

Senator NELSON. Thank you very much, gentlemen. We appreciate your taking the time. I am sorry your testimony was interrupted. It was more entertaining than your testimony, but not more effective, nor more valuable.

Our next witness is Dr. Spellacy. Dr. Spellacy is from the University of Miami Medical School.

Would you just—you did not submit any biographical data. Would you just want to briefly recite your medical background?

STATEMENT OF DR. WILLIAM N. SPELLACY, ASSOCIATE PROFESSOR, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE

Dr. SPELLACY. Mr. Chairman, I am an associate professor in the department of obstetrics and gynecology at the University of Miami Medical School, Miami, Fla.¹

I have been asked to review the oral contraceptives and their metabolic effects on the liver, lipids, and carbohydrates, but before reviewing these areas, let me point out the difficulties and dangers in any generalizations that I may make.

It would appear that investigation of these problems would be easy. Careful thought, however, will show that this is not true. The medical literature on the oral contraceptives is expanding at a fantastic rate. However, this does not mean that all of the experimental and clinical data can be related into a central theme. Quite the opposite. Since there are so many synthetic estrogens and progestins used in oral contraceptives, and since the dosage of each is likely to vary considerably in each commercial product, and since the duration of treatment also seems to be important as well as the characteristics of the subject taking the drug, the task of interpreting the literature is enormous. In addition, many reports do not deal with information on a pure drug-dosage-duration group, but rather upon a group of heterogenous subjects taking a variety of drugs for varying lengths of time. As a consequence, these results are virtually uninterpretable. Cross-sectional studies, where women are investigated only while taking the drugs, do not guarantee that any changes noted were not existing prior to beginning the oral contraceptives. Isolated case reports of complications may point out areas of concern to receive special study, but they do not reveal incidence figures because the size of the total treated group is unknown. Finally where animal experimental data exists, its application and relevance to humans is not always known. As a consequence, a review of this large experimental literature does not answer all of our questions, and perhaps it raises more problems than it resolves.

To find these answers will require large in-depth prospective studies of each organ system for all synthetic steroids at many dosages and drug combinations carried out for many years in a variety of different environments on many types of people. This is not practical. With this ideal in mind I will attempt then to review the existing medical knowledge in each of these three areas and to show any interrelationships and central themes that may exist.

¹ The complete prepared statement and supplemental information submitted by Dr. Spellacy begins at p. 6439.