

made in syndicated newspaper articles and in such geriatrics journals as *Look* and *Vogue*, provoked the FDA. In November, 1966, it notified Searle, Dr. Wilson's research sponsor, that he had "publicized the use of Enovid in lay publications, stating that it is effective in preventing symptoms of the menopause. Our investigational drug regulations provide that neither the sponsor nor anyone on its behalf may disseminate promotional material claiming that the drug has been shown to be effective for the conditions for which it is being investigated. Dr. Wilson has disseminated such information. He is therefore unacceptable as an investigator for 'Enovid in the Menopause.'"

One of the most troubling questions about The Pill is what relation it may have to cancer. The fact is that the Food and Drug Administration, when it let the first Pill go on sale in 1960, was as ignorant about that relation as it was about an association with clotting. The agency's documented experience as to cancer involved 400 women for four years—a ridiculously inadequate number and much too short a time period, the latency period of all substances known to be carcinogenic in humans being about ten years. As of 1966, published data on the incidence of cancer in women under 40 who had received The Pill continuously for at least four years involved merely eighty-five women. Dr. Roy Hertz, a member of the FDA's Advisory Committee on Obstetrics and Gynecology, has pointed out. Was the number sufficient, then Commissioner James L. Goddard was asked in January, 1967, on *Face the Nation*. "No," he said frankly, "I don't believe it is."

The same view was held at the National Institutes of Health. On February 17, 1965, the late Representative John E. Fogarty, chairman of a House Appropriations subcommittee, had taken up the possibility of a relation between The Pill and cancer. There was this exchange with Dr. James A. Shannon, then director of NIH:

Mr. Fogarty. So people are really taking a chance.

Dr. Shannon. I believe so. There are a great many studies on experimental animals that indicate that they probably can be taken without hazard, but *there has not been adequate human exploration to be certain* [my italics].

The subcommittee hearing containing the exchange was published later in 1965 but the message was largely unreported, despite the authoritativeness and prestige of the source and the significance of the message.

In its report of August, 1966, the FDA's Advisory Committee dealt with claims made by various purported experts that The Pill provides probable protection against certain kinds of cancer. Disagreeing, the committee said that "there is not sufficient evidence to support the contention that contraceptive pills may protect against the development of carcinoma of the cervix," that available data "do not permit any conclusions relative to the effect, either adverse or beneficial . . . on endometrial [uterine] cancer," and that the relation of The Pill to human breast cancer is "unknown."¹

On the day in April, 1967, when *The New York Times* ignored the cautionary speech given by FDA Commissioner Goddard in Atlanta, it carried from Palm Beach an optimistic, 17-paragraph story by Jane E. Brody. It began: "Oral contraceptives not only seem not to cause cancer, but they also apparently prevent at least one type of cancer from developing, a Harvard gynecologist reported there today." The conclusion of the FDA advisers that the evidence was insufficient to permit *any* conclusions was not mentioned. The Harvard gynecologist was Dr. Robert W. Kistner, who in 1964, it will be recalled, had told of experts who "completely exonerated" The Pill as a cause of clotting. And *Time*, in its "Freedom From Fear" cover story, said, "Despite dark fears, there is not a shred of evidence that the pills cause cancer. In fact, they may even give some protection against it." Again, the FDA advisers were ignored.

¹ Charging that Merck & Co. failed to report promptly the discovery of breast cancer in beagles given MK-665, an experimental oral contraceptive, the FDA in April, 1968, asked the Justice Department to undertake a criminal prosecution.