MINUTES, MEETING NO. 12, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES, MAY 16-17, 1968.

The Advisory Committee on Immunization Practices met at the National Communicable Disease Center on May 16-17, 1968. Those in attendance were:

Committee

Dr. H. Bruce Dull, Secretary
Dr. Geoffrey Edsall
Dr. Johannes Ipsen
Dr. David T. Karzon
Dr. Roderick Murray
Dr. Ira L. Myers
Dr. Donald R. Peterson
Dr. Jay P. Sanford

Representing American Academy of Pediatrics

Dr. Robert H. Parrott

CDC Staff--Participants and Discussants

Office of the Center Director: Mr. Charles Gozonsky

Epidemiology Program:
Dr. William E. Dismukes
Dr. Ronald F. Johnson
Dr. George Hardy
Dr. A. W. Karchmer
Dr. Stephen Schoenbaum
Dr. R. Keith Sikes

Immunization Program: Dr. John J. Witte

Laboratory Program:
Dr. Roslyn Q. Robinson
Dr. Marion T. Coleman
Dr. Walter R. Dowdle
Dr. Milford H. Hatch
Dr. Kenneth L. Herrmann
Mr. Harold S. Kaye
Mr. Richard J. Larsen
Dr. Steven R. Mostow
Dr. Charles B. Reimer

Pesticides Program: Mr. Douglas Rohrmann

INFLUENZA

In the pattern of annual ACIP review of influenza, Drs. Roslyn Robinson, Walter Dowdle, Marion Coleman, Stephen Schoenbaum, Steven Mostow, and Mr. Harold Kaye described the occurrence of influenza in the United States during the past year, antigenic variations in prevalent A2 viruses, and major NCDC and other vaccine investigations. It was clearly evident that, both in terms of epidemic reports and excess pneumonia-influenza mortality, widespread A2 influenza occurred in much of the eastern two-thirds of the country during the winter months 1967-68. The viruses responsible for the country's influenza showed continuing antigenic drift from previous A2 strains. New strains were interpreted as showing the most significant differences from the original A2 variant (1957) and closer to Japan/170/62 than to either Japan/305/57 or Taiwan/1/64.

Based on the reports of cases, mortality, and antigenic characterization of the prevalent viruses, the Committee concurred in expecting little A2 influenza in the United States except for the Far West which was not substantially involved in the 1967-68 season. Immunologically, although the recent A2 strains show continuing variation from earlier strains, they have not changed to a degree suggesting that wide susceptibility could be expected.

Reports from other countries, particularly as to characterization of viruses recovered elsewhere, do not suggest trends different from those seen in the United States. Considerable A2 influenza caused by strains comparable to ours occurred in Japan and parts of Australia. The illnesses described in these outbreaks were, like ours, characteristic of influenza.

Vaccine potency studies carried out by NCDC in the Seal Beach retirement community and in other populations, approximately 6,000 participants in all, compared bivalent and polyvalent vaccines (400-200 CCA units A2, B; 300-300 CCA units A2, B). There was indication of a somewhat better A2 response to the bivalent product as might be expected because of its greater A2 antigenic component. The vaccines utilized were of the highly purified, flow centrifuged sort. They were observed to induce many fewer reactions than commonly associated with influenza vaccines. Influenza did not occur in any of the populations where vaccine studies were established, and it was not possible, therefore, to interpret vaccine efficacy.

Mr. Kaye presented a report on comprehensive study of monovalent A2/Japan/305/57 influenza vaccine in mice, where two doses of various dilutions of vaccine were administered prior to heterotypic and homotypic challenge. Both infection and mortality were interpreted. In brief, there was clear evidence that there was less protection to the newer A2 strains of influenza virus used in challenge in previously immunized mice than to strains more like that in the vaccine itself.

A draft statement on the influenza forecast for 1968-69 and vaccine recommendations was reviewed in detail. Final revision and editing were referred to a working group. In essence, the Committee espoused the previously stated forecast and agreed that vaccine should be recommended only for high risk groups as regularly stated.

IMMUNE SERUM GLOBULIN--HEPATITIS PROPHYLAXIS

Dr. Ronald Johnson and staff re-reviewed the draft statement on use of immune serum globulin for prophylaxis of infectious hepatitis. The statement has been under consideration for approximately 6 months and was presented for final review. Concepts of simplifying the dosage of globulin by recipient weight categories was accepted as most simple and yet well within the scientific evidence for graded effectiveness. A simplified geographic division of areas where immune globulin would be useful was adopted by the Committee as part of the Committee's formal recommendation. Final editing was referred to a working group.

LEGAL IMPLICATIONS OF IMMUNIZATION--PRELIMINARY DISCUSSION

For some time, the Committee has indicated awareness of trends in litigation associated with immunization. It has appeared to many Committee members that a public health and general preventive medicine impact is presaged by legal opinions on selected cases in which liability, negligence, implied warranty, etc. could jeopardize future vaccine programs. Liability for untoward vaccine reactions or associated events, the question of warnings to recipients, and the adequacy of consent in community-wide or mass programs are examples of court cases where vaccines have been directly involved.

For all of these reasons, the Committee encouraged a preliminary discussion of trends in legal implications of immunization. Its hope has been to propose constructive methods for showing these trends and to provide useful supports to public health programs

where legal "overtones" are evident.

For this reason, during the final hours of the Committee meeting Mr. Charles Gozonsky, Office of the General Counsel and Legal Advisor to the Center, and Mr. Douglas Rohrmann, Legal Coordinator, Pesticides Program, presented brief reviews of the current attitudes. Thereafter, the Committee discussed its own experience, being particularly concerned over the current Davis vs. Wyeth opinion where a manufacturer of oral poliovaccine was judged to have been responsible for directly warning the ultimate consumer of the vaccine in a program where a community-wide project was sponsored by the medical society. The Committee focused attention on this case not to refute the concept of adequate warnings to recipients of vaccines but rather to question the long-term implications to requiring a vaccine producer to assume this responsibility.

The Committee encouraged the PHS to undertake a full exploration of trends in litigation with various professional medical and health groups and prepare recommendations which could be effective in "counteracting" the interpretations of the trends.

FINAL REVIEWS--CURRENT STATEMENTS

The Committee reviewed the drafts from the working groups dealing with influenza and immune globulin recommendations. With some editorial changes, the Committee accepted in principle the two statements and requested the Center staff to complete the editing.

AGENDA FOR FALL MEETING

The Committee suggested that rubella vaccine and mumps vaccine be included in the fall meeting scheduled for October 8-10, 1968, at which time the NCDC immunobiologics activities are to be reviewed in detail.

With thanks to the participants, the meeting was adjourned by the Chairman.