MEDICINE

Drug Linked to Deformity

Doctors recommend abortion for pregnant women using drug blamed for thousands of deformed European children and tested by 1,230 U.S. doctors, Vincent Marteka reports.

➤ OBSTETRICIANS in the United States are urging abortion for pregnant women who took thalidomide, a tranquilizing drug which can cause deformed babies.

This drug, developed in West Germany, has been blamed for more than 5,000 malformed infants in Europe, Canada and Australia. Very few of the drug-caused defective births have occurred in the United States because a doctor in the Food and Drug Administration consistently refused to issue a license for its manufacture and sale.

However, a U.S. drug company sent samples to some 1,200 physicians for "investigational usage."

A few New York mothers who took the drug early in their pregnancies have given birth to deformed children: one legless, others with horribly malformed limbs.

A young woman in Arizona is attempting to obtain a legal abortion because she took the drug. The abortion was advised by a group of local physicians.

In a SCIENCE SERVICE poll of leading U.S. obstetricians, a majority believe abortion is justified for women who have taken thalidomide during early pregnancy. Those who opposed abortion did not state their reasons.

Dr. Alan F. Guttmacher, chief of obstetrics and gynecology at Mount Sinai Hospital in New York City, said that "to compel a woman to bear a child who has a high likelihood of being born seriously abnormal robs life of human dignity and distorts the Deity's plan of procreation. In the year 1962, it is inconceivable that rational ethical behavior of this type is still shackled by religious dogma, promulgated at a time when medicine and science were then in their infancy."

Dr. John I. Brewer, Chicago obstetrician, said, "Abortion is justified when thalidomide is taken during the early stage of pregnancy."

The drug has been found to be most dangerous in causing malformations during the early months of pregnancy.

This flat, unequivocal position was taken by most of the doctors polled, among them Dr. Samuel M. Dodek, head of the departments of obstetrics and gynecology of Washington Hospital Center, Washington, D. C. Dr. Dodek also pointed out the importance that the pregnancy be terminated in the early stages since termination in the later months would result only in the premature birth.

Dr. Charles Buxton of Yale University Medical School noted that abortion is permitted when women contract German measles early in their pregnancies. About 15% of the babies are born deformed.

"If the possibility of abnormality after thalidomide were this high, I would assume abortion would also be permitted," he said.

Dr. Helen Taussig of the department of obstetrics and gynecology of Johns Hopkins University Medical School has estimated that up to 20% of the babies born of women who had used thalidomide were deformed.

A leading Catholic obstetrician argued that abortion is not justified under any circumstances. A high Catholic official told SCIENCE SERVICE that Catholic dogma views abortion as a violation of the Fifth Commandment, "Thou Shalt Not Kill."

The number of patients who were administered the drug in the United States is confidential, the Food and Drug Administration reported.

Two cases of children with deformities possibly linked with thalidomide are being studied at the Children's Medical Center, Boston.

William S. Merrell Company, Cincinnati, distributed the drug. The company warned physicians last December not to give the drug to women in early months of pregnancy, when reports linking the drug with deformities were received from Germany.

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PUBLIC HEALTH

Legislative Protection From Drugs Weakened

➤ LEGISLATIVE reforms that would better protect the public against the hazards of drugs such as thalidomide, were watered down to virtual ineffectiveness by Congress.

The few improvements retained in the amended legislation are "better than nothing," Sen. Estes Kefauver (D.-Tenn.), author of the original drug reform bill, told SCIENCE SERVICE. They do not, however, provide the essential safeguards to prevent the licensing and sale of such a drug as thalidomide.

The reforms sought by Sen. Kefauver were opposed by the pharmaceutical industry and the American Medical Association as unnecessary. The AMA Council on Drugs now has announced it will begin a comprehensive study of the effect of thalidomide on unborn infants.

Commercial sale of the drug in the United States was blocked, not because of present regulations, but because Dr. Frances O. Kelsey of the Food and Drug Administration felt there were indications that it might be harmful to unborn children. It caused peripheral neuritis, a numbing and tingling in extremities after prolonged use. Dr. Kelsey assumed this symptom might be transferred to the unborn child; but she did not suspect it would cause such terrible damage as misshapen limbs, children born limbless and otherwise deformed.

It was Dr. Kelsey's reservations, not FDA regulations, that prevented the wholesale use of the tranquilizer in the United States.

The purpose of the original Kefauver bill was to reduce the price of drugs, establish more rigid testing for safety and effectiveness, and require labeling which would fully represent all the effects of the drug. As it now stands, there is nothing in the bill to reduce prices or require full disclosure in labeling. Nor are the standards for effectiveness and safety sufficient to prevent the sale of a drug with such side effects as those of thalidomide.

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MEDICINE

Effects of Thalidomide On Male Users Studied

➤ POSSIBLE damage to the reproductive cells of male users of thalidomide is under investigation by Government scientists, SCIENCE SERVICE learned.

If the sperm is damaged by the drug, defective embryos could result. Since 1960, thousands of infants with deformed limbs and some without arms or legs have been born to European mothers who used the drugs in the early weeks of pregnancy. The drug was not licensed for sale in the United States.

Investigators thus far have failed to determine whether the malformations are a result of cell mutation or whether the thalidomide compound or a substance in it retards the growth mechanism, Dr. Frances O. Kelsey of the Food and Drug Administration said.

The drug was supplied by four subsidiaries of Richardson-Merrell, Inc., of New York to more than 1,200 doctors for experimental investigational use. The company has since recalled all samples.

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BIOCHEMISTRY

Beta-Carotene Process Improved by Substitute

➤ CITRUS BY-PRODUCTS have been successfully substituted for the expensive chemical beta-ionone in experimentally producing beta-carotene, an important source of vitamin A.

Beta-carotene is used to supply vitamin A to pharmaceuticals and animal feeds and as a food coloring.

Either citrus pulp or citrus molasses can replace betaionone in the process, which involves fermentation by a carotene-producing mold.

This development, by Alex Ciegler, G. E. N. Nelson, and H. H. Hall of the Agricultural Research Service northern utilization research laboratory, Peoria, Ill., represents further refinement of the beta-carotene fermentation process announced by U. S. Department of Agriculture a year ago.

The lower cost, possible with citrus by-products, should make the fermentation process competitive with present-day chemical methods of synthesizing beta-carotene. The fermentation process provides a fiber-free, high-vitamin-A product needed in mixed feeds, especially for poultry.

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