

In order to avoid bias on the part of medical officers, we took pains to analyze every single patient, and have somebody inspect every patient data sheet before it was used in the analysis, and we tried to overcome personal bias by reviews.

Mr. GORDON. It is not just Dr. Knox, but it is four other physicians, so you would have to say five of them were biased.

Dr. SCOVILLE. Well, it is hard to argue with those, without going back and reviewing the ways the opinions were expressed, and the basis.

I gratuitously suggest that even in the worst case, it is unlikely that all 22 studies on a single drug were invalid, which is what one of the medical officers proposed.

Senator NELSON. I think this raises some important questions, but the Food and Drug Administration will appear.

We do not expect you to recall off the top of your head all of these statistics without having them before you, so we will put these questions to the Food and Drug Administration.

Dr. SCOVILLE. Thank you, sir.

Mr. GORDON. Now, in the FDA document dated February 17, the reviewing medical officers claimed the total weight loss for those groups on diet plus drugs was small compared to those on diet alone.

I will read this:

"It is generally agreed that there is a definite danger of abuse connected with the use of these drugs.

"While there is no unanimity of opinion as to the efficacy of these drugs, the following opinions merit careful consideration:

"The British Medical Association has concluded that 'These drugs should be avoided so far as possible in the treatment of obesity * * *

"Arthur Grollman has stated that ' . . . There is no evidence to indicate that these agents suppress appetite as has been claimed, which is the basis usually for advocating their use. The only rationale for their use is the hope that by counteracting the depression induced by hunger the patient is better able to abstain from overeating. However, the anorexigenic agents have proven of little efficacy in actual practice * * *

"* * * The results obtained with anorexiants therefore (1) are in many instances inferior to those obtained with unsupplemented diets, (2) show the same marked variations present in the tabulated results of diet alone, and (3) indicate that the newer agents often compared poorly with the older ones whose deficiencies they presumably were intended to correct. * * *

"* * * I stand with a minority of physicians in feeling that these drugs no longer have any place in the practice of medicine, with one or two rare exceptions. * * *

"I understand that one or two other countries have actually banned the use of those highly dangerous drugs. There is no justification for our continuing their 'legal' use. To continue it would be simply to perpetuate one more massive inconsistency in our standards of morality. * * *

"The present labeling fails to give the physician any idea of the degree of efficacy which has been demonstrated in the MDAs for these compounds. It is unlikely that anyone reading the present labeling would suspect that the supporting data in the MDAs revealed such a limited degree of efficacy. Although we customarily do not include such information in package inserts, the amphetamines constitute a special case and must be dealt with accordingly. * * *

"I urge that the labeling of these compounds be revised to include, in each case, a factual tabulation of the actual amounts of weight loss which have been reported by the various investigators, to include the duration of therapy, so that the physician will be in a better position to decide as to whether or not use of a sympathomimetic amine is warranted. The common practice of expressing results in terms of rate of weight loss per week is particularly objectionable and should be discontinued. * * *