

If we find somebody, and we have on many occasions found somebody that requires medical attention, they will be referred or told to go to their own individual physician, and many times we will find people who are ill.

Senator NELSON. So you are testing healthy patients.

What are you testing for?

Dr. JOLLY. Mainly for safety. Sometimes for effectiveness, in the case of amphetamines, this is strictly for effectiveness.

Senator NELSON. So in that testing, what was your protocol?

Dr. JOLLY. The protocol was devised by the company. Very often I will design protocols for people, because I have had a wide experience in this area. But the protocol I received was very, very well designed, and I think Dr. Scoville actually participated in some of the designs, or at least had a chance to review some of them, just to make sure that everything was covered.

Senator NELSON. Did you do any bioavailability studies?

Dr. JOLLY. That is another part of my presentation.

We are probably the largest, we have done more studies than anybody in the world in this area.

There are bioavailability comparisons on antibiotics, let's say, that are marketed, and we have done a tremendous number of those.

Now, these studies, because we want to prove, or we want to determine that the generic drug is equivalent to the referenced standard, and sometimes we find they are not, but most often they are.

Senator NELSON. So if we have a generic producer, he wants to go into the marketplace on an unpatented drug or the patent runs out, and they come to you with their formulation, their compound, you test it to determine whether it achieves a particular blood level or what the bioavailability is on a certain time schedule compared with the standard one in the marketplace, the brand name, is that what you do?

Dr. JOLLY. Yes.

Senator NELSON. All right.

Dr. JOLLY. Those are controlled studies as well.

Senator NELSON. But you do not do any testing on sick patients to determine the effectiveness of a particular drug against a particular target organism?

Dr. JOLLY. No; we practice research only, but I will state this, we do outside clinical work at hospitals, at places overseas, in Haiti we do some work.

Senator NELSON. What do you mean outside hospital work?

Dr. JOLLY. We do not do any clinical work for people and patients in our facility; however, we might conduct a study at New York Hospital, or someplace else.

We do some work in Puerto Rico, and at a hospital under the direction of doctors at the hospital.

Now, what is our function?

Our function is to monitor these studies, the thing is to make sure that they are completing the case reports, the way they were designed, that they are conducting the studies that were designed according to the protocol.

Senator NELSON. That they are what?