

would not transfer the animal data to the human on the basis of the details that I have described. This does not mean that I am not in favor of progressive, prospective studies. I think these are most needed in the primate, and if your committee were to suggest that, and I think that some of these studies are already started, that a crash program of study in the primate with the estrogen and/or the progestin be started as soon as possible, and carried to fruition as soon as possible, I think this would be invaluable.

I think there is only one problem there as Roy Hertz has pointed out, the lagtime is 10 years. Unfortunately, some of the primates when brought into this environment do not live their natural life so one might have to do it in their native habitat. Third, I think that by the time this study could be concluded we will be using something entirely different from the pill as an oral contraceptive.

Senator McINTYRE. Well then, you have no strong objection to pursuing this estrogen experiment with animals and applying that knowledge—

Dr. KISTNER. I have been a clinical researcher all my life and I would be the last one not to be in favor of research.

Senator McINTYRE. On page 3, Doctor, of your statement, you state that cancer of the breast occurs in one of every 16 women, pill or no pill. On what do you base this statement?

Dr. KISTNER. That is the incidence of cancer of the breast in the human female overall. It says one in 16. You read different figures. Roy quoted one in 20 and there is another study, one in 18. This is the incidence rate of cancer of the breast.

Senator McINTYRE. Do you know, Doctor, of anyone who has done a controlled study of the frequency of breast cancer among users and nonusers of the pill?

Dr. KISTNER. I know of no prospective studies that have been done with the pill of any type. This is what is needed.

Senator McINTYRE. You stated earlier, Doctor, that you had given the pill to thousands of women and had observed only one case of breast cancer among them?

Dr. KISTNER. That is right.

Senator McINTYRE. If in fact breast cancer occurs in one of every 16 women, pill or no pill, should you not have observed a much larger number of such cases among the thousands of women you have treated with the pill?

Dr. KISTNER. No; because breast cancer occurs in an older age group than the patient to whom I give the pill.

Senator McINTYRE. On page 4 you quote Dr. Hertig to the effect that "No convincing evidence is available to show that estrogen stimulation alone will produce endometrial."

Dr. KISTNER. Endometrial.

Senator McINTYRE. "Endometrial cancer and many estrogen studies fail to mention such changes as carcinoma in situ as occurring with regularity." However, on the next page you cite a study of your own in which you say that using estrogen alone you induced severe degrees of carcinoma in situ within 90 days. How do you reconcile this finding with the statement that you quoted from Dr. Hertig?

Dr. KISTNER. I think I stated at the time that this is a dose-related response and it is also related to time. In other words, if I had given