

My data came from very tightly controlled very definitive clinical investigation.

I was trying to prove that these drugs produced significantly more weight loss than placebos.

Senator NELSON. And was this short term?

Dr. JOLLY. It is short-term, so I do not think the two can be compared, and I do not practice medicine, so I do not think I could argue with the results with Dr. Scoville, for example, who evaluated these drugs to a much greater degree than I.

Senator NELSON. You are looking at it solely from the aspect of the short-term impact of amphetamine related to weight loss, and it was a double blind study?

Dr. JOLLY. Very tightly controlled, very rigid, in everything.

Senator NELSON. So your conclusion is only related to short-term use of the amphetamines in cases of obesity in connection with the diet, versus the placebo with diet?

Dr. JOLLY. Right.

Senator NELSON. And it has nothing to do with the long-term result?

Dr. JOLLY. That is correct.

My evaluation of the research work accomplished with amphetamine-like drugs has been requested. With the disclaimer that specific projects cannot be evaluated with precision unless they are monitored and the data thoroughly reviewed, my general opinion is that the background of animal and clinical work on these drugs is both extensive and adequate to make a judgement of effectiveness under conditions of use. The actions of these drugs are clear-cut and even under relatively lax experimental conditions, should be reproducible. Controlled studies to demonstrate effectiveness in comparison to placebos require hard work but no unusual skills. Study administrators may frequently be tempted to guess which patients are being treated with active drugs because of the side effects exhibited. This is a research problem common with the study of most pharmacologically active drugs. Experienced researchers discourage such speculation by the technical personnel.

Those who do engage in guessing games will often find out that they were wrong. The actions of a placebo will often match and sometimes exceed those of an active material. Conversely, a very potent drug may not elicit any remarkable signs or symptoms in some individuals. Regardless, when objective endpoints are available, such as actual weight loss, assessments are simplified and data are more concrete. Moreover, when results obtained from a number of research sites prove essentially equivalent, it can be concluded that the findings are valid. On this basis, the effectiveness of amphetamine-like products as adjuncts in the treatment of obesity has been generally accepted by experts qualified by training and experience to make these judgements. Our data, confirmed by other investigators and resulting from separate investigations of amphetamine formulations and two related drugs can be summarized as follows:

1. Patients treated with amphetamines who complete the study requirements, weekly clinical visits, maintenance of the prescribed dosage intake, continued diligence during study periods ranging from 8 to 16 weeks, on the average will lose more weight than patients who