KEY TERMS

Addiction
Chemical name
Clinical trials
Compassionate use
Control group
Controlled Substances Act
Double-blind
Drug Enforcement Administration (DEA)
Food and Drug Administration (FDA)
Generic name
Investigational New Drug (IND)
New drug application (NDA)
Patent medicine
Placebo
Substance abuse

HISTORY OF DRUG REGULATIONS

In the early 1900s, many adults in the United States were addicted to drugs in large part because of legal **patent medicines.** An early definition of patent medicine referred to remedies of questionable value that had the potential to cause intentional or accidental harm. Patent medicines were often called "tonics," "elixirs," or "therapeutic agents." Manufacturers sold their patent medicines to unsuspecting people, with exaggerated claims of cures for their ailments. More addictive than curative, these toxic substances contained alcohol, morphine, heroin, or opium. They provided temporary euphoria and therefore relief from pain, but they also caused many deaths from overdoses, especially in children. Even Coca-Cola, developed in the late 1800s, was rumored to use coca leaves, from which cocaine is produced.

The roots of the **Food and Drug Administration (FDA)** can be traced back to Abraham Lincoln, who created the Bureau of Chemistry in 1862. The office was formed to evaluate agricultural products. This bureau had a difficult time passing many resolutions until new and serious concerns arose regarding public food consumption and its safety. During the Spanish-American War, it was rumored that soldiers were fed "embalmed beef," which caused serious illness. As a result of these concerns and the patent medicine problems, Congress passed the first federal drug law: The Pure Food and Drug Act of 1906 (Box 4-1). This bill required accurate labeling of drugs to prevent substitution or mislabeled ingredients.

In 1927 the Bureau of Chemistry was divided into the Food, Drug and Insecticide Bureau, which dealt with regulatory functions and the Bureau of Chemistry and Soils, which dealt with nonregulatory functions. In 1930 the Food, Drug and Insecticide Bureau was shortened to the Food and Drug Administration, or the FDA.

The Food, Drug, and Cosmetic Act of 1938 (Box 4-2) replaced the previous law with more specific regulations including holding the drug developer responsible for drug safety, which oversees the safe

BOX 4.1 The Pure Food and Drug Act of 1906

- States are outlawed from buying and selling food, drinks, and drugs that have been mislabeled and/or tainted.
- Ingredients now must be clearly labeled by quantity or percentage.
- Imitation of popular items is banned.
- False or misleading claims are banned, including claims about contents of the labeled item.
- Habit-forming drugs must now have a warning label.

BOX 4.2 The Food, Drug, and Cosmetic Act of 1938

- Placed cosmetics and medical devices under government control
- Required preapproval of all new drugs after manufacture proved safety to the FDA
- Prohibited false advertising about medication therapeutic properties
- Required correction of deficiencies in food quality and packaging
- Authorized manufacturing inspections