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

MINUTES OF MEETING

Immunization Practices Advisory Committee
October 28-29, 1987
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control, Atlanta, Georgia, on October 28-29, 1987. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

Dr. Samuel L. Katz, Chairman
Mrs. Betty F. Bumpers
Dr. Jeffrey P. Davis
Dr. David S. Fedson
Dr. W. Paul Glezen
Dr. F. Marc LaForce
Dr. H. Denman Scott

Ex Officio Members

Dr. John R. LaMontagne (NIH)
Dr. Elaine C. Esber (FDA)

Liaison Representatives

Dr. J. Michael Dixon (NACI)
Dr. William Schaffner II (ACP)
Dr. Edward A. Mortimer, Jr. (AMA)
Dr. Michael R. Peterson (DoD)
Dr. Stanley A. Plotkin (AAP)
Dr. John M. Tudor, Jr. (AAFP)

Executive Secretary

Dr. Jeffrey P. Koplan

Invited Consultant

Dr. James D. Cherry

HHS STAFF PRESENT

FOOD AND DRUG ADMINISTRATION

Office of Biologics Research and Review

Dr. Carolyn Hardegree
Dr. Paul Albrecht, Jr.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Ms. Joyce Smith
Dr. Charles Xintaras

HHS STAFF PRESENT (continued)

CENTERS FOR DISEASE CONTROL

Office of the Director

Dr. Mary Guinan
Mr. Gene Matthews
Mr. Kevin Malone
Ms. Verla Neslund

Center for Infectious Diseases

Dr. Jim Allen
Ms. Nancy Arden
Dr. Claire Broome
Dr. Mitchell Cohen
Dr. John Feeley
Dr. Helene Gayle
Dr. Bruce Gellin
Dr. Lee Harrison
Dr. Noreen Hynes
Dr. Mark Kane
Dr. Alan Kendal
Dr. William Martone
Dr. Fred Murphy
Dr. Margaret Oxtoby
Dr. Andrew Pavia
Dr. Jack Poland
Dr. Benjamin Schwartz
Dr. Robert Tauxe
Dr. Jay Wenger

Center for Prevention Services

Mr. William Atkinson
Mr. Steven Barid
Dr. Roger Bernier
Dr. Edward Brink
Dr. Steven Cochi
Ms. Debra Combs
Mr. Larry Dodd
Ms. Jessica Gardom
Dr. Brad Hersh
Dr. Alan Hinman
Mr. Phil Horne

Center for Prevention Services (continued)
Dr. Sonja Hutchins
Dr. John Livengood
Dr. Lauri Markowitz
Mr. John Mullen
Dr. Ida Onorato
Dr. Walter Orenstein
Dr. Stephen Preblud
Dr. Myron G. Schultz
Dr. Dixie Snider
Mr. Don Stenhouse
Dr. Roland Sutter
Mr. John White
Dr. Walter Williams

Epidemiology Program Office
Dr. Robert Gunn

International Health Program Office
Dr. Kenneth Bernard

OTHERS PRESENT

Ms. Leslie Chapman
Mr. Robb Chapman
Dr. Connie Cheng
Dr. Pinya Cohen
Dr. Corry Dekker
CDR Mark Dembert, MC, USN
Dr. Ingram Douglas-Hall
Dr. Bruce Dull
Ms. Phillis Freeman
Dr. Kevin C. Geraghty
Dr. Gary Griffith
Dr. Jill Hackell
Dr. Victor Jegede
Dr. Sandy Kaufman
Dr. Douglas Kelsey
Dr. Saul Krugman
Dr. Andre LaMotte
Dr. Ellen McGuire
Dr. John Moderwell
Dr. Michael Osterholm
Dr. E. W. Pearson
Dr. Evelyn Quiles
Dr. B. A. Rubin
Dr. David Smith
Dr. Robert Steinglass
Dr. Mason Stout
Col. Ernest T. Takafuji
Mr. Charles Taylor
Dr. Franklin Top
Dr. Joe Trudelle
Dr. Ralph Vosdingh
Dr. Allen Woodhour
Dr. Barbara Zajac

The meeting was opened at 8:30 a.m. on October 28 by Dr. Samuel L. Katz, Chairperson. Dr. Katz introduced Dr. John LaMontagne, new ex officio member from NIAID, NIH; Dr. Edward A. Mortimer, new AMA liaison representative; and Dr. Stanley A. Plotkin, new AAP liaison representative. Dr. Elaine Esber represented Dr. Paul Parkman, FDA. Dr. Katz stated that an invited consultant, Dr. James D. Cherry, Professor of Pediatrics at the University of California School of Medicine, Los Angeles, would arrive late.

Vaccines and HIV Infection/AIDS

Dr. Walter Orenstein, Division of Immunization (IM), Center for Prevention Services (CPS), CDC, gave introductory comments on background information to be presented on human immunodeficiency virus (HIV)-infected patients and discussed a meeting on AIDS in Geneva, Switzerland, August 12-13, 1987. Dr. Ida Onorato, IM, reviewed classification of HIV-infected children and discussed epidemiology and seroprevalence (by year) of pediatric HIV infections. She presented information on the safety of Bacillus of Calmette and Guerin (BCG) immunization of HIV-infected children in Zaire and France. She also reviewed data on the

safety of oral polio vaccine (OPV) and measles-mumps-rubella (MMR) vaccine, gathered primarily in a study of HIV-infected persons in New York City. In addition, data were presented on the immunogenicity of the type 2 component of OPV and the measles component of MMR as well as a review on immunogenicity of inactivated polio vaccine (IPV) and diphtheria and tetanus toxoids.

Following deliberations of the meeting on June 23-24, 1987, regarding measles vaccine and HIV-infected children or other manifestations of HIV, a draft update, "Measles Immunization of Children with HIV Infection," was distributed for the committee to review and discuss. Dr. Lauri Markowitz, IM, explained that the draft included a new recommendation that administration of single antigen measles vaccine should be considered for symptomatic HIV-infected children if they are at increased risk of exposure to measles, such as in the setting of an outbreak. In such settings, vaccine may be given to infants as young as 6 months of age, with revaccination at >12 months of age with single measles antigen vaccine. This represents a change from previous recommendations for patients with immunodeficiencies, including symptomatic HIV infections. The committee had previously recommended that such patients should not receive live viral or bacterial vaccines because of concern that replication of live, attentuated vaccine organisms may be enhanced in such persons and produce serious adverse events following immunization. Dr. Katz asked the members to carefully review the draft overnight and stated that the agenda would be modified to begin the meeting at 8:15 instead of 8:30 a.m. the following day to allow time to continue discussing the draft.

Beginning at 8:15 a.m. the next day, the committee had a lengthy discussion on immunization of children for measles, as well as other diseases, and children with HIV infection. It was agreed that vaccination with MMR of symptomatic HIV-infected children should be considered. These children could be vaccinated in the same schedule used for normal children. The draft should be broadened to incorporate a table for overall vaccination recommendations of HIV-infected children. Suggested changes were to be circulated to the committee for comments before it is published as a supplement to the recommendation "Immunization of Children Infected with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus" dated September 26, 1986. Additional comments should be returned to Dr. Koplan within 2 weeks to enable Dr. Markowitz and her coworkers to revise the draft.

Meningococcal Vaccine

Dr. Benjamin Schwartz, Division of Bacterial Diseases (DBD), Center for Infectious Diseases (CID), gave an overview of problems with distribution and availability of the vaccine. The quadrivalent vaccine (Connaught) is the only one licensed in the United States. At times, there has been a shortage of the vaccine. The availability of single-dose vials as an alternate to the 10-dose vials is desirable due to the short shelf-life after reconstitution. Dr. Katz asked Dr. Hinman to place this subject on the agenda of the November 18, 1987, National Vaccine Program meeting. Dr Schwartz also reported the results of a chemoprophylaxis study, conducted during an outbreak of Group A meningococcal disease in Saudi, Arabia, which compared the efficacy of ceftriaxone and rifampin. The study showed ceftriaxone to be significantly more effective than rifampin in eradicating pharyngeal carriage.

Japanese B Encephalitis - Update

Dr. Jack Poland, Division of Vector-Borne Viral Diseases, CID, Fort Collins, Colorado, gave an update on the status of Japanese B encephalitis vaccine use and availability in the United States. Surveillance continues for U.S. citizens traveling or working overseas. Surveillance for adverse reactions to the Biken JE vaccine is required as long as it remains an investigational drug. Serological diagnostic testing is done on suspected cases. Three cases were recorded in 1986. Co-investigators were recruited to deliver vaccine; 12,500 doses have been distributed. Objectives include obtaining licensure of the Biken JE vaccine and a mechanism for indemnification of Biken, increase the number of qualified vaccination centers to about 200 to accommodate the increase in demand by travelers, obtain information from Korean public health officials and other sources to determine the level of risk to humans and equines traveling to the 1988 Olympic Games in Korea, and establish and maintain a close liaison with USDA advisors concerning equine risk of JE and assist in establishing recommendations. Dr. Poland led a discussion on efficacy of a 2-dose and a 3-dose schedule. The 3-dose is favored. The committee felt that because of probable increased requests for vaccine for travelers to Asia in 1988 (Olympic Games, etc.) there is pressing need to have Japanese B encephalitis vaccine available. Dr. Katz asked Dr. LaForce to work with Drs. Poland and Fedson and Mrs. Bumpers to draft a report suggesting a mechanism to make vaccine available in the United States.

Miscellaneous Issues

A. National Vaccine Program

Dr. Katz congratulated Dr. Alan Hinman, IM, on being named Coordinator for the National Vaccine Program (NVP).

Dr. Hinman reviewed information he presented at the June 23-24, 1987, committee meeting regarding statement of organization, and functions and delegations of authority for the NVP. He stated that the National Vaccine Advisory Committee for the NVP has not been formed. Nominees are being solicited. A staff is being recruited. A plan of activities for the NVP will be submitted to Congress in early 1988. Dr. Hinman stated that his office in Washington is in the Parklawn Building; phone (301) 443-0715. The committee discussed the National Vaccine Injury Compensation Program. Mrs. Leslie Chapman, representing Dissatisfied Parents Together (DPT), stated that they are not pleased with a proposed last-minute change in the NVP which now covers medical care providers.

B. Varicella Vaccine - Update

The status of a varicella vaccine in the United States was given by Dr. Stephen Preblud, IM. A study by Gershon et al. on live, attenuated varicella vaccine in healthy adults revealed that the vaccine is less protective for healthy adults than for healthy children, but it modifies the illness even if varicella-zoster virus antibodies are no longer detectable. Dr. Preblud stated that draft recommendations are being prepared for use upon licensure of the vaccine.

C. Dr. Hinman reported that President Reagan signed a Bill designating the week of October 25, 1987, as Adult Immunization Awareness Week.

Copies of the following Proceedings were made available to the committee:

Proceedings of the 2nd Community Forum on Adult Immunization, Atlanta, Georgia, April 27-28, 1987

Proceedings of the 21st Immunization Conference, New Orleans, Louisiana, June 8-11, 1987

D. Institute of Medicine (IOM) Poliomyelitis Study - Update

As a followup to an issue discussed at the meetings in February and June, 1987, regarding policy for use of IPV in the United States, Dr. Hinman announced that a workshop, under the auspices of IOM, National Academy of Sciences, is scheduled on Thursday, January 21, 1988, in Washington, DC, with the committee remaining Friday and Saturday, January 22-23, to complete draft recommendations. The report should be available to ACIP at the spring 1988 meeting.

E. Acellular Pertussis Vaccine - Update

Dr. Roger Bernier, IM, led a discussion on the acellular vaccine study in Sweden, and read a press release stating that the results will be presented on December 14-15, 1987, to the scientific community in Stockholm.

Haemophilus influenzae Type B - Update

Dr. Jay Wenger, DBD, presented published data on PRP-D conjugate vaccine in chidren of various age groups, including antibody response and associated reactions.

Dr. Franklin Top, Praxis Biologics, gave a summary of work at Praxis on their conjugate Haemophilus influenzae type b (Hib) vaccine, including antibody responses and associated reactions.

Dr. Claire Broome, DBD, referred to a report given by Dr. Mortimer at the previous meeting on the April 1987 "Haemophilus b Polysaccharide Vaccine Workshop" on efficacy of the Haemophilus polysaccharide vaccine in the United States, and she presented an update. The committee discussed case control studies of polysaccharide vaccine efficacy in different areas of the United States. Four of the five studies continue to show efficacy ranging from 41-88 percent. The relative risk of Hib disease within 7 days following vaccination was elevated in one of the studies and not significantly elevated in two of the studies. Discussion focused on a recent deliberation of the Red Book Committee of the American Academy of Pediatrics (AAP) to withdraw recommendations for universal use, advising pediatricians that use of the polysaccharide vaccine should be optional rather than universal. After hearing comments from Dr. Michael Osterholm, Minnesota Department of Health, and Dr. David Smith, Praxis Biologics, Dr. Katz asked the committee to vote on whether the ACIP recommendations for use of the polysaccharide vaccine should

be changed. The committee voted to continue with the current recommendations. Dr. Katz asked Dr. Broome to keep the Executive Secretary updated, and if pertinent information becomes available before the next meeting, the committee would be so advised. Also, Dr. Katz suggested that representatives of the ACIP and the Red Book Committee coordinate/reconsider the recommendations.

General Recommendations on Immunization

Ms. Jessica Gardom, IM, led a discussion of a draft revision of "General Recommendations on Immunizations" which was mailed to the members for review before the meeting. Changes include the addition of the new recommended schedule for immunization of normal infants and children, clarifications on the spacing of immune globulin and live and inactivated vaccines, and the addition of a new section listing conditions that often are inappropriately considered contraindications. Dr. Katz requested the committee members to send any additional comments on the draft to Dr. Koplan within 2 weeks so that the draft can be revised to incorporate all suggested changes.

Cholera Vaccine

Following Dr. Katz's suggestion at the June 1987 meeting that a draft revision be prepared to include a paragraph on simultaneous administration of cholera and yellow fever vaccines, Dr. Robert Tauxe, DBD, presented a revision of the 1978 Cholera Vaccine recommendation. The only change in the draft is the addition of a paragraph to discuss the potential interaction with yellow fever vaccine. A revision will be issued to include additional references and the following paragraph:

> Some data have indicated that persons given yellow fever and cholera vaccines simultaneously or 1-3 weeks apart had lower-than-normal antibody responses to both vaccines. Unless there are time constraints, cholera and yellow fever vaccines should be administered at a minimal interval of 3 weeks. If the vaccines cannot be administered at least 3 weeks apart, then the vaccines can be given simultaneously or at any time within the 3-week interval.

The committee agreed that the Yellow Fever recommendation should be updated to include the same caveat. Additional comments on the cholera draft should be sent to Dr. Koplan within 2 weeks.

Typhoid Vaccine

Dr. Andrew Pavia, DBD, presented a draft revision for consideration in anticipation of the licensure of a live attenuated Ty21a, oral vaccine in the United States. He emphasized that when the manufacturer finalizes the product label, the draft should again be reviewed by the committee before being published. Additional comments should be sent to Dr. Koplan within 2 weeks.

Poliomyelitis

A. Enhanced Potency Inactivated Vaccine - Update

Dr. Paul Albrecht, Center for Biologics Evaluation and Research, FDA, gave a presentation on (1) methods of production and vaccine composition for the "old"

inactivated vaccine and the enhanced potency inactivated vaccine, and (2) results of clinical trials, including antibody response and reactions, using the enhanced IPV.

B. Interim Recommendations

Dr. Edward Brink, IM, led a discussion on a supplementary draft recommendation "Enhanced Potency Inactivated Poliomyelitis Vaccine" which was mailed to the committee for review before the meeting. Dr. Brink stated that the supplement is being finalized so it can be published as soon as the product (vaccine) is licensed in the United States. The draft provides information on and recommendations for the use of enhanced potency IPV. The position of the ACIP is that in the United States primary reliance on OPV for polio immunization with selected use of enhanced potency IPV continues to be warranted but that the subject should be reviewed on a continuing basis. An extensive review of polio vaccines and potential vaccine policies is planned during 1988. The committee discussed specific dose and route. Any additional comments should be sent to Dr. Koplan within 2 weeks.

Influenza - Update

Dr. Alan Kendal, Division of Viral Diseases (DVD), CID, reviewed efforts being made in promoting an influenza education program, targeted toward nursing homes; 20,000 copies of the manual, "Strategies for Clinical Practice," are being distributed. Influenza B infections were documented in the United States during summer and early fall. From April through September an increasing number of Asian and Pacific countries reported A(H3N2) isolates. Brazil reported an outbreak of influenza A(H3N2) in Rio de Janeiro during May and June. In the United States, a Vermont resident had a serologically confirmed case of influenza A(H3N2). The patient was among a group of tourists who developed respiratory illness while on a cruise ship off the coast of Alaska in late August. It is likely that both type A(H3N2) and type B viruses will circulate this winter. Dr. Kendal reviewed a 10-year program by the Allegheny County Health Department (Pennsylvania) promoting vaccination of all persons considered to be at high risk of complications and death following influenza infections. To accomplish its goal, the health department offered free vaccine and technical support to physicians, chronic-care facilities, and other medical providers who were willing to administer the vaccine free of charge.

Regarding the antiviral drug rimantadine hydrochloride, Dr. Kendal reported that his staff in conjunction with Drs. Davis, Fedson, and Glezen have drafted provisional recommendations to present to the committee for review, as a supplement to the current recommendation, should this drug be approved for marketing in the United States. Dr. Nancy Cox, DVD, reviewed the molecular epidemiology of influenza H1N1 viruses, including the circulation of nonrecombinant and recombinant viruses, schematic illustration of genome evolution of influenza A(H1N1) virus, oligonucleotide differences between pairs of H1N1 influenza viruses, and evolutionary pathway of influenza A(H1N1) viruses.

Hepatitis B - Update

Dr. Mark Kane, DVD, gave an overview of why the screening of women at high risk for HBsAg should be undertaken and led a discussion on the concept of universal screening of pregnant women for HBsAg, citing the complexity and lack of sensitivity of the current strategy. His presentation included data on (1) women for whom prenatal HBsAg is recommended and studies on sensitivity, specificity, and prevalence by ethnic groups; (2) study on physician knowledge about perinatal transmission in San Diego, Atlanta, and Seattle; (3) proportion of prenatal patients screened for particular infectious diseases and number screened for hepatitis B virus (HBV) infection; (4) proportion of responders identifying particular high risk groups; (5) recommendations for infants born to HBV carrier mothers; (6) study on HBsAg positive births and carriers by race (Asian, Black, Hispanic, White, AmerInd); (7) comparison of blood bank and maternal HBsAg screening; cost effectiveness of maternal and blood bank HBsAg and of maternal HBsAg screening by racial group; and (8) cost per case prevented for various health programs.

Dr. Katz asked Dr. Kane to make necessary modifications in the draft update "Prevention of Perinatal HBV Transmission" (presented at the February 5-6, 1987, meeting) and reintroduce it at the next meeting. The committee suggested that coordinated efforts regarding testing should be made with the Academy of Pediatrics and the American College of Obstetrics and Gynecology (ACOG). Dr. Kane will invite a representative from ACOG to attend the February 1988 meeting.

Monitoring System of Adverse Events Following Immunization (MSAEFI) - One-Year Followup of Patients with Adverse Events Following Immunization

A. Dr. John Livengood, IM, stated that in 1985 the MSAEFI form was modified to include results of a one-year followup of serious adverse events. He reviewed methods used and follow-up status of persons reporting encephalopathy after immunization and of persons reporting convulsions after receiving measles-containing vaccines and/or DTP. He reviewed the risks of seizure recurrence for febrile and nonfebrile convulsions. The committee further discussed the risks for convulsions following immunization and noted the publication of the article, "Diphtheria-Tetanus-Pertussis Immunization and Sudden Infant Death Syndrome," by Walker et al. in the August 1987 AJPH.

B. Mrs. Leslie Chapman distributed copies of a 2-page statement, which she read on behalf of Dissatisfied Parents Together (DPT), disagreeing with Dr. Livengood's presentation on Sudden Infant Death Syndrome (SIDS) at the June 23-24, 1987, meeting. She included two attachments: a list of studies and documents that suggests a link between DTP and infant deaths, and additional questions regarding the DTP issue.

C. Dr. Kevin C. Geraghty, also representing the DPT, distributed a publication, "DPT-Gate: Reagan's Baby," and made a presentation stating that his purpose is to advocate the immediate adoption of the Japanese acellular pertussis vaccine.

BCG - Status

Dr. Dixie Snider, Jr., Division of Tuberculosis (DTBC), CPS, explained the status of the draft revision of the BCG recommendation discussed at the previous meeting. Secretary Bowen recently authorized a newly formed advisory committee, Advisory Committee for Elimination of Tuberculosis (ACET). During its first meeting on September 22-23, 1987, ACET discussed the draft. In order to have sufficient time to receive responses from those committee members, the decision was made to refrain from presenting the draft for discussion by ACIP at this time. The ACET will meet in January 1988, make their suggested changes in the draft, and then it will be presented for deliberation at the winter ACIP meeting.

Other ACIP Business

The next meeting was scheduled for February 2-3, 1988.

PLEASE NOTE: Since the meeting, it was necessary to change the date to February 10-11, 1988 (Wednesday and Thursday).

Tentative agenda items will include BCG, Hepatitis B, influenza, and poliomyelitis.

Dr. Katz invited everyone to remain for the Dr. Joe Mountin Lecture/Ten-Year Smallpox Eradication Celebration to begin at 2 p.m. The lecture was presented by Dr. Donald A. Henderson, Dean of the School of Hygiene and Public Health, Johns Hopkins University.

With the thanks of the Chairman, the meeting was adjourned at 11:50 a.m.

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

Samuel L. Katz M.D. 29 Dec. 1987

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