March 10, 1959

Progress Report on ORIMUNE Oral Polio Immunization

Dear Doctor:

In October of 1956 we sent you a communication regarding the then current status of the Modified Live Poliovirus which has now been in course of development by Lederle Laboratories under the direction of Dr. Herald R. Cox for over ten years.

Since that time expanded clinical studies have been going forward under careful medical supervision. To date more than 550,000 people have been immunized with at least one type of the Lederle Modified Poliovirus. Of these, 250,000 have received all three types.

A carefully controlled trial was recently conducted under the auspices of the Minnesota State Board of Health involving the immunization of 600 persons in a single community. Based upon the Minnesota results, far more extensive trials with the approval and cooperation of the respective ministries or departments of public health are being conducted in Argentina, Colombia, Costa Rica, Finland, Mexico, Nicaragua, Puerto Rico and Uruguay. Currently trials are just getting under way in Haiti and Peru. Most of these trials are being conducted under the auspices of the Pan American Health Organization.

The field trials in Uruguay and Costa Rica are of special interest because they are on an unprecedented scale. In the present phase of the Uruguayan study, the entire population under 15 years will be immunized. In the Costa Rican trial, immunization of the entire population under 13 years is being attempted, with the expectation that some 400,000 immunizations will be given in the coming months.

Although authoritative evaluation of results must await the outcome of the epidemiologic and immunologic studies currently being performed -- which will be transmitted to the medical profession in due course through established professional channels -- we would like to emphasize that ORIMUNE (R) Oral Polio Immunization is being subjected to far more extensive trials than those performed on any previous vaccine before it was made available for general use. Lederle is now committed to supplying sufficient ORIMUNE to immunize up to five million persons.

There have been two instances in which Oral Polio Immunization was used in the face of an outbreak of poliomyelitis, one in Colombia and the other in Nica-
ragua. Although the incidence of polio fell off sharply after oral immunization was given to members of the most susceptible age groups in the affected areas, it cannot be claimed with any authority that the outbreaks were checked by the immunization. However, it is significant that not a single immunized person later contracted the clinical disease.

In all the studies performed to date, involving more than 550,000 persons, not a single adverse reaction has been reported. For obvious reasons, it has not been possible to make antibody titer tests on all subjects, although a statistically significant number of such tests are being performed. Additional tests will be performed as the various clinical trials progress. The results of all the tests will be published in appropriate professional journals in due course. Among the persons immunized with all three types of our vaccine there have been no cases of clinically significant polio reported.

We are frequently asked for the reason why the more extensive trials of ORIMUNE Oral Polio Immunization are being carried out in Latin America rather than in the United States. The reason is that the Latin American countries afford the most accessible large reservoir of subjects without induced immunity to polio. A comparable reservoir, particularly of subjects in the most susceptible age groups, does not exist in the United States.

Overall, the most that can be said at the present time is that the prospects are good for the development of an immunizing agent which will confer lasting immunity against all three types of polio infection. No prediction can be made as to when, or even if, an effective modified live poliovirus oral agent will be made available to you. We therefore repeat the recommendation made in our communication to the medical profession in 1956, that no change in the presently accepted methods of immunization should be contemplated on the basis of information now available.

We wish to reaffirm our intention of informing the medical profession first, through established professional channels, of significant future developments.

Very truly yours,

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