Senator NELSON. Was that for the DBS?

Dr. LEY. That was a source of plasma for use in preparing gamma globulin, as the situation was outlined to me by Dr. Murray.

Senator NELSON. I realize that is not your field. But it was drawn for DBS, then?

Dr. LEY. It was drawn for production of gamma globulin by commercial processors.

Senator NELSON. I see. Under the supervision of DBS?

Dr. LEY. Again, you are getting into detail, Mr. Chairman, that——

Senator NELSON. All right. I will inquire of them.

(The subsequent information was received and follows:)

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C., August 13, 1969.

Dr. RODERICK MURRAY,
Director, Division of Biologic Standards, National Institutes of Health, Public Health Service, Department of Health, Education, and Welfare, Washington, D.C.

DEAR DR. MURRAY: The Alabama Medical Association and the New York Times have reported on the plasmapheresis program recently carried on in various state prisons by the Southern Food and Drug Research Company.

It is my understanding that Drs. Stough and Long, officers of the company, and their assistants were collecting plasma for use in preparing gamma globulin, an activity which comes under the jurisdiction of the Division of Biologic Standards.

It would be greatly appreciated if you would send me a detailed description of the past and present activities of Southern Food and Drug in this field, your relationship to these activities and your findings with respect to the quality of the work of its personnel.

Sincerely,

GAYLORD NELSON,
Chairman, Monopoly Subcommittee.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
Bethesda, Md., September 12, 1969.

Hon. GAYLORD NELSON,
U.S. Senate,
Washington, D.C.

DEAR SENATOR NELSON: This is in reply to your letter of August 13th concerning the activities of Southern Food and Drug Research Company in relation to the collection of plasma for processing to albumin and globulin. The events referred to occurred in 1964 and we have had some difficulty in identifying the records relating to this matter since our information came to us through the reports filed by the processors of the plasma to albumin and globulin.

What follows may seem lengthy but this description of the elements involved in the production of albumin and globulin are essential to an understanding of what is involved as far as the safety and effectiveness of these products is concerned.

The "biological products" provisions of the Public Health Service Act apply to the safety, purity and potency of such products. In the case of albumin and globulin, which are prepared from human plasma, these criteria are met if the final product is safe, pure and potent. Thus, for example, the residual blood present in human placentas has provided a valuable source of these materials (particularly immune serum globulin) for many years. On the basis of this and other experiences, it has been fully accepted for the past 15 years or more that the method of processing plasma to globulin and albumin renders the final product safe for administration. There is no recorded instance of hepatitis having developed following the administration of albumin or globulin prepared by the Cohn method used by industry (alcohol fractionation followed by heating developed by Dr. Edwin Cohn and associates during the period 1940–1947). Since the incidence of hepatitis following blood transfusion is 0.1 to 1.0%, it is