two years. All the cases diagnosed as such were on the oral contraceptives except one."

Instead of the relaxed attitude suggested by Dr. Sadusk, they urged "awareness of the possible existence of a causal relationship."

Among four stroke patients aged 20 to 29 who had been referred by private practitioners, there had been no previous symptoms of predisposing conditions. A fifth, 39, had had mildly high blood pressure for 23 years. All had been taking oral contraceptives for between six months and three years.

A sixth woman, 29, who had been taking the pills for a year, developed a fatal clot in a major vein in the brain, although "without a precipitating factor," this condition "is rare," the researchers said.

10,000 'ADVERSE EXPERIENCES'

A few weeks ago, FDA said that a computer was "memorizing" more than 10,000 instances of "adverse experiences" with oral contraceptives. The agency said it had a "crash program" to catalogue every scrap of information connected with the pills.

Perhaps inadvertently, the agency thus acknowledged that, despite the gravity of the problems involved, its surveillance of adverse effects had to be strengthened by a crash program.

In explaining the program, FDA said it was about to convene a special Advisory Committee on Obstetrics and Gynecology "to look at broad, overall problems of adverse experiences with all contraceptive drugs," including discrepancies in labeling of identical and similar products that the committee is expected to ask be made uniform.

In its initial meeting Nov. 22–23, the committee said that its preliminary review "finds no evidence of a cause-effect relationship" between the pills and reports of eye damage, strokes and other injuries associated with blood clotting.

The committee did not include in its statement the usually expected counterbalance: that it has no evidence that a causal relation does *not* exist. Yet by adopting a resolution endorsing FDA's request for an interim eye-damage warning in the labeling, the committee clearly indicated that a causal relation might indeed exist.

The committee is scheduled to meet again Jan. 20–21 and to issue its final report after a third meeting next March. Its chairman is Dr. Louis M. Hellman of the State University of New York College of Medicine.

Although certain consultants have been enlisted, Dr. Hellman and the six other committee members are all obstetricians and gynecologists. Such relevant specialties as endocrinology, hematology and cardiovascular and blood-clotting diseases are not represented.

One crucial problem area in the committee's deliberations is the significance of the 10,000 instances of "adverse experiences" and the worth of such studies as have been made about the safety of the pills.

The 10,000 reactions are a potpourri of often sketchy reports in medical literature, of cases from manufacturers' files, of cases reported with uneven precision by private physicians, of cases from a small proportion of hospitals.

On Nov. 29, Drug News Weekly said that the committee "reportedly found the data useless—at least in its present form." Another warning, this one about assumptions that computers can provide magic answers, came recently from Dr. John T. Litchfield Jr., a drug industry scientist who spoke at the dedication ceremonies for FDA's new building.

In trying to enlist computers, he said, many people in industry are "learning a few hard facts of life. 'Gigo' is the word—garbage in, garbage out. Computers cannot improve data."

The real fear of some competent, knowledgeable scientists and statisticians is of "garbage results" as a basis for making judgments about the safety of the pills. In addition to being dubious as a sampling of reality, the 10,000 reactions almost certainly understate the reality.

Underreporting of adverse reactions is a fact of life about drugs recognized almost universally by persons familiar with the situation, including officials of FDA. Especially among private practitioners, underreporting is tremendous.

The magnitude of underreporting has probably never been more dramatically illustrated than it was last year at Johns Hopkins, a top-rank teaching hospi-