Senator NELSON. Would this be compulsory?

Dr. EDWARDS. No. At least we are not in any position at this point to make reporting compulsory. But I think with the right kind of a system, a computerized system, where the medical record is far more computerized than it is at the present time would be helpful. I do not think it would have to be a compulsory system to get a reasonably good response in terms of drug reporting.

Senator NELSON. We had that, of course, in some of the communicable diseases.

Dr. EDWARDS. I think though that for this, Senator Nelson, for this to be effective, really an effective reporting system, we are eventually going to have to get the record out of the doctor's office. Obviously this is where some of the minor reactions occur and it is not just the hospital record.

I think the time is coming when we will have a medical record that is automated, a centralized medical record, if you will. When this happens, I do not believe it will be a matter of whether reporting will be compulsory or noncompulsory, it will be on the record.

And I think all of this is within the realm of possibility.

Senator NELSON. I must say, in looking at one of the reports submitted to the physician by the FDA, the number of questions and the fine lines, that it is a kind of discouraging thing for the physician to fill out. As you know, all Federal forms somehow or another get to be enormously detailed. It might help, I suppose, if there were some way to simplify it.

Dr. EDWARDS. I suspect you are correct, and I have not had an opportunity to look at the system that we use, but I am certain that what you say is true.

And I think in terms of developing an adverse reporting system, we have to look at what the FDA requires, as well as what the system provides generally. So we will be looking at our capabilities in this regard, too.

Senator NELSON. Thank you.

Dr. EDWARDS. Under the present system we try to keep the physician abreast of adverse reactions as we become aware of them. This is certainly true with regard to the oral contraceptives. There is no question that it is vitally important to communicate this information to the physician, but there is also corresponding need to keep the patient well informed. I believe that the patient should receive as much accurate information as is necessary for her to make certain decisions.

Let me examine for just a moment how women are currently being informed as regards the oral contraceptive.

They get a good deal of information and misinformation from sources other than the physician—through newspapers, pamphlets, books, television, and from discussion with others. This additional information is reaching a large number of people in a short period of time. While we can control the prescribing information which goes to the physician and any printed or graphic matter that may ultimately reach the patient through him, we have no such opportunity to see that other presentations are accurate, balanced, and properly informative.