

Actually, the absolute numbers are not so important as the point. But we have nine patients in whom we withdrew the medication. In three, the blood pressure came back to normal. In three, the blood pressure greatly improved. The last remaining three, the blood pressure stayed high.

Senator NELSON. Which of those groups had a prior history of hypertension?

Dr. LARAGH. Five of them had hypertension which was known prior to taking the pill.

Senator NELSON. Of those five, what happened when the use of the pill was terminated?

Dr. LARAGH. Of those five, three of them improved.

Senator NELSON. Will you explain the significance, then, of these statistics?

Dr. LARAGH. Well, first of all, these numbers are much too small, Senator, to have statistical significance. But maybe as I develop the story, you will see why I think the connection of a cause-and-effect relationship has been established.

What we did, having observed that three became normalized, three greatly improved, and three remained unchanged of the nine that we stopped the medicine in, two of the women wanted to go on with the pill, for obvious reasons, and we decided on what we call a rechallenge trial, since there was no evidence prior to this that hypertension would be any risk. In both of these women, when we gave the pill again, the hypertension would be reproduced and then, on withdrawing the pill, the hypertension disappeared again.

Senator DOLE. Would you have observed the same results had these women been pregnant?

Dr. LARAGH. What would happen had these women become pregnant?

Senator DOLE. Would you have observed the same results of your study as a result of normal pregnancy?

Dr. LARAGH. I am not sure that I—maybe you had better set up the model so that I can understand it.

Senator NELSON. I think the question he is raising is whether the introduction of the estrogens as a consequence of pregnancy would have caused these women to get hypertension in a fashion similar to that from the artificial causes?

Dr. LARAGH. I cannot tell you about these particular women, but what I can tell you generally, Senator Dole, is that it is a well-known fact—I think no one has exact figures because it is an epidemiological figure, but some 10 percent of all women develop high blood pressure during pregnancy, something of that order. So that the relationship is not really a surprising one if you appreciate that we are producing chemical pregnancy in the hormonal sense. It almost would be more surprising if nobody ever got hypertension, because hypertension is a recognized complication of pregnancy.

It usually goes away on cessation of the pregnancy, just as it seems to go away on cessation of the pill.

Senator DOLE. So the results are not necessarily surprising?

Dr. LARAGH. No, they are not surprising. But I would say that, like the evolution of knowledge with many other drugs, the usage of the