

of the years that it takes in carcinogenicity studies in animals when we talk about mutagenicity we are basically talking about studies that can be concluded in a period of months rather than years. So I think the methodologies are with us, I think they are quite feasible and I expect that within a comparatively short period of time we will get on with testing many of our materials by these techniques.

Senator NELSON. I meant to get at that. Does your department propose to undertake this kind of study on food additives and other chemicals of various kinds?

Dr. LEGATOR. The lag that we have now really is in training, training biologists to carry out these procedures. As I said there are as few as three laboratories that can comprehensively screen materials in this area so we need a training program initially, and then we can proceed from there.

Senator NELSON. What is involved in terms of funds for the tests and does your department have it? I suppose one of the department heads should respond himself.

Dr. LEGATOR. The only thing I can say here is that the cost should be considerably less, let's say, for carcinogenicity testing.

Senator NELSON. Your statement and those procedures outlined will be put in full in the record. These procedures were recommended for evaluating pesticides, but with suitable modifications, can be used to evaluate steroids.

Dr. LEGATOR. Yes; I have a supplement that I will attach further details on the procedure. Let me sum up by saying the total lack of experimental data in this area and I am again referring to mutagenicity with the exception of the few cited cytogenetic studies and I know Dr. Carr will talk about this later, make it imperative that a large-scale study of potential mutagenic agents be initiated. It is absolutely essential that we know of any potential mutagenic effect of drugs, such as oral contraceptives, that are used widely by healthy women of childbearing age.

Mr. DUFFY. May I just interrupt you?

Dr. LEGATOR. Yes.

Mr. DUFFY. That last statement is somewhat confusing to me. I initially thought that the danger here was to one who took these drugs during an actual pregnancy.

Dr. LEGATOR. This is when we are talking about teratogenicity. When we come to mutagenicity, it is quite another matter. Here we have a potential danger during the entire period that the drug is being ingested, not just during critical periods of pregnancy.

Mr. DUFFY. So it is strictly confined to mutagenicity?

Dr. LEGATOR. We are talking about a very limited risk with a teratogen. This does not apply to mutagenicity.

Senator NELSON. In other words, a drug or a chemical of some kind may have a mutagenic effect on a child, on a child's child, when he grows up.

Dr. LEGATOR. Right. So the risk period here is spread over a far longer period than with a teratogenic effect.

Since the possibility of teratogenic effects exist, the number of women inadvertently using the steroids during pregnancy should be determined. Even if the number of women using oral contraceptives while pregnant is minimal, it is still our responsibility to attempt to