

Senator NELSON. With the present system of reporting how would you know it occurred?

Dr. SEIGEL. Well, deaths are reported through the vital statistics systems, and you would be immediately sensitive to this in the trends in overall mortality—

Senator NELSON. Do the vital statistics that are filed indicate that a person who dies was taking the pill?

Dr. SEIGEL. No; but it would not be necessary. I think a 20-percent increase in mortality in women would be a very striking phenomena. In recent years there has been very little change in mortality in these age groups and, if anything, it has been going down.

Senator NELSON. I just wonder how you get these statistics if the death rate from thromboembolism was—I have forgotten what you said, but the incidence, I guess, is reportedly around three in 100,000 as the British say, and then out of that you upped the percentage of deaths with women taking the pill over those who do not take the pill by double, which might be 1 percent or whatever, and with the reporting system you have got, how would you know it occurred?

Dr. SEIGEL. Mr. Nelson, I think Mr. Gordon's question was with respect to mortality from all causes. Now, I would certainly agree with you that minor changes in mortality from specific causes would be very difficult to detect.

Senator NELSON. That is what I am getting at. If the death rate was, you know, one per 100,000 for a particular reason, and then in those who take the pill it became two in 100,000, we do not have any statistical compilation that would permit you to detect a difference between the one and the two, do we?

Dr. SEIGEL. It would depend on the diagnosis, and if it were a diagnostic area that is "sloppy," one in which it is easy for physicians to move back and forth between possible diagnoses. But the relative risk in the thromboembolic disorders was estimated by the British to be something like eight or nine. We have had no studies of deaths in this country from thromboembolic disorders. Dr. Sartwell's study was of cases, hospital admissions.

Now, with an increase on the order of eight times, I think it is possible to look at the statistics. One would expect an increase in mortality from those causes in U.S. mortality statistics, and indeed, there are changes in U.S. mortality from thromboembolic disorders that are consistent with the British data.

Senator NELSON. But every time the issue has been discussed here concerning the increased incidence of this disorder or that disorder, they always end up by saying, "but the statistical sample is so small that there is room for error, and we can only make sort of an educated guess."

If you had all the statistics on everybody for all causes, taking the pill or not taking the pill, I can see how statistically you can do it. I am just concerned with the fact that the reporting of these side effects and their effect on the cause of death may not be related to the pill at all.

Dr. SEIGEL. I am in full agreement with you, Senator, especially in the area of morbidity as opposed to mortality, because we do not have adequate systems of reporting hospital admissions and other types of morbidity.