their own peculiar endocrinologic condition. But as a matter of policy and recommendation, I think that at the present time the FDA should seriously consider removing these high dose preparations from the market for general contraceptive use while retaining them for the treatment of disease.

Senator McIntyre. That would be your recommendation?

Dr. Davis. Yes, sir.

Senator McIntyre. Lastly, Doctor, does the fact that many of the dangers of the pill which you have described here this morning are just now coming to light, some 10 years after they were approved for the market, indicate to you that they were not properly tested before they were allowed to market?

Dr. Davis. Well, I am not Solomon, but I think there are many things that we would not do today that were being done in 1959 and 1960. The experience with a few hundred women in Puerto Rico prior to the approval of the pill, was certainly very limited.

On the other hand, the world population problem was enormus at that point in time, and I think that the judgment on the release and marketing of the pill was probably accelerated or pushed because of this factor. At the time, it did not appear that we had other means of dealing with the problem, and those who approved the pill were perhaps not thinking about the long range problems that have since turned up. I don't think today you could possibly market a pill, a new drug, with as little testing as had been carried out at that point in 1958, 1959, 1960.

Senator McIntyre. Thank you, Dr. Davis, for your very helpful and excellent statement and answers to questions.

Senator Nelson. I just had one more question, Doctor.

You contrasted the birth control devices, separated them into systemic, such as the pill or localized, such as several other items. Do I understand you to say that those birth control devices such as the IUD or the diaphragm, whatever side effects they have are localized as contrasted with systemics?

Dr. Davis. That is substantially correct.

Senator Nelson. What is the incidence of rejection on the new IUD that you are experimenting with on the 300 women, as I understand it, and what is the known incidence of side effects of a localized nature and their character and danger from the IUD?

Dr. Davis. Several devices can be retained by as much as 90 to 95 percent of women without significant bleeding complications or side effects at the present time. There are other devices which produce significant cramping and bleeding and complaints in as much as 30 to 40 percent of women, so it is a matter of choice of techniques, and the technique has improved during the past 5 years.

The dangers related to condom, foam, jelly, diaphragm, this sort of local contraceptive approach, for practical purposes, are an occasional mild alergic reaction to one of the creams or jellies, this sort of thing, and no really serious complications other than failures from a motivational point of view.

The dangers of the use of an intrauterine device are presented in the January 1968 report of the Food and Drug Administration. The late Dr. Roger Scott surveyed over 8,000 obstetricians and gynecologists in the United States, and the Armed Forces and in Puerto Rico