

METHADONE FOR HEROIN ADDICTION

FDA plans to sanction increased use of methadone as a substitute for heroin. Maintenance treatment of patients 18 years and older with oral dosage forms of methadone will be available at about 450 Drug Addiction Centers throughout the United States. Each Center is being inspected by health officials and is subject to FDA approval.

To control illicit traffic in methadone, the drug will be available only in approved Centers and hospital pharmacies. Accurate record-keeping for the drug will be required. These restrictions do not prohibit use of methadone in the treatment of severe pain or for detoxification of addicts in hospitals.

Methadone taken by mouth prevents heroin withdrawal symptoms and, in general, controls the intense desire or need for heroin. Addicts who stay on methadone maintenance programs are often able to return to a normal life pattern.

FDA's decision was made after consultation with the National Institute of Mental Health and the Justice Department's Bureau of Narcotics and Dangerous Drugs, and was endorsed by The Special Action Office for Drug Abuse Prevention of the White House. FDA also had the advice and opinion of many other groups, such as the AMA's Council on Mental Health. The consensus is that current evidence on the safety and effectiveness of methadone is sufficient to permit its use for narcotic addiction in adults.

IODOCHLORHYDROXYQUIN AND TRAVELERS' DIARRHEA

The Food and Drug Administration recommends that iodochlorhydroxyquin (Entero-Vioform) not be given to prevent "travelers' diarrhea."

FDA's conclusion is based on recent findings in Japan, Australia and Sweden implicating iodochlorhydroxyquin as the cause of a frequently severe neurologic complex, subacute myelo-optic neuropathy (SMON). Evidence is not yet available to confirm this association, but it appears that too-long-continued dosing with iodochlorhydroxyquin may be a major factor in SMON.

There is no acceptable evidence that other halogenated hydroxyquinolines, chiniofon and diiodohydroxyquinoline (Diodoquin), are effective in the treatment or prevention of "travelers' diarrhea."

Travelers to areas where hygiene and sanitation are poor may be able to prevent diarrhea by eating only recently peeled or thoroughly cooked foods, and by drinking only boiled or bottled water, bottled carbonated soft drinks, beer or wine. Tap water used for brushing teeth or for ice in drinks may be a source of infection. The cause of the diarrhea is uncertain.

Most tropical disease specialists believe iodochlorhydroxyquin is ineffective for "travelers' diarrhea." Labeling of the product cites only intestinal amebiasis as an indication.

IMIPRAMINE AND ALLEGED BIRTH DEFECTS

Recent alarm about possible implication of imipramine (Tofranil), an anti-depressant drug, in birth defects (amelia and phocomelia) appears to be without firm foundation. A report of an association between imipramine given pregnant mothers and congenital deformities in their offspring came from Australia in early March.

The Australian Department of Health recently informed FDA that it regards as inconclusive the data on which the report was based. In addition, the Department of Health and Social Security in London told FDA that during the eight years the British Committee on Safety of Drugs has been in operation, only one report of congenital abnormality of a limb associated with imipramine

has been received. Amelia and phocomelia occasionally occur without known association with drugs.

FDA-approved imipramine labeling in use since 1965 contains the following warning: "Safe use of imipramine during pregnancy and lactation has not been established; therefore, in administering the drug to pregnant patients, nursing mothers, or women of childbearing potential, the potential benefits must be weighed against the possible hazards. Animal reproduction studies have yielded inconclusive results. There have been clinical reports of congenital malformation associated with the use of this drug, but a causal relationship has not been confirmed."