

BIOCHEMISTRY

Drugs Worth Risk-Taking

➤ NO DRUG IS 100% safe for all people, U.S. Food and Drug Administration officials remind us after having removed another death-dealing medicine from the market. The question uppermost in permitting the sale of a questionable drug is whether its lifesaving properties outweigh its risk.

Chloromycetin, for example, is a valuable antibiotic, Dr. Howard Weinstein, director of Medical Review in FDA's bureau of medicine, told SCIENCE SERVICE. Physicians who prescribe it know from the label that serious and even fatal blood disorders have been known to occur after its use. They must weigh, and the FDA must weigh, the number of people who will live after taking the drug against those who may die.

"In the case of Parnate, just taken off the market, the drug is not lifesaving," Dr. Weinstein said. "There are other tranquilizers that have not shown the serious side effects and deaths resulting from this anti-depressant. Therefore, in my opinion, it should not be used. FDA bends over backward in the interest of safety."

Dr. Frances O. Kelsey, chief, investigational drug branch, division of new drugs, FDA, who kept thalidomide off the U.S. market when it was killing and crippling thousands of babies in other countries, said that in spite of the most careful testing beforehand, drugs will have some toxic effect on some people.

"Nothing is absolutely safe," Dr. Kelsey said. "Even aspirin can cause reactions. The problem is to figure out what the drug is going to be used for and how important it is."

The newly organized Drug Research Board of the National Academy of Sciences-National Research Council "will not be inclined to look into specific situations" such as the Parnate case, an official said.

Smith, Kline and French of Philadelphia, which has been manufacturing Parnate, trade name for tranlylcypromine was given 30 days by FDA in which to decide whether it wants a hearing on the proposed withdrawal of approval of the new drug application. Although the firm disagrees with FDA, it has taken the drug off the market.

Fifteen patients died among 50 who had strokes, or cerebral vascular accidents, after taking the drug. Six of the fatalities occurred in the United States, the FDA said. Worldwide reports showed some 400 cases of high blood pressure among Parnate users.

Smith, Kline and French, in the 1964 Physicians' Desk Reference, advises caution in its use when patients have cardiovascular disease because of the "possible effect on blood pressure and because antidepressants may increase physical activity."

In cooperation with FDA, the company revised its labeling in October 1963, issuing a drug-warning letter to all physicians pointing out the new and revised contraindications.

The first report of a stroke associated with the drug appeared in Lancet in June

1963. The FDA said a side effect in many persons being treated with Parnate for depression is a lowered blood pressure. Increases in blood pressure have particularly been noted when it is administered with other drugs, including amphetamines, reserpine and some diuretics.

Parnate functions through its effect upon the monoamine oxidase enzyme system, one of the enzyme systems helping to regulate body processes.

• Science News Letter, 85:180 March 21, 1964

MEDICINE

Acute Kidney Failure Prevented by Diuretic

➤ ACUTE KIDNEY FAILURE, which often follows major abdominal surgery, war wounds and other severe body injuries, can be prevented by mannitol, a drug used as a diuretic.

A team of Albany Medical Center surgeons administered the drug to 100 consecutive high-risk patients, none of whom developed kidney failure. Before using mannitol, a compound derived from a form of sugar, the normal yearly incidence of kidney failure following surgery was eight to ten cases at the Center in New York.

This drug is also being used at other medical centers with similar results, the researchers report.

Drs. Samuel R. Powers Jr., Antonio Boba, William Hostnik and Arthur A. Stein reported the study in Surgery, March, 1964. Their work was supported by a grant from the U.S. Public Health Service.

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GENERAL SCIENCE

Scientific Study of Tax Reduction Effects Urged

➤ A SCIENTIFIC STUDY of the major changes the U.S. tax reduction program will bring about is advocated by Dr. Dael Wolfe, psychologist-administrator of the American Association for the Advancement of Science.

In the tax reduction program the nation "is undertaking one of the greatest economic and fiscal experiments in modern history," Dr. Wolfe said in Science, 143:999, 1964.

President Johnson's war on poverty and integration are also bringing about a variety of changes that should be studied basically before, during and after to gain understanding of the social processes involved, he advocated.

Months before the first satellite went into orbit Dr. Wolfe and a few others tried to persuade social scientists to set up a study on the popular knowledge about space and how people felt about space exploration. But social scientists "were too busy or for some other reason could not take part."

• Science News Letter, 85:180 March 21, 1964

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