



DEPARTMENT OF  
HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
WASHINGTON 25, D. C.

IN REPLYING, ADDRESS THE  
PUBLIC HEALTH SERVICE

REFER TO

Dear Dr. Koprowski:

Your letter of January 26th, concerning oral poliovirus vaccine made from attenuated strains which you have developed, expresses the hope that I "...will take the necessary steps to have these vaccines licensed..." Since your letter states among other things "...we, at Wistar Institute, are most eager to have our oral polio vaccines licensed for manufacture", it would be well to clarify what the word licensing actually means when applied to biological products.

According to the Public Health Service Act biological products, as defined, may not be sold, bartered, or exchanged in interstate commerce unless manufactured in a licensed establishment and upon a showing that the establishment and the product meet standards designed to insure the continued safety, purity, and potency of such products. The objective of this is, of course, to protect the public and the intent of the Act is accomplished by licensing establishments and products which meet the provisions set forth in formally adopted Regulations.

Thus, to make a particular vaccine available as a commercial product requires that a manufacturer (1) qualify for an establishment license and (2) demonstrate that the product for which the license is sought meets the prescribed standards as set forth in the PHS Regulations. Within this context it is clear that no such action as "... to have... oral polio vaccines licensed for manufacture" can occur.

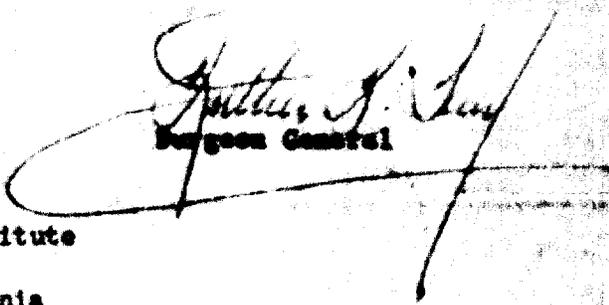
As I interpret your letter you would like to see live, oral poliovirus vaccines prepared from your attenuated strains available commercially in this country as licensed products.

The August 24, 1960 report to which you refer was based upon the information available at the time and was designed to indicate the state of the very complex and sometimes confusing body of information concerning

vaccination against poliomyelitis by a means of vaccines produced from attenuated poliovirus strains. The Regulations relating to live poliovirus vaccine, which became effective on March 25, 1961, represent the rules applicable to the licensing of live poliovirus vaccines in this country. Without going into technical discussions of the details of the Regulations -- a matter which can most profitably be taken up with the Division of Biologics Standards -- it is clear that the Regulations do not specify strains by name or by source, and a manufacturer could qualify for a license by demonstrating that his product meets the prescribed standards as set forth in the Regulations, irrespective of the source, origin, or designation of the strains used. There is, therefore, no bar to a vaccine being prepared from either your strains or from any other source, provided there is a demonstration that the provisions of the Regulations have been met.

I note from your letter that you plan to attend the Subcommittee meeting called to take place in Atlanta on February 15th and 16th. I am pleased to know that you will attend and that the Subcommittee will have the benefit of your advice. As we understand it, the main task of the Subcommittee will be to review matters relating to dosage, scheduling, and other factors concerning vaccination with live vaccines against the background of the information which has developed during the past year and in view of the fact that while the last recommendations of the Subcommittee were made more than a year ago, it has not been possible to exploit the potentialities of live vaccines fully in this country since not all three types were available commercially.

Sincerely yours,



Arthur J. Sidel  
Surgeon General

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