CHAPTER 3

Drug Use, Regulation, and the Law

Photo by John B. Snyder. Courtesy of U.S. Army.

Did You Know?

- Some patent medicines sold at the turn of the 20th century contained opium and cocaine and were highly addictive.
- For fiscal year 2015, the U.S. federal budget request for interdiction efforts, which includes intercepting and ultimately disrupting shipments of illegal drugs and their precursors, as well as the proceeds, totaled approximately $3.9 billion.

Learning Objectives

On completing this chapter you should 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.

Introduction

Society mandates that it maintains control over which drugs are permissible and which drugs are prohibited. Through legislation, we decide which drugs are licit or 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. 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 opposite ends of the spectrum, regulation of drug manufacturing and abuse actually evolved from similar processes.

Cultural Attitudes About Drug Use

Currently, cultural attitudes in the United States regarding the use of drugs blend beliefs in individuals' right 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, more than 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, in part, as a consequence of the 1906 Pure Food and Drug Act. This legislation required manufacturers to indicate the amounts of 11 dangerous products, including alcohol, cocaine, heroin, and morphine, on the label of each product (FDA 2012c). It became obvious at this time that many medicinal products on the market labeled "non-addictive" 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.

The shortcomings in the Pure Food and Drug Act quickly became obvious. In particular, the law did not allow the government to stop the distribution of dangerous preparations. As one example, an extract of horsetail weed, Banbar, was marketed by a shirt salesman as an injection-free cure for diabetes. Although the FDA established in court that diabetics were dying while on this preparation even though insulin was available, the government lost its case because it could not meet the standard of establishing fraud (FDA 2009a, 2012c). As another example, no federal statute prevented the sale of a dangerous diet preparation containing dinitrophenol, a product that accelerated metabolism and created serious side effects, including cataracts (FDA 2012c). Further, in 1911, the U.S. Supreme Court ruled that this act did not prohibit false therapeutic claims, but only misleading and false statements about the identity or ingredients of a drug (FDA 2009b).

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).

It was not until a drug company unwittingly produced a toxic product that killed over 100 people, many of whom were children, that the FDA was given control over drug safety in the 1938 federal Food, Drug, and Cosmetic Act (FDA 2012b; 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) that was comparable to antifreeze. 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 the term *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. 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 provide instructions regarding safe use of the drug. The act demanded that safe tolerances be set for unavoidable poisonous substances and authorized the establishment of standards of identity, quality, and fill-of-container for foods. In addition, the act eliminated a Sherley Amendment requirement to prove intent to defraud in drug misbranding cases (FDA 2014g).

Before passage of the 1938 act, an individual could go to a doctor and obtain a prescription for any nonnarcotic drug or go to the pharmacy directly if this person 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 FDA's actions 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 (FDA 2014g). Basically, if a drug does not fall into one of the following three categories, it is considered nonprescription:

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

In addition, the Durham–Humphrey Amendment required any drug that is potentially harmful or habit-forming to be dispensed under the supervision of a healthcare practitioner as a prescription drug and must carry the statement, "Caution: Federal law prohibits dispensing without prescription" (FDA 2009c).

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 was to be marketed in the United States. **Thalidomide** had been used in Europe, Canada, and Africa to treat morning sickness in pregnant women. Despite ongoing pressure, medical officer Frances Kelsey refused to allow the request to be approved because of insufficient safety data (FDA 2012a). 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 the United States, the manufacturers had distributed more than 2 million tablets in the United States for investigational use—a type of use that the regulations

Characteristic limb deformities caused by thalidomide.

of that period left largely unchecked. Once the damaging effects of thalidomide became known, the FDA attempted quickly to recover the drug from patients and providers. For her efforts, Kelsey received the President's Award for Distinguished Federal Civilian Service in 1962, the highest civilian honor available to a government employee (FDA 2014a; National Library of Medicine [NLM] 2015).

Although standard testing probably would not have detected the congenital effect of thalidomide and the tragedy would likely have occurred anyway, these debilitated infants prompted 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

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, 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

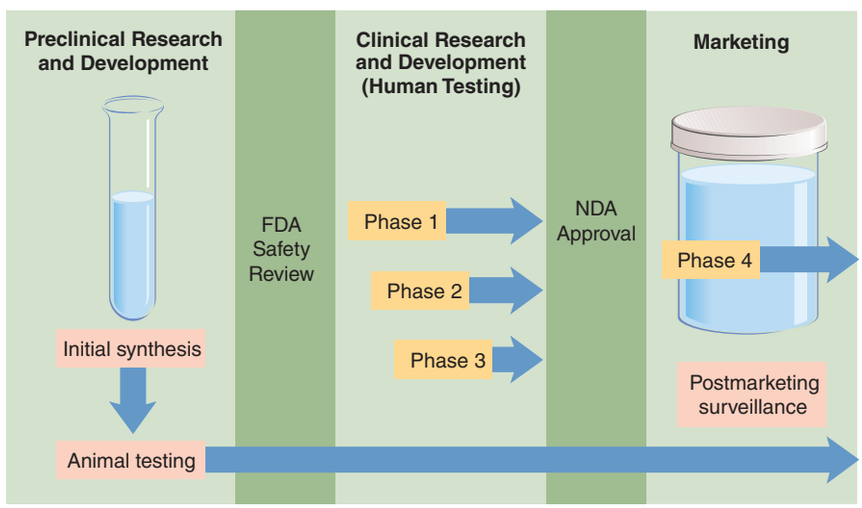


FIGURE 3.1 Steps required by the FDA for reviewing a new drug.

determined along with potency, and then the risk and benefit of the substance must be calculated. 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 to 100), typically healthy people but sometimes patients, are recruited to establish drug safety and dosage ranges for effective treatment and to examine side effects. Medical students, paid college student volunteers, and other volunteers are often studied 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 to 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 as many as thousands of volunteer patients who have given informed consent.

This stage makes the drug available on a wide experimental basis. Sometimes, by this point, the new drug has received some publicity, 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 2014, the average cost of developing a new drug was $2.6 billion (Tufts Center for Drug Development 2014; see "Here and Now: The Cost of Prescription Drug Development").

Once the drug is marketed, it continues to be closely scrutinized for adverse effects. This postmarketing surveillance is often referred to as Phase 4, and it 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.

HERE AND NOW

The Cost of Prescription Drug Development

According to a 2014 study by the Tufts Center for the Study of Drug Development, the development of a new prescription medicine that successfully obtains marketing approval is estimated to cost $2.6 billion. This figure is based on an estimated average "out-of-pocket cost" of approximately $1.4 billion and expected returns that investors forgo while a drug is in development of approximately $1.2 billion.

According to the study, the estimated average cost of post–FDA-approval studies to test new indications,

(*continues*)

HERE AND NOW

The Cost of Prescription Drug Development (*continued*)

dosage strengths, dosing regimens, and new formulations, as well as to monitor safety and long-term side effects as an FDA condition of approval, is an additional $312 million, with all figures expressed in 2013 dollars.

These newest figures are substantially higher than in past years. According to the study's principal author, Joseph A. DiMasi, these increases have been driven largely by both increases in out-of-pocket costs for individual drugs and higher failure rates for drugs in human trials.

Data from Tufts Center for Drug Development. "Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion." 18 November 2014. Available: http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

EXCEPTIONS: SPECIAL DRUG-MARKETING LAWS

Concerns have been raised 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, acquired immunodeficiency syndrome (AIDS), and some other diseases. Fast tracking is a process designed to expedite the review of drugs to treat serious diseases and fill an unmet medical need. Filling an unmet medical need is defined as providing a therapy where none exists or providing one that may be potentially better than therapy available currently (FDA 2014e).

According to the FDA,

> Determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one. AIDS, Alzheimer's, failure and cancer are obvious examples of serious conditions. However, diseases such as epilepsy, depression and diabetes are also considered to be serious conditions. (FDA 2014e)

Many drugs that qualify for fast tracking also qualify for *priority review* by the FDA. A priority review designation "will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications" (FDA 2014f). Its goal is to reduce the time it takes for the FDA to review a new drug application, with a goal of completion in 6 months (compared to 10 months under standard review). Significant improvement may include (1) enhanced effectiveness in treatment, diagnosis, or prevention, (2) increased patient compliance that is predicted to lead to fewer serious adverse outcomes, (3) evidence of safety and effectiveness in a new subpopulation, or (4) substantial reduction or elimination of treatment-limiting drug reactions (FDA 2014f).

The *breakthrough therapy designation* is designed to accelerate the review and development of agents that are intended to treat a serious condition. It requires clinical evidence indicating that the drug may provide significant improvement over existing therapy on a clinically significant endpoint(s). For purposes of breakthrough therapy designation, a "clinically significant endpoint generally refers to an endpoint that measures an effect on irreversible morbidity or mortality (IMM) or on symptoms that represent serious consequences of the disease" (FDA 2014c). The designation has several benefits, including eligibility for all fast-track designation features (FDA 2014c, 2015b).

Of note, it is possible that drugs for serious conditions that fill an unmet medical can be approved based on a **surrogate** or **intermediate clinical endpoint**. This process is referred to as *accelerated approval* (FDA 2014b).

KEY TERMS

surrogate endpoint
a physical sign, laboratory measurement, radiographic image, or other measure that is expected to predict clinical benefit, but is not itself a measure of clinical benefit

intermediate clinical endpoint
a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality

Processes such as fast tracking, breakthrough designations, accelerated approval, and/or priority review have shortened review periods for drugs that treat very serious conditions. As one example, the FDA reviewed Gleevec, a treatment for chronic myeloid leukemia, in 2.5 months (Motl, Miller, and Burns 2003). According to the FDA (2014d), 46% of the 41 novel new drugs approved in 2014 were designated as fast track, breakthrough, or both; 61% were designated for priority review; and 20% were approved under the FDA's accelerated approval program.

Another special marketing law that has had considerable impact is the Orphan Drug Law. It 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. Fewer than 10 products supported by industry for rare diseases came to market between 1973 and 1983. The Orphan Drug Act provided the first significant incentives to drug developers to support needed medical products for approximately 25 million Americans with rare diseases. Since its passage in 1984, over 400 products for rare diseases have received approval for marketing (FDA 2015a).

One additional attempt to accelerate the drug review is 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 facilitate the review processes (FDA 2014g).

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. Panels of drug experts that included physicians, pharmacologists, and pharmacists reviewed the so-called active ingredients in the OTC medications. Based on the recommendations of these panels, the active 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.

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, OTC medicines will contain fewer active ingredients but that 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. According to the Consumer Healthcare Products Association, 700 drugs that would have required a prescription only 20 years ago have been switched to OTC status (FDA 2011). 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

KEY TERM

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

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. Some concerns remain, 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 spent by the pharmaceutical industry to promote its products. However, according to data cited by The Pew Charitable Trusts (2013), the pharmaceutical industry spent over $27 billion on drug promotion in 2012. This included over $3 billion on advertising to consumers (primarily through television commercials) and $24 billion on marketing to physicians.

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 2015c).

According to the FDA (2015d), 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 the following:

- Most physicians surveyed agreed that because their patient saw a DTC advertisement, he or she asked thoughtful questions. Approximately the same percentage of physicians thought the advertisements made their patients more aware of potential therapies.
- 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. In contrast, 40% of physicians indicated that their patients understand the possible *risks*. In addition, 65% responded that DTC advertisements confused patients.
- Approximately 75% of physicians surveyed indicated that DTC advertisements cause patients to think that the drug is more efficacious than it is, and many physicians felt some pressure to prescribe something when patients mentioned DTC advertisements.
- The physicians surveyed reported that patients understand that they need to consult a healthcare 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 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 summarized 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 products. The solutions to these problems will not be simple. Nevertheless, efforts to keep drug advertisements accurate, and informative are worthwhile and are necessary if the public is expected to make rational decisions about drug use (see "Here and Now: Drug Advertising: 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 released and cause serious side effects, the FDA is condemned for being ineffective in its control of drug marketing.

Importantly, federal regulations do not ensure drug safety or effectiveness for everyone. Too many individual variables alter the way individuals respond 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 is ineffective.

It is always difficult to predict the future. 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.

Drug Abuse and the Law

The negative experiences described earlier in this chapter 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

HERE AND NOW

Drug Advertising: What's in an Ad?

The FDA regulates the advertising of prescription drugs. Federal law does not bar drug companies from advertising any kind of prescription drug, even ones with the potential for severe injury, addiction, or withdrawal. The FDA cannot limit the amount of resources spent on prescription advertisements. It encourages pharmaceutical companies to use language that is clear and understandable to the general public.

According to the FDA, requirements of product claim advertisements include the following, but are not limited to:

- The generic and brand name of the drug
- An FDA-approved use for the drug
- A statement that a product is available by prescription only
- "Fair balance" description of the benefits and risks of the product

Data from Food and Drug Administration (FDA). "Product Claim Ad (Correct)." 2016. Available http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm082284.htm

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 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, in general, 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 among *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. Department of Justice [USDOJ] 2011). Specific findings are not

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.

Reproduced from U.S. Department of Justice, U.S. Drug Enforcement Administration (DEA). "Drugs of Abuse." 2011. Available http://www.justice.gov/dea/docs/drugs_of_abuse_2011.pdf. Accessed December 29, 2015.

required for each factor. The factors include the following:

- The actual or relative abuse potential of the drug.
- Scientific evidence of the pharmacological effects of the drug.
- The state of current scientific knowledge regarding the substance. (This factor and the one above are closely related. However, the above factor is primarily concerned with pharmacological effects, whereas this factor deals with all scientific knowledge with respect to the drug.)
- Its history and current pattern of abuse.
- What, if any, risk there is to the public health.
- The psychological or physiological dependence liability of the drug.
- The scope, duration, and significance of abuse.
- 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.

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 3.1**).

Noteworthy, the Controlled Substance Act made no provision for disposal of unwanted or unused prescription medications, except to relinquish these to law enforcement. This lead to the accumulation of unused drugs in homes, and increased the likelihood of misuse and abuse. The Secure and Responsible Drug Disposal Act was enacted to address this problem (see "Here and Now: Secure and Responsible Drug Disposal Act").

TABLE 3.1 Federal Drug-Trafficking Penalties

Drug/Schedule	Quantity	Penalties	Quantity	Penalties
Cocaine (Schedule II)	500–4999 g mixture	**First Offense:** Not less than 5 years and not more than 40 years. If death or serious bodily injury, not less than 20 years or more than life. Fine of not more than $5 million if an individual, $25 million if not an individual. **Second Offense:** Not less than 10 years and not more than life. If death or serious bodily injury, life imprisonment. Fine of not more than $8 million if an individual, $50 million if not an individual.	5 kg or more mixture	**First Offense:** Not less than 10 years and not more than life. If death or serious bodily injury, not less than 20 years or more than life. Fine of not more than $10 million if an individual, $50 million if not an individual. **Second Offense:** Not less than 20 years, and not more than life. If death or serious bodily injury, life imprisonment. Fine of not more than $20 million if an individual, $75 million if not an individual. **2 or More Prior Offenses:** Life imprisonment. Fine of not more than $20 million if an individual, $75 million if not an individual.
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	**First Offense:** Not more than 20 years. If death or serious bodily injury, not less than 20 years or more than life. Fine $1 million if an individual, $5 million if not an individual. **Second Offense:** Not more than 30 years. If death or serious bodily injury, life imprisonment. Fine $2 million if an individual, $10 million if not an individual.
Flunitrazepam (Schedule IV)	Less than 1 g	

(*continues*)

TABLE 3.1 Federal Drug-Trafficking Penalties (*continued*)

Drug/Schedule	Quantity	Penalties
Other Schedule III drugs	Any amount	**First Offense:** Not more than 10 years. If death or serious bodily injury, not more than 15 years. Fine not more than $500,000 if an individual, $2.5 million if not an individual. **Second Offense:** Not more than 20 years. If death or serious injury, not more than 30 years. Fine not more than $1 million if an individual, $5 million if not an individual.
All other Schedule IV drugs (other than 1 g or more of Flunitrazepam)	Any amount	**First Offense:** Not more than 5 years. Fine not more than $250,000 if an individual, $1 million if not an individual. **Second Offense:** Not more than 10 years. Fine not more than $500,000 if an individual, $2 million if other than an individual.
All Schedule V drugs	Any amount	**First Offense:** Not more than 1 year. Fine not more than $100,000 if an individual, $250,000 if not an individual. **Second Offense:** Not more than 4 years. Fine not more than $200,000 if an individual, $500,000 if not an individual.

Drug	Quantity	First Offense	Second Offense
Marijuana (Schedule I)	1000 kg or more mixture or 1000 or more marijuana plants	Not less than 10 years or more than life. If death or serious bodily injury, not less than 20 years, or more than life. Fine not more than $10 million if an individual, $50 million if other than an individual.	Not less than 20 years or more than life. If death or serious bodily injury, life imprisonment. Fine not more than $20 million if an individual, $75 million if other than an individual.
Marijuana (Schedule I)	100–999 kg mixture or 100–999 marijuana plants	Not less than 5 years or more than 40 years. If death or serious bodily injury, not less than 20 years or more than life. Fine not more than $5 million if an individual, $25 million if other than an individual.	Not less than 10 years or more than life. If death or serious bodily injury, life imprisonment. Fine not more than $8 million if an individual, $50 million if other than an individual.
Marijuana (Schedule I)	50–99 kg mixture or 50–99 marijuana plants	Not more than 20 years. If death or serious bodily injury, not less than 20 years or more than life. Fine $1 million if an individual, $5 million if other than an individual.	Not more than 30 years. If death or serious bodily injury, life imprisonment. Fine $2 million if an individual, $10 million if other than an individual.
Hashish (Schedule I)	More than 10 kg		
Hashish oil (Schedule I)	More than 1 kg		
Marijuana (Schedule I)	1–49 marijuana plants; less than 50 kg mixture	Not more than 5 years. Fine not more than $250,000, $1 million if other than an individual.	Not more than 10 years. Fine $500,000 if an individual, $2 million if other than individual.
Hashish (Schedule I)	10 kg or less		
Hashish oil (Schedule I)	1 kg or less		

Data from U.S. Drug Enforcement Administration (DEA). "Federal Trafficking Penalties." n.d. Available: https://www.dea.gov/druginfo/ftp3.shtml. Accessed April 22, 2016.

HERE AND NOW

Secure and Responsible Drug Disposal Act

Prescription drug abuse is a major problem. According to the 2014 Substance Abuse and Mental Health Services Administration (SAMHSA) National Survey on Drug Use and Health, 2.5% of Americans aged 12 or older had abused prescription drugs in the past month prior to the survey. In 2013, approximately 2 million persons aged 12 or older used psychotherapeutics nonmedically for the first time within the past year, which averages to about 5500 initiates per day. Rates averaged across 2012 and 2013 indicated that more than 50% of nonmedical users of tranquilizers, pain relievers, stimulants, and sedatives aged 12 or older got the prescription drugs they had most recently used "from a friend or relative for free."

The Controlled Substances Act made no legal provisions for patients to rid themselves of unwanted pharmaceutical controlled substances except to give them to law enforcement. Pharmacies, physician offices, and hospitals were not permitted to accept the drugs. To combat this problem, President Barack Obama signed into law the 2010 Secure and Responsible Drug Disposal Act. This act authorized the Drug Enforcement Administration (DEA) to develop and implement regulations that outline methods to transfer unused or unwanted pharmaceutical controlled substances to authorized collectors for the purpose of disposal. The act also permitted long-term-care facilities to do the same on behalf of residents or former residents.

In 2014, the DEA implemented its final rule for the disposal of controlled substances. It authorizes certain DEA registrants (distributors, reverse distributors, manufacturers, retail pharmacies, narcotic treatment programs, and hospitals/clinics with an on-site pharmacy) to amend their DEA registration to become authorized collectors. Law enforcement continues to have autonomy with respect to how these agencies collect pharmaceutical controlled substances, including holding take-back events.

Drug Enforcement Administration (DEA). *DEA Releases New Rules That Create Convenient but Safe and Secure Prescription Drug Disposal Options*. 8 September 2014. Available: http://www.dea.gov/divisions/hq/2014/hq090814.shtml; Substance Abuse and Mental Health Services Administration (SAMHSA). *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings.* NSDUH Series H-48, HHS Publication No. SMA 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

Center for Behavioral Health Statistics and Quality. *Behavioral Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*. NSDUH Series H-50 HHS Publication No. SMA 15-4927. Rockville, Md. Substance Abuse and Mental Health Services Administration, 2015.

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, even with stricter laws and greater support for law enforcement.

Nationwide, law enforcement made an estimated 12,196,959 arrests in 2012. Of these arrests, an estimated at 1,552,432 arrests were for drug abuse violations. An estimated 1,282,957 were for driving under the influence (Federal Bureau of Investigation [FBI] 2013). 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.

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 distinguished from the distributor 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 3.1 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 proved difficult to eliminate.

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

interdiction
a policy of cutting off or destroying supplies of illicit drugs

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 2014, approximately 38.7% of 12th graders used an illicit drug during the prior 12 months; marijuana/hashish was used by 35.1% and cocaine by 2.6% (Johnston et al. 2015). 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.

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 includes 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 2015, the U.S. federal budget request for interdiction efforts, which includes intercepting and ultimately disrupting shipments of illegal drugs and their precursors, as well as the proceeds, totaled approximately $3.9 billion (Office of National Drug Control Policy [ONDCP] 2014). Although seizures of large caches of illicit drugs are reported routinely in the national press, the evidence is mixed as to whether the availability of drugs has diminished substantially. 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.

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. As part of this strategy, support for medical and group drug treatment programs for abusers is encouraged. Although this approach does not address the drug supply, it does attempt to curb and eventually eliminate the need to purchase drugs by reducing the buyer's demand.

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 stage of development 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. 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 June 2014, more than 3400 drug courts were in place in the United States. More than half target adults, including DWI (driving while intoxicated) offenders and a growing number of military veterans; others address juvenile, child welfare, and different case types (National Institute of Justice [NIJ] 2015). 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.

Recent statistics indicate that drug courts are effective. For example, the National Institute of Justice's Multisite Adult Drug Court Evaluation (National Criminal Justice Referral Service [NCJRS] 2015) found that:

- Participants reported less drug use (56% vs. 76%) and were less likely to test positive (29% vs. 46%) than comparable offenders.
- Participants reported less criminal activity (40% vs. 53%) and had fewer rearrests (52% vs. 62%) than comparable offenders.
- Treatment investment costs were higher for participants, but because there was less recidivism, drug courts saved an average of $5680 to $6208 per offender overall.

An example of the many public awareness advertisements that caution against drinking and driving.

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:

- National Survey on Drug Use and Health (NSDUH) data indicate that, in 2013, 9.4% of individuals 12 years or older had used illicit drugs during the month prior to the survey (SAMHSA 2014).
- In 2011, the overall rate of current illicit drug use among persons aged 12 or older (9.4%) was similar to the rates in 2010 (8.9%) and 2012 (9.2%), but it was higher than the rates in 2002–2009 and 2011 (SAMHSA 2014).

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.

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 dealing with and arresting abusers have asserted that many of the drug laws are wasteful and/or ineffective.

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

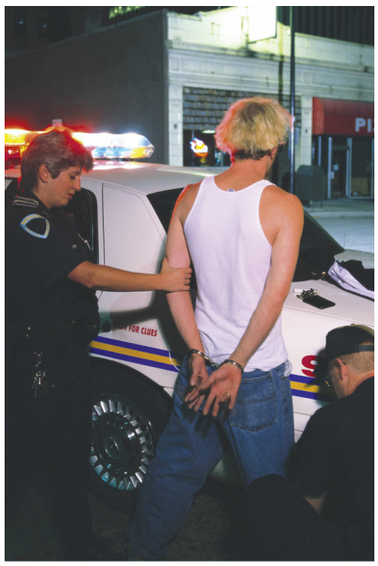
Proponents claim that drug legalization would allow users the right to practice a diversity of consciousness. Just as diversity of race, ethnicity, sexual orientation, religion, and other varied lifestyles is allowed, legalization of drugs would permit individuals to alter their consciousness without 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.

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 substantial 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,



Substance abuse can lead to serious legal problems.

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, including complications from hair treatment (e.g., hair coloring) and environmental absorption, before hair can be used as a definitive proof of drug use.

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.* In many cases, drug testing can have punitive consequences (e.g., 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, 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, 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 some experts to question its value in dealing with drug abuse problems. 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 often 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 (e.g., airline pilots, train engineers, and truck drivers).

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:

- 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 (e.g., as did the Prohibition laws banning all alcohol use). Used properly and selectively, however, laws can reinforce and communicate expected social behavior and values (e.g., 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 crusading tactics. Society needs to engage in more collaborative programs in which drug-using individuals and their families, communities, and helping agencies work together.

LEARNING PORTFOLIO

Key Terms

Discussion Questions

1. Describe the FDA approval process for assessing the safety and efficacy of a newly developed drug. What are advantages and disadvantages of this process?
2. Identify 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 nonusers 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. 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. 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 best to 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. 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 manufacture 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, including complications caused by hair treatment and environmental absorption, before it can be used as a definitive proof of drug use.

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