

Senator NELSON. Would this not also be true of any potent compound that any person took over an extended period of time during child-birth?

Dr. LEGATOR. Any number of agents that we are exposed to in our environment would fall in this category.

Senator NELSON. So no one will be misled we are not selecting this as a special case over any other drug over an extended period.

Dr. LEGATOR. Absolutely not. We would be just as concerned with the 800 compounds on the generally recognized as safe list and over 400 pesticides which have not been evaluated in this area. I think one should realize that toxicity is really what we define toxicity as at a given moment in history and it is an ever-changing pattern. The compounds we thought were beneficial, say, 10 or 5 years ago, we now find to be dangerous when studied by recent methodologies. It is a moving area, and in mutagenicity we have developed newer techniques that we think will give us a greater assurance of safety.

I would like to mention the major tests that can be used and include the details of the procedure in a supplement to my document. I will not discuss these methods here, but merely indicate that the specific methods that can be used are of recent origin and that there are three separate types of evaluations that can be used in animals to define a mutagenic response.

Dr. Carr, I believe, who follows my presentation, will discuss one of these methods, the cytogenetic analysis. I would just like to indicate that the production of chromosome abnormalities by various agents should be viewed as an indication of subvisible changes in the genetic material. And I might also say that when one conducts in vivo cytogenetic analysis in animals we find it to be a selective technique, and only a small percent of compounds tested produce chromosome abnormalities.

Senator NELSON. Do I understand you to say that the methodology for determining mutagenetic effect is recent?

Dr. LEGATOR. Yes; the cytogenetic techniques, of course, have been with us since the early 1960's.

Senator NELSON. But you are saying the mutagenetic ones are in the past year or two?

Dr. LEGATOR. Correct.

Senator NELSON. It is a methodology that is relatively efficient and—

Dr. LEGATOR. Well, we are talking here about a number of tests, three to be exact. If they are used concurrently we feel these tests are capable of characterizing mutagenetic agents.

Senator NELSON. I am raising the question for this reason. You mentioned food additives, generally accepted as safe, the so-called GRAS list, of the 500 list of additives as well as the herbicides and pesticides used, DDT and so forth. Is it practical to start applying now this methodology to seek this information on mutagenetic effect on all of these types of chemicals?

Dr. LEGATOR. I certainly believe it is, and I might mention in this context that when we talk about testing on animals for mutagenetic activity we are talking about studies that are considerably less time consuming than some of the other types of investigations we currently conduct in the area of chronic toxicity. For instance, instead