

The feeling persists that several companies do have significant mechanism data in endocrinology but save it for two reasons: It could lead to new products or, if publicized, could also lead to disfavor on the part of the Government. So industry plays it conservatively.

In FDA's oral contraceptive report last year, Dr. Schuyler G. Kohl of the State University of New York, Brooklyn, suggested that companies pool some of their money and establish a thorough surveillance program of patients under contraceptive therapy. (Surveillance is the biggest drawback to reliable safety data.) The same suggestion might apply to an interindustry research effort on fundamental problems, perhaps through a special institute of basic studies. The closest approach to this is the Pharmaceutical Manufacturers Association Foundation, which, as of now, is a low-key effort of modest support to some investigators.

[From The AMA News, Vol. 9, No. 34, August 22, 1966, pp. 1, 6]

ORAL CONTRACEPTIVES SAFE, FDA SAYS

The U.S. Food and Drug Administration's Advisory Committee on Obstetrics and Gynecology reported that in a comprehensive study it found no proof that oral contraceptives are unsafe. Among the committee's recommendations was one that the time limitation on the use of the drugs be discontinued.

But the committee added in its 21-page report that it had "nevertheless taken full cognizance of certain very infrequent but serious side effects and of possible theoretic risks suggested by animal experimental data and by some of the metabolic changes in human beings."

"In the final analysis, each physician must evaluate the advantages and the risks of this method of contraception in comparison with other available methods or with no contraception at all," the committee of 13 physician experts said.

CHANGE PREDICTED

The committee reported the efficacy of current oral contraceptives in fertility control as "exceptionally high," but said they probably will be replaced by others in five or 10 years.

"Drugs with even less potentially adverse effect, utilizable in smaller dosage, will undoubtedly be developed through continuing research," the committee said . . . "It would be indeed unfortunate were such research and testing to be stifled by unnecessarily complicated, unscientifically harsh, and inelastic administrative procedures."

The committee made 10 recommendations:

A large case-control (retrospective) study of the possible relation of oral contraceptives to thromboembolism.

Continuation and support of studies such as the ones being carried out by the Kaiser Permanente group in California and the U. of Pittsburgh group in Lawrence County, Pa.

Support of additional controlled, population-based prospective studies utilizing groups of subjects that are especially amenable to long-term follow-up, such as married female employees of certain large industries, and graduate nurses.

Continuation and strengthening of the present surveillance system of the FDA.

Review of the mechanism of storage, retrieval and analysis of surveillance data.

A conference between FDA and the respective drug firms concerning uniformity and increased efficiency of reporting.

That priority be given to support laboratory investigations concerning all aspects of the hormonal contraceptive compounds.

Uniformity in labeling of contraceptive drugs.

Discontinuance of time limitation of administration of contraceptive drugs.

Simplification of administrative procedures to allow reduction in dosage of already approved compounds.

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