

Dr. LEGATOR. Not at the present time.

I might say that again the methods are rather recent and there are certain recommendations in FDA files that will be looked upon to see if this should become a standard part of our testing protocol.

Senator McINTYRE. I understood your testimony to indicate that the mutagenic test was relatively new, but the others went back quite a ways.

Dr. LEGATOR. Yes. I was addressing the answer to the mutagenicity. As far as the teratogenecity studies, they go back to 1962, as you know, as a consequence of thalidomide. There is a standard protocol in this area.

Senator McINTYRE. Doctor, do you think such tests should be required?

Dr. LEGATOR. For mutagenicity?

Senator McINTYRE. No, that the tests for teratogenesis and carcinogenesis should be required by FDA of the manufacturer before they are submitted?

Dr. LEGATOR. Well, this is normally done.

Senator McINTYRE. This is normally done?

Dr. LEGATOR. At the present time. Again I think the Commissioner would be able to certainly address himself to this question far better than I can.

Senator McINTYRE. I think what I am trying to get at here is whether these mutagenic and other tests should be required by the FDA prior to approval of a manufacturer's submission.

Dr. LEGATOR. Again let me clarify that by saying that mutagenic tests are not required at this time.

Senator McINTYRE. And these other tests have been required for a long time, and they have been required——

Dr. LEGATOR. Since 1962 they have been required.

Senator McINTYRE. They have been?

Dr. LEGATOR. Yes, of course.

Senator McINTYRE. Are tests on these applications with reference to carcinogenicity required routinely?

Dr. LEGATOR. Yes, they are.

Senator McINTYRE. At the beginning of your statement you mentioned a number of substances, some drugs, some food additives, some pesticides which have recently been found to cause genetic toxicity. Are all of these substances still on the market?

Dr. LEGATOR. With the agricultural fungicide, Captan, the answer to this is yes.

I talked about DDT. Of course, you are aware of the recent discussions, the ban on DDT. I talked about the antifungal antibiotic, griseofulvin, so basically those examples that I cited are materials that are currently in commerce. But there again I would say that these three compounds, the disclosures of possible toxic hazards is recent.

Senator McINTYRE. Doctor, I understand that cyclamates were originally ordered off the market and now they are back on, and——

Dr. LEGATOR. I do not believe that is quite correct.

Senator McINTYRE. Are they generally recognized as safe?

Dr. LEGATOR. I do not believe that is quite a correct statement that they are back on the market. I think there has been some change or there has been a modification of the initial announcement, but, to the