Senator JAVITS. Could that go into the record? He said he has not read it.

Senator NELSON. It has been in. I assumed, since it was a "Dear Doctor" letter, Dr. Guttmacher had read it.

Dr. GUTTMACHER. Unfortunately, I do not get all my mail.

Senator JAVITS. May I ask unanimous consent that if the letter is not in the record, it be put in the record?

Senator NELSON. We can put it in the record at this point in the hearings.

(The letter referred to follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., January 12, 1970.

DEAR DOCTOR: I am enclosing revised labeling for oral contraceptives to reflect the latest findings on safety and efficacy, as reported by the Obstetrics and Gynecology Advisory Committee in August 1969. An American study confirms previously reported studies in Great Britain which show a relationship between the use of oral contraceptives and the occurrence of certain thromboembolic diseases. These carefully designed retrospective studies show that users of oral contraceptives are more likely to have thrombophlebitis and pulmonary embolism than non-users. Studies in Great Britain also show increased risk of cerebral thrombosis and embolism in users of oral contraceptives. A British study found a hospitalization rate (an index of morbidity) in women age 20–44 to be 47 per 100,000 in users compared to five per 100,000 in non-users.

The American study, although not designed to evaluate differences between products, also suggests there may be an increased risk of thromboembolic disease in users of sequential products. This difference in risk cannot be quantitated, and further studies are needed to confirm the observation.

The British Committee on Safety of Drugs recently advised practitioners in that country that only products containing 0.05 mg. or less of estrogen should normally be prescribed because reports of suspected adverse reactions indicated there is a higher incidence of thromboembolic disorders with products containing 0.075 mg. or more of estrogen than with products containing the smaller dose. This finding has not been confirmed by other studies.

The FDA is planning studies that will determine, among other things, the thromboembolic effect of various products. You will be kept informed as results become available.

Other aspects being investigated in separate studies underway or pending are cervical cytology, carbohydrate metabolism, serum lipids, urinary tract function, blood coagulation, effects on endocrine function in adolescents, breast pathology, outcome of pregnancy, and cytogenetic effects.

In the United States during 1969 an estimated 8.5 million women took oral contraceptives monthly. The unsurpassed clinical efficacy of these products is well established. Although reported pregnancy rates vary from product to product, the effectiveness of sequential products appears to be somewhat lower than that of the combination products.

I strongly urge you to familiarize yourself with the labeling, particularly with the cautionary material contained in the sections headed Contraindications, Warnings, Precautions, and Adverse Reactions. As the prescribing physician, you are in the best position to determine the extent of your discussion of this material with your patient. In most cases, a full disclosure of the potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risk associated with this method.

I also request your assistance in continuing our assessment of the safety of A supply of the standard reporting form (FD 1639), shown in facsimile below, may be obtained from the Bureau of Medicine, Food and Drug Administration, Washington, D.C. 20204.

Sincerely yours,

CHARLES C. EDWARDS, M.D.,
Acting Commissioner of Food and Drugs.

Attachment:
Revised labeling