mals. This reminds me, Doctor, very much of the situation we now face with respect to the cyclamates. Last October they were banned from the market as food additives because they were shown to cause cancer in animals. However, under an order published in the Federal Register on December 31 of this year they apparently will now be allowed to return to the market as drugs to be sold over the counter without a doctor's prescription and without having gone through the New Drug Application procedure which has been required of all drugs coming on the market since 1938.

Now, Dr. Hertz, can you see any medical or scientific justification for allowing a substance which cannot be used as a food additive because it causes cancer in an animal to be marketed as a drug, and particularly if it is to be sold over the counter?

Dr. HERTZ. I do not see the justification. However, I would hasten to point out that the situation is not parallel with respect to the oral contraceptives since as of this time legally, although we all know of contraband use, the oral contraceptive remains a prescription item, legally exclusively.

Senator MCINTYRE. Dr. Hertz, finally, on page 9 you point out that FDA now requires that the labeling of the pill include the instruction that women taking it are to be carefully monitored by Pap smears to detect changes in the cervix which might lead to cancer.

First of all, the package insert which contains this information is never seen by the woman and is not necessarily seen by the physician. Moreover, as you point out on page 10 the existing clinical and laboratory facilities for conducting these tests can accommodate only a small fraction of the estimated 8½ to 9 million now receiving the pill.

In view of these factors, is this requirement in the FDA-approved labeling really going to provide adequate protection to women taking the pill?

Dr. HERTZ. Only to the extent that it affects the conduct of the medical profession in prescribing the pill.

It is the medical professions' professional and legal responsibility to adhere to the instructions contained in those package inserts, and to the extent that those package inserts will significantly alter and influence the conduct of the profession in prescribing the pill, which I emphasize is still a prescription item, to that extent the protection extends to the consumer.

I might add that in daily practice, unfortunately, this does not universally obtain, and as a result the consumer, in the end, does not have the protection she needs.

Senator MCINTYRE. You have probably answered my final question: Can this committee rely on the medical profession to adequately inform women using this pill of the hazards and dangers, and the benefits, too?

Dr. HERTZ. I think they can to the same extent that they can rely on the profession to control and monitor the use of any medication, whether it be digitalis, ether anesthesia, morphine, or whatever. A public surveillance of the activities of the profession in this area will, I think, have a very salutary influence, and is well advised.

Senator MCINTYRE. Thank you very much, Doctor.

Dr. HERTZ. Thank you, Mr. Chairman.

Mr. DUFFY. Dr. Hertz, I have just a few questions I would like to ask you.