Very, very little research and development money has been allocated to developing safer local alternatives.

There have been studies of motivation and studies of almost anything you can imagine but very little research money put into the development and the application of safer alternatives to the systemic approach to contraception.

Senator NELSON. How good is our method right now of collecting the statistics, for example, of side effects as a consequence of the use of contraceptives of any kind, including the pill? Or to add to it, if I may, in the clinics in Maryland and those you are familiar with when a side effect of some kind or another that is considered to be of consequence enough to note, what do you do with it, what do you do with the statistic?

Dr. DAVIS. I think in general there has been an undereporting, at least that has been the impression of the FDA Committee.

Most of the data we have are from relatively limited studies. There are some larger studies underway now which have been initiated by the Food and Drug Administration, for example, on abnormal Pap smears in relation to the oral contraceptives. In general, however, we really do not accurately know how many women are on the pill, and we know even less, there is even less accurate reporting, about many of these complications.

The British were in a much better position because of the reporting of the National Health Service. This enabled them to answer the question of thromboembolism before we could, because they could identify who had been admitted, who had not been admitted, who had lived on the pill and who had died.

Senator NELSON. Senator McIntyre.

Senator MCINTYRE. Thank you, Mr. Chairman.

Dr. Davis, at the beginning of your statement you said it is medically unsound to administer such powerful synthetic hormones, as the pill, in order to achive birth control objectives which can be reached by simple means of greater safety.

You also say that this view was expressed by prominent experts prior to the approval of the pill for contraception some 10 years ago.

Could you tell this committee who some of these experts were and where and to whom this opinion was expressed?

Dr. DAVIS. Certainly.

If you look in the 1958 Survey of Obstetrics and Gynecology, which I can certainly supply you with, you will find that exact statement almost verbatim with respect to the experience with a few hundred women in Puerto Rico commencing in 1956.

At the time this statement was made, the drugs in question or the drug in question, was being used in the United States for the treatment of such conditions as endometriosis and for the treatment of menstrual disorders, and so that this statement very specifically attempted to discriminate between the use of the drug for gynecologic disorders, and the projected general use of it on a chronic basis for contraception. That particular statement was made by Dr. Georgianna Seegar Jones, who is the author of several text books in gynecologic endocrinology.

Senator MCINTYRE. Do you know whether or not, Doctor, these opinions were expressed to the Food and Drug Administration?

Dr. DAVIS. They were expressed? I do not know. I was not privy to their considerations at the time the decisions were made.