DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA

SUMMARY MINUTES OF MEETING

May 6-7, 1976

The Immunization Practices Advisory Committee met in Atlanta, Georgia, May 6-7, 1976.

COMMITTEE MEMBERS PRESENT

Dr. H. Bruce Dull, Executive Secretary, Acting Chairman
Dr. E. Russell Alexander
Dr. Elizabeth Barrett-Connor
Dr. William R. Elsea
Dr. Edwin D. Kilbourne
Dr. Reuel A. Stallones
Dr. Thomas M. Vernon

Ex Officio

Dr. Harry Meyer, Jr., Bureau of Biologics, FDA

Liaison

Dr. Samuel Katz, American Academy of Pediatrics
Dr. John Davies, Laboratory Centre for Disease Control, Canada
(for Dr. John D. Abbatt)

COMMITTEE MEMBERS ABSENT

Dr. David J. Sencer, Chairman
Dr. Lonnie S. Burnett

OTHER PARTICIPANTS

Ms. Hope Hopps, Bureau of Biologics, FDA
Dr. George J. Galasso, Infectious Diseases Branch, NIAID

CDC STAFF PRESENT

Bureau of Epidemiology:

Dr. Philip S. Brachman
Dr. John Bryan
Dr. Michael B. Gregg
Dr. Barry Hafkin
Dr. Michael Hattwick
Dr. Charles H. Hoke
Dr. Richard J. O'Brien
Dr. Jerry Winkler
Dr. Ronald Zweighaft

Bureau of Laboratories:	Dr. Alan Kendal Dr. Gary R. Noble
Bureau of State Services:	Dr. Lyle Conrad Dr. Greg Hayden Dr. Donald Millar Dr. Walter Orenstein Dr. John Witte
Office of Information:	Mr. Donald Berreth

OBSERVERS

Mr. William Freilich, Merck, Sharp, and Dohme
Mr. Don Nunes, Washington Post
Ms. Frances Ogasawara, American Lung Association
Mr. Robert Pear, Washington Star
Mr. Harold Schmeck, Jr., New York Times
Mr. Charles Taylor, UPI
Dr. A. C. True, Merck, Sharp, and Dohme
Mr. Lawrence Wright, New Times Magazine

DAY ONE: THURSDAY, MAY 6, 1976

The meeting was called to order at 8:30 a.m. by Dr. H. Bruce Dull, Executive Secretary, in the absence of the Committee's regular Chairman, Dr. David J. Sencer.

The Acting Chairman welcomed those present, introduced new Committee members, Drs. Kilbourne and Vernon, and noted that Dr. John Davies was representing Dr. John D. Abbatt, Director General, Laboratory Centre for Disease Control, a new liaison member. He described the agenda and objectives for the meeting which included review of influenza surveillance and laboratory data from the 1975-76 season, presentation and discussion of the National Influenza Immunization Program (NIIP), summary of the current swine influenza vaccine studies, and consideration of plans for influenza surveillance and NIIP evaluation in 1976-77. It was proposed to the Committee that ACIP recommendation on influenza vaccine this year be in two installments, Part I to include a review of the evolution of and rationale for the already announced National Influenza Immunization Program and general recommendations on influenza vaccination; Part II, to be published a month later, to contain the specific data on expected side effects, dosages, contraindications, etc. for 1976-77 influenza vaccines based on the outcome of field tests currently underway.

Influenza

Surveillance: A/Victoria/3/75(H3N2) caused widespread epidemics of influenza in the United States and in many parts of the world during the 1975-76 influenza season. Scattered cases of influenza B were also recognized in this country. Pneumonia and influenza mortality was elevated from late January through April 1976, an estimated 11,000 excess deaths occurred during this period. A weekly telephone survey showed all States had some influenza, and 75%

reported widespread illnesses. The World Health Organization reported that 38 countries experienced epidemics of A/Victoria, many of which were extensive. The United Kingdom had its greatest influenza-associated excess mortality since 1968-69.

Laboratory surveillance showed that several influenza A(H3N2) subtypes were in circulation in the world: A/Port Chalmers/1/73(H3N2) was isolated in Brazil, Guatemala, Africa, and once in the United States; A/England/868/75(H3N2) was isolated in England, Canada, Jamaica, and once in the United States; A/Tokyo was limited geographically to Japan.

No influenza cases caused by A/New Jersey/8/76(HswlN1), swine influenza-like virus, have been identified since the IPAC meeting on March 10, 1976. (At that time, swine influenza cases had been described in Rochester, Minnesota (1974); Sheboygan, Wisconsin (1975); Charlottesville, Virginia (1976); and Ft. Dix, New Jersey (1976).) As a result of the isolation of the swine influenza-like virus in the United States, many countries have intensified their laboratory surveillance. Numerous specimens have been processed, but no swine influenza-like viruses have been identified.

National Influenza Immunization Program: Plans for the National Influenza Immunization Program were described in detail to familiarize the Committee with overall strategies for implementing the recommended nationwide vaccination effort. Current program organization addresses responsibilities such as vaccine distribution, influenza surveillance, laboratory analysis, public awareness, State and local project coordination, and program evaluation. Program proposals from more than 30 States have been received thus far. Most are "biphasic" with an early emphasis on high-risk groups and later emphasis on mass vaccination. Vaccine need is State-determined, derived from population and demographic data.

Influenza Vaccines: Vaccine production involves four manufacturers. All vaccines are allantoic fluid-derived, zonally purified, concentrated, and formalin-inactivated. They are either whole- or split-virus products. Final dosage is to be determined from studies on immunogenicity and reactogenicity currently underway. Prototype vaccines from the four manufacturers are being tested among persons of various ages. Currently, the monovalent A/swine vaccines are being used. Bivalent vaccines will be studied as soon as they are available.

General Discussion: There was considerable discussion of influenza and the vaccination program. One item of particular interest was hypersensitivity to the egg components of vaccine. Based on available data and experience, it was felt that the actual relationship between a history of sensitivity to eggs or egg protein and the likelihood of serious reactions to influenza vaccines could not be clearly quantitated. Although about 1% of the population may have a history of egg intolerance, only a fraction of them appear to be hypersensitive. It was suggested as a preliminary plan that individuals with a history of hypersensitivity to ingested egg protein might be screened in mass clinics and referred to private physicians for evaluation.

Another discussion topic was childhood immunization. Since children frequently experience febrile reactions and occasionally febrile seizures following influenza vaccination, the current studies of reactogenicity of vaccines in children will be very important in selecting dosages for children and specifying age limits for vaccination.

The question of the liability of those administering influenza vaccine with respect to claimed untoward side effects was discussed at length. It was suggested that the current plans for fully informing all potential recipients of the reasonably expected side effects of vaccination should minimize liability. To this end an informational document on influenza vaccines is being developed at CDC for use in mass clinics and wherever else it would be helpful.

Influenza immunization in pregnancy was considered at length. Although data are not specific as to any effect of killed vaccine on the developing fetus, there is no evidence that influenza vaccine or other comparable inactivated antigen poses a risk of adverse effect in terms of fetal teratogenicity or mortality. On the other hand, because of an increased maternal mortality during past pandemics--but not interpandemic periods--it was felt that the national program should emphasize use of monovalent vaccine during pregnancy.

There have been isolated reports of post-vaccinal encephalitis and a single, somewhat anecdotal, report of a death following influenza vaccine. It was noted that even then, direct relationship between vaccine and complication had not been established. Surveillance of such adverse effects is important, but data are insufficient to conclude that encephalitis and death should be considered among reasonably expected risks of vaccination.

The Committee believed that other necessary immunization programs (i.e., immunization against measles) should not be neglected during efforts to vaccinate everyone against influenza. Although regularly coupling influenza and other vaccination efforts was not felt to be feasible or desirable, ongoing and epidemic control immunization activities should be continued.

Regarding concurrent immunizations, it was agreed that because influenza, measles, and DTP vaccines have been associated with fever among recipients, influenza vaccine should not be given with DTP vaccine or within 14 days of measles vaccination. Concurrent administration of influenza vaccine with mumps, rubella, or polio vaccines was not felt to be contraindicated.

The Committee devoted considerable time to reviewing a draft recommendation on influenza vaccine for 1976-77. To incorporate the group's suggestions, a subcommittee, consisting of Drs. Vernon, Stallones, and Kilbourne, was appointed to revise the statement prior to the next day's review. Besides the issues already discussed, it was suggested that the redraft include a clear indication of the basis for the changes in the IPAC's recommendations this year as compared with previous years and that a special concept of "need for vaccination" be developed in order to help determine priorities within vaccination programs.

DAY TWO: FRIDAY, MAY 7, 1976

The influenza vaccine redraft was considered in detail, and additional suggestions were made. In particular, it was felt that further detail on vaccination in pregnancy should be included. A subsequent draft will be prepared for circulation by mail.

Hepatitis

The Committee was provided with an advance printed copy of the Joint Statement on "Perspectives on the Control of Viral Hepatitis, Type B" prepared by the Committee on Viral Hepatitis, Division of Medical Sciences, National Academy of Sciences, National Research Council, and the IPAC. It is to be released soon as a Supplement to the Morbidity and Mortality Weekly Report.

The Committee's updated statement on Immune Serum Globulin which had been reviewed at previous meetings was examined for consistency with the Joint Statement. Several suggested modifications were made.

Polio

The Committee reviewed its past discussions on the policies for immunization against poliomyelitis in the United States, particularly the use of inactivated polio vaccine (IPV). Although the Committee generally continues to favor reliance on OPV as the basic immunizing agent against poliomyelitis, it wishes to fully describe IPV in its revised polio vaccine statement, indicating particular areas for its use. The Committee was provided with draft material prepared by the Committee Secretary incorporating suggestions from members in correspondence following the January 1976 meeting. It was requested that comments on the new draft be returned by June 1.

Rabies

The Committee reviewed an updated draft statement on Rabies Prophylaxis. The current revision incorporates recommendations for using human rabies immune globulin (HRIG) whenever serum prophylaxis is indicated. Equine anti-rabies serum, which causes a high incidence of serum sickness, was felt to be acceptable only when HRIG is unavailable. It was stressed that rabies antibody levels should be obtained following pre- and post-exposure prophylaxis so that the need for further boosters can be documented. (In countries where antibody titers are not readily obtained, WHO recommends that a booster be given 90 days after completion of the initial series to enhance the likelihood that protective levels of antibody have been achieved.)

A section entitled, "Accidental Inoculation with Live Rabies Virus Vaccine" had been added. It suggests that anti-rabies prophylaxis is not indicated following exposure to Flury or SAD strain (formerly ERA), but that it should be given following inoculation by newer attenuated strains of unknown pathogenicity.

Other Business

A special meeting of the IPAC was scheduled for Tuesday, June 22, 1976, at NIH, Bethesda, Maryland.

The meeting adjourned at 3:00 p.m., May 7, 1976.

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

H Burwell 5/26/76

Acting Chairman Date