"the wisdom of administering such compounds to healthy women for many years must be seriously questioned." The editorial took into consideration the clotting risk, the cancer possibility, and the metabolic derangements that now number near 50.

The waters were further muddied in 1968 when FDA required new pill warnings. The British results were carried in detail. However, the reader was then advised that the British data, particularly as to the magnitude of the increased risk, cannot be applied directly to women in other countries. This advisory had the effect of neutralizing the British data. This advisory has raised questions because there was no prior precedent in regard to drug-vascular complications. In addition, favorable data from outside the continental United States, and that includes Great Britain and Puerto Rico, has been used without qualification. Perhaps most unexplainable is the fact that the United States is now partially financing pill studies in Great Britain and Yugoslavia.

It is apparent that physician and patients are being told very different things from various authoritative sources. G. D. Searle & Company is the only manufacturer to come forth with such a survey paper attempting to specify risk in the United States. However, by denying the risk in 1968 and 1969 they have left the ranks of majority opinion and essentially stand alone. The responsibility is awesome as some healthy young women who have no need or desire to assume a death risk have been reassured and encouraged.

Mr. GORDON. Dr. Kassouf, two questions.

Up on the top of the page you say: "In addition, favorable data from outside the continental United States has been used without qualification."

What other drugs have you been referring to here?

Dr. KASSOUF. Well, one that comes to mind is the drug Parnate. It was discovered in Great Britain. This drug could cause stroke in some people—immediately the warning was recognized there, and warnings were placed here, and no qualification was stated that it might not apply to U.S. citizens. Aside from that particular one, I know of no other precedents. I do not recall that we treat British data differently in other instances as we have in the case of the pill.

Mr. GORDON. What you are referring to, then, is the statement in the labeling that said British data indicating the magnitude of the increased risk to the individual patient cannot be directly applied to women in other countries in which the incidences of spontaneously encouraged thromboembolic disease may be different. That is what you are referring to?

Dr. KASSOUF. This has troubled many physicians. The implication of that is, the incidence of complications would be less in the United States.

Mr. GORDON. Let me ask you this——

Dr. KASSOUF. Let me complete that. The fact was it could be greater, but this does not imply that. It leaves the physician to believe, perhaps, it does not apply to U.S. subjects at all. It implies we are different from the British, and there may be no risk here, but we did not know that.