MEDICINE

FDA Revises 'Pill' Labeling

After two inconclusive reviews of the safety of oral contraceptives on its own, and a review of the reviews which was announced by the Public Health Service, the Food and Drug Administration has decided to require uniform warnings on all manufacturers' labeling of "the pill."

FDA is warning against use of the pill where a wide range of diseases may be present.

But in one area—use of the estrogen-progesterone compounds to prevent spontaneous abortion in pregnant women—FDA lacks sufficient evidence to require cautionary labeling.

There is no reason to assume any harm may come to an unborn child from the small amounts of the hormones present in contraceptive pills, FDA reported. But tests on female rats given high doses of the drugs throughout pregnancy have shown that offspring may be sterile. Because the long-range effects of the drugs on the human fetus are unknown, FDA advises against taking any chances.

Masculinization has been reported in the female infants of some women given high doses of the contraceptives late in pregnancy but male characteristics disappear shortly after birth when the baby is no longer receiving drug residues from her mother.

Active ingredients in oral contraceptives have been found in detectable amounts in the milk of nursing mothers. Because the significance of these amounts on the long-range health of the infant are unknown, FDA advises, against their use.

Formally required contraindications of contraceptive drugs were cited by FDA in announcing requirements for strict, uniform labeling of the eight brands now on the market and of any new contraceptives that may be licensed in the future. Although all brands in current use are essentially the same, the indications and warnings they carry on their labels vary widely. This is because each drug was granted approval on its own merits and since the early ones were intended for a variety of purposes and the later ones manufactured primarily for sale as contraceptives, the companies gave FDA varying statements regarding their use and effectiveness.

The new labels will caution physicians to observe patients with a history of depression and to discontinue the pills if there is a serious recurrence. The "occasional occurrence" of a painful inflammation of a clotted vein (thrombophlebitis) and the possibility of a sometimes fatal lung clot will be mentioned in the new labels. Available data are insufficient to prove that a causal relation between blood clots and oral contraceptives does or does not exist; hence the term "occasional occurrences."

A history of clotting, liver disease, breast or genital cancer and undiagnosed vaginal bleeding will be specific contraindications listed on all labels under the new regulations. In addition, they will advise that the pills be discontinued in event of sudden onset of migraine headaches or eye damage, including loss of vision, and will uniformly recommend the pills be "used with caution" in women who have had strokes. They also should be used "judiciously" in young women with incomplete bone growth to prevent the possibility of premature closure of bone joints.

Manufacturers' efforts to produce effective oral contraceptives of lower dosage will probably place a number of additional brands on the market in the near future.

Bishops, HEW Clash

The long-standing controversy between church and state flared up again last week when Roman Catholic prelates charged the federal government with using its power to establish a "contraceptive way of life." The government responded with an immediate denial.

The Catholic clergymen—The Cardinals and Bishops of the United States—said that health and welfare assistance from federally supported agencies must not hinge in any way upon a couple's willingness to limit the size of its family.

Answering the prelates' statement, Dr. Philip R. Lee, assistant secretary for health of the Department of Health, Education and Welfare, said HEW policies and programs in family planning are intended to "make available to all Americans a freedom which is already available to most Americans."

At this time, the Roman Catholic Church does not condone any artificial means of contraception.

Scientists are pursuing fertility studies to determine exactly when a woman ovulates and is fertile.

And manufacturers are pursuing a pill that would regulate the time of ovulation—to overcome stated ecclesiastical objections to current artificial methods of contraception.

PUBLIC HEALTH

Goddard Rebukes Drug Tester

COMMISSIONER James L. Goddard of the Food and Drug Administration is no foe of birth control pills. But he has cracked down on a doctor who has been writing freely about the pills' value as a defense against menopause.

This "claim" exceeds those for which the drugs have been officially approved. Goddard doesn't question Brooklyn gynecologist Dr. Robert A. Wilson's ability as a physician, but has declared that the doctor is now "unsuitable" to continue to test drugs in humans for purposes of FDA drug clearances.

Dr. Wilson has published in the lay press claims that birth control pills can prevent women from ever "suffering menopause." He views menopause as an estrogen-progesterone deficiency disease which can be prevented by supplying women proper amounts of the female hormones.

Dr. Wilson, who has been conducting tests for G. D. Searle & Co., a drug manufacturer in Chicago, is the author of "Feminine Forever" in which he states that oral contraceptive pills provide probable protection against breast and genital cancers thanks to keeping the women estrogen-rich. This is also beyond FDA-allowed claims.

FDA has previously banned publications, under the food and drug law, when they make unallowed claims for specific drugs or allegedly therapeutic processes. This is not the case here.

Enovid, manufactureed by Searle, has not been named specifically by Dr. Wilson in any of his writings, though he has recommended norethynodrel as an estrogenic progestogen in combination with a suitable estrogen to prevent menopause and signs of aging.

Norethynodrel is an estrogenic progestogen found only in Searle's product and may simply be the compound Dr. Wilson knows best.

Searle has received notification from FDA Commissioner Goddard that test data submitted by Dr. Wilson will no longer be considered acceptable.

A spokesman for Searle said Dr. Wilson enjoys a private relationship to the company like that of any scientist whose work it sponsors. Dr. Wilson is a "recognized leader with much experience" in the field, the spokesman said, adding that the doctor's public statements are made on the basis of that experience and are not connected in any way with Searle.