

and I would think it is one that is quite understandable and ought to be used.

Dr. EDWARDS. I think your point is well taken, and I would emphasize that this is not the final package. This is for discussion purposes primarily, and we certainly anticipate making changes, as requested by groups such as your committee and others.

I think your particular point is a good one.

Senator DOLE. Dr. Edwards, this insert has been in the making for sometime; is that correct?

Dr. EDWARDS. Right.

Senator DOLE. I am not certain whether the average person realizes there is any great risk if it is one out of 200,000 or six out of 200,000. We have had witnesses indicate we should not include a laundry list with medication, because to do so would confuse the patient.

I am not certain where you draw the line, whether you should indicate any numbers, whether you should indicate there is some risk. The question is how to best communicate with patients, but we do not want to frighten the few people left who are not frightened as a result of these hearings.

I would hope that we do not try to rewrite the memorandum in committee hearing.

Senator NELSON. I hope the Commissioner did not think I was trying to rewrite the memorandum; I was just asking the question for information purposes because I thought it was a good question. I would not think of trying to write the memorandum, but I would think it is within the province of a member of the committee or any citizen in America, and there are 200 million of them, to ask a question.

Senator DOLE. We have asked several questions.

Dr. EDWARDS. Certainly our intent is not to frighten anyone away from the pill, but it is our intent to prepare a document, and as I say, I will not stand on this particular document, but prepare a document that gives the facts in an unemotional way so that the many, many patients in this country who are receiving the oral contraceptive by renewal of prescriptions, et cetera, will at least have some access to appropriate information.

Senator DOLE. Will this be an additional piece of information, in addition to what the drugmaker himself may include? Are we going to have two pieces of literature to read, or does this supersede anything else?

Dr. EDWARDS. I believe I am correct—Dr. Jennings can correct me—that at the present time there are no inserts in these packages per se, are there?

Dr. JENNINGS. No, there are not.

Dr. EDWARDS. Except for the physician.

Dr. JENNINGS. That is right. But I think the Senator is referring to the booklets that are frequently prepared.

Senator DOLE. Right.

Dr. JENNINGS. For patient use.

Senator DOLE. You have one entitled "So Close to Nature" which we had last week.