Advisory Commission on Childhood Vaccines

December 3, 2009

Day One

Minutes

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

Department of Justice

Mark Rogers, Deputy Director, Torts Branch

Division of Vaccine Injury Compensation

Geoffrey S. Evans, M.D., Director, DVIC
Elizabeth Saindon. General Counsel, DVIC
Andrea Herzog, Principal Staff Liaison, DVIC

Welcome, Report of the Chair and Approval of Minutes

Ms. Castro-Lewis called the meeting to order and after introductions, called for approval of the minutes of the September 17-18, 2009 meeting. On motion duly made and seconded, the minutes of that meeting were unanimously approved.

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

Dr. Evans welcomed Commission members, staff and guests and, after reviewing the agenda for the two-day meeting, announced that Dr. Mary Rubin, a pediatrician, had joined the Medical Operations Branch.

Turning to the statistics, Dr. Evans commented on two notable trends. In part because of the inclusion of influenza vaccine as a compensable injury and because of the widespread administration of the vaccine, the number of non-autism claims has significantly increased. For information, 41% of claims filed in FY ’09 were based on influenza vaccination. The number of claims for other injuries was much lower -- DTAP 10%, MMR 8%, human papillomavirus vaccine (HPV) 7%, Gullain-Barré syndrome 7% and hepatitis 5%. An ancillary aspect of this trend change is the increase in adult claims, which comprised 60% of total claims, mainly because of the coverage provided for influenza vaccines. Finally, the second trend is a dramatic decline in autism claims, only three so far this year, versus 108 for FY ’09.

Dr. Evans turned to FY ’09 adjudication statistics, which reveal 227 dismissed claims, most of which were autism cases that failed on the basis of jurisdiction or statute of limitations. In terms of compensable claims, the majority (83% in FY ’09) settled, and there appears to be a

trend in motion such that the number of concessions and court decisions are declining. The average compensation for petitioners' awards was $74 million (2003-2009), with attorneys' fees and costs at $6 million. Fiscal year 2009 petitioners' awards were in line with that average amount, but attorney's' fees were considerably higher ($15 million) because of the new interim payments rulings. Petitioner's' awards are more than $20 million thus far in FY '10. At that rate the annual amount would exceed $120 million, a substantial increase.

Dr. Evans reported that the trust fund balance was $3.1 billion on September 30, 2009. Influenza vaccine accounts for a substantial share of the annual contribution, about a third of $235 million in excise tax revenues. Interest of $100 million on the trust balance accounts for 30% of the gross income of $334 million. The net increase, after awards and other outlays, was about $250 million for FY '09.

Asked about the temporal correlation between final adjudication and final award, Dr. Evans explained that there was often a disconnect between the two in terms of correlating with the fiscal year in which the adjudication occurred. At times the final award is made in the following fiscal year.

Dr. Evans reported on DVIC activities since the last meeting, including a presentation on October 14 to graduate students in the Department of Immunology at the Children's Hospital in Philadelphia. He served as an ex officio member representing DVIC at the October 21-22 meeting of the Advisory Committee on Immunization Practices. At that meeting ACIP approved recommendation for routine use in females age 9 to 26 of Cervarix, the newly approved HPV vaccine. Although stopping short of recommending routine use in boys, the Committee did approve coverage for boys in the Vaccines for Children Program, making it possible for boys aged 9 to 18 to receive the vaccine if they are uninsured or through Medicaid. Dr. Evans emphasized that these recommendations have nothing to do with eligibility for injury compensation. The vaccine is covered under the VCIP.

Report from the Department of Justice
Mark Rogers, J.D., Deputy Director

Mr. Rogers explained that his office was still in the process of hiring two attorneys, who should be in place before the next ACCV meeting.

Turning to the numbers, Mr. Rogers noted that his statistics reflected the period from the last report to ACCV to the first week of September 2009, so they would not perfectly match the statistics presented by Dr. Evans. Since the last meeting the Torts Branch has seen 121 claims files, five of which were non-autism. Of the remaining 116, about half were influenza claims mainly for adults and most were bunched and filed by two law firms. Therefore the Commission should not rely on a simple extrapolation to estimate an annual rate.

Mr. Rogers reported that his office handled 25 compensated cases, 20 of which were settled, two resolved by proffer and two by decision. A settled cases is one in which the two parties may differ on the desired award but achieve an agreement on the final award; proffers are a rarer circumstance in which the two parties agree at the outset on an award. Award decisions are made by the court when such agreement does not happen and those awards are subject to appeal. Thirty-four claims were considered not compensable. In the case of autism claims the basis is usually jurisdictional, procedural or related to statute to limitations requirements. .

Mr. Rogers described the predominant route that a newly filed claim takes through the system -- first it is reviewed by HHS and, if denied (not conceded), it proceeds to settlement if possible, or a decision by a Special Master if there appear to be irreconcilable differences. A significant majority of cases are settled.

Providing an update on the current cases in the courts, Mr. Rogers noted that the hearing on the theory one cases (Cedillo, Hazelhurst and Snyder) had been completed and a ruling handed down. Appeals had been filed in Cedillo and Hazelhurst, but not Snyder. In the three cases related to theory two (Mead, King and Dwyer), the trials have been completed and the ruling is under consideration in the Office of the Special Masters.

Finally, Mr. Rogers outlined the appeals cases currently in the system, noting that since the last meeting three new appeals had been filed by petitioners (Cedlillo, Brokelschen and Hazelhurst). He added that almost all appeals are filed by petitioners. The majority of appeals concern fees and cost decisions since those results are litigated and subject to appeal. A recent decision was handed down in Avera that interim fees and costs are available under the Act, and that will result in an increase in the number of appeals.

ACCV Causation Work Group Report
Jeffrey Sconyers, Work Group Co-chair

Mr. Sconyers reported that the Commission had charged the Work Group with reviewing the provisions of the VICP provisions in light of the recent decisions in Althen and Capizzano. The Work Group was composed on Mr. Sconyers, Dr. Herr and Ms. Tempfer. There were also contributions by Dr. Evans, Ms. Saindon and Ms. Castro-Lewis. Mr. Sconyers stated that after careful consideration the Work Group agreed that no recommendation should be prepared for the Secretary. There was agreement that the two decisions were based in the existing law that the Special Masters would rely on in administering the program.

Mr. Sconyers noted that the Work Group's consensus was influenced by the fact that the program appears to be working, the percentage of cases settled is increasing over time as are the percentage of cases receiving compensation. It is also clear that those cases that might be specifically affected by Althen and Capizzano are being settled, and to a lesser extent conceded when appropriate. He also observed that opinion is varied concerning the standards in the two decisions, some maintaining that cases will be settled with too little scientific evidence, others taking the opposite side. Ms. Tempfer added that the cases reviewed by the Work Group support the fact that medical and scientific evidence is being carefully considered. Dr. Herr noted that a physician would expect a direct cause and effect to be demonstrated (as in the case of a virus that causes a specific illness), but that the decision supports the statute which involves both science and policy. He supported the program process of moving the claims through the court and through settlement as provided in the law. He observed that settlements are often not disclosed to protect the privacy of the parties involved and that precedent may play a greater role in the lack of transparency of the VCIP process than any design by the government to frustrate a more open process.

Offering a contrary opinion, Ms. Buck stated that the original statute was meant to create an open process which would provide significant information about specific injuries, their causes, the details of the awards made and so on. She felt the litigated risk settlement process, although perhaps expediting the final award, was preventing that kind of information from being released. She noted a contradiction in claims that the results of the decisions were published and suggested that clarification of the policy would be helpful. Ms. Gallagher added that, although the process is somewhat complicated and cumbersome, it is described in the law and that to make it different would require an amendment to that law. Dr. Evans conceded that the amount of information published about settlements was limited and might not be helpful to prospective claimants. He added that the Institute of Medicine report includes significant information about adverse events (although no quantification in terms of specific adverse events). He agreed that his office would assess the issues raised and consider means to provide additional information about the settlements.

Mr. Sconyers concluded his report by stating that the Work Group carefully addressed the issue, agreeing on the recommendation to the Commission that no recommendation be

prepared for the Secretary. He added that the Work Group agreed that there would be no benefit in continuing the Work Group's activity in this regard.

ACCV Petitioners Payment Work Group Report
Sherry Drew, Work Group Chair

Ms. Drew reported that the Work Group reviewed the proposal to provide interim payments to petitioners, especially when a petitioner has incurred exceptional early expenses or has serious financial difficulties as a result of caring for an injured child. Although on the face of it the concept appeared appropriate to the intent of the program, the Work Group's review of the issue revealed legal and practical limitations. First, the Vaccine Injury Compensation Act requires that a petitioner accept a judgment before a monetary award can be made. An interim payment would constitute a "pre-judgment" payment that, if accepted, would be tacit acceptance of the final judgment before it was ultimately determined. In effect, that would lock the petitioner into the entire process and disallow the option to pursue civil tort procedures should the final judgment be deemed insufficient by the petitioner.

Second, when an award is made on behalf of a minor, that award goes from the federal court system to the local court jurisdiction where the local judge determines how the money is disbursed based on the best interests of the child. That may or may not be favorable to the parent's needs. In the case of an award to an adult, the award is usually based on unreimbursed expenses related to the injury and to lost wages. Although such a claim might be reasonable, a pre-judgment award would lock the petitioner into the final determination of award by the court.

Ms. Drew commented that the Work Group approved a recommendation for consideration by the Commission that the Secretary should seek an amendment to the Act that would provide for an interim payment when a claim is conceded or when the Secretary deems such an interim payment appropriate (and when the interim payment constitutes amounts that are not in contention by the Department of Justice). In those cases the petitioner should be allowed, but not required, to make a request for interim payment. However, even with this provision in the law the petitioner who takes advantage of an interim payment opts into the final settlement and could not subsequently pursue a civil suit.

Ms. Hoiberg, a member of the Work Group, commented that the concept of interim payment seemed advantageous to the petitioner at the outset, but upon consideration of the limitations was clearly not an advantage. Once the interim payment was accepted and the petitioner was locked into the final settlement, the petitioner would be in a weakened position in terms of negotiating the final award. She added that one positive step would be to significantly expedite the claims process so that final awards are made on a much timelier basis.

In conclusion, Ms. Drew stated that the Work Group felt that there was no benefit to further consideration of this issue at the work group level.

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

Dr. Salmon briefed the Commission on the activities of the National Vaccine Advisory Committee's two working groups. The NVAC Safety Working Group completed a review of the CDC Immunization Safety Office research agenda and published its report in early 2009. The Working Group is now reviewing the vaccine safety system more broadly and will create and publish a series of white papers outlining an optimal safety system that would include identification and characterization of vaccine adverse events, methods to prevent them, and a program to maintain and improve public confidence in vaccinations. The Safety Working Group held a two-day conference in June to gather expert testimony from a broad variety of experts and stakeholders. There are five subgroups using the information from that meeting and other sources to develop the white papers. Three subgroups are content-based -- one focusing on

structure and governance, one on epidemiology in the surveillance process, and the third looking at biological mechanisms of adverse events. There are two process-focused subgroups -- one considering stakeholder engagement and the other working on an implementation plan. It is hoped that the latter group will facilitate the actually influencing of policy making. The target for publication of the report or reports is fall 2010.

Dr. Salmon explained that the second working group was focusing on vaccine safety particularly with regard to influenza (H1N1) vaccines. This working group will collect safety data from various sources as that data is developed and create a safety profile for H1N1 vaccines. Much of the data comes from VAERS, but other surveillance systems are under way and will accumulate and report data until the end of the flu season. The working group is composed of representatives of five advisory committees (VRBPAC, ACIP, NVAC, NVSB and the DoD Defense Health Board) plus a number of outside experts to augment the expertise of those five members. The working group meets by phone every other week and NVAC meets monthly to consider the cumulative data. The objective is to provide rapid response advice to the Department on the latest safety data available.

Finally, Dr. Salmon briefly discussed the National Vaccine Plan, which is about halfway to completion. The next significant input will be from the IOM, which has a committee reviewing the plan.

During discussion, Dr. Evans explained that the VRBPAC, which recommends the composition of each year's flu vaccine combination, usually gathers information from international sources (mainly the WHO which has approved the addition of an H1N1 vaccine to the seasonal flu mix for the next flu season) and meets in January or February to determine the final strains that will be included in the vaccine for the following flu season. He added that, concerning safety data, VAERS is an early and important source of data, although the system is passive and, because anyone can make a report valid or not, the data is sometimes difficult to interpret.

Update on the National Institute of Allergies and Infectious Diseases Vaccine Activities
Barbara Mulach, Ph.D. NIAID, NIH

Dr. Mulach reported that the NIH, and NIAID in particular, is conducting clinical trials to add to the base of information about vaccine safety, especially in special populations such as the elderly, pregnant women, individuals who are HIV-positive, and asthmatics. One aspect of some clinical trials is the issue of compatibility of the two flu vaccines, the trivalent seasonal flu vaccine and the H1N1 vaccines. Thus far in the trials there has been no indication that the combination or simultaneous administration of the vaccines has any deleterious effects and no indication that the immunogenicity of the vaccines is negatively affected. Individuals may obtain more details about the various trials on the federal government web site clinicaltrials.gov.

Ms. Hoiberg noted that groups with special health problems should be tested. Certain unique cohorts have been shown to have a greater adverse event potential, such as children with neurological deficits. She also suggested that since the NIH is only testing inactivated vaccine, that tests should also be conducted using the live attenuated vaccines. Ms. Buck added that vaccines tested only in healthy children should not be presumed to be safe in other higher risk pediatric populations. Ms. Mulach pointed out that, that for a number of reasons, it was impractical to mount clinical trials of every special population and every vaccine. For example, there are wide variations in the autism spectrum disorder population that makes it difficult to develop a homogenous cohort. Similarly individuals with neurological disorders can have quite different characteristics that could confound research results. She added that every version of every vaccine undergoes stringent testing in the process of achieving FDA approval. Dr. Salmon added that the seasonal flu vaccines were not "new" vaccines, but were vaccines containing different strains from those distributed in the previous years. The basic process of manufacture was unchanged from year to year.

Update on the Immunization Safety Office (CDC) Vaccine Activities
Jane Gidudu, M.D., MPH, ISO, CDC

Dr. Gidudu discussed the safety monitoring program conducted by the Immunization Safety Office noting that the objective is to identify and evaluate significant adverse events caused by vaccines, identify important public health concerns and communicate related information to the public health community and the public in general.

The ISO relies on VAERS to identify potential adverse event issues (rapid signal detection) and both the Vaccine Safety Datalink (VSF) and the Clinical Immunization Safety Assessment (CISA) to assess the VAERS signals and to more thoroughly evaluate vaccine safety issues. She noted that VAERS receives over 20,000 reports annually from physicians and other in the public health community, and of course the general public since anyone may submit a report. Its advantage is that VAERS is national in scope, covering diverse populations, and is capable of reporting events as they occur. Data is cumulated daily. The limitations are inherent in its uncontrolled acceptance of reports such that there is risk of both over-reporting and under-reporting, and there is no effort to develop a denominator for the risk equation -- that is, there is no information on epidemiology or the total number of individuals who may receive a specific vaccine.

Dr. Gidudu stated that H1N1 reports, which began on September 15th, are monitored daily. Almost 60 million doses had been shipped by manufacturers as of November 30. The reports are grouped according adverse events resulting in death, non-fatal but serious adverse events, and adverse events considered non-serious. She provided the results of a recent analysis:

Vaccine	Total	Fatal	Serious	Non-Serious	Gullain Barré
Seasonal Live attenuated	506	0	38	468	5
Inactivated (TIV)	4,259	16	241	4,002	50
Unknown	201	3	24	174	3
Total	**4,966**	**19**	**303**	**4,644**	**58**
H1N1 LAV	1,271	3	55	1,213	1
H1N1 TIV	3,029	15	159	2,855	8
Unknown	305	1	23	281	2
Total	**4,605**	**19**	**237**	**4,349**	**11**

Mr. Sconyers asked if there was an estimate available on the total number of vaccinations administered which could be compared with the adverse events reports. Dr. Salmon explained that CDC does not develop that estimate, per se, partly because of resource limitations. However, the total number of vaccines shipped is available (an overestimate of vaccinations administered), some states provide such data but again because of resource limitations CDC does not compile the data; and finally there are CDC surveys through the National Immunization Survey, but those results are not timely in terms of comparisons with VAERS adverse event reports. Dr. Salmon added that the VAERS reports of death are carefully investigated by CDC, but that some of those reports may not be directly related to the vaccine (e.g., one of the deaths reported was the result of a vehicle accident). In addition, Dr. Gidudu noted that many of the individuals who were the subject of adverse events had serious co-

morbidities. Finally, with regard to flu vaccines, Dr. Gidudu explained that they are shipped by the manufacturer to the states.

Dr. Gidudu moved to a report on the recently approved vaccine for the human papillomavirus (HPV), Cervarix, approved for use in females 10 to 25 years of age for the prevention of cervical cancers. She explained the monitoring process, which is sensitive to signals generated in VAERS and more thorough follow-up by VSD and CISA. VSD is a collaboration between CDC and eight managed care organizations (MCOs) that have a total patient base of 9.2 million with an annual birth cohort of over 90,000 infants. Because of the controlled nature of the data gathering by the MCOs, information analyzed by VSD is much more specific and accurate than VAERS. The prospective study of HPV adverse events will include data from Phase III and IV clinical trials and will specifically look at Gullain Barré, neurological events (stoke) and syncope, among others.

Finally, Dr. Gidudu outlined the safety monitoring for Rotateq vaccine, which is being monitored by VSD for any increased incidence of intussusception in children (an earlier rotavirus vaccine appeared to cause the intestinal disorder). The initial results of the study of about 200,000 doses administered to children 4 to 34 weeks of age showed five cases of intussusception within a 30 day period after receiving the Rotateq vaccine. That number is consistent with the cases that should occur in an unvaccinated population. The study concluded that there was no increased risk of intussusception in the children who received the vaccine.

Update on the Center for Biologics Evaluation and Research (CBER) Vaccine Activities
Theresa Finn, Ph.D., CBER

Dr. Finn commented that at the last meeting the Commission had heard about four vaccines approved for H1N1 influenza. The vaccines are manufactured by CSL Limited, MedImmune, Novartis and Sanofi Pasteur. On November 10 the FDA approved an H1N1 vaccine for adults 18 and over distributed by GlaxoSmithKline and based on the Flulaval manufacturing process. On the same date the FDA approved Afluria for children 6 months of age through 17 years of age (it had previously been approved for adults), a seasonal flu vaccine manufactured by CSL. Another seasonal flu vaccine, Agraflu, manufactured by Novartis, was approved for use in adults on November 27. Finally, on October 19, FDA approved the use of Fluarix in children three years of age and older.(also previously approved for adult use).

Dr. Finn reported that FDA had approved Cervarix on October 16 for use in females aged 10 through 25 years. It is a vaccine manufactured by GlaxoSmithKline designed to prevent cervical cancers. On the same day the FDA approved the use of Gardasil in males aged 9 through 26. The vaccine is designed to prevent genital warts caused by HPV 6 and 11.

Dr. Finn commented that a number of other drugs are currently under review, including a meningococcal conjugate vaccine for prevention of disease caused by *Neisseria meningitides,* and a seasonal flu vaccine. She noted that the VRBPAC had reviewed a number of vaccines, including Prevnar 13, a pneumococcal conjugate vaccine for use in infants. VRBPAC also discussed FluBlok, a recombinant seasonal flu vaccine, but arrived at no recommendations concerning the drug.

Public Comment

Theresa Wrangham, representing Safe Minds, commented that data collected concerning vaccine safety should be used to increase vaccine safety, add to the understanding of the biological mechanisms of vaccine injury and add to data not collected by the CDC through the ISO. She expressed concern that the increased reliance on settled VICP claims (now about 80% of cases) may be restricting the availability of important information that should be available to the public. Finally, referring to the data provided earlier in the meeting about H1N1 adverse events,

she suggested that the data should be matched to other federal data to enhance the value of the general information about vaccine safety.

Closing remarks

Ms. Castro-Lewis requested that Mr. Sconyers prepare a brief synopsis of the Causation Work Group activities and recommendations. She also noted that the election of the succeeding ACCV chair and vice chair would be considered at the next meeting. She asked that the members leaving the Commission (Mr. Sconyers, Ms. Buck, and Ms. Tempfer) serve as a nominating committee and present a slate of nominees at the next meeting. All agreed.

The meeting recessed at 4:30 p.m., to reconvene the following morning, December 4, at 9:00 a.m.

Advisory Commission on Childhood Vaccines

December 4, 2009

Day Two

Minutes

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

Division of Vaccine Injury Compensation

Geoffrey S. Evans, M.D., Director, DVIC
Elizabeth Saindon. General Counsel, DVIC
Andrea Herzog, Principal Staff Liaison, DVIC

Welcome and Unfinished Business from Day One
Magdalena Castro-Lewis, ACCV Chair

Ms. Castro-Lewis called the meeting to order and announced that there would be an opportunity for public comment since the meeting adjourned early the day before.

Public Comment

James Moody, representing Safe Minds, expressed concern that there was not a clear enthusiasm on the Commission for disclosure, which is contrary to the announced position of the Justice Department that the business of the federal government should be conducted in public with due regard to security and privacy issues. He urged that the Commission establish a position in favor of full disclosure of settlements, whether resolved by litigated risk negotiation, concession of proffer.

ACCV Outreach Work Group Report and
Report of the VICP Outreach Contract.
Sarah Hoiberg, Work Group Chair
Merrel Hensen, Banyan Communications
Kathleen Souder, Banyan Communications
Namratha Swami, Altarum Institute

Prior to the presentation by Banyan Communications the Commission engaged in a discussion about the level of information provided to the commissioners before the meeting. Mr. Sconyers noted that members of the Commission had requested a copy of the Banyan contract and Dr. Evans explained that the contract had been submitted through the HRSA procurement process (and not DVIC), and that a FOIA review was required. After that review, which would

take up to 20 days, a redacted version of the contract would be available. Staff indicated that a copy of the RFP had been sent to members who specifically requested it. Ms. Buck expressed concern that a contract, reported to be nearly $300,000, had been moved forward with relatively little information being provided to the Commission. Ms. Hoiberg expressed a related concern that the funds would be spent only to identify the potential outreach audience and not to create any specific outreach materials, and that the product would not be delivered until the end of 2010. Mr. Sconyers commented that it would have been helpful if the substantial Banyan presentation materials had been sent to members in advance of the meeting so that a dialog could have been facilitated between the Commission and the representatives of Banyan Communications.

In response to a comment about the extent to which the Commission should be involved in the contract process, including the selection of the contractor, Dr. Evans explained that the responsibility lies solely within HRSA. He added that the Commission's charge is to advise the Secretary on matters related to the VCIP. He expressed regret that information about the outreach contract had not been provided in the way that Commission members anticipated it should have been, and he stated that in the future such information would be provided in a timely manner.

Ms. Hansen discussed the outreach plan, noting that her company, Banyan Communications is the prime contractor with 15 years' experience in supporting federal and non-profit public awareness programs. The research subcontractor is Altarum Institute, represented by Namratha Swami, with whom the Commission had worked before on the client satisfaction survey. Ms. Souder described some of the projects that Banyan has been working on in the recent past. One program for DHHS, Department of Transplantation, is a public awareness campaign designed to increase interest in organ donation. Another national campaign is a longstanding program to enhance public awareness of the Boys Town National Hotline, a resource for children, teens and parents to provide a personal contact to discuss various family crisis issues -- depression, family violence, suicide, and so on. Ms. Hansen described a project for CDC that targets individuals who hold CDC grants as well as the general public, an effort to provide training in handling violence prevention, including family and youth violence. Part of this program is web-based. Finally, Ms. Souder described a more focused public awareness program targeting pregnant women, to provide information about the risks of smoking during pregnancy.

Ms. Swamy briefly described the Altarum Institute, which is a nonprofit health system research and consulting organization providing research services mainly to government agencies, state, local and federal. The mission of Altarum is to provide a sound foundation of knowledge to effectively inform decision making with regard to programs and policies.

Ms. Hansen described the outreach project, noting that the objective of the contract is to create for the VICP a comprehensive outreach and marketing plan for the public and for healthcare providers. As a measure of success, the contract must accomplish the goals of the legislative mandate; assure DVIC's satisfaction with the scope and content of the research plan; and exceed DVIC's expectations with regard to the marketing and outreach plan. The contractor team will seek to define measures of success, develop credible research, engender support from the healthcare community, develop a message that informs the public but does not discourage vaccinations; and create a product that has shelf life.

Ms. Hansen explained that experience has proved that knowledge through research provides the best foundation for developing a public awareness program -- who to target, what do they know about vaccines, what motivates them, what message to use and where to use it (Internet, blogs, television/radio). Can a message be developed that links the individual to his or her personal relationships with the community and with society as a whole?

Ms. Hansen explained that the project will have three parts -- first, pulling together the research; second, developing strategies and tactics for the outreach campaign; and third, putting it all together and presenting the plan to DVIC. The timeline indicates that Phase I, research, will

be completed by April; Phase II by July, development of the marketing and outreach plan; and the final report to DVIC by September. Asked about whether there will opportunities to interact with the contractor team, Ms. Hansen explained that four teleconference opportunities had been included in the schedule (February, June, August and November), all scheduled a week or so before the regular ACCV meeting. Asked if the timeline could be amended enough so that the Commission could receive a briefing before the final presentation of the plan to DVIC,, just to provide an opportunity for some last minute comments, Ms. Hansen agreed that it should be possible to provide a draft of the plan on that kind of timetable. Ms. Drew suggested that in addition to the teleconferences a week or so before each ACCV meeting, it would be helpful to have a short update by telephone at each meeting. Ms. Hansen agreed.

Mr. Sconyers noted that the final report misses the federal budget guide deadlines for FY '11, which indicates that there might not be funding available for FY '11 implementation of the plan. Dr. Evan commented that the HRSA allocation of almost $300,000 for the project connotes a change in thinking out outreach for the VICP, and therefore there should be funding included in the FY '11 budget to implement at least some parts of the plan. Ms. Buck expressed concern that a large amount of money is being spent on creating a plan that may not be delivered on time (the satisfaction survey was delivered late and was somewhat disappointing insofar as the results were concerned), and may or may not be funded depending upon the funding climate at the time. She expressed the opinion that such a substantial change in priorities should merit more time on the ACCV agenda. Ms. Tempfer commented that the petitioner's satisfaction survey was initiated by the Commission and, although the results might have been disappointing, the effort should be considered successful. Ms. Buck disagreed that the survey was conducted on the initiative of the Commission, since there was a GAO audit that included a requirement to assess customer satisfaction in the VICP.

Dr. Evans commented that the funding has been significantly increased over the past two years such that DVIC is in a better position to pursue such a program or outreach. He added that it is important to provide evidence-based support for the program, which is what this contract is meant to do. Asked about whether the RFP that would come out of the recommendations from the contract would further delay implementation, Dr. Evans stated that there would be continual consideration of the interim reports from Banyan as well as some planning of future activities related to implementation, some of which could occur even before the final report is delivered to DVIC.

Returning to the Banyan presentation, Ms. Swamy explained that Phase I, the research phase, would begin with a standard literature search followed by an environmental scan (looking at media, newspapers, magazines, books, advertisements and the Internet). One new aspect of this type of research is the ability to look at public response (online forums, message boards, blogs, etc.) to the information published in both the print media and the digital media. .Ms. Souder briefly discussed the technical aspects of both qualitative and quantitative analysis of Internet resources. She also described an example of public responses related to a specific article in the online magazine Wired. It was noted that Wired is a somewhat radical publication that might not elicit comments from the average citizen and reliance on such sources might bias the analysis. Ms. Souder stated that the Wired article and others subsequently described to the Commission were simply examples to demonstrate the utility of the environmental scan.

Finally, at the end of the research phase, contact will be made with actual individuals through five focus groups around the country and directed interviews with experts (e.g., researchers who have conducted surveys of parents concerning vaccine safety attitudes). The final report will be composed with an executive summary, a compilation of the research results, and specific discussion of the various aspects of the final marketing plan. Ms. Hansen noted that the plan will be constructed so that it could implemented in whole or in part without delay, but it will also be constructed so that implementation could be delayed if required with affecting the outcome

Asked about whether the plan will include any useable products, Ms. Hansen stated that the plan will include recommendations for that type of product -- verbiage, conceptual ideas on design, and suggestions for vehicles for getting those messages out -- but there will not be specific products, such as ads or PSA scripts and so on.

Finally, Ms. Hansen described Phase III, the presentation of the final report which is scheduled for September 2010.

Adding Hepatitis A, Trivalent Influenza, Meningococcal and Human Papillomavirus Vaccines as Separate Categories in the Vaccine Injury Table
Geoffrey Evans, M.D., DVIC

Dr. Evans stated that the VICP requires consideration by the Commission of vaccines that the Department desires added to the Injury Table. Since 2004, four vaccines have been added in a special placeholder category -- Hepatitis A, trivalent influenza, meningococcal and human papillomavirus. They appear in a relatively small footnote that, because of its appearance, may cause some confusion. This action is of a technical nature and has no effect on petitioners' rights to file claims for injuries resulting from the administration of any or all of the vaccines.

As background Dr. Evans explained that the Omnibus Budget Reconciliation Act of 1993 prescribed the requirements for adding vaccines and related adverse events to the Injury Table. Congress must levy an excise tax, the vaccine must be officially recommended for administration to children, the Secretary of DHHS must publish a notice of coverage in the Federal Register, after which is placed in a special placeholder category. To move the vaccine into the Injury Table as a separate category the Secretary must submit a proposal to the ACCV and allow 90 days for review and recommendation. Dr. Evans indicated that this was the step being taken at the meeting. After the Commission reviews the proposal and makes a formal recommendation to add the vaccines to the Injury Table a Notice of Proposed Rulemaking is published in the Federal Register, which provides for a 180-day public comment period that must include a public hearing. Usually that public hearing is held immediately following a regular ACCV meeting, although in the past no member of the public has attended. Following the public hearing the Department may publish a final rule and the vaccines would be added to the Injury Table. This usually occurs within 30 days of the notice.

Dr. Evans noted that the process has occurred three times since 1995 involving four vaccines. Each process took several years and included a review by the Institute to Medicine. After the Commission review, the Secretary will wait for the IOM report (no adverse events would be added to the Table without that report)).

After due consideration, on motion duly made and seconded, the Commission unanimously approved the addition of hepatitis A vaccine, trivalent influenza vaccine, meningococcal vaccine and human papillomavirus vaccine as separate categories in the Vaccine Injury Table.

Public Comment

Speaking as the parent of an injured child, Ms. Polling expressed concern that the contractor for the outreach and marketing plan would place any emphasis on comments by the public in response to articles in the online Wired magazine, a publication she considered of dubious quality and veracity. She encouraged the contractor to contact individuals who had experienced participation in the VICP, parents like herself or individuals actually injured by vaccines, to learn how they became aware of the program.

Theresa Wrangham, representing Safe Minds, commented that it was difficult to follow the Banyan presentation without access to the visual aids provided to the Commission. She

suggested that such visual aids be available on the web in the event of future presentations. Ms. Wrangham reiterated her comments from the previous day, that attention should be paid to improving the availability of information regarding awards of compensation made through the program. She suggested that the media should be encouraged to more clearly convey information about those vaccines that cause injuries and the state of the science related to those vaccines. Finally, she observed that if the statute of limitations was a major cause of failed claims perhaps the time for filing should be reconsidered and the statute of limitations expanded.

Mr. Moody, who spoke at the beginning of the meeting during the public comment period, supported the contention that Wired magazine is an unreliable source of information. He added that HRSA also published erroneous information in stating that the federal government had never compensated a claim based on autism. He said in fact that since 1991 there were at least 13 published decisions that compensated autism as an adverse event

Future Agenda Items

Ms. Castro-Lewis expressed appreciation to Ms. Hoiberg for her participation in the agenda work group for this meeting, and invited volunteers for the agenda work group for the next meeting. Drs. Fisher and Herr volunteered.

Ms. Castro-Lewis invited suggestions for agenda items for the next meeting. Ms. Drew suggested including a discussion on transparency. Ms. Hoiberg renewed her request that the Secretary attend an ACCV meeting, perhaps when the new members are installed. She also suggested that outreach should be included as a discussion during the next meeting.

On motion duly made and seconded, there was unanimous agreement to adjourn. The meeting adjourned at 11:30 p.m.

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Magdalena Castro-Lewis
ACCV Chair

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Sherry K. Drew
ACCV Vice-Chair

_____
Geoffrey Evans, M.D.
Executive Secretary, ACCV

_____
Date