ommended its use for only 2 years. But the warning seems to get lost in the shuffle of patients' enthusiasm and is probably not widely observed. Some researchers and gynecologists have wondered whether 11 years of clinical testing is adequate for a drug whose implications are for the full 25 years of a woman's child-bearing span. Questions have been raised about Enovid's possible long-term effect on the body's hormonal balance and on the pituitary gland as well as its relation to thrombophlebitis and certain female cancers.

These questions might have remained academic had it not been for the increase in public skepticism about new drugs that the furor over thalidomide seems to have engendered. As early as December 1961, Searle and the Food and Drug Administration were receiving reports of deaths from thrombophlebitis (blood clots), but these received little attention outside of professional circles until the thalidomide story broke, in the summer of 1962. Senator Humphrey, in his investigation of FDA's handling of thalidomide, raised certain questions about Enovid, and appeared satisfied by the answers. Public agitation continued to increase nonetheless, and in January 1963 the FDA took what was for it an unusual step—it appointed an expert committee, headed by Irving S. Wright of New York, to investigate the possible relationship between Enovid and thromboembolic conditions. At that time, 350 cases of blood clots, and 35 deaths, had been reported.

More Questions than Answers

The narrow task of the committee—to investigate one possible effect of Enovid—was narrowed still further by its discovery that data on the occurrence of thromboembolism were not available, and that it could neither exclude nor establish the possibility that Enovid increased the clotting tendency. Statistics on mortality from thromboembolic complications in users and nonusers of Enovid could, however, be assembled, and the committee focused its attention on the deaths. Only 12 or 14 of the 35 reported deaths could be conclusively attributed to thromboembolism, and after figures supplied by the company had been pared down to match the sample from the general population, 1 million was taken as the number of women using Enovid. With this base, the committee found that through age 34 there was no significant difference in the rates of death from thromboembolism for users and nonusers of Enovid, but that for women in the 35–39 age group the rate among Enovid users was 2.4 times that for nonusers, and that for women in the 40–44 group the rate was 3.8 times as high for users as for nonusers.

In the closing paragraph of its report, submitted to the Food and Drug Administration 2 weeks ago, the committee warned that "any firm reliance on the risks as calculated is tempered by the assumptions made." One of the assumptions that troubled it most was that concerning the number of users of Enovid.

Accurate distribution figures are impossible to obtain—the number of prescriptions refilled or lapsed cannot be determined, and company sales records are apparently not kept in a manner conducive to precision. But if only 10 percent fewer patients took Enovid than the committee calculated, it reported, the death rate from the drug would come very close to statistical significance for all ages; and if 50 percent fewer people took it, the rates would be very significantly greater. If 50 percent more people are presumed to have taken the drug, the danger declines for the 35–39 year group but remains significant in the 40–44 year range.

The committee's report, in sum, is by no means a clean bill for Enovid. The committee set out to answer the question of the possible relation between Enovid and thromboembolism, which was only one of the several questions that have been raised about the safety of Enovid. Its answer was that there were not enough data to give an answer. On the single question of deaths from blood clots, the committee's report can hardly be called reassuring.

This being the case, FDA's reaction to the report is more than a bit puzzling. In announcing the continued availability of Enovid for prescription sale, FDA took note of the "apparent hazard" for women over 35 but recommended that this be weighed against the demonstrated hazards of pregnancy—and not against the hazards of other methods of contraception. In addition, the FDA chose this occasion to extend its sanction of the drug—which is now recommended for a 2- to 4-year instead of a 2-year period—at the same time it announced that further studies need to be undertaken.

Although there is no hard evidence against the drug, there are clearly some uncertainties, and FDA's action is more positive than it might be. Part of the explanation is that science can tolerate more uncertainty than can bureaucracy, and that, unlike the committee report, which could say "maybe," the FDA had no noncommittal alternative. When the FDA said "yes," drug law, drug promotion, and Enovid's popularity being what they are, the decision opened the possibility that millions more women may be exposed to a drug whose effects are not yet unimpeachably established. Had it said "no" and insisted that Enovid be withdrawn from the market for a further period of experimentation, the FDA would not only have antagonized the present and future manufacturers (and reversed a past decision of its own physicians) but would have disappointed the growing number of women who have become converts to oral contraception as well. The FDA may have its private reasons for supporting Enovid, but its public reasons—in terms of the medical evidence alone—do not seem above dispute.—ELINOR LANGER

Announcements

Rice University has established a **satellite research laboratory** as a basis for the experimental program of the school's space science department. The laboratory includes facilities for design, construction, checkout, and testing of instruments and payloads; a telemetry and command station; and facilities for data reduction and analysis. Curtis D. Laughlin, former research physicist at the State University of Iowa, is chief of the laboratory.

A center for research on **enzymes** has been established at Tufts University, Boston, under a grant from the U.S. Public Health Service. The major purpose of the new center is to expand the production of enzymes for use in research at hospital and university laboratories. Enzymes commercially available will not be produced at the Tufts center. Stanley E. Charm, associate professor of biomedical engineering at the university, has been named technical director of the facility.