

crease was roughly that observed in similar British studies. These studies and others, such as the important work of Dr. Sartwell, permit us to estimate that the number of thromboembolic deaths in the United States in 1969 due to oral contraceptives was about 240.

We also have interest in the metabolic effects of oral contraceptives. Such problems are being examined in the Kaiser-Permanente study that I mentioned. We also support the studies of Prof. Victor Wynn and his associates at St. Mary's Hospital in London. Dr. Wynn's group is one source of information on the effects of these agents on carbohydrate and lipid metabolism. Another source is the work of Dr. Spelacy, who is testifying today. His work is supported by the Food and Drug Administration. Such data have appeared in the medical literature and were discussed in considerable detail at a recent meeting at the National Institutes of Health.

One area of concern which has not yet been adequately examined is the effect of oral contraceptives on children conceived after a woman has ceased medication. Such concern is based on animal data which show that any form of medication that suspends ovulation may produce congenital anomalies. The center has negotiated a project to investigate thoroughly the effects of oral contraceptives on the woman's chromosomes. Studies of this topic are exceedingly complex and difficult, but we are developing a collaborative study involving several hospitals to examine this issue.

In summary, I wish to refer to the first four recommendations of the advisory committee on obstetrics and gynecology. Recommendations 1 and 2 refer to the need for "well-designed studies and the long-term support for studies on carcinoma of the breast and uterus and the metabolic alterations produced by the hormonal contraceptives." These problems are an important part of the research program at the Center for Population Research and we have initiated several studies. The fourth recommendation is that NIH support a national fertility survey in 1970 and, as I told you, we intend to do so.

The third recommendation, and maybe the key one, is that "substantial support be supplied to develop new methods of contraception." We agree with this recommendation. Even though oral contraceptives are undoubtedly the most effective method currently available for certain women, they are not fully satisfactory. We need others and NIH has joined other agencies in an effort to develop new ones.

Senator NELSON. If you were to recommend the studies that you think ought to be done, what would you recommend and what notion do you have as to the cost? You mentioned \$1 million. If we conducted the protocols that ought to be conducted—I realize they can vary all over the lot—what do you think we ought to do?

Dr. CORFMAN. To answer what question, Senator Nelson?

Senator NELSON. Pardon?

Dr. CORFMAN. To answer what questions?

Senator NELSON. To find the answers that we ought to find to the problem of the side effects of the pill, and the research we ought to be doing on improving the pill, to get some of the answers to the questions that the witnesses day after day say that we ought to have the answers to. So just what studies ought to be done?

Dr. CORFMAN. We should have work underway on at least three levels.