

Senator NELSON. Go ahead.

Dr. CORFMAN. I do not know if this work is being done with estrogens. I certainly agree with Dr. Salhanick that this would be something important to do.

I hasten to point out that such studies would be difficult to undertake in this country because the problem of unwanted pregnancies in women who are willing to be experimental subjects. This is one of the real problems we have in developing new contraceptives in this country.

Senator NELSON. But at the Kaiser Institute they are making studies of 10,000 women.

Dr. CORFMAN. But we are not doing dose-response studies there.

Senator NELSON. I understand.

Dr. CORFMAN. We are monitoring women who are under the ordinary care of their obstetricians in a normal clinical setting.

Senator NELSON. As I said to Dr. Salhanick, given patient-user consent by those who are spacing a pregnancy, who at some stage are going to stop taking the pill, so they can have another baby—is it not possible that there would be those who would say, well, they were willing to test a much lower dose pill as a clinical test because it is not of great significance to them whether they had another baby in 6 months or a year, that sort of thing?

Dr. CORFMAN. I think that could be done, but it would be difficult to do it this way.

Senator NELSON. Doesn't it seem that it is critically important to find out the minimum dosage of progestogen and estrogen that can be put in a pill and still be effective?

Dr. CORFMAN. I agree with you.

Senator NELSON. Has anyone, NIH or another qualified group of individuals, drafted the protocol for the type of studies that ought to be made in this whole field?

Dr. CORFMAN. Dr. Seigel and I prepared a protocol on the kind of epidemiological studies we think should be undertaken.

Senator NELSON. If the experts who have whatever knowledge there is do not prepare the proposals for research and study, how can anyone expect that the Congress would have any notion what funds ought to be appropriated?

Dr. CORFMAN. I agree. Our paper, which appeared in the Journal of the American Medical Association, described the kinds of epidemiological studies that we think should be undertaken. It also pointed out some of the very serious problems and difficulties in answering these questions.

Senator NELSON. What I am really getting at is that there are now eight and a half million women using the pill in this country, and about 10 million elsewhere in the world. It involves a very important problem, and I would hazard a guess that if proposals for appropriate protocols to do important studies were made to the Congress, the Congress would be willing, by overwhelming majority in a bipartisan way, to say this was important enough to have these studies conducted and to appropriate the money to do it.

The problem is I have no notion of what it would take, and nobody else in Congress is qualified, and we are handicapped in trying to do something about a problem that concerns everybody, without knowing what we ought to do about it.