Winter of G. D. Searle. I quote part of his comment that he submitted to Senator Gruening that is referable to these fatalities:

The testimony of August 7 made much of certain fatalities occurring in Puerto Rico.

In the first place, these fatalities, from whatever cause, would have absolutely no bearing on a statistical evaluation of differences in fatality rates in the continental United States. Therefore, it is difficult to see why this point was raised in the context of the testimony. There was no reason to include these fatalities in any event, since there is nothing to suggest that these patients died of pulmonary embolism, except that their deaths were sudden and not subject to autopsy.

I would like the privilege of reading this again for the benefit of physicians who may be hearing this testimony.

There is nothing to suggest that these patients died of pulmonary embolism, except that their deaths were sudden and not subject to autopsy. If such fatalities are to be included as pulmonary embolism, one must then include all sudden deaths, which are not autopsied, as being fatal pulmonary embolism in the National Vital Statistics in the continental United States. Such a procedure would create a statistical nightmare, and would raise the "normal" incidence figure arrived at by the Wright Committee by a factor of many times.

However, when these Puerto Rican fatalities were brought to our attention as possibly deserving further investigation, they were investigated by us, as well as by the Food and Drug Administration. William C. Stewart, M.D., of G. D. Searle & Co., made a personal investigation in Puerto Rico in December 1962 and a report of that investigation was forwarded to the Food and Drug Administration on December 7, 1962. Subsequently, we also received a report from the Departmento de Salud, in Puerto Rico, covering these fatalities which was in turn forwarded to the Food and Drug Administration on March 15, 1963. The report was in Spanish; the original report and an English translation from exhibit J herein. It will be seen that the report gives no basis to suspect Enovid as being causal in these fatalities, which would seem to dispose of the matter.

I, too, would dispose of the matter except there are fundamental issues in contention in regard to research data and its management.

First, there were five deaths, the three sudden, one subarachnoid hemorrhage and one suicide. Five such deaths in a research series of 850 is high. All five deaths are, in fact, reasonable suspects for a pill link.

Mr. DUFFY. Doctor, if I may just interrupt, would you explain to me how you would interpret the suicide death being attributable to the pill?

Dr. KASSOUF. I would like to point out in the original article that was published—and I think this is interesting—that death was reported as death due to burns and, of course, that escaped my attention. It was not until I got to the report from the FDA that it was classified as a suicide.

If the pill causes depression, suicide becomes very relevant, and in 1959 and 1960 I think any death had to be considered as such a possibility.

I certainly do not think a suicide can be disregarded on new medication since hormones are known to upset the psyche and sometimes give depression in premenstrual tension, so I think it was misreported or not completely reported in the article that appeared in the Journal of the American Medical Women's Association.

Mr. DUFFY. You say, "I think." Is this speculation on your part, then, that such a death was caused by using the pill?

Dr. KASSOUF. Are you asking me whether I said that suicide was due to the pill? I do not think anyone can answer that. I do not know