

den's committee and its report, it had been told nothing of these things by FDA.

Nor, according to Dr. Holden, had the committee been aware that FDA had approved inconsistent labeling for different brands of identical pill formulations. This permitted a physician to believe one brand was safer than another, although both brands were chemically the same.

About three years ago, a Senate subcommittee headed by then Sen. Hubert H. Humphrey published a revealing FDA document, of which Dr. Holden was—and other members of his committee apparently were—unaware.

The document disclosed the situation in 1960 when FDA released Enovid, the first oral contraceptive, for birth control purposes in possibly millions of women.

At that time, when the agency recommended a maximum consecutive use limit of two years, the grand total of patients on whom Enovid had been tested for safety for from 12 to maximum of 38 *consecutive* menstrual cycles was 132. Dr. Holden said the 132 were "not enough."

The number of Enovid tests has greatly increased since 1960, but similarly small numbers were involved last spring when FDA released the first sequential oral contraceptives, which employ a different concept of action with a recommended maximum consecutive use limit of 18 months.

The number of women who as of last spring had taken Mead Johnson's sequential product, Oracon, for 18 consecutive cycles was 274, for 24 cycles it was 148 and for 36 cycles it was 16.

For Eli Lilly & Co.'s C-Quens, the total for 18 cycles was 445, for 24 cycles it was 180 and for 30 cycles it was four.