By accepted scientific standards, this kind of challenge (taking a drug a second time) and response (reappearance of a side effect) is overwhelming evidence.

To demand evidence of this quality for such side effects as lung clots or strokes is to risk lifelong disability or life itself.

Inescapably, then, the lack of proof of a causal relation—the standard repeatedly invoked by Dr. Sadusk—requires acceptance of evidence less conclusive than that in the migraine situation.

These questions, then, arise:

Has FDA been adequately protecting the public health—has it been reverent of life and scientifically responsible—in taking the position that it must wait in such problems as clots and strokes for the kind of proof of a "cause-and-effect relationship" that is available for migraine?

In the labeling of oral contraceptives, has FDA promptly given physicians full information about all of the known factors in the benefit/risk ratio so they can make informed, intelligent decisions about whether to prescribe the pills?

Are women who can reliably use other methods "taking a chance for nothing?" as Dr. John R. McCain put it. He is professor of gynecology and obstetrics at Emory University, Atlanta.

Last March, Dr. Lasagna of Johns Hopkins disclosed that two of his colleagues, Drs. David B. Clark and Frank B. Walsh, had collected data on about 20 young women who had suffered strokes—some of them fatal—after using birth control pills.

An autopsy on one showed clotting in "practically every artery and vein in her body." Dr. Lasagna said.

Yet, he noted, most of these causes had not been reported in American medical literature although there have been reports of similar episodes in the British Medical Journal since 1962. Thus, many physicians were ignorant of possible serious and sometimes fatal hazards.

Last Oct. 25, the Journal of the American Medical Association published a report on all methods for AMA's eight-member Committee on Human Reproduction.

None of the authors was an endocrinologist, although the oral contraceptives involve the endocrine system. And the article makes no clear, specific mention of the possibility of strokes in pill users.

Dr. Lasagna, asked for comment, said he believed the article, "in its concern for the benefits to be obtained from effective contraception, neglects what I consider to be all too definite warning signals on the horizon in regard to the ability of the oral contraceptives to cause vascular catastrophe."

Vascular catastrophe includes serious or fatal clots in the bloodways. Those that block brain arteries are called strokes. Those that reach the lungs are called pulmonary embolisms.

In a recent interview, the chairman of the AMA Committee, Dr. Raymond T. Holden of Washington, said frankly of the article, "Maybe it wasn't strong enough . . . It's possible we didn't stress the side effects," although "we thought we were being emphatic."

Relying on the theory that the safety of the pills, if used as directed under medical supervision, has been assured by FDA, the article emphasizes their effectiveness ("virtually 100 percent") and says that their acceptability is "of prime importance."

Yet on Nov. 16, FDA said that "several months ago"—that is, before the article was submitted to the AMA Journal—it had had a copy in hand of a report on 61 injuries involving blood clotting, including strokes and eye damage.

EYE DAMAGE EVIDENCE

That report, which was published in the November issue of Archives of Opthalmology, included only those cases disclosed by ophthalmologists responding to an invitation to do so, and was therefore an obvious and large understatement of the reality.

Only when asked for comment on the Archives report did FDA disclose that —30 days after deciding to do so—it was just then in the process of asking manufacturers to include an eye hazard warning in the labeling for the pills.

Despite the great reliance the medical profession would place on Dr. Hol-