making capacity is the essence of the role of a physician. It is a quality that we call clinical judgment. It is a measurable capacity to weigh all the variables for the individual patient.

The way that you weigh the variables is you consider first of all the medical status of the patient, the age of the patient, the psychological factors involved in the patient's situations. She may have nine children or none, which would certainly vary your attitude.

In addition to all the medical and psychological and physical considerations involved in the individual, you then have to take into account sociological factors. The population explosion is a serious problem. Pregnancy itself has a risk. And the doctor and the patient, both together, cognizant of these risks, must make the judgment as to whether or not to use them.

I think you cannot have recriminations when one person in a thousand, or whatever the rare case is, has phlebitis or a stroke. You will not have recriminations when the essence of the information is the point of departure in the beginning.

As you point out, full disclosure and consent, and all these words are nice words that you and I like to use. But getting the message across to someone who is not as oriented as we are medically, even though you may try, is not a perfect art.

I think we have to do everything we can to simplify communication, to use education, to use techniques of repetition, to simplify the package insert. We can only go ahead in this area, and with many other powerful drugs, by using the knowledge positively and by full disclosure.

Senator DOLE. I think it has been pointed out by counsel that the FDA is moving in this direction, as indicated in their letter of January 12. The only thing that concerns me because I do not have all the expertise in this area, and I am not certain how many of the 8.5 million of the recipients of the pill may have, what do we put on it? I think it is a good idea to inform them through the doctor-patient relationships and perhaps by other means.

If we end up with a long list of things the pill may cause, how do we get the message to the patient?

In your case, you might say, the pill may cause high blood pressure, correct?

Dr. LARAGH. I would say that this is a rare—the incidence we do not have. We are dealing in frequencies. We are dealing in risks which are small. And I think there is a great danger, as you indicate, in scaring or alarming people while we are trying to digest the information ourselves.

Senator DOLE. And as you say, the patient must make a value judgment, and she has to consider all the factors. I assume somewhere along the line, we have to draw a line and say these are minimal and these are maximal.

I just wonder where you say your suggestion might fit in that picture, because pregnancy might cause hypertension. I think you indicate that as a very predictable result of your study.

But at the same time, I think we have some obligation to make a full disclosure to the user. I am just wondering as a matter of practical information, how can the patient ever make the value judgment if we confound her with so many different things that may happen? Where do we draw the line?