

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13665

STATEMENT BY
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SENATE SMALL BUSINESS COMMITTEE
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Mr. Chairman. I speak as a member of the Biometric Society Committee on Biometric Aspects of Controlled Clinical Trials whose report is under discussion today.

Professor White has outlined our problem and our findings, and Professor Zelen will speak about some of the particular criticisms made of the U.G.D.P. report. I shall speak a little more generally about the role that I see for clinical trials in guiding our decisions about modes of therapy.

It happens that in March of 1970 I testified before this committee on the subject of risks of Thrombo-embolism due to the use of oral contraceptives. I spoke then of the deplorable lack of prospective controlled clinical studies on the effects of oral contraceptives. I discussed possible reasons for that lack. Let me quote a few lines from that earlier testimony. My explanation for the lack of substantial research on this important problem was as follows:

"Frankly, the required research, although important, is not especially appealing to scientists. It is not fundamental and it is not exciting. It is difficult, it is expensive, and it is fraught with the risk of attack from all sides. Who would willingly prepare himself for such a study, make an application to be weighed competitively with others on scientific merit, and risk the loss of support halfway through the study when a review committee with different views or priorities comes to consider renewal of support, when he stands to gain so little in scientific recognition or otherwise?

Evidently, for whatever reasons, there is no sound body of scientific studies concerning these possible effects available today, a situation which I regard as scandalous. If we proceed in the future as we have in the past, we will continue to stumble from one tentative and inadequately supported conclusion to another, always relying on data which come to hand, and which were not designed for the purpose. The planning of better studies is difficult, and the recruitment of investigators willing to commit their efforts to these purposes may be more difficult still. I believe both are possible and essential to the public welfare."

At the time those words were written, I had no knowledge of the U.G.D.P., but they could scarcely have been more apt.