Would you mind elaborating on that?

Dr. EDWARDS. Certainly. In categorizing this drug as safe, I do not want to imply, by any stretch of the imagination, that this is an innocuous drug. It is a very potent drug, and when arriving at this decision to call it a safe drug we had to utilize the same standards we use for all other drugs.

As you well know, most of the other "safe" drugs, the powerful drugs, have certain contraindications. There are certain dangers in taking any drug, and they have to be taken under the conditions which are stated very clearly in the labeling.

So again, I would like to emphasize that in establishing this classification, we applied the same standards for the oral contraceptives as we have for all other drugs in categorizing them as safe.

Senator NELSON. The use in this context, then, was not in the ordinary dictionary use of the word——

Dr. EDWARDS. It certainly was not. It was a Food and Drug Administration description of the word "safe", which really is "safe under the conditions of labeling," and which perhaps is a more accurate definition.

Senator NELSON. This is a legal question. Dr. Hellman mentioned that he discussed the phrasing—do you have Dr. Hellman's phrasing?

In any event, he discussed how it should be phrased with your counsel, Mr. Goodrich. Perhaps you may wish Mr. Goodrich to respond to this. But it raises another question of some significance, it seems to me.

Dr. Hellman said:

> Now, I therefore wrote the sentence that has caused you and Mr. Gordon and other people some difficulty. I take full responsibility for writing this sentence "safe within the intent of the legislation." But I did have consultation in writing the sentence.

And so forth, and he refers to your counsel, Mr. Goodrich.

If it had been my responsibility, I might have come to the same conclusion, but it does raise a question about the intent of the law and its meaning.

In 1938 Congress passed the statute requiring that to market a drug proof of safety must be submitted, adequate proof of safety or proof of safety acceptable to the FDA must be presented.

I would just like to ask Mr. Goodrich what he thinks was intended at that time. Let me state it this way:

In 1938 there were no oral contraceptives. In 1938, I would assume that the Congress was thinking of a drug for treatment of a specific target organism in a specific disease situation. In fact, it was in response to a particular safety problem that arose at that time respecting sulfanilamide, and maybe Mr. Goodrich will have a different view—and correct me if you do—that Congress was thinking then of a drug in which the issue was, is it safe for the particular disease situation which it is being used for, that is, the drug does have side effects, we are well aware of that; however, under the circumstance the illness of the patient indicates that on balance the risks of the side effects from the use of the drug are far outweighed by the benefits that the patient would get from the use of the drug for the particular disease situation that exists.