

Dr. KASSOUF. That is unlikely, but if it were printed we would have been alerted to this problem in this country a lot sooner than we were.

Stroke problems originated in Great Britain. So I think someone might look into the problem of why the AMA did not publish this. I think it would be very important. We seem to follow the British by 2, 3, and 4 years in finding out about side effects.

FDA is unwilling to reveal any other details. In March 1963 the AMA Council of Drugs reviewed Enovid. It omitted mention of thromboembolism under precaution, and the drug was under precaution at that time. Since the Drill-Calhoun paper represents a major policy statement by the manufacturer one would perhaps expect extraordinary standards by the AMA in regard to excellence, reliability, and full disclosure.

This brings up the question of the now well-known report by Dr. H. Dubrow and Dr. M. Melamed, entitled, "Prevalence rates of uterine cervical carcinoma in situ for women using the diaphragm or contraceptive oral steroids." According to the Medical Tribune, this paper was refused publication by the AMA except by the condition of extensive revision and editorial criticism. After many months the authors withdrew the paper and submitted it to the British Medical Journal where it was quickly published. The fact the British published it speaks for its viability. The fact Dr. Roy Hertz discussed the paper in the FDA report adds evidence to its importance.

I believe it is evident that for a physician to be reasonably well informed he will have to read other American journals, unpublished studies, and FDA reports. All this would not be enough unless he read the British journals. In the end it is the patient who takes the risk. The last bit of information she is apt to receive from the doctor's office or clinic is in the form of pamphlets produced by the contraceptive manufacturer. The samples I brought are all in circulation. None have ever been recalled by the manufacturer or FDA.

A few excerpts will illustrate the problems. A 1967 pamphlet by Ortho-Pharmaceutical is entitled, "A Woman's Guide to the Methods of Postponing or Preventing Pregnancy."

Mr. GORDON. Do you have it there? Could you hold it up?

Dr. KASSOUF. Yes. Here it is. It discusses the IUD and the pill. The introduction states:

The first consideration obviously is safety. The ideal method of preventing pregnancy must be one that is harmless to use. None of the methods mentioned in this book is harmful to a woman in normal health.

This is untruthful and dangerous advice.

Another, entitled, "Planning Your Family," copyright 1966, by G. D. Searle & Co., responds to a question concerning long-term safety of the pill. In part, it answers:

There is no evidence that Ovulen interferes with nature to any extent greater than repeated pregnancies * * *

It concludes the answer with:

The effects of birth control pills have been studied, possibly, more thoroughly and for a longer continuous time in the same persons and in more women than any other drug. Evidence of their safety and effectiveness has been continuously confirmed.