Drug Regulation

Because drugs can produce harmful effects when manufactured or taken improperly, most governments control drug development as well as availability. In the United States, the FDA determines how drugs are produced and how they are sold. Drugs that can be sold over the counter (OTC)-that is, without a prescription from a physician-are called proprietary drugs. They are considered safe for unsupervised use by the general population. Drugs that must be prescribed by physicians and dispensed by pharmacists are known as ethical drugs. Their use is monitored closely by medical personnel.

The FDA regulates the sale and manufacture of drugs in the United States as outlined in applicable laws enacted over the past century. Legal standards for composition and preparation of drugs in the United States are found in the publication known as the United States Pharmacopeia (USP). Drugs that can be abused, such as the powerful narcotic heroin, are regulated by the Drug Enforcement Administration (DEA) of the U.S. Department of Justice to ensure that they are not prescribed or sold illegally.

Before 1900 any individual could sell a drug and claim it offered therapeutic benefits without medical proof. This changed after 1906 with the passage of the Pure Food and Drug Act, which required drug manufacturers to state the content, strength, and purity of each drug they produced. The Pure Food and Drug Act ended the practice of including morphine, cocaine, and heroin in drugs without the public's knowledge. In 1914 the U.S. legislature began to strictly regulate the trade of narcotics with the enactment of the Harrison Narcotic Act; in 1937 the government added marijuana to this list of controlled substances (the Marijuana Tax Act).

The Federal Food, Drug, and Cosmetic Act was enacted in 1938 requiring that new drugs be safe for humans; however, it did not require that manufacturers prove their drugs' effectiveness. It would be 24 years before legislation was passed that would require proof of the efficacy of new drugs (the Kefaver-Harris Amendments, 1962). Enforcement of this law was entrusted to the FDA.

Two laws enacted in the 1960s strengthened the FDA's efforts to reduce drug abuse. The Drug Abuse Control Amendments of 1965 provided penalties for the illegal sale or possession of stimulants, sedatives, and hallucinogens, and the Narcotic Addict Rehabilitation Act of 1966 set up a federal program for addicts that provided them with the option of receiving treatment for their drug problems in place of a prison sentence.

In 1970 the Comprehensive Drug Abuse Prevention and Control Act established rules for manufacturing and prescribing habit-forming drugs. It stipulated that physicians can prescribe all drugs, but a special license is required to prescribe drugs with a high abuse potential. This license is issued by the Drug Enforcement Administration. The Anti-Drug Abuse Acts, signed into law in 1986 and 1988, set up funding for the treatment of drug abuse and for the creation of law-enforcement programs to fight the illegal sale of drugs. These acts also detailed severe punishments for individuals selling and possessing drugs illegally. Harsh penalties for using anabolic steroids (hormones that promote the storage of protein and the growth of tissue that are

sometimes abused by competitive athletes) were included in the 1988 act, along with the requirement that all alcoholic beverages be labeled with warnings about alcohol's potentially dangerous effect on the body. The 1988 act also established the Office of National Drug Control Policy to develop an action plan that would involve the public, as well as private agencies, in eliminating the illegal sale of drugs; in helping individuals who use drugs to stop; and in preventing nonusers from ever starting to use drugs.

The U.S. government and its regulatory agencies continually monitor the development and use of all drugs sold in the United States to ensure that the American public has access only to drugs that are safe and effective. Recently, the FDA introduced legislation requiring warning labels on all over-the-counter medication after research indicated that the nonaspirin pain reliever acetaminophen can cause liver damage when taken in high doses with large quantities of alcohol.

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