Senator McIntyre. Thank you, Doctor.

Dr. Cutler. In this controversy, those who suspect a possible link between the oral contraceptives and breast cancer point to the following evidence:

(1) Removal of the ovaries in lower animals and in women mark-

edly reduces the risk of breast cancer.

(2) Breast cancer has been induced in five different animal species by the administration of estrogens.

(3) Chemical agents having carcinogenic effects in man also

induce cancer in animals—often at the same site.

(4) Bilateral breast cancers have developed in two male transsex-

ual individuals treated with estrogenic hormones, and

(5) The discovery of a high incidence of breast cancer among males, 6.6 percent compared to the general incidence of 1 percent, in certain parts of Egypt where a parasitic infection of the liver inter-

feres with the destruction of estrogens.

Those who argue against a possible link, point to the lack of convincing evidence now available, after some 10 years of use of the oral contraceptive, that breast cancer is caused by the pill. They call attention to the extensive use of estrogens by millions of women for many years in the treatment of menopausal symptoms without definite evidence of a carcinogenic effect, and finally, they are not willing to accept the animal experiments as being applicable to women.

With respect to the effect of estrogens on menopausal women, it should be pointed out that here we are dealing with replacement therapy. This cannot be compared to the prolonged addition of estrogens to a young woman's natural hormones. Furthermore, when one considers the prolonged latent period of carcinogenicity, many women in their menopausal and postmenopausal age brackets (late forties and fifties) may not live long enough for the carcinogenic effect to exert itself as clinical cancer.

Considering the question of the transferability of animal data to man, it is difficult for me to escape the conclusion that the results

are relevant and must be regarded as significant.

The difficulty of demonstrating a causative relationship between the oral contraceptives and breast cancer obviously relates to the long latent period between exposure and final effect. A minimum of 10 years is required before reliable results can be expected. Unfortunately, this experiment upon millions of women might prove to be

too costly to contemplate.

When the oral contraceptives were introduced some 10 years ago, they were hailed as a solution to the world's population explosion and a safe means of preventing birth of unwanted children. The simplicity and effectiveness of the pill have constituted a veritable blessing to millions of women. Unfortunately a broad area of disagreement as to their safety has developed. Thus a serious cloud has appeared, and the question has arisen as to whether the benefits outweigh the risks.

Although there is no conclusive evidence that oral contraceptives cause breast cancer, the potential hazards involved in their protracted use—and I emphasize protracted—by young, healthy women