

The next section is possible reactions.

Then we have a special note about cancer:

Scientists know the hormones in the pill, estrogen and progesterone, have caused cancer in animals, but they have no proof that the pill causes cancer in humans. Because your doctor knows this, he will want to examine you regularly.

Senator NELSON. May I ask a question at this point?

On the phrasing, "because your doctor knows this he wants to examine you regularly", I guess the one thing that there was universal agreement about by all witnesses who testified was on the point of physical examinations. They were all agreed that, without any question whatsoever, there should be a regular physical. A specialist in cardiovascular disease recommended an examination once in three months for blood pressure. Another said once a year, all other witnesses saying six months, or one witness saying six to eight months. Most recommended every six months.

I am wondering—and it appears some significant percentage are not examined at all—I am wondering if it would be worthwhile to have a statement that all doctors agree that there should be a regular physical examination without trying to designate a time.

Dr. EDWARDS. I think that would be very appropriate. I think we certainly would agree with you, that anyone taking the oral contraceptive should have a regular physical examination.

Senator NELSON. Let me say, Doctor, I think this is a tremendously significant step that you have taken and that it requires considerable courage to do so, since it has never been done before. And I have some understanding of the kinds of problems that are raised by requiring a packaging insert for the user.

So I do commend you for your courage and far-sightedness in doing it.

This is the specific issue that we raised last year. We called the hearing for the purpose of informing the public, and I expressed my opinion at that time that I thought it was very important for the user to have some information about it, because of the nature and the widespread use of these drugs and the difference between them and drugs prescribed for disease situations. So I think this is a significant step forward. I commend you for it.

Senator MCINTYRE. Mr. Commissioner, a question has risen in my mind that I think you can help me with.

Now, this proposed official draft of information that you feel should be known to the potential user, it is my understanding that many of the pharmaceutical houses put out pamphlets which explain problems, and which discuss the product that they have, and give general information on its characteristics.

I have been wondering if under the Food and Drug Administration regulations, would it be required that these pamphlets that are put out by individual business concerns contain a summary of this, I will call it, official enclosure in the package. Would it be required under your regulations that a summary of this information be contained in all of the pharmaceutical houses' promotional material?

Dr. EDWARDS. I would like to have Mr. Goodrich answer that.