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U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE Public Health Service Bethesda, Maryland

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HEW-C15

The Public Health Service, U. S. Department of Health, Education, and Welfare, made public late today a summary of conclusions and recommendations of an advisory group of experts in the fields of poliomyelitis and immunology which has just concluded a two-day meeting at the National Institutes of Health, Bethesda, Maryland.

The meeting was called by Surgeon General Leonard A. Scheele to advise on an investigation of the poliomyelitis vaccine produced by the Cutter Laboratories of Berkeley, California, which was withdrawn from distribution this week.

In addition to the consulting group and staff members of the Public Health Service, today's meeting included technical representatives of the six pharmaceutical houses manufacturing the vaccine. Dr. Scheele said they were included so that the Service might benefit from their special knowledge regarding the production and distribution of vaccine.

In arriving at its conclusions and recommendations, the group was guided by last minute data obtained by telephone from health officials in various parts of the country concerning cases of paralytic poliomyelitis occurring among children who have been vaccinated.

As of Noon Saturday, the number of cases reported to the Public Health Service was as follows: California, 16; Idaho, 8; Louisiana, 2; Illinois, 1; Colorado, 1; and Georgia, 1.

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The vaccine manufactured by the Cutter Laboratories had been used in all but 3 of these cases.

In releasing the latest tabulation, the Surgeon General pointed out that as of the present moment this represented a total of only 29 cases.

Approximately 4 million children have been vaccinated.

"It is important to remember," Dr. Scheele said, "that the field trials of the vaccine indicated that it was from 60 to 90 percent effective. It must be anticipated that additional cases will inevitably occur among some of those for whom the vaccine is not effective."

The Surgeon General reiterated the belief of the Service that the mass inoculations now under way should be continued.

It was emphasized in the advisory group; s report that at the present time there is no reason to suggest that vaccine of manufacturers other than Cutter should be withheld.

A summary of the recommendations follows:

The consultants agreed that the data presented on reported cases of paralysis following infection with vaccine manufactured by the Cutter Laboratories justify the action of the Public Health Service in ordering discontinuance of the use of Cutter vaccine pending necessary investigations.

The group said that the failure of significant numbers of cases to occur following the administration of vaccine prepared by manufacturers other than Cutter warrants the continuation of vaccination with products prepared by other manufacturers.

The group's discussion of the Cutter vaccine centered around three basic questions, upon which continuing studies were recommended:

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- (1) Is the appearance of poliomyelitis among people inoculated with the Cutter vaccine merely coincidental?
- (2) Could the injection of the vaccine have provoked the appearance of paralysis in a manner similar to the provocative effect which has been observed after the use of other immunizing agents?
- (3) Was a live virus introduced by the injection of vaccine?

The consultant group agreed that the incidence and distribution of poliomyelitis in the next several weeks would shed light on these questions.

The group recommended that every effort be exerted to stay abreast, on a day-to-day basis, of the incidence of poliomyelitis among those who have received vaccine--securing both medical and laboratory data on each case reported.

In addition, the group felt that it is particularly important that practicing physicians themselves should keep careful data on all inoculations they administer, including manufacturer's name, lot number, site of inoculation, and general health of the individual and that these data be reported to health departments.

In addition to obtaining epidemiclogical and physical data, the group recommended that careful laboratory studies be conducted on affected individuals who have been injected with vaccine and their families. The group recognized that this will mean a severe strain on the laboratory facilities of the Public Health Service and suggested that the Surgeon General investigate the possibility of enlisting other laboratory resources. The group agreed to serve on a continuing basis to advise the Surgeon General as necessary.

The names of the scientific consultants follow:

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Dr. David Bodian, Johns Hopkins University, School of Hygiene & Public Health, Polio Laboratory

Dr. John Enders, Head, Department of Bacteriology and Immunology, Harvard University Medical School

Dr. Thomas F. Francis, Jr., University of Michigan School of Public Health

Dr. W. McD. Hammon, Head, Department of Epidemiology & Microbiology, University of Pittsburgh Graduate School of Public Health

Dr. Edward Lennette, California State Health Department, Director, Viral & Rickettsial Disease Laboratory, California

Dr. Ford McGinnes, Medical Consultant, National Foundation for Infantile Paralysis

Dr. H. J. Shaughnessy, Director of Laboratories, Illinois Department of Public Health

Dr. John R. Paul, Professor, Preventive Medicine, Yale University Medical School

Dr. Albert Sabin, Fellow-in-Charge, Infectious Disease Division, Children's Hospital Research Foundation, Cincinnati Department of Pediatrics, College of Medicine, University of Cincinnati

Dr. Jonas E. Salk, University of Pittsburgh, Virus Research Laboratory

Dr. Joseph Smadel, Chief, Department of Virus & Rickettsial Diseases, Army Medical Service Graduate School, Walter Reed Army Medical Center.