believed that a plasma pool used for fractionation, representing usually 1,000 or more donors must have some hepatitis virus in it. There is no way of preventing this. Even if a pool does contain such virus, it is clear that a safe, pure and potent product is assured by the method of processing plasma to albumin and globulin.

Plasma for fractionation is frequently obtained by manufacturers under the so-called "short supply" provisions of the regulations concerning biological products. Under these provisions the manufacturer establishes procedures with the suppliers, determines that these are adhered to and informs the Division of Biologics Standards of the arrangements, together with the names of the suppliers operating under these provisions—usually a great many sources of various kinds such as licensed and unlicensed blood banks, plasmapheresis centers, blood collecting stations, etc. Personnel from the Division check on these suppliers from time to time to determine adherence to the agreements between the manufacturer and the supplier which spell out the procedures to be followed. Copies of these agreements are filed with DBS.

There are no provisions within Sec. 351 of the Public Health Service Act, which addresses itself only to the safety, purity and potency of final products, for the development of requirements for the protection of the blood donor except as they might affect the safety, purity and potency of the final product. If the donor is injured by the bleeding process used to obtain plasma for fractionation; e.g., by suffering anemia, infection or physical damage, recourse may be made to local laws—laws relating to malpractice, etc. In the case of products where the procedures may affect the safety and purity of the final product, as in the case of blood for transfusion, regulations are adopted.

When the Division of Biologics Standards became aware in June 1964 of the occurrence of a number of cases of hepatitis in the Alabama prison, presumably related to the plasmapheresis program, it conferred with the National Communicable Disease Center which collects epidemiologic data on infectious diseases, including hepatitis, and attempted to investigate the plasmapheresis operation. However, an on-the-site inspection was not possible because operations had been indefinitely suspended.

In order to be sure that the safety of the albumin and globulin had not in some way been compromised, the following actions were taken:

(1) An embargo was placed on any lots of albumin and globulin which may have been prepared from plasma pools which contained any plasma coming from this source. This was done on July 2, 1964. The manufacturers complied.

(2) Surveillance of hepatitis in relation to products already released to the market was instituted by the manufacturers and by the National Communicable Disease Center.

Since 1964 there has been a considerable voluntary tightening of the plasma collection procedures used under the "short supply" provisions. These included more frequent inspections by representatives of the manufacturers and the formulation of more detailed instructions to be followed by the supplier of plasma. Manufacturers have provided us with detailed statements of the procedures used. Those operations which we have inspected since this time have been satisfactory.

Our records indicate that in 1963 three manufacturers of albumin and globulin were receiving plasma from Dr. Stough and his associates. In 1964 there were two. Since 1964 only one manufacturer is indicated as having obtained plasma intermittently from this source.

There is no indication from the record to indicate that the plasma supplied by Southern Food and Drug Research Company was not suitable for producing satisfactory albumin and globulin.

If we can provide any further information in this matter, we would be happy to be of assistance.

Sincerely yours,

RODERICK MURRAY, M.D.
Director, Division of Biologics Standards.

Senator NELSON. You have read the medical association comment, has the FDA done a comparable study in depth of the work being done by Dr. Stough, in the kind of depth that was done by the Alabama Medical Association peer group, so called?