Indications are that most doctors generally agree.

But Sen. Gaylord Nelson (D–Wis.), persuaded by his recent hearings that women have been inadequately informed about demonstrated and possible risks, told the FDA that "users are entitled to know what the government and the experts know." He urged the FDA to hold public hearings on the issue.

His position is supported by consumer advocates, some scientists and the Women's Liberation Movement, among others.

The AMA and Nelson statements are among about 500 formal comments filed with the Department of Health, Education and Welfare since April 10, when HEW published the warning statement proposed for inclusion in every package of oral contraceptives. Yesterday was the deadline for submission of mailed comments.

William W. Goodrich, FDA's counsel, said that all of the statements filed by organized medical groups take positions similar to the AMA's, which is that "the best way to inform patients effectively is through the physician."

During the Nelson hearings, Newsweek for Feb. 9 reported that two out of every three women on the pills told poll-takers that their doctors had not advised them of the risks.

The proposed warning leaflet, which is subject to modification, blends the views of HEW Secretary Robert H. Finch and FDA Commissioner Charles C. Edwards. It is a dilution of a long, strong statement that Dr. Edwards originally had proposed.

The statement says the pills are "powerful, effective drugs," should not be taken "without your doctor's continued supervision," "may cause side effects in some cases" and cause "rare instances of abnormal blood clotting." Five symptoms are listed which if experienced should cause a user to notify her doctor.

In a speech last Tuesday in Philadelphia, Dr. Edwards said the FDA is "giving careful consideration to all views, but it is our intention to carry through with a final order" requiring a leaflet in every package of pills.

He said he saw no other answer to the fact that "a very substantial number" of pill users "are not under medical supervision." His hope is that a leaflet in the package "would lead them to seek medical advice before continuing to take the pill."

For the AMA, Dr. Ernest B. Howard, executive vice president, said there should be no statement to the user at all, "in the best interests of the patient and the practice of quality medicine . . . It intrudes upon the patient-physician relationship" and "would lead to confusion and alarm among many patients and could result in harm to some."

Because the pills are prescription drugs, it is "the responsibility of the physician to inform his patients of the potential hazards," Dr. Howard continued.

"In counseling on family planning . . . he should provide information that will enable the patient to make an intelligent decision," Dr. Howard added. "When medical supervision is lacking, however, it is unlikely that the proposed leaflet will correct the situation."

Nelson, in his formal comment to FDA, commended Commissioner Edwards for giving "positive recognition" to "the importance of the concept of informed consent in the use of oral contraceptives."

The senator agreed that "the fundamental responsibility rests with the prescribing physicians." But, he said, "a simple, direct reminder notice should be available to the user at all times since it cannot be expected that millions of people are going to remember their physician's advice for long periods of time."

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[From the Washington Post, June 24, 1970]

AMA Pledges All-Out Fight Against Birth-Pill Warning

(By Victor Cohn)

Chicago, *June 23*—The American Medical Association today promised a "legal and legislative battle" against a printed warning due soon in every package of birth control pills.

But Dr. Charles C. Edwards, commissioner of the Food and Drug administration, defended the warning as a kind of "insurance policy" in the patient's interest.