

You say that due to the estrogen components of the pill it was recognized from the very beginning that their long time use might increase the incidence of cancer and that Dr. Pincus and his colleagues incorporated studies relating to this risk in their earliest efforts. I don't believe this could have been in their earliest efforts, could it, since the study you cite on this point is dated 1964, whereas Dr. Pincus' earlier studies date back to the 1950's and the pill was actually approved for contraceptive purposes in 1960. That is just a small point here but I think that you are a little bit out of line.

Dr. HERTZ. No, I think I should tell you that the normal processes of medical publication in scientific journals frequently involve about a year. We usually cite the date of the actual publication. In most scientific journals you will find cited also the date the article was submitted for publication. Then there is frequently about a year's backlog in the publication. What I cited is in fact their initial observations and the initial phases of their study and I was there and saw it. And they were finally published in 1964. Some of these things, as I have indicated, do take a protracted period of time to collect sufficient data to be even as unconvincing as those initial data were. The effort started with the very earliest observations and I might say on personal consultation between myself and Dr. Pincus on this whole issue at this time.

Senator McINTYRE. Good. That straightens it out for me.

On page 2 of your statement you say the 1964 study by Dr. Pincus and his colleagues was evidence of an ameliorative effect of the oral contraceptives on the early phases of the cancer process in the cervix, but that a later study which they completed in 1967 led them to conclude that the pill had no significant effect on the early phase of cervical cancer. However, on page 8 you state that the small number of women involved and the limited extent of their followup render these studies virtually useless.

Now, Doctor, were the deficiencies of these studies not recognized at the time that they were done?

Dr. HERTZ. They most definitely were by those of us concerned with the matter professionally who had sufficient epidemiological understanding of the requirements for such studies.

I might say though that in that particular setting at that particular time, the universal acceptance of such a statistical basis for such studies had not reached a point of sophistication which we have today. As an example the thrombophlebitis study, the type of study which we now see with the thrombophlebitis phenomena would probably not have been immediately or readily available to most physicians but only to a few specialists in epidemiology in that setting at that time.

Senator McINTYRE. So the deficiencies were realized at the time and they were taken into account.

Dr. HERTZ. Yes, sir; and they were commented upon quite openly in scientific meetings and so on.

Senator McINTYRE. Now, also on page 3 I was interested in the paradox you pointed out whereby FDA approved the estrogen containing pill as safe for daily consumption almost immediately after the agency had banned the use of estrogen in chicken feed because it constituted a food additive which was known to produce cancer in ani-