

Now my final remarks really amount to this. Where do I stand in relation to this medication.

It gives me no pleasure to give such an account on this subject. I derive no satisfaction from having to give a detailed description of events which we all would prefer not to be occurring in women, but it is my duty to do so.

The metabolic changes are there. It is necessary that those with responsibility examine the health of women in such a way that they can detect in good time whether these changes are deleterious or not, and if so what is the order of magnitude of the risks, but there is no time to be lost. Far too much time has already gone by without these relevant studies having been carried out.

I have read today of the decision of the Food and Drug Administration to have regular meetings every 4 to 6 weeks, according to the report in the Washington Post, and I am very well satisfied with that report.

I think you must review the position and review it in detail, and keep it constantly under review, but on no account can we overlook this sort of data.

Thank you.

Senator NELSON. Thank you, Doctor.

(The complete prepared statement and supplemental information submitted by Dr. Wynn follows:)

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METABOLIC EFFECTS OF ORAL CONTRACEPTIVE STEROIDS

Mr. Chairman and Members of the Committee, oral contraception as we know it today, may be said to have begun in April 1956 when Dr. Edris Rice-Wray, in collaboration with Dr. Gregory Pincus and others began the large-scale administration of the drug Enovid to healthy women in the fertile age group, residents of the town of San Juan in the island of Puerto Rico. Enovid is still a widely used oral contraceptive, although the strength of the two steroids used, mestranol and norethinyodrel have been substantially decreased in the more modern formulations. The technical efficiency of oral contraceptive medication is not in doubt. What is uncertain is the effect of the medication on the health of the user, especially if the drugs are consumed for several years. I propose to submit to you evidence of the wide ranging changes in the chemistry of the body which oral contraceptives produce. These changes are referred to as metabolic effects and they were largely unknown when the drugs were first introduced. In his book, "The Control of Fertility" * Dr. Pincus, who may rightly be considered the originator of oral contraception, deals only cursorily with the metabolic effects of the medication. This is not surprising, because although the book was published in 1965, up until that time, very few metabolic studies had been published and some of the original observations were either inconclusive or contradictory. Even now, 14 years after the introduction of oral contraception, opinion is divided as to exactly what are the metabolic effects of this medication and more particularly what are the implications so far as the women's health is concerned.

Before describing the metabolic effects of oral contraceptives, I would like to go back to the period of the 1950s to discuss another but related topic, because it gives insight into what may be considered to be the undesirable effects of the contraceptive drugs, and it gives me an opportunity of explaining how my research in this field originated and how I have come to those conclusions which I shall shortly put before you.

*The Control of Fertility, by Gregory Pincus, 1965, Academic Press, New York and London.