News Highlights

Pregnancy Warning Set for Tranquilizers

The Food and Drug Administration has ordered the manufacturers of the largest-selling tranquilizers to warn physicians that these drugs should almost always be avoided by women during the first three months of pregnancy.

Three recent studies indicate there may be an association between use of the tranquilizers in early pregnancy, and malformations such as cleft lip in babies.

The tranquilizers affected by the order are the drug meprobamate, best known by the brand names Miltown and Equanil, and a group of drugs known as the benzodiazepines, the most familiar of which are diazepam (Valium) and chlordiazepoxide (Librium). These drugs are widely prescribed for the relief of anxiety and tension. The warning will be required in the labeling of generic and brand-name versions of these drugs.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said: "The studies do not demonstrate conclusively that these drugs, taken during early pregnancy, can cause cleft lip or other birth defects. But use of these tranquilizers during pregnancy is rarely a matter of urgency, and their use during this time should almost always be avoided. The warning label we are now requiring will provide physicians with the information they need to prescribe these drugs safely."

The warning will appear in the labeling provided to physicians. It must appear in bold face type, set apart from other label warnings.

The labeling for these drugs for many years has carried a general statement that the use of any drug in pregnant women requires that the potential benefit of the drug be weighed against the possible hazard to the mother and child, but this is the first time the labeling will specifically warn against using these drugs during the first three months of pregnancy.

The new warning also will advise physicians that, before prescribing these tranquilizers for a woman of childbearing age, they should consider the possibility she may be pregnant.

The warning will further advise physicians to tell women of childbearing age that if they become pregnant or wish to become pregnant while taking these drugs, they should discuss with their physicians the desirability of discontinuing the drug.

FDA told the manufacturers they must add the warning to labeling within 60 days or at the next printing of the labeling, whichever comes first. FDA will withdraw approval of any drug that fails to carry the label warning. The order appeared in the FEDERAL REGISTER of Friday, July 23, 1976.

Michigan Issues Warning on Lake Fish

The State of Michigan has issued a press release saying that people who eat sports fish caught in Lake Michigan have more polychlorinated biphenyls (PCB's) in their blood than people who do not.

Polychlorinated biphenyls are industrial chemicals that are used for a variety of purposes.

The State made clear that the amount of PCB's found in the blood has not caused any detectable illnesses. But the State cautioned the public against eating more than one meal per week of Lake Michigan sports fish, especially coho, chinook, and steelhead and lake trout, and said pregnant women probably should not eat such fish at all.

The State based its report on a two-year study funded by FDA.

FDA endorses the action taken by the State of Michigan in warning the public about consuming sports fish caught in Lake Michigan.

FDA has been encouraging State governments to take action whenever significant problems of fish contaminated with PCB's are found. In February, FDA supported action by New York State to ban commerical fishing, except shad, from the Hudson River and to advise sportsfishermen to restrict their consumption of fish caught in the Hudson and salmon caught in Lake Ontario.

FDA will review further the Michigan data and will communicate details of the study to other States and to Federal agencies involved in controlling PCB pollution.

FDA will continue to encourage States to monitor PCB's and to take action whenever significant problems are found. FDA is also encouraging States to seek FDA assistance on the PCB problem when needed.

FDA's tolerance level for PCB's in fish is 5 parts per million. FDA will act against all fish in interstate commerce found to exceed that level.

The PCB problem in fish affects only fresh water fish because of the continued industrial discharge of PCB's into lakes and streams. Most fish intended for human consumption come from salt waters which have not been contaminated with PCB's.

Use of Chloroform in Drugs, Cosmetics Banned

FDA has banned chloroform as an ingredient in human drugs and cosmetics. The ban was based on a study by the National Cancer Institute which found that chloroform induces liver cancer in mice and kidney tumors in male rats.

Under the ban, which went into effect July 29, no drug or cosmetic product with chloroform as an ingredient may be shipped in interstate commerce. The ban had been proposed April 9, 1976. Virtually all manufacturers had stopped using chloroform before the ban took effect. Chloroform was used in liniments and as a flavoring agent in cough medicines and two toothpastes.

FDA Budget of $245 Million Approved

A budget of $245 million for the Food and Drug Administration for the fiscal year beginning October 1, 1976, has been approved by Congress and signed by the President. This represents an increase of more than $35 million or 17 percent over the budget for fiscal year 1976.

The new budget authorizes 7,299 positions for FDA, an increase of 996 over fiscal year 1976. The bulk of the increases in money and positions are for two programs. An additional $16 million and 606 new positions are autho-

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