

PUBLIC HEALTH

FDA Can Limit Drug Tests

The clinical testing of thalidomide could have been prevented if the Food and Drug Administration had made full use of their authority, Lillian Levy reports.

► THE FOOD AND DRUG Administration could have prevented the widespread clinical testing of thalidomide, a tranquilizer known to cause birth defects, under its existing laws, SCIENCE SERVICE learned.

The Food and Drug Administration has had authority under the law since 1938 to fully regulate and limit clinical investigative use of drugs, Wilbur J. Cohen, assistant secretary of Health, Education and Welfare, told SCIENCE SERVICE. However, "until now, the FDA has not used this authority adequately or effectively. But better controls will be instituted in the near future," he emphasized.

More than 1,200 doctors were used as "investigators" to test thalidomide. FDA Commissioner George P. Larrick said at a recent Congressional hearing that this was a larger number than may have been necessary. Dr. Frances O. Kelsey, the FDA physician who prevented licensing of thalidomide for commercial sale in the United States, also pointed out that merely being a physician does not qualify a person as an expert drug investigator.

As a consequence of this large number of "investigators" for thalidomide, 15,904 patients are known to have received the dread

drug in this country. Of this number 3,272 were women of child bearing age. Although at least 207 of the women were pregnant at the time the drug was taken, but no defective births from this usage have yet been reported; some may be expected in the next six months.

The drug was not withdrawn by William S. Merrell Company, Cincinnati, until March, 1962. More than 70 doctors still had the drug at the end of July, 1962, according to Anthony J. Celebrezze, newly appointed Secretary of Health, Education and Welfare.

It is highly probable that many more physicians have thalidomide since many of the Merrell Company "investigators" gave the drug to colleagues.

This sharing of an experimental drug is in violation of the FDA regulations, which prohibit an investigator to so distribute any experimental drug. These violations probably were made through ignorance of the regulation, never strictly enforced by the FDA.

If the FDA had clearly defined standards for "investigators" it is unlikely that so many physicians would have been used or even been available for such services.

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MEDICINE

Abortion Possible for Thalidomide Takers

► ABORTION may be possible in the United States for pregnant women who took the child-deforming drug thalidomide.

Although abortion is, in general, illegal in all states, most states have exceptions to the rule in which a physician may legally perform an abortion.

Nine states make a special exception if the pregnant woman's or child's life is in danger: Connecticut, Minnesota, Missouri, Nevada, New York, South Carolina, Virginia, West Virginia and Washington.

It has not been legally determined whether a woman taking this drug during early pregnancy would fall under this category.

Other states have more restrictive laws governing abortion.

In 21 states, abortion can be performed if necessary to "preserve" the life of the woman. They are: Alabama, Alaska, California, Delaware, Idaho, Illinois, Indiana, Kentucky, Maine, Michigan, Montana, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont and Wyoming.

In seven states—Arizona, Arkansas, Hawaii, Iowa, Texas, Virginia and West Virginia—it is permitted if necessary to "save" the woman's life. No substantial difference seems to exist between statutes urging to "preserve" or "save" the woman.

Recommendations from one or two physicians that abortion is necessary is required in 11 states: Arkansas, Florida, Georgia, Kansas, Maryland, Mississippi, Nebraska, New Hampshire, New Mexico, Ohio and Wisconsin.

If an abortion is needed to prevent serious and permanent bodily injury to the pregnant woman, Colorado and New Mexico will grant permission for an abortion.

All abortions are illegal without exception in Massachusetts, Louisiana and Pennsylvania. In New Jersey any abortion that is malicious or without justification is a crime. In the nation's capital, abortion is legal to preserve the life or health of the woman.

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New Drug Proposals Set No Standards for Tests

► NO STANDARDS are set for clinical testing of experimental drugs in the new regulations "strengthening control over testing of new drugs in clinical trials," just proposed by Secretary of Health, Education and Welfare Anthony J. Celebrezze.

The regulations will require only that the Food and Drug Administration be informed that a drug is to be tested and be given details about the distribution of the drug for human testing. No advance FDA approval is needed for the selection of investigators or the plan of clinical investigation. No specific standards are set under present or proposed regulation for selection of investigators or program of testings.

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SPACE BREATHER—Two aerospace physicians watch the subject (left) pump away on an "exercycle" as he breathes pure oxygen. How an astronaut can function while breathing an atmosphere of up to 100% oxygen is the subject of a study being conducted under the auspices of the National Aeronautics and Space Administration in a giant space simulator at Republic Aviation Corporation, Farmingdale, N.Y.