

or lasting harm may befall his patient as a result of the medication. Instead, a leaflet written by the government in clear, simple English will be included in every package of oral contraceptives sold.

The draft text as printed in the Register will spell out the slight added risk of blood clots (pointing out that few are fatal); warn users to see their doctors if they experience such symptoms as sudden headaches, leg or chest pain and counsel that people with breast cancer, serious liver disease or unexplained vaginal bleeding should not take oral contraceptives at all.

The industry will have 30 days to "offer comments." Several months later a final version of the leaflet should begin to become as familiar to women of child-bearing age as "the pill" itself.

A recent Gallup poll reports that two-thirds of the doctors prescribing oral contraceptives make no mention to their patients of its possible side-effects. One possible result of the leaflet, then, will be to protect such doctors against possible malpractice suits.

Nevertheless, its reception by the medical profession is bound to be mixed. Some physicians probably will construe it as "interference in the private practice of medicine" and the drug companies, too, are hardly likely to be pleased.

The way in which the FDA commissioner, Dr. Charles C. Edwards, handled the announcement then must be counted as a master stroke. The last day of the hearings on oral contraceptives conducted by Sen. Gaylord Nelson, D-Wis., as chairman was, of course, a natural forum. But Edwards went beyond merely telling Nelson what in general terms his agency intended to do.

He released the provisional text of the brochure to senators and the press, thus assuring that its contents would become widely known. In this way, it should be more difficult than it otherwise would be for the industry to try to bar the leaflet or to water down the language describing the hazards of contraceptive drugs.

Despite rumblings of dissatisfaction from doctors and industry spokesmen, the FDA's general counsel said he expects no serious opposition and that drug makers will be required to include the leaflets within four months.

The point was often made at the Senate Hearings that nothing was disclosed that was not already available in scientific papers. This is perfectly true. However, what these critics failed to mention was that little of this information had been made known to the public at large.

Will the FDA's consumer leaflet be followed by others for other drugs? Perhaps. Drug side-effects increasingly are the cause of death, disability and illness and both Edwards and his FDA predecessor, Dr. Herbert L. Ley, Jr. are known to favor the principle of "informed consent" and greater consumer education.

In their view, the patient who knows what he may experience from prescription medicine is the one who will call his doctor in time to avoid becoming seriously ill. It would not be surprising, therefore, if the oral contraceptive leaflet were the beginning of a trend.

[From The Evening Star, March 8, 1970]

'PILL' SALES AND STOCKS COOLED BY CONTROVERSY

(By Bailey Morris, Star Staff Writer)

As the controversy over harmful side effects of the pill has heated up, sales of oral contraceptives and stock prices of their manufacturers have cooled off.

Estimates by Wall Street analysts of the number of women who have stopped using the pill since hearings conducted by Sen. Gaylord Nelson, D-Wis., centered national attention on blood clotting and other side effects range as high as 2 million of about 8.5 million users in the United States.

The figures are speculative, but they do give substance to comments from four of the nation's eight largest pill manufacturers that soon after the Senate hearings began, the impact on oral contraceptive sales could be detected.

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This negative effect on an oral contraceptive market estimated at more than \$95 million in the U.S. alone has set off a dual alarm in the financial community. It has affected both drug manufacturers worried about public impact in