

Drill and Calhoun have structured their report on a study whose authors, in effect, say, Don't use this for an evaluation of thrombophlebitis. The reader should have been forewarned. The physician who depended on the Drill-Calhoun report and simultaneous AMA editorial would not be aware of this fundamental discrepancy. To be aware, he would have had to search for the unpublished study or read the FDA report.

Mr. GORDON. Doctor, may I interrupt for a moment. Let me read from the FDA report on this study. This is on page 29 :

It is our opinion that the evidence presented by Drill and Calhoun which constitutes the main negative evidence published to date is inadequate to show that the incidence of thromboembolism is either unaffected or reduced by oral contraceptives.

Now, what, in your opinion, has been the effect of this Drill-Calhoun report, who were, as you say, employees of a pharmaceutical firm?

Dr. KASSOUF. I think you must go back to that point in time in September 1968. A physician, if he read the British journals, was told in 1967 and 1968 that the pill does kill. It does cause pulmonary embolism. However, that was neutralized by the explanatory statement—mentioned before—by FDA that it might not be applicable to us.

So, therefore, the average American physician, as late as 1968, could, with assurance, tell his patient, if he was unaware of the British work, that the pill is absolutely safe. This would be a disservice to his patient, and is not consistent with the majority of opinion today.

I think the physicians deserve better than this report as the lead article in the AMA. This journal carries much of the advertising. The AMA editorial made no criticism of this Drill-Calhoun paper which would advise the reader as to what the weight of the evidence was. Was the British work more substantial or was it not. They merely pointed out there seems to be a difference of opinion.

Mr. DUFFY. Doctor, does this quote say that the Drill-Calhoun study is wrong? I have read it three or four times.

Dr. KASSOUF. No—

Mr. DUFFY. It says it is inadequate.

Dr. KASSOUF. To prove their conclusion.

Mr. DUFFY. It does not say it is wrong. It just leaves the question unanswered because the study is inadequate.

Dr. KASSOUF. I think in one sense it is wrong in that they drew a conclusion from these statistics, and FDA is saying very clearly that the statistics they used are inadequate to justify their conclusions. I do not know what you call that, but it's not consistent with the data they used.

The conclusion is not consistent with their own data. What I am saying is the American physician deserves a little better treatment than to have this Puerto Rican data presented to them now which was not presented to them in 1962, to have an unpublished study presented to them. In fact, I am a pill watcher, but I never went back to track down the unpublished report. I agree wholeheartedly it is not actually a report. I found it with some difficulty. It is a press release. I think I have it here.

This is the unpublished study, and it is labeled a news release by Planned Parenthood World Population. It is not a formal article, and