

to document the thromboembolic problem. It could be extremely difficult to really determine whether this hazard existed or not.

Senator NELSON. Are you saying that the scientific evidence we have thus far is such that we are not able to draw a specific conclusion that the introduction of these additional synthetic hormones into the system actually does induce or accelerate carcinoma of the breast?

Dr. DAVIS. Well, we know that it will induce it in animals. The steroids have been shown to contribute to the induction of breast cancer in five different species of mammals.

We also know that when human males have been given these hormones breast cancer has appeared and this is a very unusual disease for men to develop, a very rare condition in men. So that there is some evidence that estrogens in particular, can contribute to the induction of breast cancer in humans when given in sufficient dosage for a sufficient length of time.

If this, if the oral contraceptives, were an article of food there would be sufficient evidence on the basis of the animal experiments to consider seriously removing them from the market. We are in a curious situation with the oral contraceptives because they are classified as a drug although they are taken chronically by many people almost as if they were an article of diet. It is chronic use beyond 2 to 3 years that is particularly disturbing from a long range point of view. The numbers of women involved, and the unknown nature of the hazard, and the very disturbing evidence we have from the animal experiment, all of these things taken together, I think, should incline us all to be extremely cautious about long-term use of these agents.

Senator NELSON. Does some of the scientific literature indicate that in certain age groups it would appear that the introduction of estrogens accelerates the growth of carcinoma, and in other older age groups it slows it down?

Dr. DAVIS. There is some evidence with regard to the breast that the administration of these hormones or the withdrawal of them can affect the rate of growth of cancer, yes, sir. The same is true with regard to endometrial carcinoma.

Senator NELSON. You made reference to the question of informed consent. Do you have any guesses or are there any statistics or is there some reasonably firm information that would indicate how many women are fully advised about the side effects they may experience which should prompt them to consult their physician? Do we know how many women are adequately furnished this information at the time of the prescription or is there no knowledge of this subject?

Dr. DAVIS. Well, it depends on the circumstances under which they are given.

I think that there has been a good deal of delinquency in some of the mass programs in dispensing and instructing and informing people on a mass basis without warning them about the significance of leg cramps, headaches, or other warning signs that might indicate potential hazards.

I think this is being corrected now. I noticed that some of the brochures that are being distributed to inform and instruct women about how to take the pill, have begun to include statements regarding possible hazards and possible contraindications.

The former FDA Commissioner Ley, in a published statement that