

kets, Dr. Rock said that when taken "under the supervision of a competent physician, and directions followed," The Pill "is perfectly safe." Similarly, Dr. Robert W. Kistner, a Harvard Medical School colleague of Dr. Rock, said in the March, 1964, *Postgraduate Medicine*, "... scrutiny of the available data by experts in the field of hematology and vascular disease has completely exonerated the drug as the etiologic factor." Such claims are, on their face, scientifically untenable. For one thing, Dr. Rock's "competent physician" has no way of detecting, say, a predisposition to clotting in a woman with no indication or history of such disease. For another, it is an axiom that no data about a drug and adverse reactions ever warrant a claim that it is "perfectly safe" or has been "completely exonerated." A scientist properly can assert only a cautious conclusion: that there is a probability of a high or low order that a cause-effect relation with adverse reactions has been demonstrated.

Dr. Kistner's claim of complete exoneration was circulated among an influential group of laymen by G. D. Searle & Co., manufacturer of Enovid, the pioneer oral contraceptive, and of Ovulen-21, another such drug. On October 15, 1965, a few weeks before the publication of my *The Therapeutic Nightmare*, Searle launched an extraordinary campaign by sending to "Book Review Editors and Book Reviewers" an 8-page "Fact Sheet." The headline was, "SEARLE SEEKS TO AVOID PUBLIC 'PANIC' ON ORAL CONTRACEPTIVES/BY ALERTING BOOK REVIEWERS TO 'MISINFORMATION' IN MINTZ BOOK". Other cover pages were prepared for other news executives, such as "Science and News Editors."³ What set off the Searle crusade was a chapter on the facts known up to that time about reasons for concern about The Pill. Coming down hard on the possibility, raised in the book, that The Pill could cause clotting, the "Fact Sheet" quoted Dr. Kistner to the contrary.

More celebrated, however, is Dr. Rock. He has told people what they want to hear. This has enabled him to shrug off criticism that was scientifically devastating. Consider a claim he made in 1963 in his book *The Time Has Come*. The claim was that The Pill is a "natural" and "physiologic" contraceptive technique. In *The New York Times Book Review* Dr. Robert E. Hall of Columbia University, an admitted "birth control enthusiast," said, "I would like to dismiss this theory as a harmless euphemism; as a doctor I must aver it is medical fantasy." Dr. Herbert Ratner has told why. The Pill, he said, induces "false pregnancy," which "is a disease, not a normal state." In true pregnancy, "the vascular system of the body adjusts to accommodate a rapidly enlarging uterus," he explained. "In false or Pill pseudo-pregnancy, the pelvic vascular system increases the blood supply, but there is no enlarging uterus to utilize the increase. This results in extensive venous congestion [which] introduces a whole series of factors predisposing to thrombosis and embolic phenomena." How can contraception with The Pill be "natural" when, as Dr. Clark, the professor of neurology at the University of Kentucky, has pointed out, a woman taking it "is, in effect, pregnant and delivering every month," and has over her child-bearing life "90 times more chances of showing the complications of pregnancy"?

THE LAST CLUES

Let us see how the present situation developed.

Particularly in the period 1954 through 1965, when the late George P. Larrick was Commissioner of the Food and Drug Administration, the agency allowed a great many potent drugs to go on the prescription market. Frequently, safety had not been actually demonstrated but merely had been asserted by companies in which the FDA had confidence. In May, 1960, Dr. William D. Kessenich, then director of the Bureau of Medicine, notified Larrick that the New Drug Branch of the bureau had "concluded that the evidence establishes the safety of Enovid tablets for use in conception control. . . ." The agency enforced rigid secrecy policies that concealed the nature and

³ I have no evidence on what impact the Searle campaign may have had. With extremely few exceptions, the book was neither mentioned nor reviewed in magazines—but it was extensively (and often very favorably) reviewed in newspapers; and I had, and accepted, numerous invitations to appear on radio and television stations in several cities.