Dr. JOLLY. That they are conducting the study designed according to protocol, that they maintain their records, their proper records, and that they maintain all of the data required by that protocol, and perhaps some I might feel would be of interest along with it.

We have also done work in Haiti. These would be large-scale testing, vaccines, for example.

Senator NELSON. Vaccines?

Dr. JOLLY. Yes.

Senator NELSON. Now is that on all healthy patients?

Dr. JOLLY. Those are not specifically under our direction.

They are under our direction, but they are conducted by physicians in these areas.

We monitor them. Usually we will select physicians who are certified.

Senator NELSON. I take it you conduct studies and investigations to determine, then, whether the particular product meets the statutory standard of efficacy.

I assume that is what you must have done with the antiobesity drugs?

Dr. JOLLY. Yes.

Senator NELSON. And so your studies complied with the statute which requires well controlled scientific studies by qualified investigators producing substantial evidence of efficacy?

Dr. JOLLY. I am pleased to assure you of that.

Senator NELSON. So some of the studies involved questions of efficacy, some involved other bioavailability, that sort of thing?

Dr. JOLLY. Basic safety; right.

Can it be applied to the skin without producing sensitivity or irritation.

Senator NELSON. You do, I take it, studies on both prescription and nonprescription drugs?

Dr. JOLLY. Cosmetics as well. Sometimes food. Sometimes we determine the effects of food on situations, stomach acids, this sort of thing.

Senator NELSON. Where is most of your work, insofar as drugs are concerned, in the field of prescriptions or nonprescriptions?

Dr. JOLLY. About half and half.

About half of our work I would say at the present time and during the last year or two has been the bioavailability work, which has been a very important aspect of the Food and Drug Administration. All of us have been interested in generic drugs in the last 2 years.

That has been a very large section of our business. During the last few years we have been involved in phase I testing. This is the test on drugs when they first come out of the laboratory, and these are again extremely complex, and very, very tightly designed tests.

We keep subjects in the unit, during several days. They actually live in the unit, and are fed there. They will have around the clock nursing care and technical people with them. This is phase I work.

Senator NELSON. In your own facility?

Dr. JOLLY. Yes, sir.

I have been told it is one of the finest clinical pharmacology units; best equipped in the country.