

I think it raises a question. I am sure Dr. Guttmacher, if he felt in 1965 he had solid evidence that the pill was not related to thromboembolism, Dr. Guttmacher, who has an excellent reputation, would have published it. Thrombophlebitis has been an issue since 1961, and 1962. But it has never been published in the journals, so far as I know.¹

So why was it used in the Drill-Calhoun report? I can only raise the question.

Mr. DUFFY. Maybe that is the reason the FDA felt that the evidence presented by Drill-Calhoun was inadequate, which is all the quote says.

Dr. KASSOUF. The study is inadequate, not because it is unpublished, but for other reasons and we do not have time to go into these statistics. Dr. Guttmacher, there is no better authority on the study than the author, states it is inadequate to deal with the question of thrombophlebitis. This study was not designed to provide a comparative incidence of thrombophlebitis. But the average physician who has a lot of trouble keeping up with the literature certainly could not go back to that unpublished study. I had trouble getting it.

So the point is, in 1968 the average American physician had good reason to believe, there was no link between the pill and phlebitis. This is in spite of two prior, British reports.

Senator McINTYRE. Doctor, I take it you have more than one copy of the so-called Puerto Rico report?

Dr. KASSOUF. Of the original study. I have it here and you may have it.

Senator McINTYRE. Would you like to submit that for the record?

Dr. KASSOUF. Yes, certainly.

Senator McINTYRE. Without objection, it will be included in the record.²

Dr. KASSOUF. The AMA has a puzzling record in regard to the pill. In 1962 a professor of ophthalmology submitted a case report involving stroke. The AMA refused to publish it because of certain controversies. The paper was finally submitted to the FDA, and the FDA was unwilling—

Mr. DUFFY. Are you aware of what these controversies are?

Dr. KASSOUF. No. FDA was not willing to give me the information.

Mr. DUFFY. You say there were certain controversies but you do not know what they were.

Dr. KASSOUF. Between the author and AMA.

Mr. DUFFY. Do you have reason to suspect that these controversies may have actually touched on the merits of the article or whether the articles submitted to be published were worthy of publication?

Dr. KASSOUF. Well, I don't know.

Mr. DUFFY. Yes or no. You don't know the controversy?

Dr. KASSOUF. I do not know the details of the controversy. This is the total information I have at the time I testified to Senator Gruening.

Mr. DUFFY. For all we know, these controversies could have involved the payment of a fee and may have had nothing to do with the scientific validity of the report; isn't that correct?

¹ The news release entitled "Mass Oral Contraceptive Study Findings Released," appears in Oral Contraceptives—Volume Three—Appendixes.

² See p. 6127.