cal practice, I have a series of patients who have had two or three breast biopsies. In some, the biopsies were performed before the patient started to take the contraceptive, and a second or third biopsy was performed after the patient had been on the contraceptive pill for several years. Study of surgical specimens under these circumstances presents a unique opportunity to observe the tissue changes that may be related to the stimulating effect of the estrogenic component of the oral contraceptive.

One has to be careful, however, in interpreting microscopic changes in tissues under the influence of hormonal stimulation because such changes can be so pronounced as to be indistinguishable from fully established cancer. I cite the following example: My colleague, the late Sir Lenthal Cheatle of London, removed the breasts of a female infant who had died at birth. He prepared microscopic slides of the breast tissue and without divulging their source submitted them to five distinguished pathologists, several of them professors of pathology. Four of the five pathologists reported the tissue as cancer of the breast. The hyperhormonal stimulation of the sensitive breast tissues caused by the high estrogen levels in the mother's circulation resulted in an erroneous microscopic diagnosis, by highly sophisticated pathologists. It is important to understand that microscopic changes of this magnitude can be reversible.

We know that every 20th woman will develop cancer of the breast sometime during her lifetime. We also know that if the mother, the sister, or the maternal aunt had breast cancer, the risk is at least doubled, so that approximately one woman in ten will develop the disease. It is manifestly imprudent to prescribe oral contraceptives as a first-choice birth control method to patients with a family history of breast cancer.

Senator McINTYRE. May I interrupt you at that point for a question. You just said, "it is manifestly imprudent to prescribe oral contraceptives as a first-choice birth control method to patients with a family history of breast cancer."

My question is this, does the current labeling of these drugs or the recent letter from the FDA contraindicate the use of birth control pills in patients with such a family history?

Dr. CUTLER. Senator McIntyre, I cannot answer that question, because having received the letter, I do not recall in detail whether that point is mentioned.

Senator NELSON. I might say that it does not.

Senator MCINTYRE. Do you have the letter before you?

Senator NELSON. This is the package insert for the layman. What it says is under contraindictions, No. 3, "known or suspected carcinoma of the breast." It does not refer to the sister, mother, or aunt.

Dr. CUTLER. That would refer to a patient who has had breast cancer or perhaps had a recurrence of the disease; in other words, in the presence of clinical cancer, but it apparently says nothing about family history.

Senator NELSON. You would recommend that the information that goes to the physician and the information on the package insert specifically include the contraindication that you have just discussed?

Dr. CUTLER. Without question.