

obligated to act? Is it to wait until the dangers become fully apparent to the consumer herself? One out of five women (estimated to be 1,232,000) once having used The Pill, has already decided on her own never to use The Pill again. (*Science* 153:1199, Sept. 9, 1966; 155:951, Feb. 24, 1967.) Do we wait until all women reject The Pill? Obviously not, since the FDA is supposed to supply expert epidemiologic knowledge in advance of the obvious fact.

In the spring of 1955, the government reluctantly removed Salk vaccine from the market, because its dangers became apparent to the man on the street. With the later Sabin vaccine, and the bitter Salk vaccine experience behind it, the government took a more sophisticated and responsible position. When doubts arose, it was ready to recall the Sabin vaccine if cases of paralytic polio caused by the vaccine exceeded one per million inoculations. It has now been established that The Pill causes 30 deaths per million women from thromboembolism, to say nothing of severe disabilities from the same condition. Again, we ask, at what point will the FDA act on The Pill?

Presumably, The Pill would have been recalled from the market if any of the four committees in considering the association of The Pill to thromboembolism found a significant relationship.

Is FDA's inaction a preview of things to come? Are we going to witness a series of future rationalizations as associations are established between The Pill and pseudo-carcinoma, chromosome damage, depression, diabetes mellitus, hypertension, liver disease, magnesium deficiency, migraine, sterility, cerebral arterial insufficiency, vaginitis, vision impairment and perhaps cancer?

Medicine's ultimate goal is the prevention of disease and the promotion of life. When one takes the incidence of individual adverse effects and calculates the numbers of women suffering from ailments generated by The Pill, the total number of women converted from a state of health to a state of illness is in the hundreds of thousands, if not in the millions. Estimated deaths from thromboembolism now amount to 180 for the six million women on The Pill in the U.S. For as long as records have been kept in the U.S., with the exception of 1916, the incidence of deaths from polio has never reached this level.

A major reason for failure to obtain a more objective assessment of the problem, including its public health dimensions, rests with the method of selecting experts for advisory committees.

Some of the experts chosen are deeply obligated to drug firms for subsidization of their research and other activities. *Chemical and Engineering News* quotes a scientist on the latter situation as follows: "Another hindrance to objective results, and I think this ought to be said, is that too many investigators have too personal an interest in the drugs they work with. All in all I get the feeling that the experimental aspects of (The Pill) are so fluid and controversial that you must be careful over who says what and why he says it." (Ibid. p. 48.)

Such investigators are capable of stating publicly that The Pill "is a perfectly safe method," (*Medical Science*, Nov. 1963, p. 47) and again, as late as January, 1968, that The Pill when "taken under the supervision of a competent physician, and directions followed, is perfectly safe." (John Rock, M.D., *Family Circle*, Jan. 1968, p. 33.) The fact is that perfect safety cannot be attributed to any drug, not even aspirin.

The opposite ploy is also used to defend The Pill; e.g., "I think we agree that there is nothing in life that is absolutely safe. 'Safe' then becomes a relative term, and we have to consider safer than what, or less safe than what." (Don Carlos Hines, M.D., Director of the Medical Special Services Division of Eli Lilly and Co. on *The Open Mind*, WNBC Television, Feb. 6, 1966, "Are Birth Control Pills Safe?")

The first committee appointed to study the question of thromboembolism, was sponsored by the manufacturers of Enovid, not the government, and conducted by the American Medical Association. (*Proceedings of a Conference: Thromboembolic Phenomena in Women*, Sept. 10, 1962, Chicago.) The latter has a well known bias in favor of the pharmaceutical industry. Within several hours of convening this meeting, before participants had an adequate opportunity to study and discuss the data presented at the meeting, the Chairman called for a vote that would, in effect, be a whitewash of The Pill. (Ibid. pp. 69, 81, 82.) He commented, "... so far there has not been a single shred of evidence that has been presented in any of these figures to suggest that it con-