Dr. HELLMAN. Yes.

Senator DOLE. There has been, of course, great use of IUD's in India and Pakistan. I have been there and seen some of the clinics in areas where they are trying to promote the use, without much success, frankly. Is it any less safe with the pill than it is with IUD as far as certain side effects or risks are concerned?

Dr. HELLMAN. If you will let me, I want to close with the discussion of safety. But I will say this, that if you just number the complaints that you get—not talking about the serious problems, but the complaints the patients give you—you get about as many with the IUD as you do with the pill. And with both methods of contraception, you have to do what I emphasized before. If you are going to treat a population, you have to have available to them constant medical information. You have to have somebody they can talk to; otherwise the thing will happen that happened in India. They had a good start on an IUD program and it just went right down. They do not have the personnel, the manpower, or the organization to carry out these things.

Senator DOLE. Let me have just one further point here. I read what you indicated with reference to discussing side effects with the doctor and the information needed. It has also been suggested that perhaps there should be some written information available to the user. How are we going to do this in a way that can be understood and still be brief enough to attract the attention of the user and be really of any benefit at all?

Dr. HELLMAN. Well, there are pamphlets that are put out by the drug houses that supposedly give patients information in language that they can understand.

Now, I would like to have delayed any discussion about these until Dr. Edwards testifies because he has gone over them much more carefully than I. There is a question of how much FDA can regulate what is put in these pamphlets. But if you would, I would like to have you ask Dr. Edwards that question, and not me.

Mr. Gordon asked me whether I would discuss the conclusions of the report with regard to safety, and I shall now do this as the closing business.

In the first report, in the chairman's summary—it is not labeled "chairman's summary" in that report, but it is the chairman's summary—we had to make some statement about safety. This was at the request of the Commissioner, and as you know, he is charged with both the efficacy and safety of drugs. It is quite apparent, if you read the report, even the first report, that the committee recognized certain very serious problems with oral contraceptives. They, however, were unwilling, and rightly, I believe, to say these things ought to come off the market. And they were faced with the dilemma, you have to make the statement.

Now, the statement we made in the first report said that these compounds are not unsafe for human consumption, which may not be the exact words, but that is what was said. That is a cute statement, more than a good statement, because we use the double negative to imply doubt. I never was very happy with that statement. I think it is kind of like the Delphic Oracle. You ask him what did you say, we did not understand it, and it is just about like that.