

had been reported to the department by the end of 1969? Do you happen to have that information?

Dr. EDWARDS. I would like to refer that question to Dr. Jennings, or a member of his staff.

Senator NELSON. On both deaths and morbidity.

Dr. JENNINGS. We have been compiling these on an annual basis for the past couple of years, and as of December 31, 1969, the total number of reported reactions for that period, July 1, to December 31, 1969, included 15 deaths and 28 nonfatal thromboembolic cases.

Senator NELSON. Over what period of time?

Dr. EDWARDS. From July to December. Is that not correct?

Dr. JENNINGS. That is right. That was for that particular year.

Senator NELSON. How many deaths?

Dr. EDWARDS. Fifteen.

Senator NELSON. And what was the other, thromboembolic?

Dr. JENNINGS. Yes, nonfatal thromboembolic, 28, with about six other miscellaneous adverse reactions.

Mr. DUFFY. Doctor, so I can understand these figures now, are these figures that are actually documented? In other words, it is clear that these are pill-related or are these just incidents which have occurred in people who have used the pill? You may or may not know.

Dr. JENNINGS. Deaths and the nonfatal. In fact, all of these adverse reactions are ones that we attribute to the use of the drug.

Mr. DUFFY. I would assume, then, that if you just looked at the gross number of deaths from thromboembolic accidents of women using the pill, there would be a larger number than 15?

Dr. JENNINGS. Yes, I am sure there would.

Mr. DUFFY. And you narrowed this down to instances where you could be sure it was pill-related?

Dr. JENNINGS. In attempting to establish a cause and effect relationship in any adverse reaction to a drug, where the adverse reaction is one that occurs for other reasons, but the linking of the two is extremely difficult. I think that we cannot always say with absolute certainty that a cause and effect relationship exists.

Now, therefore, even in our labeling, the retrospective studies, for instance, that were done, can establish only that; that they do not establish the precise cause and effect relationship.

We have here the tabulation that we do on these, and although I do not have handy the figure that I think the Senator was asking for, the total that we have to date, we can tabulate this fairly rapidly for you, if you want us to do that.

Senator NELSON. Do you want to submit it for the record?

Dr. JENNINGS. Yes, sir.¹

Senator NELSON. I was getting at another aspect of this. We have had witnesses over the past 3 years, distinguished physicians, who deplored the state of reporting on various diseases as being wholly inadequate. By coincidence, last week we had an internist before the committee, who talked about the forms he had to fill out and that he used to religiously report but never got any playback from FDA—this was several years ago—and finally he stopped reporting entirely.

¹ See p. 682.