STATEMENT

By Leroy E. Burney, Surgeon General, Public Health Service, August 28, 1959

Live Poliomyelitis Vaccine Status

The present status of attenuated live poliovirus vaccines has been reported by the Public Health Service's Committee on Live Poliovirus Vaccine, headed by Dr. Roderick Murray, chief of the Service's Division of Biologics Standards.

The committee has reviewed the rapidly accumulating data on the development and field use of attenuated live poliovirus vaccines and has considered the initial problems involved in the preparation of provisional specifications for their production. It has been given responsibility for evaluating all available information, for determining what additional information is needed, and, where necessary, for initiating studies to supply the answers to questions that must be resolved before licensing can be recommended.

If energetic efforts are continued to find answers to the remaining technical questions concerning safety, effectiveness, and manufacturing procedures, one or more of the three vaccines now being proposed may be under production within 1 to 2 years. Meanwhile, in the Salk vaccine there already is at hand a potent weapon whose value and effectiveness have been proved. I continue to urge all persons, particularly those under 40 years of age, to complete their series of Salk injections so that no one will remain unprotected at the time of the next poliomyelitis season.

The status of live poliovirus vaccine as reviewed by the committee follows:

1. Three sets of attenuated poliovirus strains have been proposed for use as oral vaccines. The Sabin strains (Dr. Albert Sabin, University of Cincinnati) have all had extensive field trials in Eastern Europe, Mexico, and Singapore. The Lederle strains (Dr. Herald Cox,

Lederle Laboratories) have been widely used in Latin America. The Koprowski type 1 strain (Dr. Hilary Koprowski, Wistar Institutes, Philadelphia) has been used in a large trial in the Belgian Congo. However, no significant amount of field information is available concerning Koprowski's type 2 strain, and only limited information is available in relation to his type 3 component.

- 2. There is considerable difference in the neurovirulence or damaging effect on nerve cells for monkeys of the three sets of strains as determined by intrathalamic and intraspinal inoculation. On this basis, the Sabin group has an advantage over the others, but none of these strains is completely nonvirulent when inoculated into monkeys by the intraspinal route.
- 3. No evidence has been reported to indicate that any of these vaccines produced any harm to the individuals to whom they were administered. The thoroughness with which the observations were made has varied in different studies.
- 4. In some studies the ability of these strains to multiply and thus produce antibodies is less than could be expected on theoretical grounds. Apparently a number of factors operate in the field which may prevent alimentary infection and the subsequent development of immunity.
- 5. A number of workers have reported that virus excreted by vaccinated individuals has shown increased neurovirulence for monkeys. There is considerable disagreement among investigators as to the significance of these reversions in virulence.
- 6. Field experience with any strain to date cannot be interpreted as affording reasonable

proof that the community of nonvaccinated persons will be free of danger from possible reversion of virulence in excreted virus under a great variety of readily anticipated circumstances. This is one of the most important unresolved problems.

7. There is evidence which indicates that under some circumstances the simultaneous administration of all three types of virus may be effective.

The committee reported the following major problems which remain to be solved before definitive decisions can be made regarding licensing:

- 1. The significance of increased neurovirulence for monkeys of virus excreted by vaccinated individuals.
- 2. The demonstration of adequate measures of effectiveness of live poliovirus vaccines in field trials which, to be definitive, must involve

large population groups. The capacity of the virus to spread among contacts means that in such a controlled field trial some nonvaccinated controls will become infected and thus presumably become immune—a complicating factor in such a study.

- 3. The development of standards to determine the possible presence or absence of stray agents in the vaccine. More than 40 simian agents, including B virus, have been encountered in the routine testing of killed poliovirus vaccine. These are derived from the monkey tissues used. Little is known of their pathogenicity for man except B virus, and even for this the minimum infecting dose is not known.
- 4. The establishment of carefully designed and evaluated studies to demonstrate the production of specific antibodies in 90 percent or more of inoculated susceptibles in order to assure the potency of such vaccines.

First 20 Years of the Crippled Children's Program

The number of handicapped children served annually by the crippled children's program of the Children's Bureau increased from 110,000 in 1937, when the program began, to 313,000 in 1957.

Between 1950 and 1957, the number of children who received care and treatment for epilepsy alone increased 387 percent. According to the Children's Bureau, changes in the attitude of the public toward epilepsy coupled with drugs which now can largely control epileptic seizures have made it possible for more and more children so handicapped to become contributing members of society. Those treated for eye conditions increased 234 percent, for diseases of the nervous system and sense organs, 162 percent, and for congenital malformations, 80 percent.

In 1950, only about 2,200 children with congenital heart malformations received serv-

ice in the crippled children's program. By 1958 because of rapid developments in diagnosis and treatment of congenital heart disease, more than 12,000 such children were helped.

At the same time, the crippled children's program is helping to establish and expand programs for services to child amputees. The Bureau has received reports from 30 States which show that they have slightly more than 2,000 children who lack one or more limbs or parts of limbs, and who can benefit from prosthetic devices and training.

At the beginning of the crippled children's program, children stayed in the hospital an average of 43.6 days. In 1957, they were staying an average of 24.4 days. From 1945 to 1957, the average cost per hospital-day went up almost 200 percent, from \$8.95 in 1945 to \$26.81 in 1957.