could not meet its financial obligations to children, that this new initiative would cease.

During discussion, Ms. Noyes suggested that contacting the new Secretary early on in the new administration would be a positive step to getting ACCV's issues on his agenda. This was in response to Dr. Herr's questions regarding what sort of efforts do we need to put forth for consideration. She suggested that the ACCV might review the recommendations developed in the past (Dr. Evans noted that a CD compilation of those recommendations was available to Commission members). Ms. Hoiberg took exception to the suggestion to use of trust fund resources for any purpose other than compensation. Ms. Noyes agreed that there has been opposition in the past that has discouraged using trust fund monies for purposes such as safety research, but the tightness of federal budgets may significantly and negatively impact vaccine safety research, as well as budgets related to other aspects of the compensation program, such as special master staffing levels. In addition, Dr. Dan Salmon commented that concerns regarding vaccine safety were presented to Secretary Leavitt who in turn plans to pass on to his successor.

Sherry Drew, J.D.
Petitioners Bar

Ms. Drew, an attorney on the Commission who represents plaintiffs in compensation cases, commented that the process of pursuing a claim under the VICP is an intense, difficult, extremely personal experience for most plaintiff's attorneys. Unlike the Justice Department attorneys who represent a single client, HHS, and whose wins and losses tend to average out over time, the plaintiff's attorney is exposed to the individual challenge represented by a single client who already has an extremely difficult situation to deal with, the injury or death of a child, and has to face the additional burden of the compensation trial process that ends not in an average outcome, but either success or total failure.

Ms. Drew noted that few of her clients considered the VICP when deciding on whether or not to accept the usually school-mandated vaccinations. Most were not aware of the program until after the injury occurred and, searching the web or other information resources, came across the compensation program. Often the three-year statute of limitations had expired so that no claim was possible. Ms. Drew noted that she began her work in the field before the Act was passed, when normal tort rules applied, attorneys could pursue discovery, and when there was no statute of limitations. She added that under the Act, representing a plaintiff unable to rely on the standard rules of evidence and the limitations on discovery is daunting to most attorneys.

Unlike other parties to compensation cases, plaintiff's attorneys take on burdens that are legally challenging and more stressful on a personal level. Ms. Drew stated her desire to return to the kind of non-adversarial system that was originally envisioned, and to see a much great proportion of the trust fund go to compensating injuries, even when the exact causation may be in some doubt.

Evolution of the Vaccine Injury Table, 1988 to 2008
Vito Caserta, M.D., M.P.H

Dr. Caserta described in detail the evolution of the Vaccine Injury Table, which was originally included in the Act to alleviate some of the burden of proof that had been required when plaintiffs pursued the traditional tort process. These petitioners were also facing very large pharmaceutical companies with extensive resources to litigate such claims. When originally established there was no extensive body of research that now exists concerning vaccine-related injuries. Therefore Congress specified that the original list would provide a very broad coverage, which would mean that some individuals would be included in the compensation program who may not have actually been injured by a vaccine. Nonetheless Congress anticipated that such research would develop and allow a more definitive approach to vaccine injury and, when that occurred, the Secretary of HHS and the ACCV would have authority to review that literature and make recommendations concerning changes in the Table. Congress mandated the Institute of Medicine to review the research literature and prepare periodic reports that could be the basis of such recommendations.

The original legislation also established the National Vaccine Advisory Committee, which oversees the National Vaccine Program and the national vaccine research agenda.

Originally the Act allowed the Secretary to recommend changes in injuries only, but the 1993 Omnibus Budget Reconciliation Act expanded the authority to include adding vaccines. There are two requirements -- that CDC recommend the vaccine for routine administration to children, and that Congress levy an excise tax on the vaccine to provide funding for compensation. Once both occur, the Secretary publishes a notice of coverage in the Federal Register. The vaccine is listed in the last box on the Table and coverage begins based on the effective date of the excise tax. A separate listing on the Table, including any associated injuries or conditions for the vaccine occurs after a notice of proposed rulemaking, a public comment period, and publication of a final rule. Revisions of the Table apply on and after the effective date, and there is an eight-year retroactive period for which individuals may file a claim for the specific change in the Table. The eight years supersedes the statute of limitation normally imposed on claims. However, during a brief discussion headed by Ms. Hoiberg about the issue, Ms. Saindon, HHS Office of General Counsel, confirmed that if the Vaccine Injury Table is changed and it gives an individual a greater likelihood of prevailing on a claim, that individual may re-file even if the original claim had been dismissed.

Dr. Caserta noted that the first IOM study (1991) looked at pertussis and rubella vaccines and the second study (1995) looked at all other vaccines -- measles, mumps, diphtheria, tetanus and polio. The Public Health Service established a task force to review the first report and to report to the Secretary. The British National Childhood Encephalopathy Study was near completion at that time, and since there were clear implications that pertussis vaccine was a factor in such seizures, the recommendations were delayed. The IOM looked at the study specifically, issued a report, and in 1994 ACCV, with some exceptions, voted in favor of the recommendations, which were endorsed by the AAP and the AMA. The final rule was published in 1995.

Dr. Caserta described the changes to the Table over time. The first table was published in October 1988 and included 7 vaccines and 12 injuries. After the first IOM study the second table, published in March 1995, contained several changes -- a new injury (chronic arthritis) was added for rubella vaccine, and two injuries related to tetanus/pertussis vaccines were removed as being transient conditions. The Act requires that an eligible injury must be persistent and serious. Dr. Caserta noted that one of the considerations in making such decisions is the epidemiological data related to the condition, which may demonstrate that there is no increased risk of a condition as it relates to immunization. The third version of the Table was based on the second IOM report, and several new vaccines were added as were a number of adverse events.

During discussion, it was noted that although new vaccines may be added, the addition of specific injuries is very slow. Dr. Caserta explained that new vaccines are generally screened more carefully for safety than was the case decades ago. Therefore it takes time for adverse events, many of which are rare, to appear in sufficient numbers to warrant adding specific injuries to the table. Asked whether all of the IOM recommendations had been implemented in the Injury Table, Dr. Caserta conceded that some had not. For example, the IOM's conclusion that Guillain-Barre syndrome was related to tetanus vaccine was based on a single case of an individual re-challenged with the vaccine. The Program's position was that to include the syndrome as an injury would probably make far more individuals eligible for compensation than are actually affected by vaccine injury. Dr. Evans clarified that the IOM's charge was not to develop recommendations for the Table, but to assess the research literature related to potential vaccine injury situations and provide information. The recommendations would be developed within the Program and by the Secretary. Ms. Hoiberg asked specifically why residual seizure disorder was removed from the table. Dr. Caserta explained that based on the finding of the IOM that these type of febrile seizures are benign and do not lead to serious sequelae. The recommendation by HHS,with approval from the ACCV, was for removal of the condition from the Table.

Dr. Caserta observed that intussusception related to the rotavirus vaccine was an exception to the pre-marketing screening that usually reveals such problems. However, it did become immediately apparent in part because of the surveillance programs, and the vaccine was removed from the market. Asked why the injury was recently removed from the Injury Table, Dr. Caserta explained that since the vaccine has been unavailable for more than three years (the statute of limitations for a claim), the injury was removed in order to maintain a more relevant and current Dr. Evans added that, since there are now two other rotavirus vaccines on the Table, keeping the old version might cause confusion. Ms. Buck made several comments during this discussion regarding the process of adding/removing vaccine and injuries from the table, commenting that it seems to be a long process. Coupled with the underreporting of VAERS and the long process of VSD, we need to get back to the basics of updating the injury portion of the Table to align with the new vaccines added allowing more petitioners to get into the program.

Mr. Sconyers invited public comment and Terry Poling commented that in the United Kingdom, because of a possible six fold increase in intussusception, rotavirus vaccine has not been included in their recommended vaccination schedule. Mr. Polling said that taking the injury off the Table would confound the effort to pinpoint the true cause of intussusception when it occurs in children who have been vaccinated.

VICP Strategic Plan and Performance Measures
Kay Cook, Policy Analysis Branch, DVIC

Ms. Cook discussed her Policy Branch's responsibilities for development of the strategic plan and for assessing performance measures. In 2002, a workgroup was formed to develop the basis for a long-term strategic plan. The eight-person workgroup held a retreat in October 2002 which was attended by a larger number of stakeholders and individuals interested in the National Vaccine Injury Compensation Program. Considering the comments and recommendations from that retreat, a final strategic plan was published in April 2006. The strategic plan for 2005 to 2010 must deal with the challenges related to the fact that there has been a dramatic shift in claims from injuries listed in the original Table to a majority of claims now being made for off-table conditions, which increases the burden on petitioners to prove causation. Other challenges include the fact that the adjudication process has become more complex and difficult resulting in the VICP not being well understood by parents, attorneys, health care professionals and the general public.

Ms. Cook explained that the strategic plan has four key goals: 1) to look at alternatives in adjudicating off-table claims; 2) to ensure that the VICP keeps up with evolving science and medicine and changes in public policy; 3) to improve the claims process (faster, more user-friendly, fairer to all parties); and 4) to increase the level of awareness of the VICP to all stakeholders -- the public, parents, attorneys, health care providers, educators, etc.

Ms. Cook noted HRSA's recently instituted contract with the IOM for the study of adverse events related to four vaccines -- varicella, influenza, hepatitis B and human papillomavirus. -- and reminded the Commission that the Petitioner Satisfaction Survey was on track to be completed by May of 2009. The Division is also involved in program performance relying on the Office of Management and Budget's (OMB) program assessment rating tool (PART) to provide information about several outcome areas. The first area tracks individuals who turn to civil litigation even though they have eligibility for program compensation -- the VICP's target of zero instances was reached in each year from FY 2005 through FY 2009. The second outcome is the number of days from date of filing to payment authorization and, except for 2007 when there was a spate of unanticipated delays in the hearing process, that goal has been met. The third outcome is a measure of timeliness on the Program's part in filing a Rule 4(b) response once a case has been filed with adequate medical documentation. The target is 90 days.

Mr. Sconyers noted that, although the VICP filed the Rule 4(b) response in, for example, 89.3% of cases in FY 2007, the VICP's goal was only 83%. Therefore, VICP exceeded the goal. Failing to

meet the deadline in 17% of cases would still be considered successfully meeting the performance standard. Dr. Evans and Ms. McInerny explained that a 100% goal is not achievable because of several factors that delay the process but which are not under the control of the VICP and DOJ. There were several additional comments made by Commission members regarding the need to examine why 100% is not our goal.

Ms. Cook continued, explaining that the fourth performance factor was a measure of the average time in which settlement payments are approved after receipt from the Department of Justice. Although the target days have increased slightly, the VICP has approved payments well within the goal. Finally, the fifth performance outcome measure is the time to make actual lump sum payments, and VICP has made payment consistently faster than the target time period. She added that there was one performance output measure, the percentage of cases for which settlements are completed within 15 weeks of initial agreement by the parties to when a final proposal is returned to the petitioner for review. The VICP performance has been 95% or higher (target performance has been set at 92%).

During discussion, Ms. Castro Lewis inquired into the outreach plan and how it is being developed. Ms. Cook stated that the outreach plan should be completed and ready for review by the Commission at its March meeting. Ms. Buck suggested that a performance standard that might be incorporated in the plan would measure the accessibility of the program to individuals injured by vaccines.

Mr Sconyers asked how the first theme of the strategic plan was being addressed, that of examining alternative approaches for adjudication of off-table claims, Dr. Evans conceded that it was the most challenging theme of the four. There have been discussions, and the AAP presented a proposal to the ACCV in 2001, but there has been not real progress toward consensus. Among other things it will require legislative intervention.

Petitioner Satisfaction Survey
Namratha Swamy, Ph.D and Kara Rudolph, MPH, Altarum Institute

Dr. Swamy explained that in 2005 Altarum Institute had contracted with DVIC to conduct a feasibility study to determine if there were aspects of VICP which could be evaluated. In March 2007 the feasibility study was delivered to HRSA, which included among several potential projects, a petitioner satisfaction survey. The project, which began in 2006 involves claimants who have completed the process either receiving an award or having their case dismissed, but not including individuals who voluntarily opted out of the process before completion. The areas covered in the survey, which was a written paper-based survey distributed to claimants through their attorneys, were: pre-claim awareness of the program, and the adjudication process, including the ease of establishing the claim, the hearing process, the time involved, the final decisions made by the court, the determination of compensation, the award itself(adequacy and timeliness), and the level of communications among the parties involved. There was also a demographic segment to gather information about age, race, ethnicity, socioeconomic characteristics of the plaintiffs.

The data was initially supposed to have been collected over a 3 month period, but that was extended to 6 months because response was lower than anticipated -- only 18% of those contacted responded. There was concern that the low response rate might have been related to the fact that, mainly for confidentiality, the surveys were sent to plaintiff's lawyers with a request to forward the survey to the client. For various reasons many attorneys may not have cooperated and in some cases the plaintiffs may not have wanted to revisit the experience.

The profile of the respondents revealed 42% were injured individuals, 58% were mainly parent/guardians with a small number partner/spouse claimants. About half were between 36 and 49 years of age, with about a quarter below that and a quarter older. The great majority were white (98%), with a smaller number of Hispanics (7%) and Asian (2%) respondents. More than

half had college degrees, about a third had some college, and only 9% either graduated from high school or had some high school experience. Finally, about half had household incomes above $60,000 per year, with about 9% indicating income of less than $20,000 a year.

Asked where they learned about the VICP, 41% found information on a web site (16% on the VICP site, 27% on other sites not specifically identified); 35% heard about the program from others involved in the VICP or from health care providers; and the remaining 26% from some sort of printed or published literature.

Concerning the specific questions, the following reflects the responses. Respondents could indicate whether they were very satisfied/dissatisfied or somewhat satisfied/dissatisfied or whether they were neither satisfied nor dissatisfied (neutral).

Obtaining information about the program -- easy 34%, difficult 38%
Whether the information available was helpful in filing -- 33% not helpful, 37% helpful
Ease in locating an attorney -- 40% found it difficult, 41% found it easy
Satisfaction with claim filing process -- 50% were dissatisfied, 34% were satisfied
Ease of obtaining additional information after filing -- 61% found it difficult, 21% easy
Satisfaction with the hearing process -- 49% dissatisfied, 35% satisfied
Monetary awards -- 57% received an award, 43% did not
Satisfaction with the award process -- 47% dissatisfied, 28% satisfied
Adequacy of the award to cover future needs -- 56% adequate, 33% inadequate
Length of the claim process -- 65% were dissatisfied, 33 were satisfied
Was the program helpful in working with Medicaid -- 26% not helpful, 33% helpful
Method of award payment -- 20% dissatisfied, 52% satisfied

In open-ended questions, the survey invited suggestions on improving the program. Concerning public awareness, there were suggestions to increase awareness on the part of physicians and perhaps to distribute information about the program at the time of vaccination. Concerning finding an attorney, there was a suggestion to publish a list of attorneys (although Dr. Evans noted that the VICP is not allowed to publish such a list or make recommendations). Ms. Hoiberg commented that, although she did receive a referral to a firm in Boston, it would be more helpful to have lists of local attorneys. Dr. Herr suggested that the VICP web site might be able to provide a link to the Court of Claims web site, which maintains a list of attorneys that practice before the bar. Mr. Sconyers noted that the Commission might review the prohibition that limits the VIPC's ability to make such referrals. Other suggestions included shortening and simplifying the application and claims process, improving communications and information sharing, and a broader effort to increase public awareness (outreach and advertising/education programs).

Dr. Swamy concluded that the data gathering process would continue until the end of December, but there was limited expectation that the level of response would improve materially. She stated that HRSA would receive the final report in May 2009, and it would be HRSA's determination as to what information to release to the public. Ms. Drew asked for a copy of the survey, to review the specific questions, which was provided to the group after the lunch break.

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

Dr. Evans provided his regular report to the Commission, noting that non-autism claims have averaged about 167 per year since 2002 and, after peaking in 2007, appear to be leveling off at close to the average. Autism cases number in the thousands, and have until now been placed in a pending status. However, the Court has decided to begin jurisdictional assessment of these cases by assigning about 200 cases per month to the Justice Department for assessment, and petitioner's attorneys are beginning to provide the requisite medical information to make the decisions in each case. In June 2007, after the Cedillo hearing, newly filed claims came under

the 90-day turnaround requirement for DVIC medical reviews. These two requirements have resulted in some challenges in managing staff workload.

In regard to petitioner awards, Dr. Evans noted the average annual awards have been about $59 million, with attorney's adding another $4 million. There was a peak in 2007 of over $91 million, because of the hiring of two special masters, and a significant increased number of settlements, although the average cost of a settlement tends to be lower versus claims that go to formal damages determination. The Trust Fund balance is currently over $2.8 billion, increasing at a higher rate than before because of the large number of influenza vaccine doses that are distributed annually -- over 100 million. The Trust Fund is increasing at a rate of about $250 million a year, about a third of which is interest income.

Dr. Evans noted that the VICP, which began in October 1988, recently celebrated its 20th anniversary. Since its inception over 12,000 claims have been filed, 7,000 adjudicated, and more than 2,200 families have been awarded compensation totaling over $1.8 billion. The program achieved one of its purposes, to reduce civil litigation in vaccine injury cases. In 1987 vaccine lawsuits reached a peak of 255; now there are fewer than two dozen claims filed annually. Dr. Evans paused to express appreciation for the efforts of professional and support staff in the DVIC, the Department of Justice and the Office of the Special Masters for dedicated service to the goals of the program during the last 20 years.

With regard to activities since the last Commission meeting, Dr. Evans noted that he and Ms. Tempfer (the Commission's liaison to the National Vaccine Advisory Committee) attended the September 16-17 meeting of the NVAC, and presented a review of the Commission's activities. As Ms. Tempfer leaves the Commission, Ms. Castro-Lewis will accept the position of liaison to NVAC. In addition, he noted that he and Dr. Rosemary Johann-Liang had attended the Advisory Committee on Immunization Practices meeting on October 23-24.

Dr. Evans stated that a contract to review four vaccines listed on the Vaccine Injury Table vaccines was been awarded to the Institute of Medicine in late September. Dr. Kathleen Stratton, IOM project officer, will provide an overview of the contract later in the meeting. Finally, he announced that an interim final rule had been filed to remove the rotavirus vaccine, Rotashield, from the Vaccine Injury Table. He briefly discussed the rationale. Rotashield was licensed in 1998 and after publication of a notice in the Federal Register, the general category of rotavirus vaccines was added to the Table in July 1999. At about that same time the CDC recommended suspension of the vaccine for children and shortly thereafter the manufacturer recalled the product. In 2002, after a notice of proposed rulemaking and the requisite public comment period, a final rule was published establishing a separate category on the Injury Table for Rotashield vaccine with the associated injury of intussusception and a time interval of onset up to 30 days after vaccination. About three dozen claims were filed, the last being in 2004. Since the vaccine had not been available for more than three years, it was assumed there was little chance of additional claims, and having no real purpose on the Injury Table, it was removed by the publication of an Interim Final Rule on October 9, 2008. Among other things, leaving it on the Table might imply that intussusception could be an adverse event related to the two remaining rotavirus vaccines, for which there is no evidence. Mr. Sconyers expressed concern that the Commission should have been informed prior to the action in order to offer comment, although he conceded that review of such an action (Interim Final Rule) was not in the charge to the Commission. He asked whether Rotashield was still an approved drug and Ms. Gallagher agreed to look into whether the company has asked for withdrawal of its license. Dr. Evans added that if the Commission desired to make a comment to the Secretary on the action, it could prepare such a comment and submit it to the DVIC for review and response. Mr. Sconyers requested that in the future the Commission be informed of such action before final publication.

Report from the Department of Justice
Vince Matanoski, J.D., Acting Deputy Director, Torts Branch

Mr. Matanoski reported that he is still serving as Acting Deputy Director for the Civil Division, Torts Branch, vaccine section at the Department of Justice (DOJ) while Mr. Rogers remains deployed to Iraq.

Personnel

There were no staffing changes since the last meeting.

Power Point Presentation Summary

Mr. Matanoski introduced his Power Point materials, entitled November 18, 2008, DOJ (DOJ PP), as part of his presentation. Using Power Point, Mr. Matanoski sought to address questions about terminology raised at the last meeting by several ACCV members. The information provided in the statistics reflects a shorter reporting period of two and one half months versus the usual three month reporting period. As an aside to the statistics, Mr. Matanoski considered the bulk of the petitions filed to be flu claims. When asked by Dr. Herr whether the claims alleged injected versus oral administration of the vaccine, Mr. Matanoski believed that the claims involved injected flu vaccines based on his understanding that the petitions were filed by individuals between 60-70 years of age.

Statistics

Using the Power Point materials, Mr. Matanoski reported that since the ACCV last met, 86 new cases had been filed. Of those, 31 were autism and 55 were non-autism petitions. (See DOJ PP, p. 3). In this period, 20 petitions were adjudicated. (DOJ PP, p. 4).
Mr. Matanoski acknowledged that there were a lot more cases coming in than were adjudicated. Of those 20 petitions adjudicated, 13 were compensable and 7 were non-compensable. (DOJ PP, p. 4). Within the category of 13 compensable, 6 were conceded by the Secretary of Health & Human Services (HHS) while 7 were not conceded but were settled by the parties without a decision by the special master. Mr. Sconyers assumed that none of the compensable cases were conceded cases. Mr. Matanoski replied that he was unsure whether the conceded cases constituted Table injury cases; they would either be Table injury or non-table cause-in-fact cases. Mr. Sconyers asked whether or not settlements are subject to Freedom of Information Act (FOIA) requests, to which Mr. Matanoski replied that it depends. The stipulation setting forth the terms of a settlement are published, subject to a petitioner's chance to seek redaction, under certain circumstances, of their name and other information. DOJ pre-decisional documents would be exempt under FOIA. Mr. Matanoski summarized the Glossary of Terms, which are set forth in detail in the materials and are to coincide with the statistics presentation. (DOJ PP, pp. 5-6). Mr. Matanoski further explained the term "decision" to mean when a special master issues a "decision" on the merits of the petition. (DOJ PP, p. 6). In this reporting period, none of the cases fell into this "decision" category as all of the non-compensable claims were decisions by the special master finding against petitioner and awarding no compensation. Mr. Sconyers thanked Mr. Matanoski for putting together this presentation and providing the terminology. Dr. Fisher asked about the term "conceded," which Mr. Matanoski confirmed means that HHS determines that the petition should be compensated inasmuch as it fits the terms of compensation. Mr. Matanoski emphasized that a petition may be compensated in two ways under the Vaccine Act: 1) it fits the presumptive injuries listed on the Table, or 2) there is sufficient proof of actual causation. Ms. Buck asked whether the conceded cases are public. Mr. Matanoski indicated that in a conceded case, the decision will reflect that a petition was filed and alleged a certain injury, which was conceded either as a Table injury or actual causation. A final decision is entered by the special master explaining the procedural history of a case, and that it would likely be a very short decision. The bulk of the decision would focus on the damages

aspect of the claim, which would likely include a series of charts explaining categories of future medical costs and the amount of compensation that will be paid out over the future, i.e., for neurological care. As noted by Mr. Sconyers and confirmed by Mr. Matanoski, the reasoning and analysis by HHS/DOJ for conceding a claim would be pre-decisional and exempt under FOIA. Court decisions, however, are public. All pleadings filed in a case are part of the court file subject to statutory disclosure to the public, which requires consent by the party disclosing it.

Mr. Matanoski turned to the Summary Flowchart: Petition Processing Under the Vaccine Act. (DOJ PP, p. 7). Regarding the Flowchart, Mr. Matanoski discussed what happens to a petition after it is filed. (DOJ PP, p. 7). Once the petition is filed, HHS reviews it, which results in the claim being conceded or not. Using the 20 petitions adjudicated for this term as an example, HHS conceded 6 of those claims. If a petition is conceded, it moves into the "Damages" phase and there is can be a determination of damages. If the petition is not conceded, it moves into the "Not Conceded" phase, where they can be "Settled" or a "Decision" can be entered by a special master. Keeping with the statistics provided as an example, 7 claims under the "Compensable" category were settled while 7 claims under the "Not Compensable" category were decided by special masters. If, however, the special masters found that one or more of those 7 claims decided by them should have been compensated, then the claim would have moved into the "Damages" phase, just like a conceded case and been reflected as a "Decision." (DOJ PP, p. 4, 7). In the "Damages" phase, the parties are able to either work together and determine reasonable damages or they are unable to resolve the damages and the special master is called upon to decide some or all aspects of damages. Ms. Buck clarified that a "decision" is an act performed by the special master, and asked for further clarification between "conceded" and "settled." Mr. Matanoski explained that "conceded" means that HHS's review has indicated that the claim qualifies for compensation either as a Table injury or under actual causation elements. "Settled" means that HHS still maintains that the claim is not compensable under the Vaccine Act (either as a Table injury or actual causation); however, the parties while maintaining their respective positions nevertheless believe that the claim can be settled. In other words, by settling, the parties have worked out an arrangement short of asking the special master to determine whether or not the claim is compensable. Some examples of factors that the parties consider to determine whether to settle a particular claim include, the strength and/or weakness of a given expert, the costs involved in continuing the litigation, as well as payment of attorneys' fees. Ms. Buck observed that there is no line on the Flowchart connecting "Settled" cases to the "Damages" box. In response, Mr. Matanoski noted that it is because settlements can go either way. It may be that the parties without the use of a life-care planner arrive at a reasonable settlement. Depending upon the assessment of risk to each side, in a settlement, a petitioner may not get the full amount of what he/she is seeking. In response to Ms. Buck's question, Mr. Matanoski confirmed that settlements are paid the same way as conceded cases, and settlements can use reversionary trusts. Regarding the Flowchart, Ms. Castro Lewis observed that the chart is circular. Mr. Matanoski acknowledged that point and noted that the endpoint, moving left to right, is "Damages." Ms. Tempfer asked about the role of special masters and Court of Appeals as their roles are not formally identified in the Flowchart. Mr. Matanoski acknowledged the good questions and emphasized that special masters participate throughout the duration of a pending claim by issuing orders and holding status conferences. For purposes of the Flowchart, they can ultimately issues final "Decisions," as well as issue a decision on the amount of "Damages." (DOJ PP, p. 7). The Court of Appeals would come into play after "Not Compensated," following a final decision by a special master, or after the "Damages" phase and a decision. (DOJ PP, p. 7). In the past decade, Mr. Matanoski could recall very few instances where a petitioner appealed a damages decision awarding an amount of damages. Generally, if a case goes to damages, petitioner does not appeal the amount awarded. If HHS appeals a decision, it is usually the finding of entitlement, not the amount of compensation awarded.

Autism

Mr. Matanoski turned to the Autism section of the Power Point presentation noting that most of this information has been covered. (DOJ PP, p. 8-9). Since the last meeting petitions for an

award of interim attorneys' fees and costs have been filed by both the petitioners in Cedillo v. HHS case, as well as by the Plaintiffs' Steering Committee (PSC). These are under consideration by the Court. In the second theory (thimerosal-containing vaccines alone can cause autism), post-hearing briefs have been scheduled, with the PSC brief due February 6, 2009, and respondent's brief due April 9, 2009. Mr. Matanoski hoped for decisions in the first theory as the briefing has been completed, but did not anticipated decisions in the second theory until after briefing has been completed in the Spring, 2009.

Appeals

Mr. Matanoski discussed pending appeals. (DOJ PP, p. 11-13). First, he commented that there is a lot of appellate activity. (Cases for this reporting period are listed at DOJ PP, pp. 11-13, and are available as listed on the Court's website). Mr. Matanoski noted that the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) decided DeBazan v. HHS and Mojica v. HHS, which he discussed at the last meeting. More recently, the Federal Circuit decided Kay v. HHS. The case was found to be time-barred and petitioner's counsel sought payment of attorneys' fees, which the Court of Federal Claims denied. The Federal Circuit affirmed that denial of fees. There was no written opinion by the Federal Circuit, it was decided *per curiam*, which means summary affirmance, without a decision. The cases, Nordwall v. HHS and Andreu v. HHS, both are fact specific and are not expected to be precedent setting.

At the Court of Federal Claims (CFC) level, there were 14 claims pending; three claims were affirmed by the CFC in favor of the Government. (DOJ PP, pp. 12-13). The companion cases Hopkins v. HHS and Finn v. HHS, were affirmed by Judge Horn, following more fact finding by the special master (denying compensation to petitioners). The case, Savin v. HHS, filed by petitioner involved an attorneys' fees decision. In Savin, respondent had objected to certain elements of the attorneys' fees petition. The special master accepted some, but not all of respondent's objections and went on to reduce the request for attorneys' fees and costs for other reasons of her own. Petitioner appealed and argued that the special master had overstepped her authority. The respondent argued that under the Vaccine Act, a special master has an independent duty to review and decide reasonable compensation for attorneys' fees and costs. The CFC agreed that the special masters have an independent duty to review, consider and award reasonable attorneys' fees and costs notwithstanding respondent's objections or lack thereof. Another pending attorneys' fees case is Carrington v. HHS. In Mr. Matanoski's view, there is more attorneys' fees activity at the CFC level. Last, four cases pending on appeal to the CFC, Myers v. HHS, Porter v. HHS, Rotoli v. HHS, and Torbett v. HHS, all involve autoimmune hepatitis cases and were decided against petitioners; Mr. Matanoski expects one CFC decision resolving all of those cases, plus one other one - for a total of five pending appeals on that issue. (DOJ PP, pp. 12-13).

Comments

Ms. Buck questioned whether interim attorneys' fees had been paid. Mr. Matanoski confirmed that several interim requests for attorneys' fees and costs have been paid. Reflecting back to the last meeting, he believed that about 15 payments have been made and payments continue to be made. The area of concern for the respondent continues to be the appropriate break points for a petitioner to apply for interim payments. Mr. Matanoski explained that there have been some multiple requests for fees arising from one petition, which have the potential of slowing things down. In respondent's view, the Court (Federal Circuit in Avera v. HHS) intended to allow for one interim award of attorneys' fees and costs where litigation is fairly extensive and ongoing for a lengthy period of time. The paradigm example would be where entitlement is not conceded, a lengthy hearing ensues with costly experts, and a decision issues awarding petitioner compensation. In that instance, the case moves to damages, which can be a lengthy process. Mr. Matanoski felt that circumstance reflects the intention of the Court (Avera v. HHS) and affords an appropriate break point in the litigation. Ms. Buck asked about single or multiple requests for interim fees and costs. Mr. Matanoski favors a single request within an appropriate case,

consistent with objective break points discussed. He is concerned that multiple requests within a case absent break points will require a lot of resources and manpower devoted to processing fees to the detriment of processing cases to resolution.

Dr. Herr appreciated the discussion on precedent setting appeals and asked whether DOJ could provide a brief reference summary of the past, precedent setting cases as part of the presentation. For purposes of future presentations, could DOJ provide any new precedent setting cases that have been decided and add those to the list. Mr. Matanoski offered to provide responsive information.

Report on Autism Hearings from the Petitioners Steering Committee
Tom Powers, J.D., Williams, O'Leary, Love, and Powers, PC

Mr. Powers explained that the Omnibus Autism Proceeding was established by the Chief Special Master when it became clear that thousands of claims for autism injury would probably be filed, a number that could paralyze the program process. The OAP was a case management solution that would rely on the premise that most of the cases would be based on similar if not identical evidence, and that looking at a number of representative cases might provide a basis for making the decision process more efficient. Since its inception in July 2002, both petitioner's and respondent's attorneys have expended immense amount of time gathering scientific and medical evidence, conducting hearings, taking testimony with the common goal of developing principles of common causation with regard to vaccines and autism. Although traditional discovery is not part of the VICP process, both petitioners and respondents attorneys arrived at certain agreements to allow discovery, which made possible the accumulation of thousands of pages of information and evidence from expert sources such as the FDA and CDC.

Ultimately, the Special Masters would have to hear cases involving perhaps hundreds of claimants, which could involve dozens of attorneys -- a challenging concept in trial management. Therefore, the plaintiffs' attorneys agreed to form a Plaintiffs Steering Committee which includes about a dozen of the law firms most active in vaccine injury cases, out of which was created an executive committee of attorneys who would actually pursue the specific hearing process. The first step was the completion of three test cases (Cedillo, Hazelhurst and Snyder), which were all completed by late November 2007. A decision in those three cases should be announced in early 2009. After those cases, three test cases examining a second theory of causation were undertaken and completed, and the final briefs by both sides will be submitted in the near future.

Each case was heard by three Special Masters, only one of which was responsible for writing a decision for each individual case. Therefore, there will be six decisions, two from each of the Special Masters. Mr. Powers noted that each of the six decisions could be subject to an appeals process, so that developing a timeframe, questioned by Dr. Herr, for the final outcome is very difficult. Theoretically, the decisions will be a major determinant in the final outcome of the thousands of cases pending, but how clearly each decision is written and how each fares on appeal will affect how unified that process might be. Ms. Hoiberg asked a question regarding the applicability of the decisions on the pending cases and whether standards who be applied to all or if cases could be reviewed on its own merits. Mr. Powers answered that it would probably be a combination of both.

As he mentioned, Mr. Powers noted that the thousands of cases filed thus far are being sorted out in terms of timeliness of filing -- that is, each case must be assessed in light of the statute of limitations that applies to all VICP cases. The law firms representing claimants are being directed to develop records to support the client's timely claim and there are three possible responses from the respondent. The first two are straightforward -- yes, the records support the timeliness of the claim; no, the records clearly show that the claim was made after the time limit imposed by the Act and the respondent files a motion to dismiss. The plaintiff's attorney can either accept that decision or move into litigation to challenge the decision. The third, that there is insufficient

information to make any decision about timeliness requires the attorney and the claimant to search for further evidence of timely filing.

There is another difficult situation, when a claimant presents evidence of timeliness that is open to dispute, as is sometimes the case in autism injury cases. Then the attorney must decide whether to incur the considerable expenses of litigating the issue, expenses that are not reimbursable under the statute. It is a practical and ethical issue for the attorney, and a policy issue for the Program and for Congress, which could alleviate the situation (for example, by easing the statute of limitations, adding discovery to the statute of limitations, providing some compensation for related costs, etc.)

With regard to interim fees, the Petitioner's Steering Committee developed the interim fee proposal and sent it to the respondent. For a certain number of attorneys, it represents nearly seven years of attorney time, costs and out-of-pocket expenses. The next step depends on the results of the respondent's review of the proposal.

Finally, in the area of civil litigation, the Georgia Supreme Court ruled that a manufacturer may be held liable if a safer product was available and the injured party was not informed of the alternative. At least in Georgia then, consistent with the National Childhood Vaccine Injury Compensation Act, litigation could be initiated against a manufacturer. Mr. Powers expressed the opinion that the OAP claimants would probably remain with the VICP process.

During discussion, asked about the financial burden that claimants may incur, Mr. Powers said that his firm (and others) represent their clients and do not bill their clients for any services or costs. The attorney fees and litigation costs are recovered from the NVICP so long as the case was brought forth in good faith and with a reasonable basis for filing. Mr. Power had a specific question for Mr. Matanoski on the number of pro se filings for autism. Mr. Matanoski indicated out of the 31 most recent filings, about 6 to 10 were pro se.

Institute of Medicine Project of Vaccines and Adverse Events
Kathleen Stratton, Ph.D., Study Director, IOM

Dr. Stratton described the Institute of Medicine, one of three honorific branches of the original National Academy of Sciences established by Lincoln in 1863. The Institute is a nonprofit entity not affiliated with the federal government, which draws its members from the most distinguished scientists and physicians in the United States. The Institute works through committees, one of which will be established as a result of the contract with HRSA to study four vaccines and their related adverse events. The committee members are chosen to represent a broad spectrum of experts in the vaccine field -- pediatrics, immunology, neurology, epidemiology, physiology and pathophysiology. It will consist of about 15 members who volunteer time for a period of about two years, during which the study will take place.

The four vaccines the IOM has been charge with looking at include influenza vaccine (live attenuated and killed), varicella, hepatitis B and human papillomavirus vaccine. If additional funds become available in a timely manner, additional vaccines could be added to the study. The main charge is to look at the causal relation between specific vaccines and specific adverse events, as well as the biologic mechanisms that might underlie such a relation. Those adverse events will be identified by HRSA before the study gets underway. However, the IOM reserves the right to add other adverse events if any appear to be relevant during the process of the study.

The recruitment of members of the committee has begun, although there is still time to entertain additional nominations. The first meeting will be held in early 2009, mainly for organizational purposes, when the committee will define its agenda and identify objectives of the study. There will follow a public workshop to discuss a framework for reviewing the literature and categorizing the evidence on biologic mechanisms as well as the factors affecting causality. There will be additional open public meetings as well as closed deliberations by the committee, and the

members of the committee, supported by IOM staff, will write the final report. That report will be reviewed by an outside committee of reviewers and finally published about two years after the first meeting. If additional vaccines are added to the study, that report may be published a few months later to take into account the additional work required to review the new vaccines.

Asked about briefings during the study process and whether or not interim reports would be available, Dr. Stratton explained that the IOM committees do not publish interim reports or provide briefing on the substance of the committee's progress. Concerning conflicts of interest, the Academy is mainly concerned with financial conflicts and current positions and circumstances in a member's affiliations that might affect objectivity. However, in this very sensitive area, that concern might extend into an individual's past activities (e.g., it would probably be inappropriate to include an individual who had served as an expert witness for either side of a compensation case).

Update of the National Institute of Allergy and Infectious Diseases
Barbara Mulach, Ph.D., NIAID, NIH

Dr. Mulach announced that the Vaccine Safety Program Announcement was published in August 2008 inviting researchers to submit grant applications to address areas of vaccine research. Interest has been encouraging and Dr. Mulach invited suggestions for specific areas of research that the Commission might be interested in. The first deadline for submission was October, probably too soon for most applicants to act. The next deadline date is February and then the final date is in the summer of 2009. She said she would keep the Commission informed of progress as applications began arriving for consideration.

Secondly, she announced that the group known as the Interagency Autism Coordinating Committee had recently become a formal federal advisory committee as part of the autism legislation. It will meet on November 21 to discuss a strategic plan.

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

Dr. Gruber announced that FDA had approved Gardasil, a human papillomavirus vaccine, adding two new indications, e.g., prevention of vaginal and vulvar cancer in females 9 to 26 years of age.

There are several biologic license applications under review including one for a human papillomavirus vaccine, a Japanese encephalitis vaccine, and an adenovirus vaccine. Finally, FDA is reviewing a meningococcal conjugate vaccine for the prevention of a disease caused by the Neisseria meningitides.

Update on the Immunization Safety Office
PerStephamie Thompson, ISO, CDC

Ms. Thompson commented that the ISO is now in transition into the Division of Health Care Quality and Promotion and Dr. Melinda Wharton is Acting Director of ISO during that transition. On October 22-23, ISO updated ACIP about vaccine safety issues with regard to HPV and MMRV vaccines, summarizing the experience of 20 million doses under passive surveillance and 375,000 doses under active surveillance. Through the VAERS passive surveillance (1) Ninety-four percent of the reports on HPV were non-serious, with adverse events commonly reported in the vaccine pre-licensing trials; (2) Most commonly reported events were consistent with pre-licensure trial data; and (3) An increase in reporting was expected due to publicity.

ISO also updated ACIP on the MMRV vaccine, noting that Merke's post-licensure studies revealed an increase in risk of febrile seizures in the first two weeks after inoculation among children 12-24 months of age. ACIP recommended separating the varicella vaccine from the MMR administration, and recommended forming an MMRV vaccine safety working group.

Although the new working group heard presentation on the issue, no votes were taken. The ACIP will continue to monitor the situation and anticipates action at the June 2009 meeting. During discussion it was noted that the company, the only source of the vaccine, is not producing MMRV vaccine because of production problems. Dr. Evans added that because of the production problems, the vaccines would continue to be administered separately -- MMR and a separate varicella administration.

Public Comment

Barbara Fisher, representing herself, commented that no trust fund monies should be used for any purpose other than to compensate individuals who are injured by vaccines.

Vicky Debold with the NVIC but representing herself in her comments, suggested that in developing performance measures the number of claims dismissed because of timeliness should be considered. It would provide an indication of the loss of opportunity for those injured who are not able to file within the time parameters set by the Act. Secondly, concerning the Table and new vaccines, the eligibility for compensation should take into consideration serious adverse event discovered by the manufacturer during the pre-licensure trials and those serious adverse events that are listed by the manufacturer on the labeling, even if those events are rare.

James Moody, representing Safeminds, commented that the Commission should endorse the premise that the VICP is consistent with the goals of encouraging public support for the vaccine program, and that to suggest that the system is not in favor of compensating individuals for vaccine injuries is counterproductive to public confidence in the program. Secondly, considering that the strategic plan for autism research is being considered on the Hill, it would seem inappropriate for a key drafter of the plan to be a witness for the government against the program. He expressed concern that the IOM study would not look at autism because the sponsor of the study preferred not to fund that aspect of the study. Finally, Mr. Moody urged the Commission to recommend a study comparing the health outcomes of children vaccinated versus the cohort of children who are not vaccinated for various reasons (religious, philosophical, etc.).

Future Agenda Items

Mr. Sconyers invited suggestions for the agenda for the next meeting, reminding the Commission that the agenda is usually set by a small subgroup which will consist of Ms. Gallagher, Ms. Castro-Lewis and a new volunteer, Ms. Sherry Drew. He suggested that an update on the outreach program be included in the agenda, that the normal updates would be included, and that the election of officers would be required at the next meeting. Dr. Fisher suggested an update of the National Vaccine Plan, and Ms. Hoiberg recommended reserving some time for consideration of draft recommendation.

Dr. Herr suggested a period devoted to a discussion of recommendations for the new Secretary and Mr. Sconyers proposed creating a smaller group to consolidate from historical records the recommendations of the Commission during the past few years for consideration by the Commission in developing recommendations for the new Secretary. There was a brief discussion that Commission members would need to review those ideas before the next meeting. Mr. Sconyers commented that working on these recommendations in the short term would not preclude consideration of other, longer range recommendations in the future. He added that the Commission is becoming fairly well informed on how the system works by the consistent and detailed reports being presented by the DVIC and the Department of Justice.

Adjournment

On motion duly made and seconded, there was unanimous agreement to adjourn. The meeting adjourned at 10:55 a.m.

_____	_____
Jeffrey Sconyers, J.D. ACCV Chair	Tawny Buck. ACCV Vice-Chair
_____	_____
Geoffrey Evans, M.D. Executive Secretary, ACCV	Date