

I believe strongly that they should be on the market, but I believe that as new knowledge is revealed and developed and exposed by people such as yourself, we have a mandate to operate from the new base of knowledge, modify our approach, and continue to modify it all the time as we learn more.

I do not think any drug can ever be completely studied before it is released. Certainly, this drug was studied much more extensively than almost any. Yet the history of powerful drugs simply reveals for us that sometimes, 8 or 10 years go by before a very serious side effect is appreciated. You cannot set up animal models to anticipate all of these things, and in a drug like the oral contraceptive, we have a very unique situation, because this is a mass population experiment in this sense, in which healthy people are taking the pill in large numbers.

Secondly, we have never had a medication in which the commitment for its usage might be daily for 20 years. There is no way that an animal model can answer this.

I think we just have to have great respect for what we are doing and set up devices so that we have very good detection systems, very good disclosure systems, and we continue to modify our usage.

At the same time, this accumulating information will help us in your goal, Senator, to realize what is wrong with the pill, and that is the first step toward developing a better one. I think we certainly have to search for better chemical methods, we have to search for methods which may reduce the dosage, for methods that may allow us to use the male as well as the female.

We have to compare the values of these compounds with mechanical devices.

Senator DOLE. Doctor, if you were going to inform a patient—

Senator NELSON. May I interrupt just one second? I have an amendment pending on the floor which will be taken up on a limited time debate at 11:30. I asked Senator Dole if he would be kind enough to complete the hearing.

I want to thank you very much for coming this morning, Doctor.

Dr. LARAGH. Thank you very much, Senator.

Senator DOLE (presiding). I am just wondering how you would state what you have stated to the committee in a very concise and effective way to a patient so that she would understand what you are telling us in a sort of complicated way.

Dr. LARAGH. Yes.

Senator DOLE. What would you put on the label for the patient, based on your study?

Dr. LARAGH. I think, Senator Dole, I think the situation has to be based—this situation and analogous situations—with many others, that are occurring all the time with many other powerful chemicals that doctors and environmental specialists now have available. It can only be solved by full disclosure on both sides. I think that our patient now has to participate in the decision in a different manner than he did perhaps 20 years ago.

In the final analysis, in considering whether a patient should use an oral contraceptive, the decision should be a value judgment that the physician makes with each individual patient. And this decision—