

However, Nelson added, the warning that goes to the druggist often is not passed on to the doctors and "it appears evident that a substantial number of users are not advised of any of the health hazards or side effects."

In examining the packages of several brands of oral contraceptives, Nelson stated, his staff was unable to find clear warnings of possible health hazards or side effects.

"Whereas the pill has proven to be effective and convenient, it also has demonstrated health hazards and serious side effects in a certain percentage of cases," Nelson said. "As a matter of equity and fairness, users of the pill are entitled to be informed of the known side effects so that they can make an independent judgement about its use."

Senator NELSON. In essence, I stated that as a result of the exposure to many conflicting reports, books, magazine articles, and statements on the risks, dangers, and efficacy of the oral contraceptives, as well as widespread drug company promotion misinformation, has been widely disseminated.

For example, in the January 1970 issue of Redbook magazine (page 36) we find the following statement:

Because of reports of complications associated with its use, there is much controversy about the safety of the pill. But it is difficult to determine whether there is direct cause and effect relationship, because reports of complications are rare in comparison to the large number of women using the oral contraceptives.

This quotation should be compared with the FDA's June 28, 1968, warning to physicians that "there is a definite association between the use of oral contraceptives and the incidence of thromboembolic disorders," and that "A statistically significant association has been demonstrated between use of oral contraceptives and the following serious adverse reactions: Thrombophlebitis and pulmonary embolism. The official labeling also cites British data that approximately one in every 2,000 who take the pill suffer blood clots serious enough to require hospitalization, some of which are permanently disabling.

An article in Bride's magazine of December 1969, which will no doubt be read by many young women, makes the following claims:

The pill is virtually 100 percent effective.

A pill user who has headaches, fatigue or leg cramps often blames these on the pill rather than on overwork or bad day at home.

The pill prevents ovulation with the same hormones that the body produces pregnancy.

The pill is probably the most thoroughly tested drug ever approved for use in the country.

Statistically a woman's chance of death during pregnancy is eight times greater than the chance of death from clotting among pill users.

These claims, as well as others, will, I hope, be analyzed as objectively and scientifically as possible, for the public is entitled to know the facts. The possible longrun effects in particular, have not been sufficiently brought to the public's attention.

The Monopoly Subcommittee of the Senate Small Business Committee has had a longstanding concern with the development, marketing, and distribution of a wide variety of drugs. It is, therefore, appropriate that we turn our attention to what has become one of the most widely used drugs over the last decade—oral contraceptives.

It is extremely important in my judgment to consider very carefully the safety of this drug and to make fully available to the public in appropriate perspective those facts which are known about the oral contraceptives now in use and their alternatives. This effort should