

Mr. GOODRICH. Under the existing situation, Senator, if the company chooses to put out a consumer book on a voluntary basis, as of now it is required to have a full disclosure in terms understandable to the ladies, which is a summary of the package insert material we now propose to make mandatory in all of the packets.

Senator MCINTYRE. The answer is generally yes, a summary of this information would be included in future pamphlets that are put out by various pharmaceutical houses concerning the pill?

Mr. GOODRICH. This document itself is the summary of the necessary information.

Senator NELSON. Did I understand you correctly, that in the literature put out by the companies, they will be required to put a summary of this?

Mr. GOODRICH. Yes. If they have a separate little booklet, like the one you were examining the other day on "So Close to Nature", that kind of booklet would have to have the essence of what is in this consumer message we are preparing now.

Senator NELSON. I want to commend you again. I did not realize it extended to the literature put out by the company, and I think it is a very sound step.

Senator DOLE. You say in the first paragraph that the patient has discussed this with his doctor, and I quote:

He has discussed with you the risk of all contraceptives and has decided that you can take this drug safely.

Then on the same page, in bold type:

Who Should Not Take Birth Control Pills.

Are we saying in effect that no doctor would prescribe birth control pills to anyone who has had any history of blood clots or liver disease, and the other things you mention in that paragraph? Are we getting into a contest here with the physician?

Dr. EDWARDS. Absolutely not. I think the point being here that in our judgment, although we certainly do not have the actual figures, there are an awful lot of ladies in this country who are taking the oral contraceptive, and are not under the supervision of a doctor. And here we are trying to accomplish two things:

We are trying to remind the lady who is under the observation of a physician that she should see her physician regularly without just calling and getting a renewal of her prescription.

We are also trying to direct it to that particular lady who gets her prescription through another friend, or someone that she never bothers to see.

We certainly do not want to get ourselves in a position where we are trying to be the doctor, because we in no way are attempting to do such.

Senator DOLE. In other words, if the doctor prescribes under any conditions, if he were qualified, and said it was safe, you are not taking issue with what he says.

Dr. EDWARDS. Yes. Our problem, as you well know, is not that we are particularly concerned with the patient who is under the good care of a physician. We are not worried about that patient.