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SPECIAL REPORT BASED ON NEW MEDICAL EVIDENCE—MUST WE NOW BAN THE BIRTH CONTROL PILLS?

Are birth control pills safe? Should doctors be more careful and selective in prescribing them? Indeed, should the pills be banned until clearer proofs of safety have been developed?

For the second time in less than four years, medical evidence has posed such questions of vital concern to the estimated five million American women using oral contraceptives. In 1962, it was disclosed that blood clotting, fatal in some cases, had occurred among a number of women who, perhaps coincidentally, were using the pills. Now, new fears about the pills' safety have been raised by a medical journal report that detailed damage to eyes and the central nervous system in some women taking the drug. After studying evidence gathered by Johns Hopkins Hospital specialists who prepared that report, the U.S. Food and Drug Administration took these steps last November:

It requested all pharmaceutical manufacturers of birth control pills to include a precautionary warning in material supplied to physicians and pharmacists on neuro-ocular side effects. This advises that patients should stop using the pill if there is a sudden onset of severe headache or dizziness, blurred vision, or if examination reveals eye nerve, retinal or vision defects.

It appointed a committee of obstetricians and gynecologists to make a *full-scale* review of the safety of birth control pills. At its first two-day meeting in November, the committee, on the basis of preliminary facts, found no evidence of a cause-and-effect relationship between the use of birth control pills and the recently reported neuro-ocular manifestations. Nevertheless, it endorsed the action of the FDA in placing a warning concerning eye problems in the material sent to doctors. In an attempt to find out whether eye problems occur more in women taking the pills than among women in general, the committee planned a study to compare two groups—one of women who take the pills and the other of women who do not. This study is expected to be completed for the committee's final report, due in March.

In 1963, another FDA advisory committee had concluded there was no statistically significant relationship between the use of pills and certain blood-clotting conditions. However, the committee strongly recommended further study of how oral contraceptives affect blood clotting. The pills' labeling was also revised to warn that they should not be used by women who have a history of thrombophlebitis or other thromboembolic disorders (the blood conditions studied). Such blood-clotting problems can cause damage to the blood vessels, lungs, heart or brain.

At its meeting in November, the new committee evaluated more than 2,200 adverse reactions which the FDA classified as "serious." The total number of reactions studied is expected to reach 12,000, including less serious ones, before the committee's final report. The FDA would not reveal how many deaths are included in the total. Subcommittees have been set up to study thromboembolism, carcinoma (cancer) potential and other possible adverse experiences. The FDA will not consider extending its present limit of four years' use of the pill until after all safety and efficacy factors have been reviewed by the committee.

A Good Housekeeping article on the pills last September noted that a few ophthalmologists had reported some patients on oral contraceptives had developed papilledema, a condition affecting eye nerves. As a result of these reports, the pill then most recently approved by the FDA for prescription sale to the public had included a warning, in material sent to doctors, against continued use if vision defects were noticed. The FDA said at that time it was studying whether this warning should be applied to the nine other birth control pills it had approved. In November, the report by Dr. Frank B. Walsh and his associates at Johns Hopkins listed 63 cases of eye and nervous-system damage to women taking the pills. The FDA then acted.

The Walsh report detailed cases of 25 women who developed stroke-like symptoms while taking the pills. Five died. Twenty-two women developed eye symptoms, 10 suffered migraine headaches, four had symptoms resembling brain tumors and two had other adverse reactions. Dr. Walsh and his associates said available data did not prove a direct relationship between birth control pills and the reactions cited in the report, but the physicians con-