vations and on observation I made in collaboration with my colleague, Dr. John Bailor some years ago.

Mr. DUFFY. That was with reference to the breast cancer?

Dr. HERTZ. And I made the statement to date that such studies are not available.

Mr. DUFFY. Thank you, Doctor.

Senator NELSON. Thank you very much, Doctor, for your valuable contribution.

(At this point there was a disturbance among several women in the audience.)

Senator NELSON. Would the gentlemen with these cameras please take your place. I am not going to allow these hearings to be interrupted.

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

STATEMENT OF ROY HERTZ, M.D., PH. D., ASSOCIATE MEDICAL DIRECTOR, BIOMEDICAL DIVISION, POPULATION COUNCIL, ROCKEFELLER UNIVERSITY

Senator Nelson, Ladies and Gentlemen:

I am Dr. Roy Hertz. From 1941 until last June I served in various capacities at the National Institutes of Health in Bethesda; from 1945 to 1965 as Chief, Endocrinology Branch, National Cancer Institute, and 1965 to 1966 as Scientific Director, National Institute of Child Health and Human Development, and from 1967 to 1969 as Chief, Reproduction Research Branch of that Institute. During 1966 to 1967 I served as Professor of Obstetrics and Gynecology, the George Washington University, Washington, D.C. My entire professional career has been devoted to biological and clinical research in Endocrinology with special emphasis on reproductive physiology and on cancer as it affects the female reproductive organs.

I have served in an advisory capacity to the Food and Drug Administration for the past 20 years and most recently as Chairman of the Task Force on Carcinogenesis for the F.D.A. Advisory Committee on Obstetrics and Gynecology.

My colleagues and I at N.I.H. conducted the initial biological and clinical investigations which introduced into gynecological practice the first orally active compound, nor-ethisterone, which still serves as a major component of several oral contraceptives currently in use (1) (2). It had been our purpose to develop this material for the amelioration of certain gynecological disorders and not as a contraceptive agent.

The pioneering efforts of the late Dr. Gregory Pincus and his colleagues, Dr. Celso Garcia and Dr. John Rock, in adapting to contraceptive use this new class of orally active compounds merits the highest commendation (3) (4). However, it was clear from the outset that such an innovation, like all new medications, carried with it certain inherent risks. Among these risks, the possibility that the protracted use of the estrogenic component of these newly developed estrogen-progestagen mixtures would increase the incidence of cancer, particularly of the breast and uterus, was immediately considered by all concerned. Accordingly, Dr. Pincus and his colleagues incorporated studies relating to this risk in their very earliest efforts and the American Cancer Society supported these detailed studies under Dr. Pincus' direction in the amount of $594,000 from 1961 through 1967.

At first, these investigators reported findings which they interpreted as evidence of an ameliorative effect of the oral contraceptives on the early phases of the cancer process in the cervix, i.e., in the neck of the uterus (5). Subsequently, they reported additional observations which led them to conclude that there was no significant effect of the medication on the early phase of cancer of the cervix (6). Unfortunately, these limited early efforts lacked the epidemiologic precision so essential for the definitive resolution of this complex problem.

Nevertheless, the widely recognized urgency of the population problem served to supplement existing industrial pressures for the hasty exploitation of these remarkable new agents. These influences led to a most prompt and indulgent

NOTE.—Numbered references at end of statement.