

of The Pill (provided, however, that one can motivate women to use it, or to stay on it, or to take it on 20 consecutive days).

The sober second look concerns itself with safety. The extent of the gap between promise and performance is highlighted by the accumulation of contraindications, precautions, warnings and adverse effects listed above, as well as by *The Sampler on The Pill*. The latter is only a token of the thousands of articles that have been written, since the introduction of The Pill, questioning safety, reporting deaths or lesser complications, or reporting unsuspected, newly discovered, systemic effects.

These reports are written by reputable physicians and are judged to be worthy of publication by editors of leading scientific periodicals. With England's recent statistical demonstration of a definitive association of The Pill with thromboembolism (*Brid. Med. J.* 5/6/67), the judgment of individual clinicians recording this association has been substantiated and has proven superior to the judgment of the four committees appointed to determine safety. (Searle-AMA 9/2/62; Wright 8/3/63; WHO 12/6/65; and Hellman 8/15/66.)

The Pill was originally and erroneously introduced as a "natural" and "physiologic" means of birth control and, by implication, safe. (John Rock, M.D., *The Time Has Come*, Alfred A. Knopf, 1963, Ch. 14.) Early investigators, thereby, focussed their greater interest on effectiveness rather than safety. Protocols, as a result, were deficient in medical surveillance. This deficiency accounts for the innocent dismissal as "heart attacks" (author's quotes) of two deaths among the 838 women using The Pill in the Harvard School of Public Health-Puerto Rican field trials. (A. P. Satterthwaite, M.D. & C. J. Gamble, M.D., *Conception Control with Norethynodrel*, J. Am. Med. Women's Assoc., 17:797-802, Oct. 1962.) These women were young, in previous good health, were not seen during their illness by staff members conducting the study, and were not autopsied. Subsequent investigations by Puerto Rican physicians (A. M. de Andino, Jr., M.D., et al *Informe Preliminar Del Comité De La Asociación Médica De Puerto Rico Nombrado Para El Estudio De Las Reacciones Adversas A La Droga Enovid*, Aug. 28, 1962; Ramon Sifre, M.D., *Statement on Enovid*, April 20, 1963) as well as a representative of the FDA (Heino Trees, M.D., Meeting conducted by Sen. E. Gruening, Aug. 7, 1963), confirmed that thromboembolism and deaths were occurring in association with The Pill, contrary to the denials of the promoters of The Pill in Puerto Rico. Because The Pill had acquired "diplomatic immunity from criticism" (D. B. Clark, M.D., *Annual Meeting, American Academy of Neurology*, Philadelphia, 1967), unknown to any other marketed drug, no publicity of these facts was forthcoming.

Klopper (*Recent Setbacks*) makes clear that The Pill is not natural and physiologic in its action. This theory was also effectively dismissed by Robert E. Hall, M.D., of the Columbia University School of Medicine: "Rock's rationalization of The Pill is to me a little short of preposterous . . . As a birth control enthusiast I would like to dismiss this theory as a harmless euphemism; as a doctor I must aver it is medical fantasy." (*N.Y. Times Book Review Section*, May 12, 1963.)

The Pill acquired its diplomatic immunity because it was promoted as the solution to the population problem in undeveloped countries, and to the growing welfare problem in the U.S. Under the thesis that the end justifies the means, imputing danger to The Pill was branded as unhumanitarian. The fact is that The Pill has not solved the population problem and, with the exception of a few episodic successes, has not received significant acceptance in developing countries and among the poor. This accounts for the subsequent major shift to other contraceptives as a solution to the problem: first to the IUD—the loop or coil, and following its failure, to new and then to old contraceptives. The Agency for International Development, for instance, is now shipping condoms to India.

When *Time* went all out for The Pill (April 7, 1967), it referred to the "latest" report of Dr. John Cobb to prove that The Pill was being successfully used in Pakistan. But *Time* was ignorant of his latest report, from which I quote: "Enthusiasm was contagious . . . But then we began to analyze our data, checking off the women who had received the IUD and other contraceptives, against our census roster for the village . . . At the most, this would reduce the birth rate from the estimated level of 50 to about 47, a long way