Advisory Commission on Childhood Vaccines Meeting

(Conference Call)

June 7, 2007

Minutes

Members Present

Jeffrey M. Sconyers, J.D, Chair
Marguerite E. Willner, Vice-Chair
Tawny Buck
Jaime Deville, M.D.
William P. Glass, Jr., J.D.
Tamara Tempfer, RN-C, MSN, PNP
Loren Cooper, J.D.

Ex Officio Members Present

John Iskander, M.D., M.P.H., Associate Director, Immunization Safety Office, Office of the Chief Science Officer, Centers for Disease Control and Prevention
Barbara Mulach, Ph.D., for
Carole Heilman, Ph.D./National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

Executive Secretary

Geoffrey Evans, M.D., Director, Director, Division of Vaccine Injury Compensation (DVIC), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA)

Staff Liaison

Delia Jones, M.H.A., DVIC, HSB, HRSA

Introduction

Mr. Sconyers convened the 66th quarterly meeting of the Advisory Commission of Childhood Vaccines (ACCV) at 1:10 p.m., via teleconference, and welcomed all participants. The minutes of the March 7-8, 2007 meeting were unanimously approved.

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

ACCV Membership

Dr. Evans expressed appreciation to the retiring ACCV members -- Marguerite WiIlner, Loren Cooper, J.D. and Don Wilber, M.D. for their dedicated service to the ACCV. After reviewing the agenda, he announced three new members. Margaret Fisher, M.D., FAAP, is replacing Dr. Don Wilber in the category of physician with expertise in pediatric medicine. She is the Medical Director of Children's Hospital at Monmouth Medical Center and Professor of Pediatrics at Drexel University College of Medicine. She is a member of the American Academy of Pediatrics Committee on Infectious Diseases, otherwise known as the Red Book Committee. Charlene Gallagher, J.D. is replacing Loren Cooper in the category of attorney representing the vaccine industry. She is Division Counsel of the Vaccines Business Unit at Wyeth Pharmaceuticals, and is responsible for clinical trial matters, and the review and approval of promotional materials and labeling documents. She was previously a pharmaceutical chemist, and has served as chair of the Pharmaceutical Research and Manufacturers of America's Product Liability Committee, and taught food and drug law as an adjunct professor at Temple University. Finally, Ms. Magdalena Castro Lewis is replacing Marguerite Willner in the category of general public member. She is the Director of the Center for Providers at the National Alliance for Hispanic Health. She directed the "Vaccines for the Family" Project and "Vaccines for the Time of Birth" Program and other initiatives. In addition, she planned and managed the National Hispanic Immunization Hotline and the National Hispanic Prenatal Hotline for the Alliance. Finally, Dr. Evans noted that Robin Stavola, who is a parent of a vaccine-injured child, had resigned from the ACCV because of personal and professional commitments.

Statistical Report

Dr. Evans stated that the number of autism claims filed continued to decline. As of April 30, only 70 had been filed this fiscal year (FY). The number of non-autism claims filed is 109, and will probably increase because of the upcoming 2-year deadline on July 1 for influenza vaccines that ends the 8-year retroactive coverage filing period whenever a new vaccine is added to the Vaccine Injury Table. Annual awards have been fairly consistent for the past several years, averaging around $58 million for petitioners and $4 million for legal fees. The FY 2007 awards are down slightly at $43.6 million to date. The Vaccine Injury Compensation Trust Fund balance is $2.5 billion and increasing at a higher rate than before because of the addition of influenza vaccine. About $300 million will be added in 2007, one-third of which derives from interest on the principal.

Awards

On April 24, the largest single award since the inception of the National Vaccine Injury Compensation Program (VICP) was made, a $10 million award consisting of three annuity contracts and four lump sums. It was awarded to Mario Arturo Rodriguez for a measles, mumps, and rubella vaccine-related injury. This case received national media attention.

DVIC Activities

Dr. Indira Jevaji, represented the VICP as an ex officio member of the Advisory Committee on Immunization Practices meeting on February 20-22 in Atlanta. Dr. Jevaji also attended the Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting on February 27. The first licensed U.S. vaccine to protect against the H5N1 avian flu virus was approved by the Food and Drug Administration on April 17. This vaccine will be part of the Federal government's vaccine stockpile.

DVIC staff and Marguerite Willner, representing the ACCV, attended the Post-Marketing Surveillance Meeting at NIH on April 10-11. The purpose of this meeting was to discuss what an ideal post-licensure vaccine system would be.

From April 24-27, Dr. Evans attended back to back meetings of the Clinical Immunization Safety Assessment (CISA) Network and the Vaccine Safety Datalink project in Atlanta. Both are CDC-sponsored efforts. CISA, which utilizes seven academic centers across the county, conducts focused research on individuals who experience serious adverse events after vaccination. The VSD is CDC's primary post-marketing surveillance tool used to monitor vaccine safety by conducting research on linked databases from eight Medical Care Organizations.

On May 10-11, Dr. Evans and ACCV Vice Chair, Jaime Deville, M.D. participated in the CDC's Immunization Safety Office (ISO) Scientific Consultancy, providing comments to the ISO on its efforts to develop a new vaccine safety research agenda. CDC plans to share results of this and other sessions with the National Vaccine Advisory Committee as part of a new effort to engage the public in setting priorities for safety research.

Finally, Dr. Jevaji attended the VRBPAC meeting on May 16. A biologics license application was under consideration from MedImmune for Flumist (the live, attentuated, intranasal influenza vaccine [LAIV]). The company is requesting an expanded indication for active immunization of healthy individuals from 5-49 years of age down to age 1. The Committee also considered which strains of flu should be included in the trivalent vaccine for the 2007-2008 flu season.

In terms of Congressional activity, Dr. Evans had nothing new to report since the last meeting.

Discussion

Ms. Willner requested a briefing for the ACCV on the criteria for selecting ACCV members. She suggested that it would be appropriate to recruit new ACCV members who had been active participants in the VICP, perhaps an individual who had been involved in an extended causation case, or an attorney who had handled a large number of cases. Dr. Evans agreed that a briefing would be appropriate, adding that it has been a

challenge to obtain a list of candidates with such experience and even a greater challenge to obtain a commitment by such an experienced individual to serve.

Ms. Buck requested that, at future meetings, the financial information on awards be expanded to include the expenditures on the Federal government for attorney's fees, expert witness fees, etc. Mr. Mark Rogers, Deputy Director, Torts Branch, Civil Division, Department of Justice explained that there is a $6 million annual budget and a detail of the expenditures can be presented in the DOJ report at the next meeting.

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

Mr. Rogers welcomed the three incoming ACCV members and expressed the Department's appreciation to the outgoing Commission members.

Staffing and Hiring

Administratively, the Office of Vaccine Litigation, Department of Justice (DOJ), has 15 trial attorneys on staff, and has extended an offer to another attorney who will be joining DOJ in 2007. DOJ plans to hire one more attorney, for a total of 17 trial attorneys, to process cases. Mr. Rogers expected an increase in staffing to assist processing influenza and autism vaccine claims.

Litigation

In the three months since the last ACCV meeting, 46 non-autism and 18 autism petitions were filed. Mr. Rogers predicted that 180 non-autism petitions would be filed annually, which is a slight increase from the last report. Mr. Rogers reminded the Commission thatthe statute of repose in the flu cases expires on July 1, 2007, and that based on DOJ's experience, a significant number of flu petitions would be filed on the last possible day. Mr. Rogers could not anticipate a number, but expressed that he would be surprised if less than fifty or more than three hundred petitions are filed.

Data for the last three months reflected that forty-five non-autism claims were resolved. Twenty-one of those were compensated; of those, fifteen were settled. Mr. Rogers emphasized that DOJ's practice is to try and resolve claims through settlement, which is a win-win situation. From DOJ's view, settlement affords the best possible outcome.

There were six entitlement decisions that went against the government, five of those went to trial and one was a death case concession by the Department of Health and Human Services (HHS).

Twenty-four cases were dismissed, all of which were non-autism. One petition was withdrawn pursuant to 42 U.S.C. 300aa-21(b), which affords petitioners the right to leave the Program if they do not receive a decision within a certain timeframe.

There were 32 entitlement decisions for the government; three of those followed some type of a hearing, twelve followed a summary judgment-type of motion. Summary judgment-type motions were typically filed in cases where petitioners requested a decision on the existing record because they could not find an expert to support their claim or they wanted the claim decided based upon the existing record. Two additional claims were dismissed for statute of limitations reasons. Using that data, and extrapolating for an annual rate, approximately 180 non-autism claims are filed annually. Thus, as many claims were filed as were disposed over the course of the last three months.

Mr. Rogers reminded the Commission that the upcoming flu deadline, as well as autism proceedings, continue to be two factors on the horizon that may affect case processing.

Appeals

The appellate practice remains fairly active. The petition for writ of certiorari to the United States Supreme Court filed by petitioners in Pafford v. HHS that Mr. Rogers mentioned at the last meeting was denied. A petition for writ of certiorari to the United States Supreme Court was filed in the case Markovich v. HHS. The Markovich case involves interpretation of the Vaccine Act's three year statute of limitations. As discussed at the last meeting, the Federal Circuit issued a published decision affirming the Special Master's dismissal of the petition. The key issue is when the three-year (or 36 month) limitations period starts to run under the Vaccine Act. Briefing in the Markovich case has not started.

At the Federal Circuit, one case was decided and a new case was filed. The new case, which was discussed as part of the Court of Federal Claims report at the last meeting, is Avera v. HHS, and involves the manner and rate of computing payment of attorneys' fees and costs. In that case, the Court of Federal Claims agreed with the Special Master's denial of interim payment of attorneys'fees and costs, so that issue was also appealed to the Federal Circuit. Pending before the Federal Circuit is Zatuchni/Snyder v. HHS, which was discussed in prior ACCV meetings. The appeal was filed by the government, and involves the parameters of a special master's authority to award attorneys' fees. The issue below involved an award of death benefits available under the Act, and briefing has been completed before the Federal Circuit.

Since the last meeting, the case of Walther v. HHS was decided against the government by the Federal Circuit. The court held that the Special Master applied an incorrect legal standard in accounting for multiple possible causes of the injury where one of the possible causes was the vaccine. The issue involved how the Special Master addressed the burden of proving or accounting for those other possible causes forming the basis for the reversal. That case will be returned to the Special Master for processing consistent with the Federal Circuit's decision.

At the Court of Federal Claims level, Mr. Rogers reported that there are ten cases pending; five are new from the last meeting. Of those new five, four were filed by

petitioners and one by the government. Since the last meeting, four cases were decided by the Court of Federal Claims. The case Hocraffer v. HHS, filed by petitioner, involves whether the Special Master erred by excluding some of petitioner's additional evidence offered during the damages phase regarding the entitlement question. Petitioner also argues that the Special Master abused his discretion in calculating the pain and suffering award. In the case McGrath v. HHS, petitioner appealed and argues that the Special Master applied an incorrect billing rate for attorneys' fees. In the case Ruiz v. HHS, filed by petitioner, the issue is whether the Special Master properly dismissed the petition for failure to establish that residual effects of the alleged vaccine-related injury lasted for more than six months a requirement under the Program for receiving compensation. In the case Moberly v. HHS, petitioner appealed, and argues that the Special Master erred by failing to consider the record as a whole and imposed too great a burden of proof on petitioner by requiring conclusive scientific literature to support the claim. In essence, the petitioner in Moberly has argued that the Special Master violated the Federal Circuit's decision in Althen v. HHS.

Autism

Mr. Rogers offered an update on the impending autism hearing. He reminded the committee that there are approximately 4,750 claims pending in the Omnibus Autism Proceeding. The first evidentiary hearing is scheduled for June 11, in the first test case, Cedillo v. HHS. Reiterating his points from the last meeting, Mr. Rogers noted that the Office of Special Masters had decided to hear evidence on petitioner's first theory of causation using three test cases. They appointed two additional special masters to hear these cases. Special Master Campbell-Smith and Special Master Vowell. The second designated test case is Hazelhurst v. HHS. The tentative trial schedule for that case is mid-October. Petitioners have not yet designated a third test case. Administratively, Mr. Rogers explained that the Cedillo hearing will be held at the Court of Federal Claims, from 9:00 a.m. 6:00 p.m., daily. The Court will open at 7:30 a.m. The hearing is expected to last approximately three weeks and is open to the public. There are two options for following the proceedings. There will be a daily transcript generated of the testimony that will be available on the Court of Federal Claims's website, as well as telephonic access using a code that is available through the Court's website.

Mr. Rogers concluded his presentation and several questions followed.

Questions

Ms. Marguerite Willner advised that a Futures Workgroup was convening the following day. She expressed that she and other members of the ACCV received complaints about DOJ attorneys using a small number of settlement brokers to purchase annuities. Ms. Willner questioned the use of brokers by the DOJ. Mr. Rogers responded by noting that the settlement broker works for the party who places the annuity. In this case, the annuity is purchased by the government, thus the broker works for the government. Mr. Rogers further explained that in such a scenario, the parties do not jointly purchase a government annuity, the settlement broker works exclusively for HHS, the purchaser of the annuity.

Noting that such concerns have been raised in the past, Mr. Rogers emphasized that a petitioner can hire a financial advisor to obtain financial advice or planning regarding how a settlement is to be structured. Such financial advice can be billed to the Program at the conclusion of the case as a cost under the fee-shifting statute of the Act.

Ms. Willner questioned whether or not reimbursement of such services for persons, whom she identified as settlement advisors or brokers**,** had been compensated under the Act previously. Mr. Rogers clarified the use of the term broker stating that one party hires a broker to purchase the government owned annuity. That is not a joint activity. Offering to explain the process briefly, Mr. Rogers explained two parts to the process. First, one develops what the stream of payments should be, which is done customarily by a settlement broker that is expected to be hired by the government for the purpose of placing an annuity. Petitioner's concern is not the cost of the annuity; rather, it is the amount of the payments and when will they be received. Conceptually, a petitioner may need the services of nurse practitioners, health professionals, or others to advise petitioner in those matters. The terms of payment are reduced to a decision issued by a special master. At that point, an annuity broker is needed to purchase the annuity on behalf of the government. Petitioner's interest is protected in setting the criteria for the annuity company from which an annuity is purchased. Once judgment issues in a case, the remaining issue is which annuity company to use according to the standards set by the special master. The selection of the company is between HHS and the life insurance company, not petitioner.

Ms. Willner questioned the percentage paid to the broker who places the annuity, which was deferred to the Futures Workgroup. Dr. Evans advised that DOJ attorney Melonie McCall was expected to speak on this topic at tomorrow's workgroup meeting. Mr. Rogers concluded his remarks on this subject in response to Ms. Buck's follow-up question on how brokers are selected by offering that, as a matter of policy, the government welcomes any brokers to participate in the process. The recurring question for DOJ in using brokers is whether or not the broker is experienced and qualified.

Petitioners' Attorney Report on Autism Proceeding: Thomas Powers, J.D.

Mr. Powers reported that the first autism case, Cedillo v. HHS, will begin June 11, and is scheduled to last about three weeks. The petitioner will call six expert witnesses and a family representative, and that testimony should take about a week. The DOJ has submitted a list of 13 experts. The petitioner's claim is based on a theory that the interaction between thimerosal-containing vaccines and the measles-mumps-rubella (MMR) vaccine suppresses the immune system in a small number of children, making them vulnerable to a viral infection that results in neurological injury, often manifested as autism.

The second autism test case is designated, and Curtis Webb is the petitioner's attorney for this case. A third case will be designated later, probably by August. All three cases will be based on the same theory. Each case will be heard by a different special master who

will write the final opinion, although all three will be present in the three cases. All opinions should be issued by early 2008.

Mr. Powers explained that there is a second theory of causation, that the form of mercury in thimerosal has a direct neurotoxic effect that causes injury, including injury that may result in autism. The three test case petitioners applying under the first theory are also submitting medical records to support a claim under the second theory.

In addition to the webcast and the transcript available on the web, a downloadable audio file of each hearing day will be made available. All require individual password registration. Based on the outcomes of the three test cases, the objective of the special masters is to develop guidance through their decisions to apply to individual cases with similar facts to the test cases. Although future petitioners may choose to pursue an independent claim, it is hoped that the test cases and the resulting guidelines will result in a workable and meaningful criteria that will obviate the need for individual claims.

Asked about a timeline for the process, Mr. Powers stated that Special Master Hastings is committed to an expeditious process, but there will be three decisions and there may be appellate issues.

Report on the CDC Immunization Safety Office Consultancy Meeting and the ACCV Futures II Work Group: Jaime Deville, M.D.

Dr. Deville reported on the CDC's Immunization Safety Office (ISO) Consultancy meeting in May that he attended. At the meeting, the activities of the ISO – the Vaccine Adverse Event Reporting System, the Vaccine Safety Datalink, the Clinical Immunization Safety Assessment Network, and the Brighton Collaboration – all of which have different, but complementary missions, were discussed. One presentation covered the history of vaccine safety monitoring and highlighted the importance of detection and rapid assessment of rare events, which is germane to the current autism issue. The speaker pointed out the importance of assessing the costs of these rare events and the timely development of contraindications for the vaccines. Finally, he discussed the appearance of chronic diseases which may occur years after vaccinations.

Dr. Deville stated that the ACCV Futures II Workgroup is currently discussing identifying stable sources of funding for future vaccine safety research. One possibility using a portion of the substantial Vaccine Injury Compensation Trust Fund, to allow some fraction of future incoming revenues to be diverted to research which might be accomplished by tapping part of interest income. This would require legislative changes to the VICP. There was also discussion about non-Federal sources of funding that might be used for research.

Secondly, the Workgroup discussed obtaining information about underserved populations accessing the VICP. Many of these populations may not be aware of the VICP because of language or cultural barriers. The Workgroup intends to develop an OMB-approved survey to gather data on this issue.

Finally, the structured settlement and the development of life care plans will be discussed at the June 8 meeting, and the Chief Special Master will discuss the delays that affect the processing of claims.

Ms. Buck asked about several outreach issues discussed at the last ACCV meeting – 1) whether a list was available of outside organization meetings at which DVIC representatives participated; 2) whether vaccine safety materials could be distributed through various associations or other non-Federal organizations; and 3) whether DVIC could develop a collaboration with the Association of Immunization Managers (AIM). Dr. Evans stated that the first two were action items that would be addressed before the next meeting, and he would look into a possible collaboration with AIM. He reminded members that DVIC stopped exhibiting at meetings several years ago when HRSA decided to centralize all program outreach activities. DOJ has continued their outreach efforts by attending several legal or medical professional meetings annually.

There was a brief discussion about both the HRSA and DOJ budgets as they affect DVIC and ACCV funding. Dr. Evans and Mr. Rogers agreed to discuss budget issues at the Workgroup meeting.

Update on the ISO
John Iskander, M.D., M.P.H., Associate Director for Science, ISO, CDC

Rotateq and Intussusception

Dr. Iskander reviewed recent developments related to the incidence of intussusception following Rotateq, an oral retrovirus vaccine. The CDC post-marketing surveillance has indicated that Rotateq is not associated with intussusception (as of February 15) and the CDC has reaffirmed its policy recommendation for vaccination of infants at 2, 4 and 6 months of age. There were 35 VAERS adverse event reports, half within 21 days of administration, the remainder out to 33 days, and there was no apparent "clustering," multiple events occurring at a specific time after administration. The Vaccine Safety Datalink indicates that the background rate for intussusception within three weeks of administration should be 52 cases, which suggests that the rate was not excessive. In a 1-year period starting on February 1, 2006, about 28,000 doses of Rotateq were administered to infants in VSD-monitored HMOs, and there were no cases of intussusception reported within the first 30 days.

Menactra and Guillain-Barre Syndrome

Concerning the vaccine Menactra, Dr. Iskander reported that the incidence of Guillain-Barre Syndrome (GBS) after Menactra vaccination appears to be slightly higher in children in the older age range of 15 to 19 years of age. However, this is soft data because there is probably underreporting in VAERS. Because of the potential serious risk of GBS, even though it is rare (about one in a million vaccinations), a larger study will be conducted by Harvard Pilgrim Health Care over a period of two years. The study

will be funded by industry, although an oversight group that will include Federal representation will be formed to monitor the study. Ms. Buck asked for additional information on how the oversight group would be constituted and Dr. Iskander said that he would provide this information.

Pertussis Vaccines

Dr. Iskander reported on data presented at the ACIP meeting on adult and adolescent pertussis vaccines (Tdap). A summary of VAERS reports indicated some minor adverse effects temporal proximity with vaccination, most of which were anticipated. There were a few deaths during the reporting period, but none appeared to be related to the vaccine. There were also a few GBS incidents, but the probable cause was confounded because multiple vaccines were involved (which often included Menactra).

Future Events

Dr. Iskander listed several topics to be discussed at the next Advisory Committee on Immunization Practices (ACIP) meeting on June 27-28. These include: safety and immunogenicity of Pentacel, vaccines during pregnancy and breastfeeding, an update on FluMist safety monitoring, and updates on Rotateq and human papillomavirus (HPV) vaccine.

Regarding the development of a research agenda for the ISO, the Scientific Consultancy meeting was held on May 10-11 and Drs. Evans and Deville attended the meeting. Now, the ISO will seek input from a variety of partners. On June 7, ISO staff are presenting to the Safety Subcommittee of the National Vaccine Advisory Committee and will be presenting to the CDC Vaccine Interest Group, the Interagency Vaccine Group and the ACIP later. The Global Advisory Committee of Vaccine Safety will meet in Geneva and ISO will present data on GBS and Menactra, Rotateq and HPV vaccine. Finally, on May 23, Judicial Watch reported three deaths following HPV vaccine, none of which appeared to be directly related to the vaccine.

Asked about mix-ups in administering pediatric versus adult/adolescent pertussis vaccines, Dr. Iskander noted that there had been such errors, but there had been no significant reports of adverse medical outcomes.

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

Dr. Mulach reported on NIAID vaccine activities focusing on early-stage research and evaluation of new vaccines. Currently, clinical studies are looking at various clades of avian flu vaccines, including the most effective use of these vaccines and the recently licensed H5N1 avian flu vaccine, the effect of adjuvants on efficacy, and how different routes of administration may affect efficacy. Six Centers of Excellence have been funded to conduct research and surveillance on animals to complement work being done in the human population. Finally, the NIAID tuberculosis (TB) working group, along with the

larger TB community, has been developing a research strategy for addressing drug-resistant TB.

Dr. Mulach noted that the Jordan Report is now available, which includes an update on vaccine development for certain diseases. This report is available at the NIAID Website at www.niaid.nih.gov.

Future Agenda Items

Mr. Sconyers stated that there would be a report on the ACCV Futures II Workgroup activities at the next meeting. He added that, in the future, ACCV members would be invited to submit agenda topics by e-mail at any time.

There was a suggestion that the process of ACCV member selection be explained in detail at the next meeting, including specific numbers if available. Ms. Buck requested that there be a report on the honoraria issue, and also asked for a discussion of the decision process that leads to conceding cases.

Adjournment

Dr. Evans announced that Delia Jones would be leaving DVIC before the next meeting. He expressed appreciation for her dedication and service.

The meeting adjourned at 3:10 p.m.

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Jeffrey Sconyers, J.D.
ACCV Chair

Marguerite Willner
ACCV Vice-Chair

_____ _____

Geoffrey Evans, M.D.
Executive Secretary, ACCV

Date