

We did so-to-speak place all drug-treated patients and placebo-treated patients into two separate pools to see what happened, but that was not the basis for the decision.

Mr. GORDON. I have a document here that I ask be put in the record in the appropriate place.

Senator NELSON. So ordered without objection.

Mr. GORDON. This is a document that was submitted by the Federal officer from the Food and Drug Administration to the HEW panel.

In it, he states as follows:

Of the 206 studies reviewed, 122 were contained in just three NDA's. As can be seen from the following tabulation derived from data accumulated by FDA statisticians, the reviewing physicians deemed less than half of the 122 to be adequate to permit valid conclusions:

NDA number and name of drug	Reviewing physician	Does study permit valid conclusions?			Total
		Yes	No	Uncertain	
16-618—Pondimin.....	Dr. Freeman.....	0	21	0	21
	Dr. Wright.....	0	16	0	16
16-880—Voramil.....	Dr. Trilling.....	33	18	3	54
17-247—Mazindol.....	Dr. Woo.....	16	6	9	31
Total.....		49	61	12	121

In spite of the above, the statisticians were instructed to include all 122 of their computer analysis.

The above judgments of inadequacy were based primarily on the inadequacies of, and deviations from, the clinical protocols; the objections raised in my Medical Officer Reviews—copies of which were submitted to Commissioner Schmidt on March 7, 1975—included serious doubts as to the validity of some of the lab data and hence are additive, rather than merely corroborative of the above tabulation.

Will you comment on that, please?

Dr. SCOVILLE. I do not suppose he comments on what conclusions would be permitted by excluding the studies that were found inadequate.

Mr. GORDON. The writer says the above judgments were based primarily on inadequacies of the data and deviation from the clinical protocol.

And he goes on as I had read.

Dr. SCOVILLE. Well, that is his opinion. Subsequent to the medical officers' individual overall reviews, each individual patient was reviewed, coded, key punched, and went through the computer.

I know the medical officers did not and could not have looked at each data sheet on the scale subsequently done.

Mr. GORDON. Actually he cites four physicians, four medical officers. They are Dr. Freeman, Dr. Wright, Dr. Trilling, and Dr. Woo.

As I see it, they put it together, they took the reviews of these four physicians, so you have really five people making this claim, people who reviewed each of these drug applications.

Dr. SCOVILLE. Well, I think Dr. Knox would agree that he has fairly strong feelings about the use of anorectics, which are known inside the FDA and not on the outside.