

Senator NELSON. Does it raise—in your opinion—raise a serious question?

Dr. SPELLACY. Yes.

Senator NELSON. Go ahead.

Dr. SPELLACY. The medical importance of these blood lipid alterations fall into two areas. First, for the patient with an abnormal blood lipid pattern, the oral contraceptive may make her even more abnormal. I think this general theme will recur in all three of these metabolic areas, that is we are dealing with two populations, a normal and an abnormal, and it is generally the abnormal woman who becomes more abnormal soon after beginning to take these drugs and it is only a speculation as to what will happen to the perfectly normal individual with prolonged drug usage.

Zorrilla and associates have reported two women whose blood lipids were elevated before receiving an oral contraceptive and who then developed extremely high and dangerous levels of blood lipids. de Gennes and colleagues have also reported a patient who had a congenitally high blood lipid pattern and who then developed higher blood lipid levels and a stroke while receiving an oral contraceptive. It is important for the physician to know his drugs and his patients before combining them. An interesting observation has recently been reported by Glueck and associates from the NIH. They treated a group of patients with these abnormal blood lipids which were corrected by giving progestin alone. The different responses between premenopausal and postmenopausal women, between estrogens and progestins, and between normal and abnormal women, must all be considered in any study.

The second concern is for those women who are normal before receiving the oral contraceptive. This area again is only open to speculation as no definite scientific data are available to draw upon. Theoretically, if coronary artery and vascular disease is found in association with elevated blood cholesterol and triglyceride levels, then the production of higher blood cholesterol and triglyceride levels in normal women by use of an oral contraceptive may produce or predispose to vascular disease. Although several investigating groups have warned of this problem, it has not been documented to occur. A note of caution should be raised, however, in that if a requirement of time is necessary before any permanent structural alteration is manifest, for example 10 to 20 years of "hyperlipidemia" then these clinical diseases should not be seen to date.

Finally we can look at the carbohydrates. It was not until 1963 that the first suggestion appeared in the literature that carbohydrates were altered in ladies taking oral contraceptives. Since that report, there have been more than 33 published articles, dealing with carbohydrate metabolism in more than 1,633 women using the oral contraceptive for periods ranging from 19 days to more than 8 years. Although an attempt will be made to summarize these data, the same problems are encountered, that is, the reports include many different drugs, dosages, durations of treatments and types of tests and women. Nevertheless, certain information is available and some generalizations can be made.

In prospective studies where the women are tested before taking the drugs and then serially thereafter, the development of elevated blood