

Dr. KASSOUF. Yes, sir.

Mr. DUFFY. Do you agree with the reason that Dr. Carr gave as to why the British were in a superior position to this country in terms of researching this question?

Dr. KASSOUF. I did not hear everything you said.

Mr. DUFFY. Do you agree with Dr. Carr's reasons why the British are in a superior position to us in terms of researching the question?

Dr. KASSOUF. I do not know. If you can briefly restate them, I do not recall that part of his testimony.

Mr. DUFFY. I recall that Dr. Carr said that one of the reasons was that Britain has a highly socialized medicine system with everybody having a number, et cetera, and this afforded a much better record-keeping mechanism.

Dr. KASSOUF. I disagree with Dr. Carr on the British studies and on the reporting. I disagree totally with Dr. Carr.

On the death studies done by Vessey and Inman, it was found only 15 percent of the deaths were voluntarily reported. That is probably in the range of the kind of reporting we have in this country. I do not see there is any reason to think that the British are in a better position to study this problem.

Mr. GORDON. Doctor, may I ask a question here. You mentioned the Puerto Rican study and, as I understand it, the approval of the New Drug Application for these pills, at least the first pill, was based on this Puerto Rican study, to a large extent.

Now, in the early Puerto Rican field trials, do you know how many women were involved prior to the release of the oral contraceptives for marketing, and can you tell us anything more about these trials?

Dr. KASSOUF. The total series, I do not know. The one I am referring to, the 4-year study, had a total of approximately 850 patients.

Mr. GORDON. Can you tell us more about the study? Did those who start go all the way through? Were there dropouts? What kind of care did they use in following it up?

Dr. KASSOUF. I will tell you some of the things that concerned me about the study, it will be brief, but it will give you an idea of the kind of research that was being done on the pill in those days.

One hundred fifteen patients out of 850 dropped out. Now, there is always a dropout rate, but with a new drug it becomes especially important what happens to them.

Secondly, 12 pregnant women were admitted into this series for preventing pregnancy. They were already pregnant, and started on the pill. This raises some question as to the thoroughness and how carefully supervised this was. The G. D. Searle Co. later said this was a carefully supervised study. This, certainly, casts doubt upon their statement that it was carefully supervised.

Finally, I think you should know that the conclusion to that article, the one with the five deaths, stated there was no evidence of damage from prolonged use of the compound had been detected. They had three deaths, that were dead, buried; with one signed out as "cause unknown," and two possible heart attacks. They were not seen by a physician before or after their deaths.

Histories were obtained from families, and these were very presumptive diagnoses. I do not know what they died from. I am only saying