

Dr. JENNINGS. That is right. No, sir, those are devised and distributed by the companies on a voluntary basis. And they are subject to regulation in the sense that they cannot exceed the approved package insert.

The dispensed package to the patient contains, as a rule, a simple set of directions for use, which we have approved for these products. This does not in any way refer to the safety or efficacy of the products, but simply tells the patient how to take the dose, and gives her a few cautions. We feel that this has not served the purpose for which the leaflet under discussion today was designed.

Senator DOLE. We still rely, I assume, on the doctor-patient relationship, we are not trying to preempt the doctor's role in dealing with patients.

Dr. EDWARDS. Absolutely not. As a matter of fact, we certainly do not want to do anything in our action that is going to interfere with this doctor-patient relationship. Being a physician, I am extremely aware of it and feel it is an absolute essential to get patient care.

You certainly know, as well as I, that we are talking about something a little bit different in the case of the oral contraceptive—and I will show you an example of what we are talking about, the patient information on the oral contraceptive package written here on the front of the package, the package insert which has all of this information which goes to the physician.

This is a difficult question, though, as to what kind of information you provide the patient—

Senator DOLE. We have had well-qualified witnesses who have discussed the pros and cons of information. Some indicate they rely solely on the physician; others indicate that we should have the insert. Perhaps this is sort of the middle ground and does not interfere with the doctor-patient relationship.

It is a relative thing to say two out of 200,000 or six out of 200,000, compared to all of the other risks that we contend with daily. I am not certain what the benefits of numbers are. It may have some effect on a person to read she may be one of the six. Perhaps not.

Dr. EDWARDS. Unless you would like, I could just indicate the sections we have here. The next section is who should not take the birth control pills.

Then the next section of the document is special problems. And here we talk about if you have heart disease, kidney, and so forth, your doctor has indicated—maybe I had better read this.

If you have heart or kidney disease, asthma, high blood pressure, diabetes, epilepsy, fibroids of the uterus, migraine headaches, or if you have had any problems with mental depression, your doctor has indicated you need special supervision while taking oral contraceptives. Even if you do not have special problems, he will want to see you regularly to check your blood pressure.

The next paragraph, we indicate some of the pregnancy warnings.

And in the last paragraph, if one has a baby, the dangers of taking the pill at that particular point in time while nursing the baby.

Next, we go into a section what to expect.

The next section is other reactions to the oral contraceptive.