DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL

MINUTES OF MEETING

Immunization Practices Advisory Committee
September 26-27, 1989
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control, Atlanta, Georgia, on September 26-27, 1989. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

Dr. Samuel L. Katz, Chairman
Dr. Stanley E. Broadnax
Dr. James D. Cherry
Dr. David W. Fraser
Dr. W. Paul Glezen
Dr. Caroline B. Hall
Dr. F. Marc LaForce
Dr. Mary E. Wilson

Ex Officio Members

Dr. Carolyn Hardegree (FDA)
Dr. John R. LaMontagne (NIH)

Liaison Representatives

Dr. David Fedson (ACP)
Dr. Edward A. Mortimer, Jr. (AMA)
Dr. Stanley A. Plotkin (AAP)
Dr. William Schaffner, II (AHA)
Dr. Susan E. Tamblyn (NACI)
Dr. Ronald C. Van Buren (AAFP)

Executive Secretary

Dr. Mary E. Guinan

NAVY ENVIRONMENTAL HEALTH CENTER

CDR David Trump

HHS STAFF PRESENT

CENTERS FOR DISEASE CONTROL

Office of the General Counsel

Mr. Kevin M. Malone

HHS STAFF PRESENT (continued)

CENTERS FOR DISEASE CONTROL

Center for Infectious Diseases

Dr. Claire Broome
Dr. Nancy Cox
Dr. Daniel Fishbein
Dr. Steve Hadler
Dr. Maurice Harmon
Dr. Helen Regnery
Dr. Paul Rota
Dr. Margaret Tipple
Dr. Jay Wenger

Center for Prevention Services

Dr. William Atkinson
Dr. Felicity Cutts
Ms. Rosamond Dewart
Dr. Laura Fehrs
Mr. Conrad Ferrara
Dr. Alan Hinman
Dr. Sonja Hutchins
Dr. Laurie Markowitz
Mr. James Mize
Dr. Walter Orenstein
Mr. George Seastrom
Mr. Don Stenhouse
Dr. Raymond Strikas
Dr. Walter Williams

NATIONAL VACCINE PROGRAM OFFICE

Dr. Yuth Nimit

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

Dr. Cynthia McCormick

Others Present

Dr. Pinya Cohen
Tony Deahl
Dr. Corry Dekker
Dr. Jill Hackell
Dr. Saul Krugman
Ms. Nancy Sabalusky
Dr. Gregory R. Istre
Dr. Roselyn J. Rice
Dr. Suzanne Dandoy
Mr. David Benor
Mr. Steve Lawton
Dr. Lawrence W. Davenport
Wayne Morges
Dr. Douglas K. Kelsey
Karlyn Shedlowski
Dr. David Nalin
Ellen McGuire
David K. McClintock
Mary L. Harvey
Dr. David West
Mr. George Moonsammy
Hal Rathfor
Joseph Oren
Dr. Rafal Wyslkowski
Hugh Mainzer

IMMUNIZATION PRACTICES ADVISORY COMMITTEE
Meeting at
Centers for Disease Control
Building 1, Conference Room 207
Atlanta, Georgia

AGENDA

Tuesday, September 26

8:30 a.m.	Welcome and Opening Remarks	Dr. Sam Katz Dr. Mary Guinan
8:45 a.m.	Infant Immunization Initiative	Mr. Jim Mize
9:15 a.m.	BREAK	
	National Vaccine Program	
9:45 a.m.	Overview	Dr. Alan Hinman
10:00 a.m.	National Vaccine Advisory Committee	Dr. Suzanne Dandoy
10:30 a.m.	Advisory Commission on Childhood Vaccines	Mr. Stephen Lawton
11:00 a.m.	Legal Aspects	Mr. David Benor
11:30 a.m.	Vaccine Injury Compensation Program	Dr. Cynthia McCormick
12:00 Noon	LUNCH	
1:00 p.m.	Hepatitis	Dr. Steve Hadler
3:00 p.m.	BREAK	
3:30 p.m.	Measles	Dr. Walter Orenstein Dr. William Atkinson
4:30 p.m.	National Adult Coalition	Mr. Conrad Ferrara
5:00 p.m.	ADJOURN	

Wednesday, September 27

8:30 a.m.	Rabies	Dr. Dan Fishbein
9:30 a.m.	Influenza	Dr. Nancy Cox
10:30 a.m.	BREAK	
11:00 a.m.	H. influenzae b	Dr. Claire Broome Dr. Jay Wenger
11:45 a.m.	ADJOURN	

The meeting was opened at 8:30 a.m. on September 26 by Dr. Samuel L. Katz, Chairperson. Dr. Katz introduced prospective new members Dr. Gregory Istre, State Epidemiologist, Oklahoma Department of Health, and Dr. Roselyn Rice, Medical College of Virginia. Attendees introduced themselves and their affiliation.

Infant Immunization Initiative

Dr. Walter Orenstein, Division of Immunization (IM), Center for Prevention Services (CPS), provided brief background on the Infant Immunization Initiative (I^3). Several months ago the Immunization Division appointed a working group to develop a plan intended to improve immunization levels in preschool children.

Mr. James Mize, IM, CPS, and a member of the working group, stated the goal of I^3 is that 90% of the nation's children are immunized by age 2. This initiative focuses on five major areas considered important in an intensified strategy: service delivery, assessment, information/education, operations research, and surveillance. He reported that review teams have just returned from a formal program review of the Texas project, with followup visits planned on 6 month intervals. These teams are making recommendations to State and local health officials on types of corrective actions needed to meet the goals of the Initiative.

The Initiative was started because there are few projects where 90% coverage has been reached. Some of the objectives and activities planned for this initiative include standardized procedures and requirements for immunization projects, new software for assessment, close collaboration with local programs, other Federal grant programs and private organizations, and an expanded analysis of existing data. A contract with NCHS is planned to obtain a national estimate of vaccination coverage in the preschool population. There will be an effort to increase parental demand for immunizations and provider awareness of recommended immunization policies and procedures in high morbidity areas. Nine cooperative agreements to evaluate different strategies for improving and assessing levels were awarded in July and August.

In response to a question from Dr. Cherry, Dr. Orenstein replied that 90% was chosen as a goal rather than 100% because it was felt this is an achievable goal for preschool populations. In school age children, goals of 96-97% have been reached. Drs. Broadnax and Schaffner commented that vaccine availability is a problem at the present time.

Dr. Orenstein stated there was no money in the President's 1990 budget submission for this program, nor in the House budget. It is estimated that this program will cost approximately $10 million a year. The Senate Appropriations Committee has $10 million for infant immunization in its budget, but it is too early to know if it will be approved. Dr. Orenstein presented an overhead of immunization funding for 1989-1990 and discussed ways in which funds for immunization might be made available. No money is in the budget for the 2-dose schedule, but funding will never be available without the recommendation. Dr. Katz stated there is a big credibility gap between the wording of national vaccine policies and what we can actually accomplish with budget constraints.

National Vaccine Program

Dr. Alan Hinman, CPS, noted that Steve Preblud, Division of Immunization, died in July. He distributed an article about Steve that appeared in Infectious Diseases in Children.

Dr. Hinman presented an overview of the current activities of the National Vaccine Program, which has been in active existence for slightly more than 2 years. The Program operates out of the Office of the Assistant Secretary for Health, with Dr. Hinman serving as the coordinator and the Assistant Secretary serving as director. They are currently recruiting for a fulltime Deputy Director. The Program is involved in activities which include pertussis and pertussis vaccine development, vaccine information pamphlets, a consolidated system for reporting adverse events, and financial support for Program office activities and furthering the Program goals of research, development, etc. They expect somewhere between $4.5 and $10 million dollars support to be made available for the National Vaccine Program in fiscal year 1990.

Within the Public Health Service, there are at least five vaccine advisory committees which relate to vaccine activities. They include the ACIP, the FDA's Vaccines and Related Biological Products Advisory Committee, the NIAID Microbiology and Infectious Diseases Research Committee, the National Vaccine Advisory Committee (NVAC), and the Advisory Commission on Childhood Vaccines (ACCV). A side-by-side comparison chart of ACIP, NVAC, and ACCV purposes and functions was distributed. Dr. Hinman pointed out there are many other groups that address vaccine issues, many of which are outside the Government, and some of which have overlapping functions.

In response to a question from Dr. Katz, Dr. Hinman responded that the Interagency Group to Monitor Vaccine Development, Production and Usage, formed in 1980, still functions (as the NVP Interagency Group) and now includes representation from CDC, FDA, NIH, Department of Defense, and the Agency for International Development. It is not an advisory group, but more of an implementation group, reporting to the National Vaccine Program.

National Vaccine Advisory Committee

Dr. Suzanne Dandoy, Chairman of the National Vaccine Advisory Committee and Director of the Utah Department of Health, stated that this Committee was established under the National Vaccine Program and works across a wide variety of vaccine activities. It consists of 15 members selected by the Assistant Secretary for Health, representing the fields of public health, pediatrics, infectious diseases, vaccine manufacturers, and the public. The Committee has met six times (quarterly) and works closely with the National Vaccine Program Office. They have developed a mission statement and a 14 point National Vaccine Policy statement. Pertussis is their first priority for vaccine improvement. The Committee is concerned with many issues, including funding, important information statements, and the work of the Claims Court and the compensation program. Members seek support for the NVP through other organizations to which they belong. It appears this effort has been effective because funding is expected to be in excess of what was requested for this

program. This funding will go through the National Vaccine Program to various agencies such as FDA and CDC. Dr. Dandoy described the seven aspects of the National Vaccine Plan which include improving existing vaccines, decreasing adverse events, financing vaccine delivery, improving vaccine utilization, maintaining adequate vaccine supply, development of new vaccines, and vaccine licensure issues. The Committee will address each of these issues and develop recommendations to go in the National Vaccine Plan.

Dr. Dandoy stated there has been a change since Dr. Mason became the Assistant Secretary. He attends each meeting, participates in the agenda, is helpful with budget constraints within his control, is increasing the staff of the office of the National Vaccine Program, and provides much more support than they had in the first year. This has encouraged the members to move ahead.

Dr. Cherry asked that the Advisory Committee minutes be made available to ACIP. Cheryl Counts will maintain these minutes and ACIP members can request copies.

Advisory Commission on Childhood Vaccines

Mr. Stephen Lawton, attorney and member of the Advisory Commission on Childhood Vaccines, stated that the purpose of the Commission is to advise and make recommendations to the Secretary regarding the National Vaccine Injury Compensation Program which provides compensation for certain vaccine-related injuries or deaths. It is composed of three lawyers, three pediatricians, and three members of the public, two of whom are parents of injured children. The Vaccine Injury Compensation Program is the first effort ever to design and administer a Federal no fault program. It is not working in the way it was envisioned. It is a brand new program, not appropriately funded, and is subject to controversy and criticism. The Program will stay in existence, will hear claims, and will pay out from a surcharge collected on vaccines. The issue is to find a way in which this Program can be fixed so it functions more properly and easily on behalf of children who are entitled to compensation. The rules implementing this Program are 51 single spaced pages long and too adversarial. The law is not absolutely clear concerning this program. The Justice Department is strapped for funds, understaffed, and did not provide lawyers to participate in this Program. They refuse to provide legal representation for HHS, the respondent in all these cases. Medical reports were inadmissible in Claims Court because Dr. McCormick (of the Program) was not authorized to appear in court without legal representation. Congress is writing legislation which will provide money from the trust fund for FY 1990 ($1.5 million) for the Claims Court, Justice Department, and HHS, and will restructure the administrative structure in the relationship of the court and the Special Masters. The 51 pages of rules will be condensed to 13 pages and will be less adversarial.

Other activities the Commission has been involved in are recommendations for parent information material and improved vaccines.

In summary, this Program was established to preserve existing vaccines from liability and to promote justice for children. The problems that exist can be addressed by legislation that hopefully will be enacted this year. Mr. Lawton

stated the Commission does not seek to assume other committees' functions, but to try to facilitate the Compensation Program.

Legal Aspects

Mr. David Benor, Office of General Counsel, stated that the statute for the Compensation Program called for significant detail and differences, but there is clearly overlap of committees, e.g. on the issue of safer vaccine and adverse events. He mentioned that ACIP might want to have liaison representation on these other committees to share information. One significant difference between the Commission and the other committees is the role of the Commission in dealing with regulatory matters such as the revision of the important information statement and the amendment to the vaccine injury table. This Commission has the most diverse and specifically mandated membership.

He went over general requirements/rules of advisory committees/commissions. They included charters, open meetings, publicizing meeting dates, disclosure of records to the public (with limited exceptions), minutes, and standards of conduct. He emphasized it is inappropriate to lobby as a member of an advisory group, but O.K. within your private capacity.

Vaccine Injury Compensation Program

Dr. Cynthia McCormick, Vaccine Injury Compensation Program, noted that since her last report, much has happened, but very little progress has been made. The Claims Court released its rules in late January and took the Departments of Justice and Health and Human Services by surprise. Resources of both Departments were overwhelmed. The Department of Justice (which received no funding for this Program) said it could not participate. With no legal representation, HHS can't participate. The Compensation Program's present involvement consists of reporting to the court their opinions which are not accepted into testimony. The Program has a new branch chief and is adding new medical staff. Of the cases submitted so far, approximately 10% do not have proof of vaccination. Many affidavits are not supported by medical records, and cases do not fit the injury table criteria. Of the 170 cases submitted (all retroactive), only three polio cases absolutely fit the criteria. They have acknowledged a table fit in about 20 cases, only one of which was recommended so far. There have been no claims for vaccines administered since enactment of the law. The last day for filing on cases occurring before October 1, 1988, is October 1, 1990. They assume there will be no suits filed until people have gone through the compensation system first. The eight Masters are attorneys with no special background selected by the court. These Masters are accustomed to making judgments based on the presentation of evidence from both sides. Special Masters' findings do not constitute law. The injury table was written by Congress (initial table was in the Hawkins legislation). A revised table was based on input from the Academy of Pediatrics and children's groups. Parents argued the table should be more generous, and some of their views were incorporated in the final table. The table may be changed by regulation, other than to add vaccines, which requires legislative action. It was hoped this program would make public health programs more available by freeing up Federal money or by decreasing the cost of vaccine from the supplier.

Dr. Orenstein stated that there has been some stabilization of vaccine prices, especially regarding DTP. Polio and MMR prices have increased, but these prices have been maintained for 2 years. The manufacturers are cautious because this system is not an exclusive remedy. Vaccine manufacturers can still be sued.

As a means of getting more involved in making the Compensation Program work, Dr. Dandoy suggested that the medical community might work with the physicians on the Commission to replace turnover members with their own members and provide input to congress for changes in the legislation.

Mr. Lawton stated that the Program must get into place and function to see if it is effective. The Program has not gotten off the ground, and it is unfair to say if it is going to work or not. It is the Advisory Commission's function to monitor the conduct of the Compensation Program.

Dr. Orenstein reported that a workshop was held at CDC on August 28-30 on Important Information Statements with various expert representatives, including parents' groups, State and Territorial Health Officers, State health departments, medical groups, national PTA, Children's Defense Fund, a communications specialist, etc. There was a failure to reach basic agreement, but substantial progress and compromises were made. Comments will be accepted from these groups, and hopefully acceptable statements will be derived from this process.

Dr. Dandoy said her Committee would welcome collaboration from ACIP either in person or by exchange of minutes. Steve Lawton said that the next meeting of the Commission will be November 1 and 2 and would benefit greatly from collaboration or input from ACIP. Dr. Katz thanked these four people for giving their time in this informative way.

Hepatitis

Dr. Steve Hadler, Division of Viral Diseases (DVD), Center for Infectious Diseases (CID), reviewed the hepatitis draft, noting the relatively minor changes that were made in response to comments received on the previous draft. Agreement was reached on several remaining issues. The recommendation will be published as a supplement to the MMWR. Dr. Katz will approve the draft for publication.

Two specific issues discussed were vaccine costs and intradermal vaccination. Handouts were provided on these issues. It was noted that the price of hepatitis B vaccine had not decreased after a new vaccine by Smith Kline was licensed in the United States in August 1989. Both vaccine manufacturers (Merck and Smith Kline) are charging the same price but will negotiate the vaccine price if approached by a group (not only the Government, but hospitals, etc.). There has not been the competition in price that was hoped for or that has been seen in Europe or Asia. The cost of Merck vaccine is 50% higher than in 1982 when it was first licensed. The price for hepatitis vaccine is 30-50% lower in some other countries. Currently, no other manufacturers are seeking licensure of HB vaccines in the United States.

Because of continued high cost of vaccine, many hospitals remain interested in intradermal vaccination with low doses of HB vaccine. Studies with plasma derived vaccine show a somewhat lower response, lower titers, and slightly higher side effects. Intradermal vaccination would not be licensed by FDA unless it is requested by the manufacturer, which is not expected to happen. The ACIP members agreed that currently there are not adequate data to make a recommendation for intradermal vaccination with recombinant vaccines. Research studies should be set up for recombinant vaccine. Intradermal administration should be carried out only using research protocols at this time.

Measles

Dr. Orenstein summarized the current status of measles surveillance. There has been a 374% increase in the number of cases over the same time last year, with the largest number of reported deaths since 1971. There have been 30 deaths--18 children and 12 adults. Adults are considered to be over the age of 19. There are 15 ongoing outbreaks occurring in 10 States.

Dr. William Atkinson, IM, CPS, discussed the most recent changes to the measles draft. Hopefully, this draft will be ready for publication by the middle of October. Dr. Atkinson would like to have any additional comments by October 6. It will take 4 weeks for publication after the recommendation is submitted.

Dr. David Fedson stated that the Guide for Adult Immunization written by the American College of Physicians with input from the Infectious Disease Society of America is scheduled for publication in November. This delay in publication will allow changes in ACIP measles and hepatitis recommendations to be incorporated in this book. He thanked the many people at CDC for their cooperation in this project.

Rabies

On the second day, discussions started with Dr. Daniel Fishbein, DVD, CID. He stated that it has been 5 years since the rabies recommendation was last updated, and there have been minor developments since then. As background for general discussion, the revised recommendation addressing some controversial subjects and new developments in rabies prevention was mailed to members. It is desirable to reword the ACIP recommendation to acknowledge the work being done outside of the United States. In many areas, the ACIP recommendations differ somewhat from those of WHO. Some WHO recommendations have been incorporated into the ACIP statement. Dr. Fishbein presented data on several recent efficacy studies. Dr. Hardegree expressed several concerns of FDA, and stated that Dr. Quinan will comment further on these concerns. Dr. Fishbein will not finalize the recommendation until data are available for review. He asked for comments on this draft by November 1.

Influenza

Dr. Nancy Cox, DVD, CID, introduced a series of presentations intended to brief the Committee on the occurrence of influenza.

National Coalition for Adult Immunization

This agenda item was moved to the second day because discussion on the draft measles statement took longer than expected. Mr. Conrad Ferrara, IM, CPS, described the purposes, membership, organization, and current activities of the NCAI. The Coalition was formed in June 1988 as a group of organizations and individuals dedicated to promoting adult immunization primarily through information and education programs aimed at physicians and members of disease specific high-risk groups. It was recognized that adult immunization efforts were highly fragmented among public and private health care organizations and that progress in achieving increased vaccine coverage required collaboration between public and private sectors to ensure optimal use of limited resources. To date, NCAI is composed of over 48 professional medical and health-care associations, consumer, voluntary and grant-making organizations, corporations, government agencies, and individuals and is expected to continue to grow. The Steering Committee has representatives from 11 organizations, with the National Foundation for Infectious Diseases serving as Executive Secretary and home office for NCAI. October 22-28 has been designated as National Adult Immunization Awareness Week. Positive attitudes in immunization practices in physicians who care for adults is the single most important factor in increasing vaccine coverage levels in high-risk groups. A draft "Standards of Care for Adult Immunization" is currently being reviewed for adoption in the near future. Three action groups are being formed for hepatitis, measles/mumps/rubella, and influenza/pneumococcal to carry out specific activities.

Influenza (continued)

Dr. Margaret Tipple, DVD, CID, announced that publication of Part II of the recommendation concerning antiviral agents for prophylaxis and therapy of influenza has been delayed until rimantadine is licensed. Until then, copies of the antiviral portion of last year's recommendation will be made available, and callers will be referred to the package insert, since no changes have been made in the indications for the use of amantadine.

Dr. Tipple presented a brief review of last year's influenza surveillance. The sources from which information was collected included 150 sentinel physicians, death certificates from 121 U.S. cities, 60 WHO collaborating laboratories, and phone calls. It is hoped that regional reporting of influenza activity will be useful for planning purposes and make people recognize the need to culture throughout the season to know which types of influenza are circulating. No vaccine efficacy studies were done by CDC duing 1988-89, but the viruses circulating closely resembled those in the vaccine.

Dr. Helen Regnery, DVD, CID, reviewed influenza activities on a worldwide basis. The origin of pandemics of influenza virus has been widely recognized as Asia. Influenza surveillance is being expanded in Asia in an effort to allow CDC to monitor circulating strains and make educated guesses for vaccine components. A significant initiative currently underway in the Influenza Branch is a collaborative effort with China. A second initiative is the assumption of a leadership role in the Pacific Basin Respiratory Virus Research Group, which was formed about 2 years ago. At a recent workshop

influenza summary data were collected from the past 10 years from about 20 participating countries. These summaries were collated, and for the first time long term seasonal trends of influenza were available. Surveillance forms sent out to participating countries will be returned to CDC each month for analysis, thus providing current surveillance information from Pacific Basin countries. These activities, along with its role of WHO collaborating center, enable CDC to obtain information and influenza isolates from throughout the world.

Dr. Paul Rota, DVD, CID, discussed influenza B viruses that were isolated last year. Evidence from sequencing studies and epidemiologic data indicated that at least two distinct lineages of influenza B have circulated since 1983, and that viruses from each lineage were isolated from cases of influenza during 1988-1989. Parallel pathways of evolution have also been described for influenza type A H1N1 and H3N2 viruses. These results demonstrate the ability of sequencing data to establish precise evolutionary relationships between viruses. Such relationships may not be apparent from the antigenic analysis. Molecular surveillance of influenza B viruses will continue to monitor the progress of each of the lineages.

Haemophilus Influenzae b

Dr. Jay Wenger, DBD, CID, stated that since the last meeting a model constructed by his Branch to show the effects of immediate licensure for children at 12 months of age on number of cases of H. influenzae prevented was mailed to ACIP members. After reviewing this model, members voted on whether to lower the age of immunization with conjugate vaccine from 18 to 12 months. The vote was 2 for and 7 against. Dr. Katz took these results to the FDA Advisory Committee meeting in July.

FDA's advisory group felt that if FDA so chose, there were adequate data available (without efficacy studies) to justify lowering the age of immunization to 12 months. They would not address the level of antibody that was needed nor the percent of children that must have a certain level of antibody. It was recognized that some vaccines might require more than one dose to achieve the same level of seroconversion, and they left it to FDA to recommend one dose or two doses if a recommendation was made for 12 months. FDA has considered all the data and decided not to recommend reduction of age of immunization to 12 months. Based on the data reviewed to date for specific products, FDA feels that rather than going to the 12 month level at this time, they would recommend something consistent with CDC's April 1989 General Recommendations on Immunization. If FDA sees data to support the use of a particular product at 15 months, they will recommend that product be labeled for permissive use at 15 months (i.e., to be given only if the child will not be seen at 18 months for vaccination), with the caveat that immunogenicity at 15 months may not be as good as it would be at 18 months. The FDA is continuing to review license applications, however, at this time none of the labels have been changed.

The FDA Committee would like ACIP and the Red Book Committee to continue to discuss this matter because issues other than safety and efficacy were not considered. These other issues include impact on other immunization programs

and scheduling. The FDA Committee was not asked to consider infant licensure at this time. Dr. Katz commented that all committees are concerned with scheduling--all vaccines in a single injection or separate visits. Dr. Wenger will prepare a draft clarifying recommendations for the conjugate vaccine (including the issue of permissive use at 15 months) for publication in the MMWR.

Other ACIP Business

The date for the next ACIP meeting will be February 27-28.

With the thanks of the Chairman, the meeting was adjourned at 11:45 a.m.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

Samuel L. Katz 7 Jan. 1990

Samuel L. Katz, M.D., Chairman Date