Dear Dr. McGuinness:

I am very sorry that I have not been able to reply sooner to your letter dated December 4, 1953 on the status of poliomyelitis vaccines to be used in the forthcoming field trials and the questions raised by Dr. Kempe. First of all, I want to make clear the position of the Laboratory of Biologics Control in this connection. Neither the Salk vaccine nor any other poliomyelitis vaccine has been approved or disapproved by the Laboratory of Biologics Control at this time. Approval would come only if and when we were to take action on an application for license for the vaccine and no manufacturer has as yet done so for this product. Consequently, no poliomyelitis vaccine has been licensed. At that time we would consider evidence of safety, purity and potency of the product and, as required by law, license would be issued only if satisfactory evidence on these points were available.

During the period of laboratory and clinical investigation prior to licensing, a biologic product is distributed and used solely on the responsibility of the responsible investigator. The product must bear on the label the statement "Caution: New Drug - Limited by Federal Law to Investigational Use." It is our understanding that the vaccine prepared for clinical investigation this winter will be so labeled.

You may also be interested to know that some time ago, in connection with the review of specifications for preparation of the Salk poliomyelitis vaccine, Dr. Joseph A. Bell, who was at that time on the staff of the National Foundation for Infantile Paralysis, asked if we would be willing to test each product for potency, safety, and sterility prior to its use in epidemiologic trial. It has been agreed that these tests would be done in triplicate by the manufacturer, by Dr. Salk's laboratory, and by the Laboratory of Biologics Control according to the criteria which
Dr. Salk has developed, and that no lot of vaccine would be used which does not pass these tests satisfactorily in all three laboratories. Although the manufacturer and the Laboratory of Biologics Control are cooperating in this testing, the responsibility for the adequacy of the tests which Dr. Salk has developed must remain with him during the period of clinical investigation and prior to licensing of the product.

In addition, I may say that I attach considerable significance to some of the questions which Dr. Kempe has raised and I believe he has every right to raise them.

It would be presumptuous of me as a non-member of the Academy to advise you as to procedure, but it does seem to me that you have among your members those who are competent and qualified to express an opinion on this matter, and I see no reason why your Committee on the Control of Communicable Diseases could not express itself on the basis of the best information which is available to you.

Sincerely yours,

W. G. Workman, M. D.
Chief, Laboratory of Biologics Control
National Microbiological Institute