terms without disclaimers or qualifications that would undermine or destroy its usefulness. There is, therefore, no mention in the proposed warning of other studies involving the oral hypoglycemic drugs. The mention of studies in which increased cardiovascular mortality was not found would serve only to encumber the warning.

Mr. GORDON. Dr. Schmidt, you say that the warning must be stated in vigorous terms without disclaimers. Why, then, does the warning include—you do not have it in your statement, but it is included in the Federal Register statement—"that, despite the controversy regarding the interpretation of these results, the findings of the UGDP study provide adequate scientific basis for this warning"? Is it not true that the presence of controversy about the need for the wording is irrelevant and is distracting? Is that not an encumbrance, in a way?

Dr. SCHMIDT. No. We definitely do not feel it is an encumbrance, and I personally feel that it is absolutely necessary to the creditibility of warning that we state that the UGDP study, despite this controversy, provides sufficient evidence for the warning. I think that were we to remain silent, or to ignore the fact that many physicians and many experts have said, in effect, forget the UGDP study—if we were to remain silent on that, it would be so obvious, cause so many questions, make people wonder why we were in a sense trying to finesse the issue, that it is to me absolutely necessary in order to have a credible statement that we say that very clearly. The UGDP study is sufficient to provide a sound basis for this warning, and the controversy does not controvert the fact that the study provides that avenue.

Mr. GORDON. Well, I thought that it is not just the UGDP study that you are basing the label on. It is the UGDP study, the Biometric Society study; you referred to the Wissler study, the Wu studies, the Tan studies.

Dr. SCHMIDT. No, I did just now in the statement. The warning is based on the UGDP study.

Mr. GORDON. Solely?

Dr. SCHMIDT. Yes, sir. I can make a couple of other points. The first is that the encumbrance of other studies is not present, and I think that the warning statement is much better for another reason; it relates to credibility. It makes the statement believable, and it renders it, I think, much less subject to attack and discredit. As I said early on, one of our goals here is to achieve a professional concensus about the use of these drugs. So I just strongly believe that the warning, stated as it is, makes a much better statement.

Mr. MERRILL. May I inject one comment? Your question, Mr. Gordon, is one that will be asked of us again. I have no doubt, that the charge will be made that we are speaking out of both sides of our mouth in these very two documents. In one it will be argued we say there can be no encumbrance of the warning, and in the other we seek to encumber it. That is not true. In the context of this warning, the statement that the administration of oral hypoglycemic drugs may be associated with increased cardiovascular mortalities as compared to treatment with diet alone and diet with insulin is two full paragraphs away from the line you just quoted. In addition, the