

FDA, who don't want to commit themselves to a statement which will get them in trouble; and, of course, always in the background is the pressure to make the product as interesting and promising as possible.

I don't think this makes for an article of communication which well serves the physician. I have been present when attorneys of a pharmaceutical company were willing to compromise on what I considered a fundamental medical point because they were afraid that, if they made too much of an issue, it could somehow hurt them in the pocketbook.

This is no way to make a useful package insert. I don't think a package insert which lists a grab bag of symptoms which have never been properly evaluated, and which have an uncertain correlation with the pill, serves to do anything except turn the doctor off, when he sees a long list which he knows can't be that bad because he just doesn't see it in his patients.

One of the most useful things that these hearings could do is to bring another orientation into the nature of the package insert or some other document, which is necessary to the physician who, I grant you, has not the time to read the 2,000 or so articles a year that are relevant to the problem of oral contraceptives. In the last analysis, wherever the doctor gets his information, it is his responsibility to share it with the patient, so that they jointly reach a sensible decision.

Thank you.

(The complete prepared statement and supplemental information submitted by Dr. Goldzieher follows:)

STATEMENT OF DR. J. W. GOLDZIEHER, DIRECTOR, DIVISION OF CLINICAL SCIENCES,
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Before entering upon the subject of my testimony, I would like to establish briefly some of the qualifications of our research group, and to indicate why we believe we can speak with some degree of familiarity on the subject of adverse reactions and risks of the oral contraceptives. The Southwest Foundation for Research and Education of San Antonio, Texas, was one of the first 3 groups in the World to undertake studies of contraceptive pills; we got into this field at the invitation of Dr. Warren Nelson of the Population Council, which supported our efforts for a number of years. Since that time, our group, with much help of experts from many fields, has often led the way in establishing the technology for measuring side effects of these drugs. We have, over the years, pointed out the technical problems posed by such studies, and the care with which the answers must be interpreted. We have helped to design and monitor the largest collaborative trial of a particular oral contraceptive which has ever been carried out, and, with the help of Dr. Hines and Mr. King, we have developed an entirely new area of statistics—that of the mathematics of very rare clinical events—such as, for example, pregnancies with the Pill. On the basis of such work as this, Dr. Louis Hellman himself asked us recently to prepare an extensive discussion on the problems of clinical trials, to be published for the benefit of clinicians generally. This work has just appeared in the American Journal of Obstetrics and Gynecology. It represents the 62nd publication from our group on the subject of oral contraceptives since our first presentation in 1961. Finally, to indicate that our experience is not exclusively with abstract statistics or with clinic populations of underprivileged women, it should be recorded that Dr. Moses and I have been in private practice for many years, and therefore have continuing face-to-face contact with the problems of women who take the Pill.

For the sake of simplicity, I should like to pose seven important questions regarding problems with the Pill, and attempt an answer to each.

Question 1. Do we know how often women have adverse effects from the Pill?

Answer: Surprisingly, we really do not. This seemingly simple question turns out, in real life, to be exceedingly complicated. As everyone knows, there are different ways of asking the same question, and depending on the way the question is asked, one gets different answers. Every Gallup Poll or other opinion