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.

The CHAIRMAN. I think everybody would agree that your last sentence would state an ideal situation which we would all hope someday would be achieved.

Dr. MEIER. Senator, I would hope that day would be early rather than late. I spoke sentiments like this 5 years ago before this committee. I described in some detail ways in which authority might be given to the FDA, and methods by which the funds could be allocated to such studies. I was pleased to see that in testimony in September Dr. Prout argued along quite similar lines. I do not think I see anything in the line of legislation that would tend to move us in that direction, and I would hope there may be some.

The CHAIRMAN. I do not think we need the legislation, but probably do need the money. But I think there is no doubt that it would be very sound to start good clinical trials once a drug is marketed, because if there is not, we would have to rely upon the reports of physicians' observations around the country. It may take a long time for individual physicians to accumulate enough data to associate with some adverse effect because individual observations would have to be reported through medical journals or to each other, and that would take quite a while. Your recommendation is very sound and I do not believe anyone would disagree with you on that.

Dr. MEIER. I would just like to point out that in this case it depended upon an interested academic group, physicians and statisticians, to decide that it ought to be done and to convince an NIH study section that it ought to be funded, at quite a high price, in NIH terms. That seems to me to be an unacceptable way to operate.

If such a drug is to be marketed, the sales of that drug not simply the taxpayers' money, should contribute to carrying out a study. I think there are proper ways in which that obligation could be laid upon the manufacturers who are selling the product to see that the funds are supplied, not because they feel like it, but because they must do so. And that is the kind of legislation I would hope to see.

The CHAIRMAN. As you might recall if you read the testimony in addition to the testimony you gave yourself 5 years ago, when I raised the question about studies to determine how many micrograms of estrogen could be put into an oral contraceptive and still be effective, the answer was, well, it would be very hard to get volunteers to run that risk. I do not think that is the case. I think there would be plenty of volunteers who are seriously concerned about whether or not they got pregnant now or 6 months later, who would be put into a test to see whether you could dramatically reduce the micrograms of estrogen in the oral contraceptive, and it seems quite