

Senator DOLE. Then, secondly, as I read your testimony, I had no opportunity to read a paper that you had written in cooperation with Dr. Seigel—but have there been any studies conducted to date which would meet the standards established in your paper? Have there been sufficient numbers for any statistical certainty?

Dr. SEIGEL. I think one must be specific with respect to which end points are desired. For some of the end points like thromboembolic disorders, enough has been done so that we have some very strong suspicions about the relationships, so we can state what the relative risk is within moderate limits.

Studies have not yet been done for other end points. An example is the implication of oral contraceptive use to the outcome of pregnancy, particularly the frequency of congenital malformation. We are attempting to bring together a number of hospitals that will collaborate in a study of the health of newborn babies and the relationship, if any, with oral contraceptive use.

So I think the answer is, yes, for some end points, excellent studies have been done. For other end points, such as cancer, no one has felt that it was timely until now to do a study of the type that the British did, but studies are now getting underway.

Senator DOLE. Well, then, in view of that, and referring to the most recent report by the Advisory Committee on Obstetrics and Gynecology, a sentence that was discussed yesterday with Dr. Hellman, "when these potential hazards and the value of the drugs are balanced, the committee finds a ratio between benefits and risk within the intent of the legislation."

In other words, that would still be true despite some of the valid studies made. Dr. Seigel—do you agree with the conclusion, maybe you do not agree with the conclusion?

Dr. CORFMAN. Whether we agree with the conclusion of the committee?

Senator DOLE. Yes.

Dr. CORFMAN. I was on the committee.

Senator DOLE. I understand that.

Dr. CORFMAN. I do not feel competent to become involved with what is meant by the intent of the law but I would repeat the conclusion of our task force, which was that oral contraceptives are the most effective method currently available for certain women but they are not fully satisfactory. We need better methods.

Senator DOLE. Well, yesterday I think it was Dr. Williams who took issue with this conclusion by the committee, particularly with reference to potential hazards. I think he designated the hazards as real, and again, maybe based on your own studies, if there have been studies conducted, as Dr. Seigel says, do you think there are some large enough for some statistical certainty? The reason I raise the question whether or not they are potential hazards or they are real hazards—I am certain there are some real hazards, maybe they are not serious and maybe we do not know how serious they may be—is that I am still troubled as a layman, and I think as maybe some of these young ladies were troubled, on what they should do or what we tell them. Can you write it down on a piece of paper in a package insert; is that going to solve the problem?