

determine the least toxic formulation to further minimize any possible teratogenic effects.

It is feasible to look at the various steroids singly and in combination to see if we can define in this area, teratogenicity, the least toxic material.

The lack of data on mutagenicity of these compounds is attributable to the comparatively recent development of definitive methodologies in this field. The threat of a mutagen not only to our contemporary generations, but to future generations makes it imperative that we adequately evaluate these steroids for mutagenic effects which is, essentially, my statement.

Senator NELSON. Thank you very much, Doctor, for your very informative presentation.

Senator McINTYRE. Doctor, since you are speaking here as an individual, did you have to submit your statement for approval to your superiors at FDA or HEW?

Dr. LEGATOR. I, of course, looked upon this presentation as important as, say, any manuscript that I have ever put together, so my colleagues have looked at it for editorial changes. But I can emphatically say that in terms of the Commissioner of FDA or in terms of HEW, the Department of HEW, there has been no attempt made to alter my basic presentation. This is my presentation as an individual and not as a member certainly of FDA or HEW.

Senator McINTYRE. Do I take that answer to mean you did not have to submit it to your FDA superiors or HEW superiors for approval?

Dr. LEGATOR. Well, I certainly would do this simply, as procedural policy. But I would say that they made no attempt to alter my statement whatsoever.

Senator McINTYRE. But you did have to submit it, and there were no changes, no substantial changes, made?

Dr. LEGATOR. I voluntarily submitted it. I would normally do this.

Senator McINTYRE. You voluntarily submitted it; so, therefore, you did not have to.

Mr. DUFFY. Senator McIntyre, perhaps I could clarify this matter by saying it is my understanding based on conversations with FDA officials that Dr. Legator was free to submit his statement to any employees of FDA of his choosing; however any such employee would be commenting on Dr. Legator's statement in their individual capacity. In other words, comment, if any, was in the same capacity that Dr. Legator is appearing here, so should they have decided to make recommendations to Dr. Legator they would have been doing so as individuals not necessarily reflecting FDA policy or position.

Senator NELSON. I take it, what we are saying is, This is your statement and not the statement of the Food and Drug Administration.

Dr. LEGATOR. This is precisely correct.

Senator NELSON. As a scientist, you have certain freedoms like everybody else to speak personally about matters in which you have some expertise.

Dr. LEGATOR. This is correct.

Senator McINTYRE. Doctor, in your statement you prescribed a number of tests in animals which you feel are useful in detecting possible genetic toxicity. Does the FDA require that such tests be performed by a manufacturer before approving a New Drug Application or a food additive petition or a tolerance for a pesticide chemical?