quality of "the evidence" from the medical and lay press and public. As a practical matter, there was little choice but to take the decision to allow marketing on faith. The assumption was erroneously but widely made that those in authority were observing a standard such as that articulated in August, 1961, by Drs. H. Cook Hale, Clarence J. Gamble, and Adaline Pendleton Sattherwaite, all of Harvard, in the *American Journal of Obstetrics and Gynecology:* "No method of pregnancy spacing, even though highly effective, is justifiable if it endangers life or health." The assumption also was widely made that the tests of large numbers of women in Puerto Rico were for safety; in fact, these tests were for efficacy.

There were times when subcommittees of the House and Senate stripped away the secrecy imposed by the FDA and bared evidence of non-feasance, misfeasance, and malfeasance. Usually, the press responded with non-reporting. Such was the case in early 1963 when a Senate Committee on Government Operations subcommittee headed by then Senator Hubert H. Humphrey, which had been monitoring the agency's performance, published some shocking internal FDA documents. One was the memo from Dr. Kessenich which provided the foundation for the decision by the FDA, in 1960, to let Enovid be marketed as a contraceptive. The "entire series of clinical cases" on which the conclusion of safety was based, Dr. Kessenich said, included only 66 women who had taken Enovid for 12 to 21 *consecutive* cycles; only 66 more had taken it for 24 to a maximum of 38 *consecutive* cycles. "*Consecutive*" is the crucial word, because *sustained* use is what must be monitored if reliable information is to be had on the impacts of taking a powerful combination of estrogen and progestogen over a long period—almost three decades, in the extreme case of a female who should use The Pill over her entire child-bearing age range of 15 to 44. Yet the number of women who had received Enovid continuously for a year or more was 132. As a basis for presuming safety in long-term use by, ulimately, millions of women, this was scientific scandal. To my knowledge, the sufficiency of the test sample since its exposure has not been publicly and specifically defended—not by the FDA, not by scientists, not by organized medicine, not even by the manufacturer. For one thing, 132 is a smaller number of women than, this year alone, in the United States alone, will die from clotting induced by The Pill.

If the adversary system somehow had reached out to the FDA and compelled it to disclose its evidence and non-evidence of safety, the agency would have been laughed out of the courtroom. And had the press not failed to call the attention of the lay and medical public to the figures blind ignorance would not so long have been perpetuated. In October, 1965—two and a half years after the Humphrey subcommittee published the data—the Committee on Human Reproduction of the American Medical Association issued, in the *Journal* of the AMA, a comprehensive guide to conception control. The Humphrey figures were nowhere mentioned. In an interview, Dr. Raymond T. Holden, the Committee chairman, acknowledged to me that he—and, so far as he knew, the seven members of the committee—had never heard of them. They were, he said forthrightly, "not enough."

Also in 1963, a report was made by the Wright Committee, a group of consultants assembled by the FDA after it had learned of 30 fatal and 242 non-fatal clotting episodes in users of Enovid. At the time the committee was named, December, 1962, Enovid was the only oral contraceptive on the market. The committee investigated the available evidence but found it too full of holes to yield a statistically significant result. Again widely and erroneously, this was assumed to mean that Enovid had been found safe. The committee's single recommendation was for a well-controlled, prospective (looking forward) study. This recommendation was of obvious, critical importance, and on a grand scale, to health and life. For years, the FDA did not implement it and did not even seek funds to implement it. This non-performance was non-monitored by the Congress. With the exception of *The Washington Post*, the press failed to call attention to the failures of the FDA and the Congress. Once again, non-reporting served to re-enforce an invalid presumption of safety.