It is true that the U.G.D.P. had defects. It is true, also, that it falls short of proving the case against Tolbutamide. Nonetheless, as Professor Cornfield remarked in testimony here last September, the U.G.D.P. today provides the best available information on the possible toxicity of Tolbutamide.

As to defects, there are no studies which are entirely free of them, and it was the judgment of our committee that this study was well conceived and executed and that those defects we could identify did not give reason to doubt the findings.

As to it being inconclusive, that was inevitable in the nature of the case. Once the investigators became convinced that there was substantial evidence of toxicity, and not of corresponding benefit, they had no choice but to withdraw the drug.

Thus we are left with an ominous yet inconclusive result, and I believe that this is a typical outcome which we may expect to see repeated in many other instances. It may be, in such a case, that the community of physicians will decide that, although not conclusive, the evidence is sufficient to abandon the drug. Or, on the contrary, as in the U.G.D.P. case, they may conclude that the evidence does not require them to give it up.

In the latter case, however, I can see no alternative to the initiation of a new clinical trial, conducted by physicians unconvinced by the first one. I should expect, in any event, that both physicians and patients should be made as fully informed about the evidence as is feasible.

I go so far as to hope that the experience to date with oral hypoglycemic drugs may convince us that clinical trials should be a continuing component of drug surveillance for any drug, from the first day of its release, and so long as substantial doubt about the balance of risks and benefits remains.