

What about breast cancer? Cancer of the breast occurs in one in every 16, somebody said one in 18, I think Roy Hertz said one in 20 in women, pill or no pill. This is the No. 1 killer of the human female as far as cancer is concerned. Thus a statistical problem of the highest magnitude exists which makes a cause-and-effect relationship between the estrogen and/or the progestin constituents of the pill and breast cancer difficult to prove. It has been estimated that with a 4-year followup of women age 20 to 30, a sample of 20,000 pill users would be required to have a reasonable chance of detecting a twofold increase in the incidence of breast cancer.

Mr. DUFFY. Excuse me, Doctor, you say a reasonable chance which would imply to me that even with a sampling that large that there is still a possibility that you would not obtain the information?

Dr. KISTNER. That is right.

Mr. DUFFY. Is that what you would say?

Dr. KISTNER. That is what I would interpret it. This is a report of Dr. Tietze and it is in the first edition of FDA report. The answer to your question is "Yes," I believe that.

Mr. DUFFY. What size studies must we conduct to eliminate any chance of error?

Dr. KISTNER. I would suggest if you have a bio statistician as one of your witnesses that you address that question to him because I am not a—

Mr. DUFFY. That would be Phil Corfman?

Dr. KISTNER. Yes, Phil Corfman. I would not know the answer to that.

Mr. DUFFY. All right.

Dr. KISTNER. That FDA Advisory Committee report had, in the first report, only one patient among the millions of pill users who developed breast cancer. They concluded:

If the oral contraceptives are at all carcinogenic for the human breast, they cannot be very potent and the occurrence from this cause must be extremely rare.

I would like to add I have been using the pill for gynecologic purposes and as an oral contraceptive since 1956 and I have given it to perhaps thousands of women and I see many women with breast cancer but I have seen, since 1956, only one patient in my own practice and in the clinic of the Boston Hospital for Women, who had been taking the oral contraceptive. By and large, the number of patients who are operated on for carcinoma of the breast are not, have not been, users of the pill. Whether this will change in the future I certainly can't speculate.

The most recent manifestation of lack of definitive evidence linking the pill to breast cancer was contained in a report suggesting that women having a family history of breast malignancy should not use oral contraceptives. A woman's chance of breast cancer increases 28 times if her mother had this disease and sisters have an increased risk 40 times as great as other women. The FDA advisory committee gave no indication that the use of the pill would increase the possibility of any woman developing breast malignancy. Although press releases suggested that women with a strong family history of the disease should not use the pill, the authors of the quoted report stated in the