PHARMACOECONOMICS

Pharmacoeconomics involves the costs of drug therapy, including those of purchasing, dispensing (eg, salaries of pharmacists, pharmacy technicians), storage, administration (eg, salaries of nurses, costs of supplies), laboratory and other tests used to monitor client responses, and losses from expiration. Length of illness or hospitalization is also considered.

Costs are increasingly being considered a major factor in choosing medications, and research projects that compare costs have greatly increased in recent years. The goal of most studies is to define drug therapy regimens that provide the desired benefits at the least cost. For drugs or regimens of similar efficacy and toxicity, there is considerable pressure on prescribers (eg, from managed care organizations) to prescribe less costly drugs.

PRESCRIPTION AND NONPRESCRIPTION DRUGS

Legally, American consumers have two routes of access to therapeutic drugs. One route is by prescription or order from a licensed health care provider, such as a physician, dentist, or nurse practitioner. The other route is by over-the-counter (OTC) purchase of drugs that do not require a prescription. Both of these routes are regulated by various drug laws. Acquiring and using prescription drugs for nontherapeutic purposes, by persons who are not authorized to have the drugs or for whom they are not prescribed, is illegal.

American Drug Laws and Standards

Current drug laws and standards have evolved over many years. Their main goal is to protect the public by ensuring that drugs marketed for therapeutic purposes, whether prescription or OTC, are safe and effective. Their main provisions are summarized in Table 1–1.

The Food, Drug, and Cosmetic Act of 1938 was especially important because this law and its amendments regulate the manufacture, distribution, advertising, and labeling of drugs. It also confers official status on drugs listed in *The United States Pharmacopeia*. The names of these drugs may be followed by the letters *USP*. Official drugs must meet standards of purity and strength as determined by chemical analysis or animal response to specified doses (bioassay). The Durham-Humphrey Amendment designated drugs that must be prescribed by a physician and dispensed by a pharmacist. The Food and Drug Administration (FDA) is charged with enforcing the law. In addition, the Public Health Service regulates vaccines and other biologic products, and the Federal Trade Commission can suppress misleading advertisements of nonprescription drugs.

Another important law, the Comprehensive Drug Abuse Prevention and Control Act, was passed in 1970. Title II of this law, called the Controlled Substances Act, regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, and anabolic steroids. These drugs are categorized according to therapeutic usefulness and potential for abuse (Box 1–1) and labeled as controlled substances (eg, morphine, a Schedule II drug, is labeled C–II).

The Drug Enforcement Administration (DEA) is charged with enforcing the Controlled Substances Act. Individuals and companies legally empowered to handle controlled substances must be registered with the DEA, keep accurate records of all transactions, and provide for secure storage. Physicians are assigned a number by the DEA and must include the number on all prescriptions they write for a controlled substance. Prescriptions for Schedule II drugs cannot be refilled; a new prescription is required. Nurses are responsible for storing controlled substances in locked containers, administering them only to people for whom they are prescribed, recording each dose given on agency narcotic sheets and on the client's medication administration record, maintaining an accurate inventory, and reporting discrepancies to the proper authorities.

In addition to federal laws, state laws also regulate the sale and distribution of controlled drugs. These laws may be more stringent than federal laws; if so, the stricter laws usually apply.

Canadian Drug Laws and Standards

Canada and its provinces have laws and standards that parallel those of the United States, particularly those related to controlled substances (see Appendix D).

Nursing Notes: Apply Your Knowledge

Using this text and a drug handbook, or the *Physicians' Desk Reference* (PDR), look up the following drugs: meperidine and diazepam. Indicate the controlled substance category for each drug. From the information you obtained in researching the drug, reflect on why each drug was placed in the assigned category. How did the resources you used differ in the organization and depth of information provided about drugs?

DRUG APPROVAL PROCESSES

The FDA is responsible for assuring that new drugs are safe and effective before approving the drugs and allowing them to be marketed. The FDA reviews research studies (usually conducted or sponsored by a pharmaceutical company) about proposed new drugs; the organization does not test the drugs.

Before passage of the Food, Drug, and Cosmetic Act, many drugs were marketed without confirmation of safety or