Since the report was issued on August 1, 1969, would you please tell the committee why it took 3½ months just to get together with the industry to discuss labeling changes?

Dr. EDWARDS. Again, Senator, if I could turn this over to Dr. Jennings. I did not happen to be on board at that time.

Dr. JENNINGS. Senator McIntyre, I was aboard at that time, but not in any capacity where I could have expedited that review. It does take a certain amount of time, first of all, to decide exactly what the report meant to us in the way of labeling. The committee, after all, did not address themselves directly to the matter of labeling. And then we had discussions individually with various representatives of industry about the labeling.

I can only blame what seems to be an inordinate delay at this time on our rather occasionally cumbersome administrative procedures.

Remember, that we were making rather significant changes in the labeling, we were in a position of persuading and sometimes with considerable resistance, some of the members of industry to go along with us. And it just took that period of time.

Senator MCINTYRE. Thank you for your frankness.

Now, on page eight, you list a number of studies presently underway which are supported by FDA. Item No. 2 is an investigation of the carcinogenic potential and other effects of two experimental oral contraceptives.

Would you please identify these compounds for us and tell us why they are being investigated.

Dr. SCHROGIE. These compounds are MK 665 and WY 4355.

Senator MCINTYRE. Just a minute. You sound like the Pentagon now.

Dr. SCHROGIE. Because they are experimental compounds, brand or generic names are not commonly used. These compounds had been in clinical investigation some years ago. Limited studies in dogs being performed at the same time, showed that they were associated with the production of breast tumors. For this reason, the clinical investigations were terminated.

It was felt as a result of these findings, which at that time were quite preliminary and limited to dogs, that much more detailed and extensive studies in both dogs and another species, the monkey, should be undertaken, not only to further evaluate what might happen under chronic dosing with these particular drugs, but also as an early warning to identify similar effects with either other investigational compounds or compounds that are presently on the market.

The FDA for its part is supporting the studies of these two particular drugs. Industry is supporting a much more extensive array of studies on investigational and some of the marketed compounds, following the same protocol which was devised by the Food and Drug Administration.

Senator MCINTYRE. Doctor, would you please tell us whether and how closely these two products may be related to products now on the market.

Dr. SCHROGIE. In terms of chemical structure, of course, there are some similarities, since they all belong to the same general series of