

I do not know of any place in the literature that I have seen where the scientific community insisted this must be the procedure and come to the Government and say: "You fund it if that is where the funds have to come from because it involves a lot of people."

Senator McIntyre, do you have questions?

Senator McINTYRE. Thank you, Mr. Chairman.

I would like to say that my attention was called to what appeared to be an apparent inconsistency or a contradiction between the task force report and that of the committee. I do believe that the exchange between the chairman and yourself, Doctor, has allayed some of my feelings about it. But I do have to agree, and it seems very interesting, that the word "safe" within the intent of the legislation, which as I understand would be the Food, Drug, and Cosmetic Act of 1938, that this word "safe" if we were stretching it to this extent must far exceed what the Congress was considering in that year of 1938.

Dr. HERTZ. All I can say in response to that is that you have the identity of the members of the committee. I will subscribe to the fact that what the chairman has stated there did, in fact, represent the consensus of the committee. That the innumerable social and other factors which came into play in their thinking, weighed heavily in their considerations, and I would say that I did not recognize in any of the membership of the group in reaching this ultimate consensus anything but the best public interest.

Senator McINTYRE. I think you have explained to my satisfaction the manner in which the committee finally came up to an agreement.

Now, Doctor, due to the long period of time which may be required for chemically induced cancer to show up in humans and the absence to date of accurate epidemiological or other studies for the detection of such effects I suppose it should not be too surprising that we do not yet have a definitive answer to the question of whether or not the birth control pills do cause cancer in humans.

However, according to your testimony, Dr. Hertz, and that of some of the witnesses we had here yesterday, it appears that animal studies can provide some clues to this question and in a relatively short period of time.

Do you know, Doctor, if such studies were undertaken on the birth control pills before they were approved for marketing as contraceptives in 1960?

Dr. HERTZ. Not specifically with respect to carcinogenesis so far as I know it. There had been a pre-existing extensive body of scientific information indicating, and I documented this in my statement, indicating that the estrogenic component of the pill was capable of producing such an effect.

To my knowledge at the time of the original approval of the marketing of the specific oral contraceptive studies relating to this particular end had not been made.

I might say that very probably this occurred since this was before the new emphasis on teratological and other biological effects of drugs had arisen.

Senator McINTYRE. Scientific knowhow to conduct such studies was probably not fully developed in 1960.

Dr. HERTZ. I wouldn't say that. I would say that the emphasis had not been fully developed.

Senator McINTYRE. Had not been in that direction.