Senator McINTYRE. Excuse me for interrupting.

Dr. WILLIAMS. Certainly. Thank you.

Obsolescence of statements in advertising, amounting to untruthful misrepresentation, has occurred from time to time, as newer knowledge superseded older. Such were not restricted to the early days of aggressiveness, however, an outstanding example of this practice appeared in the past year. This was at a time when past events and warnings should have made everyone, everyone on the side of promotion, more vigilant than ever to be promptly forthright with physicians and their patients. This relates to the British statistical data, first published in 1967 as preliminary findings on thromboembolism then in 1968 as firm conclusions, about the increased risk of thromboembolism in pill users.

In May 1968 that data was added to the labeling on the pill, all brands, as an emergency measure by the FDA. However, the manufacturers successfully persuaded the FDA to allow a neutralizer in the material.

This has been mentioned before by other witnesses, but I think it deserves some emphasis in this analysis. The impact of the British data was in fact negated, in the minds of many American physicians, by this language:

No comparable studies are yet available in the United States. The British data, especially as they indicate the magnitude of the increased risk to the individual patient, can not be applied directly to women in other countries in which the incidences of spontaneously occurring thromboembolic disease may differ.

Mr. DUFFY. Excuse me, Doctor. Before you leave that statement I would just like to understand something. It was my understanding that Dr. Hellman testified earlier that there is a very strong possibility that the rates of thromboembolism may differ widely between the United States and Great Britain and, in fact, may differ widely among countries and locations. At least, that is what I got from his statement.

How do you justify your previous statement with that of Dr. Hellman?

Dr. WILLIAMS. I cannot justify a lot of things Dr. Hellman says, Mr. Duffy. This has been a matter of concern for many years. If there is a difference, we ought to know it. And they are not to keep relying "may be different." If it is different, let us find out about it. I do not think anything is being done to find out for sure what the incidences are.

Mr. DUFFY. Do you feel that the type of study which is necessary to accomplish this world figure of incidence is an easy thing to do?

Dr. WILLIAMS. No, but because it is not easy does not mean it should not have been done years ago. There are many difficult things in this field, but that is no excuse for delaying them.

In November 1968, Drs. Markush and Siegal of NIH disclosed that their study of mortality data "indicate an association of oral contraceptives with an increase in mortality from diseases of the veins * * *" Although that study was not comparable in technique, it was certainly comparable in conclusion—it did indeed exist. It seems to me it may