

CHAPTER 3

Drug Use, Regulation, and the Law

The chapter outline provides you with an organizational guide to the topics and ideas presented in this chapter of the text.

Introduction

Cultural Attitudes About Drug Use

The Road to Regulation and the FDA

- Prescription Versus OTC Drugs
- The Rising Demand for Effectiveness in Medicinal Drugs
- Regulating the Development of New Drugs
- The Effects of the OTC Review on Today's Medications

The Regulation of Drug Advertising

- Federal Regulation and Quality Assurance

Drug Laws and Deterrence

Factors in Controlling Drug Abuse

Strategies for Preventing Drug Abuse

- Supply Reduction Strategy
- Demand Reduction Strategy
- Inoculation Strategy
- Drug Courts

Current and Future Drug Use

- Drug Legalization Debate
- Drug Testing
- Pragmatic Drug Policies

■ Key Terms

Define the following terms:

1. **Thalidomide** _____
2. **Phocomelia** _____
3. **Switching policy** _____
4. **Supply reduction** _____
5. **Interdiction** _____
6. **Inoculation** _____
7. **Drug courts** _____
8. **Demand reduction** _____
9. **Harrison Act of 1914** _____

■ Fill-in-the-Blank

1. The _____ required manufacturers to indicate the amounts of alcohol, morphine, opium, cocaine, heroin, and marijuana extract on the label of each product.
2. _____ is a birth defect that involves impaired development of the arms, legs, or both.
3. The first legitimate effort by the U.S. government to regulate addicting substances was the _____.
4. The _____ allows drug companies to receive tax advantages if they develop drugs that are not very profitable.
5. _____ involves attempts to decrease individuals' tendencies to use drugs with emphasis on reformulating values and behaviors.
6. The policy of cutting off or destroying supplies of illicit drugs is called _____.

■ Identify

1. Identify society's two major guidelines for controlling drug development and marketing.
 - a. _____
 - b. _____
2. The Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act established criteria for determining whether a drug should be classified as prescription or nonprescription. Identify the three categories that determine whether a drug is considered nonprescription.
 - a. _____
 - b. _____
 - c. _____
3. Identify and explain the regulatory steps for developing new prescription drugs.
 - a. _____
 - b. _____
 - c. _____

4. Identify the criteria that must be satisfied if a drug is to be switched to OTC status.

- a. _____
- b. _____
- c. _____

■ Discussion Questions

1. Name and explain an example of a law or an amendment that has been passed to allow an exception to FDA new prescription drug regulations. Explain why the regulation is important. _____

2. Discuss the effects of advertising on the drug industry. _____

3. Why are drug laws not always a satisfactory deterrent against the use of illicit drugs? _____

4. Discuss the drug legalization debate. What are the arguments being presented for and against the legalization of drugs? What are some possible compromises? What do you think is the best option?

5. Discuss the pros and cons of drug testing. _____

