Mr. GORDON. You feel it mitigates the warning?

Dr. KASSOUF. It completely neutralizes the warning so far as I am concerned.

Mr. GORDON. Well, when they used the Puerto Rican experiments to show safety——

Dr. KASSOUF. This is exactly my objection. There were no qualifications in regard to the Puerto Rican studies, which are inadequate, I think, to demonstrate safety anyway. We will be going into that. And why we continue to finance studies there if we are not going to accept the results is something I cannot explain.

There are some areas worth looking at more closely. In September 1962, G. D. Searle & Co. sponsored a conference of 29 experts. It was based on data in Searle's files, Canadian control statistics, data which participants recalled, and data submitted by physicians in response to the August 7, 1962 "caution letter." This conference has been criticized by many. The participants dealt with 10 deaths, five of which were in G. D. Searle's files prior to the "caution letter."

The short span between the "caution letter" and the conference guaranteed underreporting. One analyst was troubled by the 10 deaths as it seemed to him on the edge of significance. Although Canadian control statistics were used, deaths other than continental United States were excluded. The participants went on to vote 27 to 1 that the available data did not reveal a risk.

They reached their decision not knowing:

1. That in the next several months FDA would receive reports of some 15 additional deaths that had occurred before September 10, 1962.
2. Puerto Rican research subjects had died suddenly with chest pain and were not attended and were not autopsied.
3. Suspicious details concerning some cases of phlebitis were omitted by G. D. Searle & Co. My reference for this last statement is the book, "Pregnant or Dead," by Dr. Harold Williams.

It is not known, of course, whether such data would have altered the decision. The conclusion reached at the conference was reassuring. Envoid cleared again according to the AMA. Word quickly spread over wire services and news media. This conclusion undoubtedly lulled the scientific community and made some users out of the doubters. The one negative vote remains as a lesson, for there are almost single voices making the same vote about the issues today.

One area deserves further attention in deciding whether the physicians, the panelists or even the public were the recipients of full disclosure. I stated deaths in an experimental series were withheld. In November 1962, I learned of two Puerto Rican deaths in the experimental series and reported this to FDA.

To my surprise, FDA had no record of these deaths and on investigation found there were three—all sudden and none autopsied. It is believed two had chest pains. FDA will not release further details and an inquiry by me in 1963 to one of the authors of this series remains unanswered. In August 1963, at an informal hearing with FDA and Senator Gruening, I made certain complaints in regard to these Puerto Rican research deaths. My complaints brought a rebuttal from Dr.