

the hazards of pregnancy with the hazards of The Pill. These are based on a statistical fallacy. This can be demonstrated by using figures cited by the British Medical Research Council in its preliminary report.

As has been noted, the Council tentatively estimated that The Pill caused deaths from clotting at the rate of 30 per million per year. This rate was compared favorably with the four-times-greater mortality rate of 120 per million completed pregnancies. Such a comparison, however, is valid only for those women who will use no contraception but The Pill; it is absolutely irrelevant—as irrelevant as traffic accidents—for the large numbers of women (especially in the middle and upper classes) who reliably will use, say, vaginal foam or a diaphragm with spermicidal cream or jelly. Among these women the failure (conception) rate is very low, on the order of 2.5 percent. This is about the same as for the so-called sequential form of The Pill, for which the regimen is ingestion of an estrogen-only tablet 15 days a month and an estrogen-progestogen tablet 5 days. Thus it is not 1 million out of 1 million such women who face the hazards of maternity, but only the 25,000 or 2.5 percent, who become pregnant. The rate at which mortality occurs in completed pregnancies, 120 per million, consequently must be applied to 25,000. The computation shows that 3 women will die—27 fewer than if all of the 1 million women had taken the almost totally effective combination (not sequential) Pill. In addition to the statistical fallacy, one must take into account other factors—the higher clotting death rates indicated last May in the Research Council's final report, the failure to allow for the less-than-perfect efficacy of the sequentials, and the distortion made unavoidable by a focus on *fatal* clotting without regard to the higher incidences of serious—and sometimes disabling—clotting episodes and to the possible range of other associated diseases.

By now, having been planted in more places than can be counted, the comparison with maternal mortality is indelibly inscribed in our medical mythology. In *Birth-Control*, a Time-Life book published in 1967, for example, Ernest Havemann said the risks of clotting from The Pill “are far less than those of an ordinary pregnancy.” Trying to cool questions in Parliament in the same year, Health Minister Kenneth Robinson emphasized the greater “total risks associated with pregnancy.” In *The Sunday Times* of London, Moira Keenan said that although there may be 30 clotting deaths per year among 1 million users of The Pill, “four times this number would die from thrombosis if they became pregnant.” On *Today* on May 2, 1968, Dr. Louis M. Hellman, the Food and Drug Administration's outside expert, said, “The British say the risk is less than having a baby.” At about the same time, *The New York Times* said, “But the British reports noted that the risk attributed to the pills was substantially less than the risk of death from pregnancy.” And *Newsweek* cited the greater “well-established risk of blood-clot complications in pregnancy.”

Worse than any of this were the efforts, which continued even after publication of the preliminary and final British reports, to deny that The Pill caused clotting at all. In October, 1967, for example, *Parents' Magazine* carried an article in which Dr. George Langmyhr, medical director of Planned Parenthood-World Population, cited data purporting to show that The Pill could not be the cause. The data were derived from a book entitled *Oral Contraceptives*, by Dr. Victor Drill, director of biological research for G. D. Searle & Co., maker of Enovid. This was not disclosed to the readers of *Parents'*. In addition, the data used by Dr. Langmyhr have been acknowledged even by Searle's Dr. Irwin C. Winter, vice president for medical affairs, to be “very likely a reflection of inadequate reporting.”

One can only speculate about how much harm has been done by efforts to downgrade the hazards of The Pill, no matter whether such efforts were humanely motivated (as in the case that follows of Dr. Louis M. Hellman, chairman of the Food and Drug Administration's outside consultants) or otherwise motivated (as in the case that follows involving G. D. Searle, manufacturer of Enovid).

In January, 1968, Dr. Hellman and the FDA held a press briefing on an Advisory Committee report on intra-uterine devices. However, questions about The Pill were asked. Dr. Hellman disclosed that—on a confidential basis pending publication in the *British Medical Journal* on April 27—he had been shown