

reference is to the controversy about the interpretation of the UGDP study, and says nothing about the significance of the warning. So I do not have any difficulty at all reconciling the two statements.

Mr. GORDON. One other thing. You also proposed a boxed warning at the beginning of the warning section of the labeling. Is that not correct?

Dr. SCHMIDT. Yes, in the proposal. That is where it is put.

Mr. GORDON. Why not put the boxed warning at the beginning of the labeling, as with chloramphenicol and lincomycin and clindamycin?

Dr. SCHMIDT. Speaking only for myself, when I went through it, its location was logical. It was at the beginning of the warning section, where many are, and the thought did not cross my mind that it could be or should be or might be removed from the warning thing, and stuck at the beginning. I think that it is an interesting suggestion, a valuable comment, and is one that we will evaluate, reevaluate. There is certainly no—it need not stay where it is.

The CHAIRMAN. With respect to the UGDP study, if my memory serves me correctly, it was reviewed at the request of Dr. Marstan, the then Director at NIH, by Dr. Chalmers, who at that time was at NIH. It was reviewed by somebody else prior to calling upon the Biometric Society to evaluate it, was it not?

Dr. CROUT. It was reviewed by a number of people, and it was reviewed by our own staff. It was reviewed by people at the NIH. It was reviewed also by critics. So, rather simultaneously, there were several reviews that appeared in early- to mid-1971. It was reviewed by Dr. Seltzer. Dr. Schor and Professor Cornfield also had detailed reviews of it.

The CHAIRMAN. Well, what were the conclusions of the other groups that reviewed it?

Dr. CROUT. The major conclusions of Dr. Seltzer and Dr. Schor were that the study had flaws in its fundamental design and execution to the extent that it was worthless, and that was the beginning of the controversy. Dr. Cornfield then felt that those criticisms, while correct in certain respects, were insufficient to negate the study. I must also say Dr. Alvin Feinstein also had a very critical review. So, the major critical reviews were those of Schor, Feinstein, and Seltzer. The major supporting review has been the Biometric Society, and the review by Cornfield.

In our opinion, the review by the Biometric Society was in far greater detail, far greater depth, than any of the others, and is again the overriding review of the study.

The CHAIRMAN. The Biometric Society was a review for the purpose of evaluating the validity of the studies. Is that correct?

Dr. CROUT. That is correct, and it is the only review conducted, in a sense, by a third party. You see, the controversy was begun by Dr. Feinstein, Dr. Seltzer, and Dr. Schor; and, in a sense, they were parties to one side of the controversy. Dr. Cornfield was a consultant to the study, and in defending it was, in a sense, on the UGDP side. So the Biometric Society review was, in our opinion, not only the most detailed and thorough, but it also was by a third party. All the people were previously involved in the controversy.