

I have come to the conclusion that the information being supplied to the patient in the case of the oral contraceptive is insufficient and that a reevaluation of our present policies is in order.

Accordingly, I have asked our Bureau of Drugs to examine this area of consumer information and to give me their recommendations.

I have with me today, which I will submit to you, a statement which we are going to publish in the Federal Register so that all interested parties will have an opportunity to comment on it. This statement is the proposed language for a reminder leaflet of uniform content which will be placed by the manufacturer into each package of oral contraceptives produced.

This leaflet is designed to reinforce the information provided the patient by her physician. I emphasize the word "reminder" as its purpose is to recall to the patient her discussion with the physician when she made her decision to begin taking an oral contraceptive.

I will not read this unless you would like.

(The statement follows:)

WHAT YOU SHOULD KNOW ABOUT BIRTH CONTROL PILLS (ORAL CONTRACEPTIVE PRODUCTS)

All of the oral contraceptive pills are highly effective for preventing pregnancy, when taken according to the approved directions. Your doctor has taken your medical history and has given you a careful physical examination. He has discussed with you the risks of oral contraceptives, and has decided that you can take this drug safely.

This leaflet is your reminder of what your doctor has told you. Keep it handy and talk to him if you think you are experiencing any of the conditions you find described.

A WARNING ABOUT "BLOOD CLOTS"

There is a definite association between blood-clotting disorders and the use of oral contraceptives. The risk of this complication is six times higher for users than for non-users. The majority of blood-clotting disorders are not fatal. The estimated death rate from blood-clotting in women *not* taking the pill is one in 200,000 each year; for users, the death rate is about six in 200,000. Women who have or who have had blood clots in the legs, lung, or brain should not take this drug. You should stop taking it and call your doctor immediately if you develop severe leg or chest pain, if you cough up blood, if you experience sudden and severe headaches, or if you cannot see clearly.

WHO SHOULD NOT TAKE BIRTH CONTROL PILLS

Besides women who have or who have had blood clots, other women who should not use oral contraceptives are those who have serious liver disease, cancer of the breast or certain other cancers, and vaginal bleeding of unknown cause.

SPECIAL PROBLEMS

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 don't have special problems, he will want to see you regularly to check your blood pressure, examine your breasts, and make certain other tests.

When you take the pill as directed, you should have your period each month. If you miss a period, and if you are sure you have been taking the pill as directed, continue your schedule. If you have not been taking the pill as directed and if you miss one period, stop taking it and call your doctor. If you miss two periods, see your doctor even though you have been taking the pill as