

CHAPTER 3

Drug Use, Regulation, and the Law

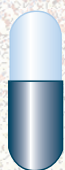
Learning Objectives

On completing this chapter you will be able to:

- ⊙ Identify the major criteria that determine how society regulates drugs.
- ⊙ Explain the significance of the Pure Food and Drug Act of 1906 and why it was important in regulating drugs of abuse.
- ⊙ Describe the changes in drug regulation that occurred because of the Kefauver-Harris Amendment of 1962.
- ⊙ Identify and explain the stages of testing for an investigational new drug.
- ⊙ Discuss the special provisions (exceptions) made by the Food and Drug Administration (FDA) for drug marketing.
- ⊙ Outline the procedures used by the FDA to regulate nonprescription drugs.
- ⊙ Outline the major approaches used to reduce substance abuse.
- ⊙ Explain the main arguments for and against legalizing drugs.
- ⊙ List the most common types of drug testing.
- ⊙ Describe four major factors required for workable drug policies (pragmatic drug policies).

Did You Know?

- ⊙ Some patent medicines sold at the turn of the twentieth century contained opium and cocaine and were highly addictive.
- ⊙ Before World War II, all drugs, except those classified as narcotics, were available without prescription.
- ⊙ Enforcement of drug use policies and drug laws differs across different countries.
- ⊙ In 2009, an estimated 21.8 million Americans age 12 or older were current (past-month) illicit drug users.
- ⊙ The United States spends approximately \$3.83 billion per year on drug interdiction.



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Introduction

Society mandates that it maintain control over which drugs are permissible and which drugs are prohibited. Through legislation, we decide which drugs are licit and illicit. We decide which licit drugs are readily available “over-the-counter” (OTC) and which can be obtained by prescription only. Thus, drug laws prohibit indiscriminate use of what society defines as a drug. As we saw in Chapter 1, licit and illicit drugs can produce vastly different effects on both mental and bodily functions. Chapters 4 and 5 focus on how and why different types of drugs affect our bodies. In this chapter, you will come to better understand how society attempts to control drug use and abuse. In particular, this chapter examines the development of drug regulations in the United States that apply to both the manufacture of drugs and the control of their use. Although many think that the regulation of drug manufacturing and drug abuse lie at the opposite ends of the spectrum, regulation of drug manufacturing and abuse of drugs actually evolved from the same process.

Cultural Attitudes About Drug Use

Currently, cultural attitudes in the United States regarding the use of drugs blend beliefs in individuals’ rights to live their lives as they desire with society’s obligation to protect its members from the burdens imposed by uncontrolled behavior. The history of drug regulation consists of regulatory swings in response to attempts by government to balance these two factors while responding to public pressures and perceived public needs. For example, 100 years ago most people expected the government to protect citizens’ rights to produce and market new foods and substances; they did not expect or desire the government to regulate product quality or claims. Instead, the public relied on private morals and common sense to obtain quality and protection in an era of simple technology. Unfortunately, U.S. society had to learn by tragic experience that its trust was not well placed; many unscrupulous entrepreneurs were willing to risk the safety and welfare of the public in an effort to maximize profits and acquire wealth. In fact, many medicines of these earlier times were not merely ineffective but often dangerous.

Because of the advent of high technology and the rapid advancements society has made, we now

rely on highly trained experts and government “watchdog” agencies for consumer information and protection. Out of this changing environment have evolved two major guidelines for controlling drug development and marketing:

1. Society has the right to protect itself from the damaging effects of drug use. This concept not only is closely aligned with the emotional and highly visible issues of drug abuse, but also includes protection from other drug side effects. Thus, although we expect the government to protect society from drugs that can cause addiction, we also expect it to protect us from drugs that cause cancer, cardiovascular disease, or other threatening medical conditions.
2. Society has the right to demand that drugs approved for marketing be safe and effective to the general public. If drug manufacturers promise that their products will relieve pain, those drugs should be analgesics; if they promise that their products will relieve depression, those drugs should be antidepressants; if they promise that their products will relieve stuffy noses, those drugs should be decongestants.

The public, through the activities of regulatory agencies and statutory enactments, has attempted to require that drug manufacturers produce safe and effective pharmaceutical products. Closely linked to these efforts is the fact that society uses similar strategies to protect itself from the problems associated with the specific drug side effect of dependence or addiction, which is associated with drug abuse.

The Road to Regulation and the FDA

In the late 1800s and early 1900s, sales of uncontrolled medicines flourished and became widespread. Many of these products were called patent medicines, which signified that the ingredients were secret, not that they were patented. The decline of patent medicines began with the 1906 Pure Food and Drug Act, which required manufacturers to indicate the amounts of alcohol, morphine, opium, cocaine, heroin, and marijuana extract on the label of each product. It became obvious at this time that many medicinal products on the market labeled “nonaddictive” were, in fact, potent drugs “in sheep’s labeling” and could cause severe dependence. However, most government interest at the time centered on regulation of the food industry, not drugs.

Even though federal drug regulation was based on the free-market philosophy that consumers could make choices for themselves, it was decided that the public should have information about possible dependence-producing drugs to ensure that they understood the risks associated with using these products. The Pure Food and Drug Act made misrepresentation illegal, so that a potentially addicting patent drug could not be advertised as “non-habit forming.” This step marked the beginning of new involvement by governmental agencies in drug manufacturing.

Shortcomings in the Pure Food and Drug Act quickly became obvious. For example, the law did not allow the government to stop the distribution of dangerous preparations designed to reduce weight. One such product contained dinitrophenol, a compound that purportedly increased metabolic rate and was responsible for many deaths (FDA 2010c).

The Pure Food and Drug Act was modified, albeit not in a consumer-protective manner, by the Sherley Amendment in 1912. The distributor of a cancer “remedy” was indicted for falsely claiming on the label that the contents were effective. The case was decided in the U.S. Supreme Court in 1911. Justice Holmes, writing for the majority opinion, said that, based on the 1906 act, the company had not violated any law because legally all it was required to do was accurately state the contents and their strength and quality. The accuracy of the therapeutic claims made by drug manufacturers was not controlled. Congress took the hint and passed the Sherley Amendment to add to the existing law the requirement that labels should not contain “any statement . . . regarding the curative or therapeutic effect . . . which is false and fraudulent.” However, the law required that the government prove fraud, which turned out to be difficult (and is still problematic). This amendment did not improve drug products but merely encouraged pharmaceutical companies to be more vague in their advertisements (Temin 1980).

■ Prescription Versus OTC Drugs

The distinction between prescription and OTC drugs is relatively new to the pharmaceutical industry. All non-narcotic drugs were available OTC before World War II. It was not until a drug company unwittingly produced a toxic product that killed 107 people that the FDA was given control over drug safety in the 1938 Federal Food, Drug,

and Cosmetic Act (Hunter, Rosen, and DeChristoforo 1993). The bill had been debated for several years in Congress and showed no promise of passage. Then, a pharmaceutical company decided to sell a liquid form of a sulfa drug (one of the first antibiotics) and found that the drug would dissolve well in a chemical solvent, diethylene glycol (presently used in antifreeze products). The company marketed the antibiotic as Elixir Sulfanilamide without testing the solvent for toxicity. Under the 1906 Pure Food and Drug Act, the company could not be prosecuted for the toxicity of this form of drug or for not testing the formulation of the drug on animals first. It could only be prosecuted for mislabeling the product on the technicality that elixir refers to a solution in alcohol, not a solution in diethylene glycol. Again, it was apparent that the laws in place provided woefully inadequate protection for the public.

The 1938 act differed from the 1906 law in several ways. It defined *drugs* to include products that affected bodily structure or function even in the absence of disease. Companies had to file applications with the government for all new drugs showing that they were safe (not effective—just safe) for use as described. The drug label had to list all ingredients and include the quantity of each, as well as provide instructions regarding correct use of the drug and warnings about its dangers. In addition, the act eliminated a Sherley Amendment requirement to prove intent to defraud in drug misbranding cases (FDA 2010d).

Before passage of the 1938 act, you could go to a doctor and obtain a prescription for any non-narcotic drug or go to the pharmacy directly if you had already decided what was needed. The labeling requirement in the 1938 act allowed drug companies to create a class of drugs that could not be sold legally without a prescription. It has been suggested that the actions by the FDA were motivated by the frequent public misuse of two classes of drugs developed before passage of the 1938 law: sulfa antibiotics and barbiturates. People often took too little of the antibiotics to cure an infection and too much of the barbiturates and became addicted.

The 1938 Food, Drug, and Cosmetic Act allowed the manufacturer to determine whether a drug was to be labeled prescription or nonprescription. The same product could be sold as prescription by one company and as OTC by another. After the Durham-Humphrey Amendment was passed in 1951, almost all new drugs were placed in the prescription-only class. The drugs that were patented

and marketed after World War II included potent new antibiotics and phenothiazine tranquilizers such as Thorazine. Both the FDA and the drug firms thought these products were potentially too dangerous to sell OTC. The Durham-Humphrey Amendment established the criteria, which are still used today, for determining whether a drug should be classified as prescription or nonprescription. Basically, if a drug does not fall into one of the following three categories, it is considered nonprescription:

1. The drug is habit-forming.
2. The drug is not safe for self-medication because of its toxicity.
3. The drug is a new compound that has not been shown to be completely safe.

In 1959, Senator Estes Kefauver initiated hearings concerned with the enormous profit margins earned by drug companies due to the lack of competition in the market for new, patented drugs. Testimony by physicians revealed that an average doctor in clinical practice often was not able to evaluate accurately the efficacy of the drugs he or she prescribed. The 1938 law did not give the FDA authority to supervise clinical testing of drugs; consequently, the effectiveness of drugs being sold to the public was not being determined. Both the Kefauver and Harris Amendments put forth in Congress were intended to deal with this problem but showed no likely signs of becoming law until the thalidomide tragedy occurred.

During the Kefauver hearings, the FDA received an approval request for Kevadon, a brand of thalidomide that the William Merrell Company hoped to market in the United States. **Thalidomide** had been used in Europe as a sedative for pregnant women. Despite ongoing pressure, medical officer Frances Kelsey refused to allow the request to be approved (FDA 2010e) because of insufficient safety data. By 1962, the horrifying effects of thalidomide on developing fetuses became known. There are two approximately 24-hour intervals early in pregnancy when thalidomide can alter the development of the arms and legs of an embryo. If a woman takes

thalidomide on one or both of these days, the infant could be born with abnormally developed arms and/or legs (called **phocomelia**, from the Greek words for flippers, or “seal-shaped limbs”). Even though Kevadon was never approved for marketing in this country, Merrell had distributed more than 2 million tablets in the United States for investigational use—use that the law and regulations left mostly unchecked. Once thalidomide’s deleterious effects became known, the FDA moved quickly to recover the supply from physicians, pharmacists, and patients. For her efforts, Kelsey received the President’s Distinguished Federal Civilian Service Award in 1962, the highest civilian honor available to government employees (FDA 2010e).

Although standard testing probably would not have detected the congenital effect of thalidomide and the tragedy would likely have occurred anyway, these debilitated infants stimulated passage of the 1962 Kefauver and Harris Amendments. They strengthened the government’s regulation of both the introduction of new drugs and the production and sale of existing drugs. The amendments required, for the first time, that drug manufacturers demonstrate the efficacy as well as the safety of their drug products. The FDA was empowered to retract approval of a drug that was already being marketed. In addition, the agency was permitted to regulate and evaluate drug testing by pharmaceutical companies and mandate standards of good drug-manufacturing policy.

KEY TERMS

thalidomide

a sedative drug that, when used during pregnancy, can cause severe developmental damage to a fetus

phocomelia

a birth defect; impaired development of the arms, legs, or both



Characteristic limb deformities caused by thalidomide.

■ The Rising Demand for Effectiveness in Medicinal Drugs

To evaluate the effectiveness of the more than 4000 drug products that were introduced between 1938 and 1962, the FDA contracted with the National Research Council to perform the Drug Efficacy Study. This investigation started in 1966 and ran for 3 years. The council was asked to rate drugs as either effective or ineffective. Although the study was supposed to be based on scientific evidence, this information often was not available, which meant that conclusions sometimes relied on the clinical experience of the physicians on each panel; these judgments were not always based on reliable information.

A legal challenge resulted when the FDA took an “ineffective” drug off the market and the manufacturer sued. This action finally forced the FDA to define what constituted an adequate and well-controlled investigation. Adequate, documented clinical experience was no longer satisfactory proof that a drug was safe and effective. Each new drug application now had to include information about the drug’s performance in patients compared with the experiences of a carefully defined control group. The drug could be compared with (1) a placebo, (2) another drug known to be active based on previous studies, (3) the established results of no treatment, or (4) historical data about the course of the illness without the use of the drug in question. In addition, a drug marketed before 1962 could no longer be grandfathered in. If the

company could not prove the drug had the qualifications to pass the post-1962 tests for a new drug, it was considered a new, unapproved drug and could not legally be sold.

■ Regulating the Development of New Drugs

The amended Federal Food, Drug, and Cosmetic Act in force today requires that all new drugs be registered with and approved by the FDA. The FDA is mandated by Congress to (1) ensure the rights and safety of human subjects during clinical testing of experimental drugs, (2) evaluate the safety and efficacy of new treatments based on test results and information from the sponsors (often health-related companies), and (3) compare potential benefits and risks to determine whether a new drug should be approved and marketed. Because of FDA regulations, all pharmaceutical companies must follow a series of steps when seeking permission to market a new drug (see **Figure 3.1**).

Regulatory Steps for New Prescription Drugs

Step 1: Preclinical Research and Development

A chemical must be identified as having potential value in the treatment of a particular condition or disease. The company interested in marketing the chemical as a drug must run a series of tests on at least two or more animal species. Careful records must be kept of side effects, absorption, distribution,

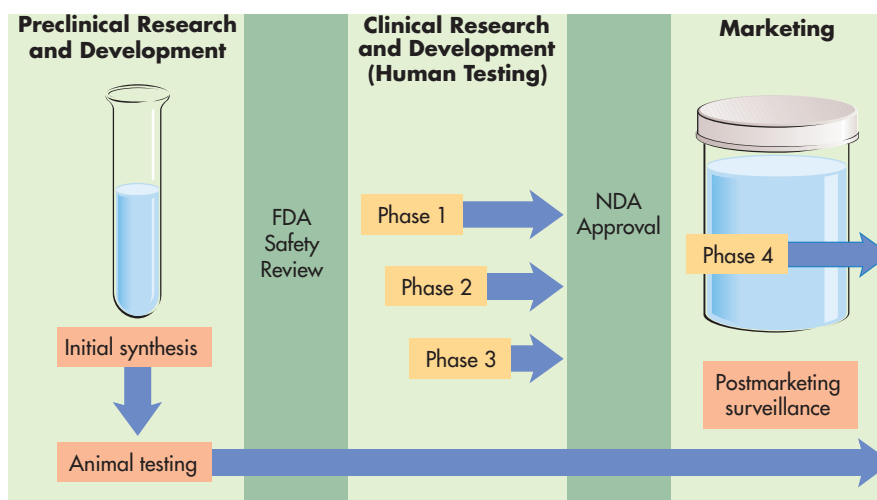


FIGURE 3.1

Steps required by the FDA for reviewing a new drug.

metabolism, excretion, and the dosages of the drug necessary to produce the various effects. Carcinogenic, mutagenic, and teratogenic variables are tested. The dose–response curve must be determined along with potency, and then the risk and benefit of the substance must be calculated (see Chapter 5). If the company still believes there is a market for the substance, it forwards the data to the FDA to obtain an investigational new drug (IND) number for further tests.

Step 2: Clinical Research and Development

Animal tests provide some information, but ultimately tests must be done on the species for which the potential drug is intended—that is, humans. These tests usually follow three phases.

Phase 1 is called *the initial clinical stage*. Small numbers of volunteers (usually 20–100), typically healthy people but sometimes patients, are recruited to establish drug safety and dosage ranges for effective treatment and to examine side effects. Formerly, much of this research was done on prison inmates, but because of bad publicity and the possibility of coercion, fewer prisoners are used today. Medical students, paid college student volunteers, and volunteers being treated at free clinics are more often used after obtaining informed consent. The data from Phase 1 clinical trials are collected, analyzed, and sent to the FDA for approval before beginning the next phase of human subject testing.

Phase 2 testing is called the *clinical pharmacological evaluation stage*. The effects of the drug are tested to eliminate investigator bias and to determine side effects and the effectiveness of the treatment. Because the safety of the new drug has not been thoroughly established, a few patients (perhaps 100–300 volunteers) with the medical problem the drug is intended to treat participate in these studies. Statistical evaluation of this information is carried out before proceeding with Phase 3 testing.

Phase 3 is the *extended clinical evaluation stage*. By this time, the pharmaceutical company has a good idea of both drug effectiveness and dangers. The drug can be offered safely to a wider group of participating clinics and physicians, who cooperate in the administration of the potential drug—when medically appropriate—to thousands of volunteer patients who have given informed consent.

This stage makes the drug available on a wide experimental basis. Sometimes, by this point, there has been publicity about the new drug, and people with the particular disease for which the drug was

developed may actively seek out physicians licensed to experiment with it.

During Phase 3 testing, safety checks are made and any side effects that might show up as more people are exposed to the drug are noted. After the testing program concludes, careful analysis is made of the effectiveness, side effects, and recommended dosage. If there are sufficient data to demonstrate that the drug is safe and effective, the company submits a new drug application (NDA) as a formal request that the FDA consider approving the drug for marketing. The application usually comprises many thousands of pages of data and analysis, and the FDA must sift through it and decide whether the risks of using the drug justify its potential benefits. The FDA usually calls for additional tests before the drug is determined to be safe and effective and before granting permission to market it.

Step 3: Permission to Market

At this point, the FDA can allow the drug to be marketed under its patented name. In 2001, the average cost of developing a new drug was over \$1 billion (Adams and Brantner 2010). The situation is similar elsewhere, although in some countries the clinical evaluations are less stringent and require less time.

Once the drug is marketed, it continues to be closely scrutinized for adverse effects. This post-marketing surveillance is often referred to as Phase 4 and is important because, in some cases, negative effects may not show up for a long time. For example, it was determined in 1970 that diethylstilbestrol (DES), when given to pregnant women to prevent miscarriage, causes an increased risk of a rare type of vaginal cancer in their daughters when these children enter their teens and young adult years. The FDA subsequently removed from the market the form of DES that had been used to treat pregnant women.

Exceptions: Special Drug-Marketing Laws

There is continual concern that the process used by the FDA to evaluate prospective drugs is laborious and excessively lengthy. Hence, an amendment was passed to accelerate the evaluation of urgently needed drugs. The so-called fast-track rule has been applied to the testing of certain drugs used for the treatment of rare cancers, AIDS, and some other diseases. As a result, these drugs have reached the market after a much-reduced testing program. For example, the FDA reviewed Gleevac, a treatment for chronic myeloid leukemia, in 4 months. Pegasys, a combination product for the treatment

of hepatitis C, was approved in 3.5 months (FDA 2010b).

A second amendment, the Orphan Drug Law, allows drug companies to receive tax advantages if they develop drugs that are not very profitable because they are useful in treating only small numbers of patients, such as those who suffer from rare diseases. A rare disease is defined as one that affects fewer than 200,000 people in the United States or one for which the cost of development is not likely to be recovered by marketing.

The federal government and the FDA are continually refining the system for evaluating new drugs to ensure that new effective therapeutic substances can be made available for clinical use as soon as it is safely possible. Some of these modifications reflect the fact that patients with life-threatening diseases are willing to accept greater drug risks to gain faster access to potentially useful medications. Attempts to accelerate the drug review are exemplified by the Prescription Drug User Fee Act of 1992. This law required drug manufacturers to pay fees to the FDA for the evaluation of NDAs. Congress required the FDA to use these fees to hire more reviewers so as to expedite the reviews.

The Regulation of Nonprescription Drugs

The Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act made a distinction between prescription and nonprescription (OTC)

drugs and required the FDA to regulate OTC drug marketing. In 1972, the FDA initiated a program to evaluate the effectiveness and safety of the nonprescription drugs on the market and to ensure that they included appropriate labeling (for more details, see Chapter 15). A panel of drug experts including physicians, pharmacologists, and pharmacists reviewed each so-called active ingredient in the OTC medications. Based on the recommendations of these panels, the ingredients were placed in one of the following three categories:

- I. Generally recognized as safe and effective for the claimed therapeutic indication
- II. Not generally recognized as safe and effective or unacceptable indications
- III. Insufficient data available to permit final classification

By 1981, the panels had made initial determinations about over 700 ingredients in more than 300,000 OTC drug products and submitted more than 60 reports to the FDA.

In the second phase of the OTC drug review, the FDA evaluated the panels' findings and submitted a tentative adoption of the panels' recommendations (after revision, if necessary), following public comment and scrutiny. After some time and careful consideration of new information, the agency issued a final ruling and classification of the ingredients under consideration.

Here and Now

Secure and Responsible Drug Disposal Act

In October 2010, President Barack Obama signed into law the Secure and Responsible Drug Disposal Act. The act addresses the problem that patients were not allowed to return drugs to a Drug Enforcement Agency registrant because this type of return would be outside the "closed chain of distribution" that was a consequence of the Controlled Substances Act. As a result of this restriction, persons seeking to reduce the amount of expired or unwanted prescription drugs in their homes previously had few disposal options.

Up to 17% of prescribed medication is never used. If improperly disposed, these medications can contribute to drug diversion, accidental poisonings, and potentially environmental problems. The bill allows consumers to give controlled substances to specially designated individuals, such as law enforcement officials, for disposal. It also allows long-term care facilities to dispose of certain prescription drugs on behalf of their residents.

Sources: Gilbert, J. A., and W. T. Koustas. "Secure and Responsible Drug Disposal Act Passes Congress." 3 October 2010. Available at: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/10/secure-and-responsible-drug-disposal-act-passes-congress.html. Accessed March 4, 2011; Utah.gov. "Proper Medication Disposal." 2010. Available at: <http://www.medicationdisposal.utah.gov>. Accessed March 4, 2011; and Govtrack.us. "S. 3397: Secure and Responsible Drug Disposal Act of 2010." 2010. Available at: <http://www.govtrack.us/congress/bill.xpd?bill=s111-3397>. Accessed March 4, 2011.

■ The Effects of the OTC Review on Today's Medications

The review process for OTC ingredients has had a significant impact on the public's attitude about OTC products and their use (both good and bad) in self-medication. It was apparent from the review process that many OTC drug ingredients did not satisfy the requirements for safety and effectiveness. Consequently, it is almost certain that, in the future, there will be fewer active ingredients in OTC medicines, but these drugs will be safer and more effective than ever before.

In addition, with heightened public awareness, greater demand has been brought to bear on the FDA to make better drugs available to the public for self-medication. In response to these pressures, the FDA has adopted a **switching policy**, which allows the agency to review prescription drugs and evaluate their suitability as OTC products. The following criteria must be satisfied if a drug is to be switched to OTC status:

- The drug must have been marketed by prescription for at least 3 years.
- Use of the drug must have been relatively high during the time it was available as a prescription drug.
- Adverse drug reactions must not be alarming, and the frequency of side effects must not have increased during the time the drug was available to the public.

In general, this switching policy has been well received by the public. The medical community and the FDA are generally positive about OTC switches as well. There are some concerns, however, that the wider access to more effective drug products will lead to increased abuse or misuse of OTC products. Hence, emphasis is placed on adequate labeling and education to ensure that consumers have sufficient information to use OTC products safely and effectively.

The Regulation of Drug Advertising

Much of the public's knowledge and impressions about drugs come from advertisements. It is difficult to ascertain the amount of money currently

KEY TERMS

switching policy

an FDA policy allowing the change of suitable prescription drugs to over-the-counter status

spent by the pharmaceutical industry to promote its products. One study estimated that total spending on promotion increased from \$11.4 billion in 1996 to \$29.9 billion in 2005. The same study reported that the percentage of sales spent on promotion grew from 14.2% to 18.2% during that same period (Donahue, Cevasco, and Rosenthal 2007).

There is no doubt that these promotional efforts by pharmaceutical manufacturers have a tremendous impact on the drug-purchasing habits of the general public and health professionals.

The economics of prescription drugs are unique because a second party, the health professional, dictates what the consumer, the patient, will purchase. As a general rule, the FDA oversees most issues related to advertising of prescription drugs. In contrast, the Federal Trade Commission (FTC) regulates OTC advertising (FDA 2010a).

According to the FDA (2009b), physicians indicate that, for the most part, the advertisements for prescription drugs on television and radio have had both positive and negative effects on their patients and practices. The FDA has conducted surveys directed toward physicians to better understand how direct-to-consumer (DTC) prescription drug promotion affects the patient-doctor relationship, with the intent of informing the agency if advertising rules need to be changed in order to ensure better consumer understanding of the risks and benefits of prescription drugs. Highlights of the surveys include:

- Most physicians surveyed agreed that because their patient saw a DTC advertisement, he or she asked thoughtful questions during the visit. Approximately the same percentage of physicians thought the advertisements made their patients more aware of possible treatments.
- The physicians surveyed indicated that the advertisements did not convey information about risks and benefits equally well. In fact, 78% of physicians responded that their patients understand the possible benefits of the drug very well or somewhat, compared to 40% of physicians who indicated that their patients understand the possible risks.
- Approximately 75% of physicians surveyed indicated that DTC ads cause patients to think that the drug works better than it does, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads.
- The physicians surveyed reported that patients understand that they need to consult a health-care provider concerning appropriate treatments. Eighty-two percent responded either

“very well” or “somewhat” when asked if they believe that their patients understand that only a physician can decide if a drug is appropriate for them.

A significant amount of prescription drug promotion is directed at health professionals. The approaches employed by manufacturers to encourage health professionals to prescribe their products include advertising in prestigious medical journals, direct mail advertising, and some radio and television advertising. Government advertising regulations control all printed and audio materials distributed by drug salespeople. Perhaps the most effective sales approach is for drug representatives to personally visit health professionals; this tactic is harder to regulate.

Many health professionals rely on drug company salespeople for the so-called latest scientific information concerning drugs and their effects. Although these representatives of the drug industry can provide an important informational service, it is essential that health professionals remember that these people make a living by selling these products, and often their information may be biased accordingly.

Many people in and out of the medical community have questioned the ethics of drug advertising and marketing in the United States and are concerned about the negative impact that deceptive promotion has on target populations. One of the biggest problems in dealing with misleading or false advertising is defining such deception. Probably the best guideline for such a definition is sum-

marized in the Wheeler-Lea Amendment to the FTC Act:

The term *false advertisement* means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account not only representations . . . but the extent to which the advertisement fails to reveal facts.

Tough questions are being asked as to how much control should be exerted over the pharmaceutical industry to protect the public without excessively infringing on the rights of these companies to promote their goods. The solutions to these problems will not be simple. Nevertheless, efforts to keep drug advertisements accurate, in good taste, and informative are worthwhile and are necessary if the public is expected to make rational decisions about drug use (see “Here and Now: What’s in an Ad?”).

■ Federal Regulation and Quality Assurance

No matter what policy is adopted by the FDA and other drug-regulating agencies, there will always be those who criticize their efforts and complain that they do not do enough or that they do too much. On the one hand, the FDA has been blamed for being excessively careful and requiring too much testing before new drugs are approved for marketing. On the other hand, when new drugs are

Here and Now

What’s in an Ad?

The Federal Food, Drug, and Cosmetic Act requires that all drug advertisements contain brief summary relating to side effects, contraindications, and effectiveness. The current regulations specify that this information disclosure must include all the risk information in a product’s approved labeling. Typically, print advertisements include a reprinting of the risk-related sections of the approved labeling, although sponsors can write this risk information in language appropriate for the targeted audience.

In addition to the specific disclosure requirements, advertisements cannot be misleading or false or omit mate-

rial facts. They also must present a fair balance between effectiveness and risk information.

In addition, all prescription drug broadcast advertisements must abide by two specific requirements. First, these must include the product’s most important risk-related information in the audio or audio and visual parts of the advertisement. Second, these must contain either a brief summary of the advertised product’s risk information or make adequate provision for disseminating the product’s approved labeling in association with the advertisement.

Source: U.S. Food and Drug Administration (FDA), Division of Drug Marketing, Advertising, and Communications (DDMAC). “DDMAC Frequently Asked Questions (FAQs).” 2009. Available at: <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090308.htm>. Accessed February 16, 2011.

released and cause serious side effects, the FDA is condemned for being sloppy in its control of drug marketing.

What is the proper balance, and what do we, as consumers, have the right to expect from the government? These are questions each of us should ask, and we have a right to share our answers with government representatives.

Regardless of our individual feelings, it is important to understand that the current (and likely future) federal regulations do not ensure drug safety or effectiveness for everyone. Too many individual variables alter the way each of us responds to drugs, making such universal assurances impossible. Federal agencies can only deal with general policies and make general decisions. For example, what if the FDA determines that a given drug is reasonably safe in 95% of the population and effective in 70%? Are these acceptable figures, or should a drug be safe in 99% and effective in 90% before it is deemed suitable for general marketing? What of the 5% or 1% of the population who will be adversely affected by this drug? What rights do they have to be protected?

There are no simple answers to these questions. Federal policies are inevitably compromises that assume that the clinician who prescribes the drug and/or the patient who buys and consumes it will be able to identify when use of that drug is inappropriate or threatening. Unfortunately, sometimes drug prescribing and drug consuming are done carelessly and unnecessary side effects occur or the drug does not work. Then the questions surface again: Are federal drug agencies doing all they can to protect the public? Should the laws be changed?

It is always difficult to predict the future, especially when it depends on sometimes-fickle politicians and erratic public opinion. Nevertheless, with the dramatic increase in new and better drugs becoming available to the public, it is not likely that federal or state agencies will diminish their role in regulating drug use. Now more than ever, the public demands safer and more effective drugs. This public attitude will likely translate into even greater involvement by regulatory agencies in issues of drug development, assessment, and marketing.

KEY TERMS

Harrison Act of 1914

the first legitimate effort by the U.S. government to regulate addicting substances

Another reason for increased regulation in the future is that many of the larger pharmaceutical companies have become incredibly wealthy. Several of the most profitable companies have become subsidiaries of large corporations, and there is concern that some may be driven more by profit margins than by philanthropic interests. In such an environment, governmental agencies are essential to ensure that the rights of the public are protected.

Drug Abuse and the Law

The laws that govern the development, distribution, and use of drugs in general and drugs of abuse in particular are interrelated. There are, however, some unique features concerning the manner in which federal agencies deal with the drugs of abuse that warrant special consideration. A summary of drug abuse laws in the United States is shown in **Table 3.1**.

Coffee, tea, tobacco, alcohol, marijuana, hallucinogens, depressants (such as barbiturates), and narcotics have been subject to a wide range of controls, varying from none to rigid restrictions. A few countries historically have instituted severe penalties, such as strangulation for smoking tobacco or opium, and strict bans on alcohol. In other countries, these substances have been deemed either legal or prohibited, depending on the political situation and the desires of the population. Historically, laws have been changed when so many people demanded access to a specific drug of abuse that it would have been impossible to enforce a ban (as in the revocation of Prohibition) or when the government needed tax revenues that could be raised by selling the drug (one argument for legalizing drugs of abuse today). A current example is the controversy over decriminalization or legalization of marijuana (see Chapter 13).

The negative experiences that Americans had at the turn of the 20th century with addicting substances such as opium led to the **Harrison Act of 1914**. It marked the first legitimate effort by the federal government to regulate and control the production, importation, sale, purchase, and distribution of addicting substances. The Harrison Act served as the foundation and reference for subsequent laws directed at regulating drug abuse issues.

Today, the Comprehensive Drug Abuse Prevention and Control Act of 1970 largely determines the ways in which law enforcement agencies deal with substance abuse. This act divided substances with abuse potential into categories based on the

Table 3.1 Federal Laws Associated with the Control of Narcotics and Other Abused Drugs

DATE	NAME OF LEGISLATION	SUMMARY OF COVERAGE AND INTENT OF LEGISLATION
1914	Harrison Act	First federal legislation to regulate and control the production, importation, sale, purchase, and free distribution of opium or drugs derived from opium.
1924	Heroin Act	Made it illegal to manufacture heroin.
1956	Narcotics Control Act	Intended to impose very severe penalties for those convicted of narcotics or marijuana charges.
1965	Drug Abuse Control Amendments (DACA)	Adopted strict controls over amphetamines, barbiturates, LSD, and similar substances, with provisions to add new substances as the need arises.
1970	Comprehensive Drug Abuse Prevention and Control Act	Replaced previous laws and categorized drugs based on abuse and addiction potential as well as therapeutic value.
1973	Methadone Control Act	Placed controls on methadone licensing.
1973	U.S. Drug Enforcement Administration (DEA)	Remodeled the Bureau of Narcotics and Dangerous Drugs to become the DEA.
1986	Analogue (Designer Drug) Act	Made illegal the use of substances similar in effects and structure to substances already scheduled.
2000	Drug Addiction Treatment Act	Allowed qualified physicians to dispense or prescribe specially approved Schedule III, IV, and V narcotics for the treatment of opioid addiction in medical treatment settings, rather than limiting it to specialized drug treatment clinics.
2010	Secure and Responsible Drug Disposal Act	Allowed consumers to give controlled substances to specially designated individuals, such as law enforcement officials, for disposal.

degree of their abuse potential and their clinical usefulness. The classifications, which are referred to as *schedules*, range from I to V. *Schedule I* substances have high abuse potential and no currently approved medicinal use; health professionals cannot prescribe them. *Schedule II* drugs also have high abuse potential but are approved for medical purposes and can be prescribed with restrictions. The distinctions between *Schedule II through V* substances reflect the likelihood of abuse occurring and the degree to which the drugs are controlled by governmental agencies. The least addictive and least regulated of the substances of abuse are classified as Schedule V drugs (see “Here and Now: Controlled Substance Schedules”).

In determining into which schedule a drug or other substance should be placed, or whether a substance should be decontrolled or rescheduled, several factors are considered (U.S. Drug Enforcement Administration [DEA] 2010). Specific findings are not required for each factor. The factors include:

1. The actual or relative potential for abuse of the drug.
2. Scientific evidence of the pharmacological effects of the drug.
3. The state of current scientific knowledge regarding the substance. (Criteria 2 and 3 are closely related. However, the second is primarily concerned with pharmacological effects whereas the third deals with all scientific knowledge with respect to the drug.)
4. Its history and current pattern of abuse.
5. What, if any, risk there is to the public health.
6. The psychological or physiological dependence liability of the drug.
7. The scope, duration, and significance of abuse.
8. Whether the substance is an immediate precursor of a substance already controlled. The Controlled Substance Act allows inclusion of immediate precursors on this basis alone into the appropriate schedule and thus safeguards against possibilities of clandestine manufacture.

Here and Now

Controlled Substance Schedules

Controlled substances classified as Schedule I, II, III, IV, or V drugs are described here.

Schedule I

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II

- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substance may lead to severe psychological or physical dependence.

Schedule III

- The drug or other substance has less potential for abuse than the drugs or other substances in Schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the United States.

- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Schedule V

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

Source: U.S. Department of Justice, U.S. Drug Enforcement Administration (DEA). "Drugs of Abuse." 2005. Available at: <http://www.justice.gov/dea/pubs/abuse/doa-p.pdf>. Accessed March 4, 2011.

Penalties for illegal use and/or trafficking of these agents vary according to the agent's schedule, amount possessed, and number of previous drug-associated offenses (see **Table 3.2**).

■ Drug Laws and Deterrence

As previously indicated, drug laws often do not serve as a satisfactory deterrent against the use of illicit drugs. People have used and abused drugs for thousands of years despite governmental restrictions. It is very likely they will continue to do so despite stricter laws and greater support for law enforcement.

As the amount of addiction increased during the mid-1960s, many ill-conceived programs and laws

were instituted as knee-jerk reactions, with little understanding about the underlying reasons for the rise in drug abuse. Unpopular, restrictive laws rarely work to reduce the use of illicit drugs. Even as laws become more restrictive, they usually have little impact on the level of addiction; in fact, in some cases addiction problems actually have increased. For example, during the restrictive years of the 1960s and 1980s, drugs were sold everywhere to everyone—in high schools, colleges, and probably every community. In the 1980s especially, increasingly large volumes of drugs were sold throughout the United States. Billions of dollars were paid for those drugs. Although no one knows precisely how much was exchanged, the amount likely approached \$80 to \$100 billion per year for

Table 3.2 Federal Trafficking Penalties

DRUG/SCHEDULE	QUANTITY	PENALTIES	QUANTITY	PENALTIES
Cocaine (Schedule II)	500–4999 g mixture	<p>First Offense: Not less than 5 years, and not more than 40 years. If death or serious injury, not less than 20 years or more than life. Fine of not more than \$5 million if an individual, \$25 million if non individual.</p> <p>Second Offense: Not less than 10 years, and not more than life. If death or serious injury, life imprisonment. Fine of not more than \$8 million if an individual, \$50 million if not an individual.</p>	5 kg or more mixture	<p>First Offense: Not less than 10 years, and not more than life. If death or serious injury, not less than 20 years or more than life. Fine of not more than \$10 million if an individual, \$40 million if not an individual.</p> <p>Second Offense: Not less than 20 years, and not more than life. If death or serious injury, life imprisonment. Fine of not more than \$20 million if an individual, \$75 million if not an individual.</p> <p>Two or More Prior Offenses: Life imprisonment.</p>
Cocaine base (Schedule II)	28–279 g mixture		280 g or more mixture	
Fentanyl (Schedule II)	40–399 g mixture		400 g or more mixture	
Fentanyl analogue (Schedule I)	10–99 g mixture		100 g or more mixture	
Heroin (Schedule I)	100–999 g mixture		1 kg or more mixture	
LSD (Schedule I)	1–9 g mixture		10 g or more mixture	
Methamphetamine (Schedule II)	5–49 g pure or 50–499 g mixture		50 g or more pure or 500 g or more mixture	
PCP (Schedule II)	10–99 g pure or 100–999 g mixture	100 g or more pure or 1 kg or more mixture		
DRUG/SCHEDULE	QUANTITY	PENALTIES		
Other Schedule I and II drugs (and any drug product containing gamma hydroxybutyric acid)	Any amount	<p>First Offense: Not more than 20 years. If death or serious injury, not less than 20 years or more than life. Fine \$1 million if an individual, \$5 million if not an individual.</p> <p>Second Offense: Not more than 30 years. If death or serious injury, not less than life. Fine \$2 million if an individual, \$10 million if not an individual.</p>		
Other Schedule III drugs	Any amount	<p>First Offense: Not more than 10 years. Fine \$500,000 if an individual, \$2.5 million if not an individual.</p> <p>Second Offense: Not more than 20 years. If death or serious injury, not more than 30 years. Fine \$1.5 million if an individual, \$5 million if not an individual.</p>		
All other Schedule IV drugs	Any amount	<p>First Offense: Not more than 5 years. Fine \$250,000 if an individual, \$1 million if not an individual.</p>		
Flunitrazepam (Schedule IV)	Less than 1 mg	<p>Second Offense: Not more than 10 years. Fine \$500,000 if an individual, \$2 million if not an individual.</p>		
All Schedule V drugs	Any amount	<p>First Offense: Not more than 1 year. Fine \$100,000 if an individual, \$250,000 if not an individual.</p> <p>Second Offense: Not more than 4 years. Fine \$200,000 if an individual, \$500,000 if not an individual.</p>		

(continued)

Table 3.2 (continued)

DRUG	QUANTITY	FIRST OFFENSE	SECOND OFFENSE
Marijuana (Schedule 1)	1000 kg or more mixture; or 1000 or more plants	<ul style="list-style-type: none"> • Not less than 10 years, not more than life • If death or serious injury, not less than 20 years, not more than life • Fine of not more than \$4 million if an individual, \$10 million if other than an individual 	<ul style="list-style-type: none"> • Not less than 20 years, not more than life • If death or serious injury, mandatory life • Fine of not more than \$8 million if an individual, \$20 million if other than an individual
Marijuana (Schedule 1)	100–999 kg mixture; or 100–999 plants	<ul style="list-style-type: none"> • Not less than 5 years, not more than 40 years • If death or serious injury, not less than 20 years, not more than life • Fine of not more than \$2 million if an individual, \$5 million if other than an individual 	<ul style="list-style-type: none"> • Not less than 10 years, not more than life • If death or serious injury, mandatory life • Fine of not more than \$4 million if an individual, \$10 million if other than an individual
Marijuana (Schedule 1)	<p>More than 10 kg hashish; 50–99 kg mixture</p> <p>More than 1 kg of hashish oil; 50–99 plants</p>	<ul style="list-style-type: none"> • Not more than 20 years • If death or serious injury, not less than 20 years, not more than life • Fine of \$1 million if an individual, \$5 million if other than an individual 	<ul style="list-style-type: none"> • Not more than 30 years • If death or serious injury, mandatory life • Fine of \$2 million if an individual, \$10 million if other than an individual
Marijuana (Schedule 1)	1–49 plants; less than 50 kg mixture	<ul style="list-style-type: none"> • Not more than 5 years • Fine of not more than \$250,000 if an individual, \$1 million if other than an individual 	<ul style="list-style-type: none"> • Not more than 10 years • Fine of \$500,000 if an individual, \$2 million if other than an individual
Hashish (Schedule 1)	10 kg or less		
Hashish oil (Schedule 1)	1 kg or less		

Source: U.S. Drug Enforcement Administration (DEA). "Federal Trafficking Penalties and Federal Trafficking Penalties—Marijuana." Available at: <http://www.usdoj.gov/dea/agency/penalties.htm>. Accessed February 16, 2011.

all illegal drugs, of which the two biggest subcategories were an estimated \$30 billion for cocaine and \$24 billion for marijuana.

Because of the large sums of money involved, drugs have brought corruption to all levels of society. Other problems associated with the implementation of drug laws are an insufficient number of law enforcement personnel and inadequate detention facilities; consequently, much drug traffic goes unchecked. In addition, the judiciary system sometimes gets so backlogged that many cases never reach court. Plea-bargaining is often used to clear the court docket. Many dealers and traffickers are back in business on the same day they are arrested. This apparent lack of punishment seriously damages the morale of law enforcers, legislators, and average citizens.

It is estimated that in 2007, over 1.6 million adults and over 195,000 juveniles were arrested in the United States for drug-abuse violations (U.S. Department of Justice [USDOJ] 2010b). This problem represents a tremendous cost to society in terms of damaged lives and family relationships; being arrested for a drug-related crime seriously jeopardizes a person's opportunity to pursue a normal life. Drug taking is closely tied to societal problems, and it will remain a problem unless society provides more meaningful experiences to those who are most susceptible to drug abuse. Improved education and increased support should be given to preteens because that is the age when deviant behavior starts. In cases in which drug education programs have been successful in involving students, the amount of drug

taking and illegal activity seems to have decreased (see Chapter 17).

■ Factors in Controlling Drug Abuse

Three principal issues influence laws regarding drug abuse:

1. If a person abuses a drug, should he or she be treated as a criminal or as a sick person afflicted with a disease?
2. How is the user (supposedly the victim) distinguished from the pusher (supposedly the criminal) of an illicit drug, and who should be more harshly punished—the person who creates the demand for the drug or the person who satisfies the demand?
3. Are the laws and associated penalties effective deterrents against drug use or abuse, and how is effectiveness determined?

In regard to the first issue, drug abuse may be considered both an illness and a crime. It can be a psychiatric disorder, an abnormal functional state in which a person is compelled (either physically or psychologically) to continue using the drug. It becomes a crime when the law, reflecting social opinion, makes abuse of the drug illegal. Health issues are clearly involved because uncontrolled abuse of almost any drug can lead to physical and psychological damage. Because the public must pay for healthcare costs or societal damage, laws are created and penalties are implemented to prevent or correct drug abuse problems (see Table 3.2 on federal trafficking penalties).

Concerning the second issue, drug laws have always been more lenient on the user than the seller of a drug of abuse. Actually, it is often hard to separate user from pusher because many drug abusers engage in both activities. Because huge profits are often involved, some people may not use the drugs they peddle and are only pushers; the law tries to deter use of drugs by concentrating on these persons but has questionable success. Organized crime is involved in major drug sales, and these “drug rings” have proven hard to destroy.

In regard to the third issue, considerable evidence indicates that, in the United States, criminal law has only limited success in deterring drug abuse. During 2009, approximately 36.5% of 12th graders used an illicit drug during the prior 12 months; marijuana was used by 32.8%, LSD by 1.9%, and cocaine by 3.4% (Johnston et al. 2010). It is clear that the drug abuse problem is far from

being resolved, and many feel that some changes should be made in how we deal with this problem.

Strategies for Preventing Drug Abuse

The U.S. government and the public became concerned about the increasing prevalence of drug use during the 1960s, when demonstrations and nationwide protests against the Vietnam War proliferated as youth (mostly college students) rebelled against what they viewed as an unnecessary and unjust war. During the 1960s and early 1970s, for the first time, large numbers of middle- and upper-middle-class youth began using licit and illicit gateway drugs on a massive scale. In response, the government developed strategies for combating drug use and abuse. Important strategies it employed were **supply reduction**, **demand reduction**, and **inoculation**. More recently, the use of **drug courts** has become a major strategy.

■ Supply Reduction Strategy

Early attempts at drug abuse prevention included both the Harrison Narcotic Act of 1914 and the 18th Amendment (Prohibition) to the U.S. Constitution. Both laws were intended to control the manufacture and distribution of classified drugs, with legislators anticipating that these restrictions would compel people to stop using drugs. The laws enforced supply reduction, which involves a lessening, restriction, or elimination of available drugs.

KEY TERMS

supply reduction

a drug reduction policy aimed at reducing the supply of illegal drugs and controlling other therapeutic drugs

demand reduction

attempts to decrease individuals' tendencies to use drugs, often aimed at youth, with emphasis on reformulating values and behaviors

inoculation

a method of abuse prevention that protects drug users by teaching them responsibility

drug courts

a process that integrates substance abuse treatment, incentives, and sanctions and places nonviolent, drug-involved defendants in judicially supervised rehabilitation programs

Supply reduction drug prevention policy attempts to curtail the supply of illegal drugs or their precursors and exert greater control over other, more therapeutic drugs. Part of the supply reduction policy includes **interdiction**, which is defined as decreasing the amounts of these agents that are carried across U.S. borders by using foreign crop eradication measures and agreements, by imposing stiff penalties for drug trafficking, and by controlling alcoholic beverages through licensing.

The United States dedicates enormous resources to interdiction programs. For fiscal year 2009, the federal drug control budget for interdiction was \$3.83 billion (White House 2008). Although seizures of large caches of illicit drugs are reported routinely in the national press, there is relatively little indication that the availability of drugs has diminished substantially. For example, according to the National Threat Assessment, cocaine availability has decreased but heroin, marijuana, methamphetamine, and methylenedioxymethamphetamine remain widely available (USDOJ 2010a). One can argue that as long as a strong demand for these psychoactive agents exists, demand will be satisfied if the price is right. Even if interdiction successfully reduces the supply of one drug of abuse, if demand persists, that drug is usually replaced by another drug with similar abuse potential (for example, substitution of amphetamines for cocaine; see Chapter 10).

■ Demand Reduction Strategy

The demand reduction approach attempts to minimize the actual demand for drugs. Through programs and activities often aimed at youth, emphasis is placed on reformulating values, attitudes, skills, and behaviors conducive to resisting drug use. (Chapter 17 provides extensive information about methods and techniques for reducing drug use.) As part of this strategy, support for medical and group drug treatment programs for abusers is encouraged. Although this approach does not address drug supply, it does attempt to curb and eventually eliminate the need to purchase drugs by reducing the buyer's demand.

KEY TERMS

interdiction

the policy of cutting off or destroying supplies of illicit drugs

Drug abuse is a complex and very individual problem, with many causes and aggravating factors. Even so, experience has shown that prevention and treatment are better strategies and, in the long run, less costly than interdiction or incarceration (Kreit 2009). The following are some suggestions and strategies for how to reduce demand for drugs:

- The top priority of any prevention program, if it is to provide a long-term solution, must be reduction of drug demand by youth. Children must be the primary focus in any substance abuse program. Achieving success requires stabilizing defective family structures, implementing school programs that create an antidrug attitude, establishing a drug-free environment, and promoting resistance training to help youth avoid drug involvement. In addition, children should be encouraged to become involved in alternative activities that can substitute for drug-abusing activity. Potential drug abusers need to be convinced that substance abuse is personally and socially damaging and unacceptable.
- Education about drug abuse must be carefully designed and customized for the target population or group. For example, education based on scare tactics is not likely to dissuade adolescents from experimenting with drugs. Adolescents are at a point in their lives when they feel invincible, and graphically depicting the potential health consequences of drug and alcohol abuse has little impact. A discussion about the nature of addiction and the addiction process is more likely to influence their attitudes. Adolescents need to understand why people use drugs to appreciate the behavior patterns in themselves. Other important topics that should be discussed are how drug abuse works and why it leads to dependence. To complement drug education, adolescents also should be taught coping strategies that include effective decision-making and problem-solving skills.
- Attitudes toward drug abuse and its consequence must be changed. The drug use patterns of many people, both young and old, are strongly influenced by their peers. If individuals believe that drug abuse is glamorous and contributes to acceptance by friends and associates, the incidence of drug abuse will remain high. In contrast, if the prevailing message in society is that drug abuse is unhealthy and not socially acceptable, the incidence will be much lower.

- Replacement therapy has been shown to be a useful approach to weaning the individual off of drugs of abuse. A common example of this strategy is the use of the narcotic methadone to treat the heroin addict (see Chapter 9). Use of methadone prevents the cravings and severe effects of withdrawal routinely associated with breaking the heroin habit. Unfortunately, many heroin addicts must be maintained on methadone indefinitely. Even though methadone is easier to control and is less disruptive than heroin, one drug addiction has been substituted for another, which draws criticism. Replacement therapy certainly is not the entire answer to all drug abuse problems, but it often can provide a window of opportunity for behavioral modification so that a long-term solution to the abuse problem is possible.

■ Inoculation Strategy

The inoculation method of abuse prevention aims to protect drug users by teaching them responsibility. The emphasis is on being accountable, rational, and responsible about drug use, and informing users about the effects of drugs on both mind and bodily function. Nonalcohol parties and responsible drinkers who use designated drivers are outcomes of applying inoculation strategy.

■ Drug Courts

Drug courts are designed to deal with nonviolent, drug-abusing offenders. As of July 2009, there were 2038 fully operational drug courts in the United States and 226 that were in the planning stages (National Criminal Justice Referral Service [NCJRS] 2009). Drug courts integrate mandatory drug testing, substance abuse treatment, sanctions, and incentives in a judicially supervised setting. These courts hold offenders accountable for their actions and provide them with the support and tools necessary to rebuild their lives and become productive members of the community.

Current and Future Drug Use

During the administrations of former Presidents Ronald Reagan and George H. W. Bush (1980–1992), the official policy of the U.S. federal government included a “get tough” attitude about drug abuse. Slogans such as “Just Say No” and “War on

Drugs” reflected the frustration of a public that had been victimized by escalating crime (many incidents were drug related); personally touched by drug tragedies in families, at work, or with associates and friends; and economically strained by dealing with the cost of the problem.

Much remains to be accomplished in the fight against substance abuse. For example, and as summarized by the USDOJ (2010a):

- National Survey on Drug Use and Health (NSDUH) data indicate that in 2008, 14.2% of individuals 12 years of age or older had used illicit drugs during the past year.
- In 2008, the NSDUH estimated that 7 million individuals age 12 or older had abused or were dependent on illicit drugs in the past year, compared with 6.9 million in 2007.
- According to the Substance Abuse and Mental Health Services Administration (SAMHSA), combined 2002–2007 data indicate that during the prior year, an estimated 2.1 million children (3%) in the United States lived with at least one parent who abused or was dependent on illicit drugs, and 1 in 10 children under age 18 lived with a substance-addicted or substance-abusing parent.
- The approximately one-quarter of offenders in state and local correctional facilities and the more than half of offenders in federal facilities incarcerated on drug-related charges represent an estimated 620,000 individuals who are not in the workforce.

Fighting the “War on Drugs” is clearly difficult and complex. Despite substantial efforts, significant problems still exist and require the attention of politicians, clinicians, law enforcement agencies, families, counselors, and all concerned citizens.



An example of the many public awareness advertisement cautions against drinking and driving.

■ Drug Legalization Debate

The persistence of the drug abuse problem and the high cost in dollars and frustration of waging the “War on Drugs” have energized the ongoing debate regarding legalizing the use of drugs of abuse. Proponents of legalization are no longer limited to libertarians and so-called academic intellectuals. Increasingly, this group includes representatives of a distressed law enforcement system. For example, some discontented judges whose courts are swamped with drug cases and police officers who spend much of their on-duty time trying to trap and arrest every drug dealer and user on the street are publicly declaring that the drug laws are wasteful and futile.

Individuals and groups promoting the legalization of all substances of abuse commonly cite several arguments. For instance, proponents often contend that if drugs were legalized, violence and crime would become less frequent. These individuals point out that users often commit crimes to pay for illicit drugs. If these drugs were legal, then the tremendous profits associated with drugs because of their illegal status would disappear and, once gone, the black market and criminal activity associated with drugs would be eliminated. Furthermore, legalization would decrease law enforcement costs by eliminating the backlog of drug-related court cases and reduce populations in overcrowded prisons.

Conversely, opponents of drug legalization believe that legalization would lead to increased availability of drugs, which would in turn lead to increased use. They point out that the use of drugs, especially methamphetamine, phencyclidine (PCP), and cocaine, is often associated with violent criminal behavior. Numerous studies demonstrate the links among drugs, violence, and crime; the link between alcohol, a legal substance, and crime is also well documented. According to legalization opponents, drug use would merely increase the incidence of crime, even if the drugs were legally purchased. Accordingly, the economic (as well as social) cost to society would increase.

Legalization proponents claim that making illicit drugs licit would not cause more of these substances to be consumed, nor would addiction increase. They note correctly that many people use drugs in moderation. Furthermore, many would choose not to use drugs, just as many abstain currently from tobacco and alcohol. Opponents contend that if drugs were made licit and more widely available, usage and addiction rates would increase.



Substance abuse can lead to serious legal problems.

These individuals contend that legalizing drugs sends a message that drug use (like tobacco and alcohol) is acceptable and encourages drug use among people who currently do not use drugs.

Proponents claim that drug legalization would allow users the right to practice a diversity of consciousness. Just as diversity of race, ethnicity, sexual orientation, religion, and other varied lifestyles are allowed, legalization of drugs would permit citizens in our society to alter their consciousness without legal repercussions as long as they do not harm or threaten the safety and security of others. Moreover, proponents argue that education, health care, road building, and a wide array of other worthwhile causes would benefit from the taxes that could be raised by legalizing and then taxing drugs. They argue that the United States has spent billions of dollars to control drug production, trafficking, and use with few, if any, positive results. They contend that the money spent on drug control should be shifted to other, more productive endeavors.

Opponents believe that health and societal costs would increase with drug legalization. It has been predicted that drug treatment costs; hospitalization for long-term, drug-related diseases; and treatment of the consequences of drug-associated family violence would further burden our already strapped healthcare system. Such a policy would increase costs to society due to greater medical and social problems resulting from greater availability and increased use of drugs. Two of the most frequently

abused substances, alcohol and tobacco, are both legal and readily available today. These two substances cause more medical, social, and personal problems than all the illicit drugs of abuse combined. Many question whether society really wants to legalize additional drugs with abuse potential.

Although arguments for both sides warrant consideration, extreme policies are not likely to be implemented; instead, a compromise will most probably be adopted. For example, areas potentially ripe for compromise include the following (Kalant 1992):

- *Selective legalization:* Eliminate harsh penalties for those drugs of abuse that are the safest and least likely to cause addiction, such as marijuana.
- *Control of substances of abuse by prescription or through specially approved outlets:* Have the availability of the illegal drugs controlled by physicians and trained clinicians, rather than by law enforcement agencies.
- *Discretionary enforcement of drug laws:* Allow greater discretion by judicial systems for prosecution and sentencing of those who violate drug laws. Such decisions would be based on perceived criminal intent.

In conclusion, drug legalization remains a highly divisive issue in the United States. Although legalization would lessen the number of drug violators involved in the criminal justice system, the problems associated with legalizing current illicit drugs cause many members in our society to view this idea with disfavor. As stated earlier, opponents of legalization argue that we already have massive problems with licit drugs such as tobacco and alcohol. According to them, legalizing additional types of drugs would produce a substantial increase in the rate of addiction and in the social and psychological problems associated with drug use. Proponents favoring legalization assert that, despite the current drug laws and severe penalties for drug use, people continue to use illicit drugs.

■ Drug Testing

In response to the demand by society to stop the spread of drug abuse and its adverse consequences, drug testing has been implemented in some situations to detect drug users. The most common types of drug testing use Breathalyzers and laboratory studies of urine, blood, and hair specimens. Urine and blood testing are preferred for detecting drug

use. Hair specimen testing must overcome technical problems before hair can be used as a definitive proof of drug use, including complications from hair treatment (e.g., hair coloring) and environmental absorption.

The drugs of abuse most frequently tested for are marijuana, cocaine, amphetamines, narcotics, sedatives, and anabolic steroids. Drug testing is often mandatory in some professions in which public safety is a concern (such as airline pilots, railroad workers, law enforcement employees, and medical personnel) and for employees of some organizations and companies as part of general policy (such as the military, many federal agencies, and some private companies). Drug testing also often is mandatory for participants in sports at all levels—whether in high school, college, international, or professional competition—to prevent unfair advantages that might result from the pharmacological effects of these drugs and to discourage the spread of drug abuse among athletes. Likewise, drug testing is used routinely by law enforcement agencies to assist in the prosecution of those believed to violate drug abuse laws. Finally, drug testing is used by health professionals to assess the success of drug abuse treatment—that is, to determine whether a dependent patient is diminishing his or her drug use or has experienced a relapse in drug abuse habits.

Drug testing to identify drug offenders is usually accomplished by analyzing body fluids (in particular urine), although other approaches (such as analysis of expired air for alcohol) are also used. To understand the accuracy of these tests, several factors should be considered.

- *Testing must be standardized and conducted efficiently.* To interpret testing results reliably, it is essential that fluid samples be collected, processed, and tested using standard procedures. Guidelines for proper testing procedures have been established by federal regulatory agencies as well as scientific organizations. Deviations from established protocols can result in false positives (tests that indicate a drug is present when none was used), false negatives (tests that are unable to detect a drug that is present), or inaccurate assessments of drug levels.
- *Sample collection and processing must be done accurately and confidentially.* In many cases, drug testing can have punitive consequences (for example, athletes cannot compete or employees are fired if results are positive). Consequently, drug users often attempt to outsmart

the system. Some individuals have attempted to avoid submitting their own drug-containing urine for testing by filling specimen bottles with “clean” urine from artificial bladders hidden under clothing or in the vagina or by introducing “clean” urine into their own bladders just before collection. To confirm the legitimacy of the specimen, it often is necessary to have the urine collection witnessed directly by a trustworthy observer. To ensure that the fluid specimens are not tampered with and that confidentiality is maintained, samples should be immediately coded and movement of each sample from site to site during analysis should be documented and confirmed.

Just as it is important that testing identify individuals who are using drugs, it is also important that those who have not used drugs not be wrongfully accused. To avoid false positives, all samples that test positive in screening (usually via fast and inexpensive procedures) should be analyzed again using more accurate, sensitive, and sophisticated analytical procedures to confirm the results.

- *Confounding factors that interfere with the accuracy of the testing can be inadvertently or deliberately present.* For example, dietary consumption of pastries containing poppy seeds can be sufficient to cause a positive urine test for narcotic opioids in some cases. Excessive intake of fluid or use of diuretics increases the volume of urine formed and decreases the concentration of drugs, making them more difficult to detect.

The dramatic increase in drug testing since 1985 has caused experts to question its value in dealing with drug abuse problems. Unfortunately, drug testing often is linked exclusively to punitive consequences, such as disqualification from athletic competition, loss of job, or even fines and imprisonment. Use of drug testing in such negative ways does little to diminish the number of drug abusers or deal with their personal problems. However, drug-testing programs can have positive consequences by identifying drug users who require professional care. After being referred for drug rehabilitation, the offender can be monitored using drug testing to confirm the desired response to therapy. In addition, tests can identify individuals who put others in jeopardy because of their drug abuse habits when they perform tasks that are dangerously impaired by the effects of these drugs (for example, airline pilots, train engineers, and truck drivers).

The widespread application of drug testing to control the illicit use of drugs in the general population would be extremely expensive, difficult to enforce, and almost certainly ineffective. In addition, such indiscriminate testing would likely be viewed as an unwarranted infringement on individual privacy and declared unconstitutional. However, the use of drug testing to discourage inappropriate drug use in selected crucial professions that directly impact public welfare appears to be publicly tolerated. Even so, it is probably worthwhile to periodically revisit the issue of drug testing and analyze its benefits and liabilities relative to public safety and individual privacy issues.

■ Pragmatic Drug Policies

Several principles for a pragmatic drug policy emerge from a review of past drug policies and an understanding of the drug-related frustrations of today. To create drug policies that work, the following suggestions are offered:

- It is important that the government develop programs that are consistent with the desires of the majority of the population.
- Given the difficulties and high cost of efforts to prevent illicit drugs from reaching the market, it is logical to deemphasize interdiction and instead stress programs that reduce demand. To reduce demand, drug education and drug treatment must be top priorities.
- Government and society need to better understand the role played by law in their efforts to reduce drug addiction. Antidrug laws by themselves do not eliminate drug problems; indeed, they may even create significant social difficulties (for example, as did the Prohibition laws banning all alcohol use). Used properly and selectively, however, laws can reinforce and communicate expected social behavior and values (for example, laws against public drunkenness or against driving a vehicle under the influence of alcohol).
- Programs that employ “public consensus” should be implemented more effectively to campaign against drug abuse. For example, antismoking campaigns demonstrate the potential success that could be achieved by programs that alter drug abuse behavior. Similar approaches can be used to change public attitudes about drugs through education without making moral judgments and employing cru-

sading tactics. Our society needs to engage in more collaborative programs in which drug-using individuals and their families, communities, and helping agencies work together.

Discussion Questions

1. Describe the FDA approval process for assessing the safety and efficacy of a newly developed drug. What are its advantages and disadvantages?
2. Name the principal legislative initiatives that mandate that drugs be proven safe or effective.
3. What are the principal advantages and disadvantages of switching products from prescription to OTC status?
4. What could account for the vast differences in attitudes and opinions regarding drug use and the law voiced by drug users/abusers and non-users of drugs?
5. Would decriminalization of illicit drug use increase or decrease drug-related social problems? Justify your answer.
6. Compare and contrast supply reduction, demand reduction, and inoculation strategies for dealing with drug abuse.
7. List the principal arguments for and against legalizing drugs of abuse such as marijuana and cocaine.

Summary

1 Societies have evolved to believe that they have the right to protect themselves from the damaging impact of drug use and abuse. Consequently, governments, including that of the United States, have passed laws and implemented programs to prevent social damage from inappropriate drug use. In addition, such societies have come to expect that drugs are effective.

2 The 1906 Pure Food and Drug Act was not a strong law, but it required manufacturers to include on labels the amounts of alcohol, morphine, opium, cocaine, heroin, and marijuana extract in each product. It represented the first real attempt to make consumers aware of the active contents in the drug products they were consuming.

3 The 1938 Federal Food, Drug, and Cosmetic Act gave the FDA control over drug safety.

4 The 1951 Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act made a formal distinction between prescription and nonprescription drugs.

5 The Kefauver-Harris Amendment of 1962 required manufacturers to demonstrate both the efficacy and the safety of their products.

6 All drugs to be considered for marketing must first be tested for safety in animals. Following these initial tests, if the FDA favorably reviews the drug, it is given IND status. It then generally undergoes three phases of human clinical testing before receiving final FDA approval.

7 In 1972, the FDA initiated a program to ensure that all OTC drugs were safe and effective. Specific panels were selected to evaluate the safety and effectiveness of OTC drug ingredients. Each of the ingredients was classified into a particular category: I, II, or III.

8 The switching policy of the FDA allows the agency to review prescription drugs and evaluate their suitability as OTC products.

9 Controversy exists as to how to best reduce substance abuse. A principal strategy used by governmental agencies to achieve this objective is interdiction; the majority of money used to fight drug abuse is spent on trying to stop and confiscate drug supplies. Experience has proved that interdiction is often ineffective. To reduce drug abuse, demand for these substances must be diminished. Youth must be a top priority in any substance abuse program. Treatment that enables drug addicts to stop their habits with minimal discomfort should be provided. Finally, education should be used to change attitudes toward drug abuse and its consequences. Potential drug abusers need to be convinced that substance abuse is personally and socially damaging and is unacceptable.

10 Major strategies for combating drug use and abuse are supply reduction, demand reduction, and inoculation. Supply reduction involves using drug laws to control the manufacturing and distribution of classified drugs. Demand reduction aims to reduce the actual demand for drugs by working mainly with youth and teaching them to resist drugs. Inoculation aims to protect potential drug users by teaching them responsibility and explaining the effects of drugs on bodily and mental functioning.

11 Drug courts are designed to deal with nonviolent, drug-abusing offenders. They require substance abuse treatment and implement sanctions in a judicially supervised program. This emerging strategy has had positive social and economic impacts.

12 In response to the demand by society to stop the spread of drug abuse and its adverse consequences, drug testing has been implemented in some situations to detect drug users. Common drug testing uses Breathalyzers and analysis of urine, blood, and hair specimens. Urine and blood testing are the preferred methods of testing for drug use. Hair specimen testing must overcome a number of technical problems before it can be used as a definitive proof of drug use, including complications caused by hair treatment and environmental absorption.

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