We have a system, of course, which is complete for reporting mortality, the number of deaths. But that system is a very weak instrument for detecting small changes or even larger ones from some of the causes that have been studied.

Mr. DUFFY. Dr. Seigel, I suppose I should ask you this question rather than Dr. Corfman. Earlier I had asked Dr. Kistner when he made the statement that in order to have a reasonable possibility of detecting a two-fold increase in breast cancer, it would be necessary to have a prospective study involving 20,000 people.

Dr. SEIGEL. I missed the first, in order to detect the what?

Mr. DUFFY. In order to have a reasonable possibility of detecting a twofold increase in breast cancer you would require a prospective study involving 20,000 people.

I asked him at that time with reference to a reasonable possibility of detecting, does that mean there is also a possibility that you would not detect it, and he said that I had better ask you.

Now, how many people would you need in a study to assure that you would detect a twofold increase in breast cancer or any other of the side effects and complications that we speak about here?

Dr. SEIGEL. The point is discussed in a paper which Dr. Corfman and I wrote in 1968, and which was published in the Journal of the American Medical Association. We addressed ourselves to the question of what sample sizes are required to deal with some of these issues. If one were to launch a prospective study to detect a doubling of the risk of breast cancer, one would need something on the order of 85,000 person-years. This would be a minimal study. By person-years I mean you could either study one group of 85,000 women for 1 year or 10,000 women for 8 years.

But the point is that you would need enormous samples, and I do not think anyone really thinks that this is an easy way to do it.

For such diseases, the principal information has come from the opposite approach—by collecting cases of breast cancer and controls and determining contraceptive histories. This occurred in the smoking and lung cancer field where such studies were used very profitably. I think they are important here as well.

Mr. DUFFY. Mr. Chairman, do you think it would be beneficial to have that paper in the record?

Senator NELSON. Yes.

Mr. DUFFY. Would you submit that for the record?

Dr. SEIGEL. Yes.

(The document referred to follows:)