



## CHAPTER 1

# The Law and the Legal System

### CHAPTER OBJECTIVES

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Upon completing this chapter, the reader will be able to:

- Identify the reasons why society regulates medications as well as the limitations of this regulation.
- Distinguish the sources and types of laws in the United States.
- Describe the federal and state legislative processes.
- Describe the structure and function of the U.S. judicial system.
- List the responsibilities of administrative agencies.
- Distinguish among criminal, civil, and administrative liability.
- Describe the relationship between federal and state law.

Pharmacy laws describe for pharmacists the basic requirements of day-to-day practice. They also define the relationship that pharmacists have with the public they serve. As health professionals, pharmacists are highly regulated because the slightest misstep in drug distribution or pharmaceutical care could cost a life. As custodians of the nation's drug supply, pharmacists are subjected to extensive regulation because the products that pharmacists control are held to the most exacting standards of any consumer product. They study the law because, through the law, society has described what is considered acceptable conduct for pharmacists, and pharmacists who fail to meet this level of acceptability will be held accountable for their failure.

In most pharmacy practice situations, the question of “What is legal?” can be addressed by answering the question “What is best for the patient?” Pharmacists may not always know the law, but they usually will know what is best for the patient, and this knowledge is ordinarily sufficient. However, sometimes,

situations are more complicated than this simplistic approach would suggest. Pharmacy laws have been drafted to describe the best general approach to specific pharmacy practice situations. They provide guidance for pharmacists by establishing rules that reflect the values of society. It is essential for pharmacists to know these rules and how to use them.

Although pharmacy laws can describe basic practice requirements, they cannot substitute for good professional judgment. Sports metaphors are not always valuable in describing professional responsibilities, but it may be useful to think of pharmacists as being on an athletic team that follows the rules of a game as interpreted and applied by referees or umpires. Pharmacy law provides the rules, whereas government agencies interpret and apply them. Within this framework, pharmacists can develop various strategies and exercise good judgment, just as athletes do. Some strategies and judgments lead to success and others lead to failure. It is not the responsibility of the law to dictate

strategy and professional judgment. The law merely establishes the overall framework within which the strategy is developed. Following the law is necessary but not enough for professional success, just as following the rules is necessary but not enough for athletic success. To succeed in pharmacy, as in athletics, an effective strategy must be used in tandem with good judgment, and it is up to pharmacists to determine this, just as it is up to athletes to determine how they can succeed within the rules. Pharmacists who look to the law for an effective practice strategy and professional judgment will be disappointed, because they will not find anything beyond the basic rules for behavior and appointed officials whose job it is to enforce the rules.

## The Nature and Role of the Law

Laws may generally be regarded as requirements for human conduct, applying to all persons within their jurisdiction, commanding what is right, prohibiting what is wrong, and imposing penalties for violations. The law, however, is much more than a collection of mandates and prohibitions. It is a framework through which people in a society resolve their disputes and problems in a way that does not involve force and consistently yields results that are acceptable to most of society. It is a socially prescribed process through which people declare their collective will and express their norms and values. This legal process takes into account the individual differences of every situation, but it recognizes the need to provide firm rules for people to follow as well. Therefore, simultaneously, the law tries to be flexible and also to maintain a reasonable degree of certainty. To achieve certainty, the law assumes the existence of a decision maker such as a legislature, an administrative agency, or a court that resolves disagreements by providing definitive, final answers that reflect society's expectations.

Answers in law are not often easily derived nor are they black and white. Many times, an attorney's reply to a legal question is "It depends." Many laws are intentionally vague and varied because they deal with human relationships. It is impossible for lawmakers to predict all of the countless, ever-evolving human relationships that may occur. Courts can often reach legal decisions only after considerable reasoning based on several factors that may include:

- Fundamental notions of fairness
- The custom or history involved

- The command of a political entity
- The best balance between conflicting societal interests

Recognizing the flexibility that is inherent in the law is essential to understanding and critiquing how and why certain laws, regulations, or judicial decisions have been written.

## Reasons to Regulate Medicinal Drugs

The government regulates medicinal drugs very heavily because of the potential risks to users. The concept of government regulation to protect people from harming themselves through risky choices creates images of an overbearing, paternalistic bureaucracy that forces people to behave in prescribed ways. If the assumption is accurate that people tend to act in their own self-interest by making decisions that will increase their personal happiness (e.g., higher income, more free time, improved health status), why does the government need to make decisions for people? Why not simply allow people to look out for themselves? One possible answer is that the free market does not always act efficiently enough to promote happiness-maximizing behavior. Such market inefficiency, often referred to as "market failure," justifies government regulation. The following four types of market failures are relevant to drug use:

1. Public goods
2. Externalities
3. Natural monopolies
4. Information asymmetry

Any legitimate government interference with a private choice to use medicinal drugs will be based on one or more of these identifiable market failures. In fact, government agencies should bear the burden of demonstrating that a market failure justifies interference with private choice. Government regulation need not occur in the absence of a specific reason to regulate.

Public goods are those necessary and beneficial commodities that private entities will not supply because there is no incentive for a private entity to provide them. National defense programs and lighthouses are classic examples of public goods; parks and intercity highways also fall within this category. The government must step in and regulate the market to provide these goods because an unregulated market will probably fail to provide them efficiently. Public goods in the drug industry include orphan

drugs and vaccines. Orphan drugs are those drugs that are sufficiently safe and effective to be marketed, but the number of patients who need them is so small that it is not commercially feasible for a manufacturer to market them. Because the open market will not make these drugs available, government must step in to ensure availability for those who need them. The need to regulate vaccines, on the other hand, stems from the fact that they benefit society as a whole by preventing epidemics; but because of acute reactions to them, they are viewed as too risky by many individuals. If every individual made a rational decision not to accept the risk of vaccines because their benefit is to all of society rather than to the individual, there would be no benefit to anyone and epidemics would be unpreventable. Prevention of epidemics is a public good and the government must regulate by requiring vaccinations. At the same time, the government must ensure the availability of vaccines. Because of mass product liability actions, most manufacturers stopped producing childhood vaccines in the 1980s, and the country faced a crisis when less than six months of vaccine storages remained. The federal government stepped in to provide liability protection for vaccine manufacturers, and manufacturers not only resumed production but also developed new vaccines that were safer than the older ones. The COVID-19 pandemic of course raised concerns regarding vaccine policies and mandates across the country. However, these lawsuits primarily involved employees suing employers or states suing CMS over vaccine mandates. Claims associated with vaccine side effects or other related countermeasures were to be filed with the Health Resources and Services Administration (HRSA) Countermeasures Injury Compensation Program (CICP).

An externality, another type of market failure, exists when the production or consumption of a good affects someone who does not fully consent to the effect and when the costs of a good are not fully incorporated into the consumer price. The parties who are directly involved in using the good may not consider the indirect impact of the production or consumption of the good for a party that is not involved in the use of that good. For example, people who purchase products manufactured in a factory that pollutes the air will probably not consider the costs associated with harm to the lungs of the people who live near the factory. In an unregulated market, where the manufacturer is not required to prevent air pollution, the purchase price of the product will not include the cost of the pollution.

Because there is a market failure, government regulation is necessary. The overuse of antibiotics is an externality in drug therapy. A person who unnecessarily uses an antibiotic to treat a cold will probably not consider the cost to other people in terms of the increased resistance to the antibiotic within the general population. In part, because of this externality, government must regulate the use of antibiotics by imposing a prescription requirement to ensure that unnecessary use by one person does not impose an indirect cost on other people.

A natural monopoly occurs when the fixed costs of providing a good are high relative to the variable costs, so the average cost declines over the time that the good is provided. For example, utilities that provide electricity, water, and natural gas are natural monopolies, because the cost of establishing the infrastructure of supply lines vastly exceeds the cost of supplying the good once the infrastructure has been developed. Governments regulate these natural monopolies to promote efficiency. In drug therapy, the cost of demonstrating the safety and efficacy of a new drug is usually far greater than the cost of providing the new drug once it has been shown to be safe and effective. Government regulation ensures that there is an incentive to develop new drugs by initially providing an exclusive right to market them. After the period of exclusivity expires, regulation promotes efficiency by permitting competition by generic manufacturers.

Information asymmetry leads to market failures when the consumer is uninformed about the true value of a good. Some goods have characteristics that are obvious to a consumer before purchase (e.g., a chair, a tablet of paper). Consumers can evaluate other goods only after purchasing them (e.g., a used car, a meal at a restaurant). It is more difficult to evaluate medications because most consumers are unable to determine their value fully even after using them. Information about the benefits and detriments of medications does not flow freely within the lay public because it often is difficult for untrained individuals to understand these benefits and detriments. To minimize the possibility of market failure caused by information asymmetry, government regulation requires the provision of information and input by educated professionals into decisions about drug use. Without government regulation to promote the dissemination of information about drugs, patients and health-care providers would find it more difficult to make good decisions about the benefits and detriments of drug therapy.

## Limits of the Law

Even though there may be good reasons for market regulations, there are limits on effective legal actions. These limits originate not only in the constitutional parameters with which laws must harmonize but also in the human condition. Attempts to achieve overly broad objectives through the law will inevitably fail if they conflict with popular attitudes, habits, and ideals.

Human relationships, to the extent that they are well defined by society, are usually best left alone by legal institutions. For example, in families, professions, and religious groups, wholly internal disagreements are generally not amenable to legal resolution. Legal agencies lack the necessary expertise to deal with these problems, and the parties involved are not usually willing to abide by a legal pronouncement that fails to account for the peculiarities of a closely knit group. Excessively harsh enforcement of the law in the face of de minimis (very minor or trifling) violations counterproductively decreases respect for the law. No pharmacy can operate without occasional, very minor technical legal violations. If they have no real impact on the quality of drug therapy, such violations usually result only in warnings by law enforcers. This is not to say that the law will condone frequent or consistent minor violations. As a practical matter, however, there is little or nothing to be gained by pursuing occasional minor violations, obvious though they may be.

Avoidance of excessive punishment that does not “fit the crime” is usually a matter of enforcement discretion left to those who have legal authority at the “street level” to charge (or not charge) violators with infractions. However, in *Young v. Board of Pharmacy*, 462 P.2d 139 (N.M. 1969), the Supreme Court of New Mexico substituted its judgment for that of the enforcement authorities. The court reacted to what it believed was excessive punishment, ruling that

charges made against a pharmacist were arbitrary, unlawful, and unsupported. The pharmacist had not kept accurate dispensing records and had been charged with “unprofessional conduct.” The court acknowledged the deficiencies of the pharmacist’s recordkeeping, but the court could not understand why accurate recordkeeping should be a test of a person’s professional character. This ruling in favor of the pharmacist does not mean that sloppy recordkeeping is acceptable, only that it should not be punished oppressively. Similarly, a Rhode Island court held that a pharmacist’s inadvertent dispensing error could not justify revocation of his license by the state department of health (*Blais v. Rhode Island Department of Health*, 2014 R.I. Super. 172 (2014)).

The fact that individuals in a free society are permitted to act in ways that they deem best for themselves—as long as their actions do not interfere with another individual’s right of action—also limits effective legal action. John Stuart Mill expressed this belief in his essay, “On Liberty,” when he said, “The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others” (p. 16). The law does not always accede to the Mill principle. Drug abuse and the use of unsafe medications (e.g., Laetrile) are legally restricted, for example, either because of the potential harm to others or because of a belief that some individuals are incapable of knowing what is in their own best interests. However, under most circumstances, individuals are free to make decisions for themselves without legal intervention.

Slogans such as “You can’t legislate morality” or its converse “There oughta be a law” oversimplify the role of the law in society. The law can influence behavior through its deterrent and educative role, but there are definite limits on that function. Society shapes the law, and the primary purpose of the legal system is to make the premises of society work.



### Take-Away Points

- Pharmacy laws provide the rules and structural framework for practicing pharmacy, within which pharmacists exercise strategy and good professional judgment.
- Laws are requirements for human conduct applicable to those within their jurisdiction, commanding what is right and prohibiting what is wrong.
- The law attempts to be flexible and, yet at the same time, provide a degree of certainty.
- Market failures pertaining to public goods, externalities, natural monopolies, and information asymmetry necessitate government regulation.
- There are limits on the extent of government regulation established by the United States and state constitutions and the human condition.



## Study Scenarios and Questions

1. You are a pharmacist talking to a patient. The patient remarks, “I really don’t understand why the FDA has to approve every drug before it can be marketed. I have cancer, and there is a very promising drug in Europe that I can’t get in the United States because of the FDA. Do you think that’s fair?” Respond to this patient using market failures to justify your answer.
2. The patient continues, “I also don’t understand why someone has to have a pharmacy degree and a license to practice pharmacy. Doesn’t it make sense that anyone should be allowed to dispense medications? All that the law should require is that the dispenser be required to post his or her credentials. Then, let the patients decide if they want to go to a high school graduate or a PharmD.” Respond to this patient using market failures to justify your answer. What are the advantages and disadvantages to society of licensure?
3. An elderly patient visits a pharmacy at night and needs a refill on her maintenance prescription medication that she has been taking regularly for 10 years. The physician customarily renews the prescription for one year at a time. However, it is the end of one year, and the patient and the pharmacy have neglected to seek refill authorization. The physician is unavailable and she is flying on a 6 am flight with her husband for a two-week trip out of the country. Assume there is no law allowing for emergency refills and the pharmacist refills the prescription anyway, violating both state and federal law. A state board of pharmacy inspector discovers what happened and files his report to the state board of pharmacy. You are on the state board and must decide what action to take. How could the board proceed as an administrative agency? How should the board proceed and why? If you were the pharmacist, what would you have done and why?

## Sources of U.S. Law

The U.S. government is a tripartite system consisting of the legislative, executive, and judicial branches. Each branch serves as a check to the power of the others, ensuring that no one branch can dominate and control the others. In general, the legislative branch of government makes the laws, whereas the executive branch enforces the laws and the judicial branch interprets them. In theory, this may be correct; in practice, however, all three branches make laws together with what can be considered a fourth branch of government—administrative agencies.

## The Constitution of the United States

The supreme law of the United States is the Constitution. Any federal or state statute or regulation that conflicts with the Constitution is invalid. The Federal Convention ratified the basic Constitution in 1787 and the Bill of Rights (i.e., the first 10 amendments) was added in 1791. In addition to the Bill of Rights, there have been 16 amendments to the Constitution since it was enacted. The passage of so few amendments to such a short document is quite remarkable and illustrates the timeless manner in which the Constitution was written.

The Bill of Rights includes rights generally recognized by everyone such as freedom of speech, freedom of religion, freedom to be secure from unreasonable searches and seizures, protection

against self-incrimination, and the right to due process. The Fourteenth Amendment, passed in 1870, applies the Bill of Rights to state governments.

## Law Made by Legislatures: Statutory Law

A legislature is an elected body of persons with the primary responsibility to enact laws, also called statutes. These statutes can be organized in a hierarchical order:

- Federal statutes
- State constitutions
- State legislation
- Ordinances

Article 1, section 1, of the U.S. Constitution provides that all legislative powers of the federal government shall be vested in a Congress, which shall be composed of a Senate and a House of Representatives. In addition to several specifically enumerated powers entrusted to Congress, article 1, section 8, provides that Congress shall have the power to make all laws “necessary and proper” for carrying out its responsibilities. The laws enacted by Congress apply nationwide.

Each state has its own constitution, which is usually much more detailed than the U.S. Constitution. Just as the U.S. Constitution is the supreme law over the whole country, a state constitution is the supreme law of the state.

Under the Tenth Amendment to the U.S. Constitution, states have the power to legislate in all areas



except those prohibited or given to Congress by the U.S. Constitution. As a result, state legislatures have extremely broad powers to pass laws to protect the health, safety, and welfare of the public.

Each state government has the authority to create political subdivisions, such as municipalities and counties, to which the state can delegate certain functions. These political entities can enact ordinances that are enforceable as laws.

## Law Made by Administrative Agencies

A legislature may create administrative agencies to implement the desired changes in policies or to administer a body of substantive law when the legislature itself cannot perform these functions. It is impossible, for example, for state legislatures to monitor the activities of pharmacists and pharmacies on a regular basis. Therefore, the legislatures have created state boards of pharmacy to administer and enforce state pharmacy practice acts. Although the legislature creates them, such agencies are housed in the executive branch of government.

Several administrative agencies affect pharmacists at both the federal and state levels. Federal agencies include:

- The Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration, which is housed in the Department of Health and Human Services (DHHS), is responsible for reimbursement policies and procedures for pharmacies and other healthcare providers participating in the Medicare and Medicaid programs.
- The U.S. Food and Drug Administration (FDA), also housed in the DHHS, administers the federal Food, Drug, and Cosmetic Act (FDCA).
- The Federal Trade Commission administers the Federal Trade Commission Act, enforcing unfair business practices and antitrust violations.
- The Drug Enforcement Administration, under the jurisdiction of the U.S. Justice Department, administers the federal Controlled Substances Act.

Some state-level agencies of importance to pharmacists include the state board of pharmacy, which administers state pharmacy practice acts; the state department of health services; and state Medicaid agencies (usually under the department of health services), which determine state Medicaid policies and pharmacy reimbursement rates. Administrative agencies generally have considerable and

broad authority, including the authority to perform legislative, judicial, and executive functions. Administrative agencies can be said to create law primarily through their authority to enact regulations and to render decisions at hearings.

## Legislative Function

Administrative agencies accomplish their legislative function through the promulgation of regulations. Administrative regulations interpret and define statutes. For example, although the federal FDCA enacted by Congress requires compliance with “current good manufacturing practices,” it is really the regulations promulgated by the FDA that precisely and extensively define these practices. Similarly, for example, several states mandate that pharmacists complete a certain number of continuing education units over a specified period of time. Regulations promulgated by state pharmacy boards provide the necessary details such as the types of continuing education units that are acceptable, the records that must be furnished to the state pharmacy board, and the requirements that continuing education providers must meet.

Because administrative agencies have a greater level of expertise than Congress or a state legislature, it makes good sense for such agencies to determine how legislative policy will be implemented on a day-to-day basis. Recognizing the technical expertise of agencies, courts generally presume the actions of an agency to be valid.

Most administrative agencies promulgate regulations pursuant to a process known as “notice and comment rulemaking.” This process ensures that constituents whose interests are affected by the actions of the agency receive notice of any proposed regulation. Constituents, then, have an opportunity to comment on the proposed regulation. The agency considers all comments and may incorporate them into the regulation before its final promulgation. Although regulations are not statutes, they have the legal force of statutes and must be obeyed as such.

In order to be valid, a regulation must generally meet three legal tests. First, the regulation must be within the scope of the agency’s authority. For example, a state board of pharmacy is charged with administering pharmacy practice laws. Thus, it generally would not have the authority to regulate such issues as pharmacy investment practices or wage standards for pharmacy personnel.

Second, and often directly related to the first test, the regulation must be based on a statute that gives the agency the authority to promulgate the regulation.

Generally, it is not legal for agencies to create new substantive law unless there is a statute enabling the agency to regulate in that area. For example, a state board regulation authorizing licensed pharmacy technicians to assist pharmacists with dispensing functions is likely to be invalidated unless there is a statute that recognizes the status of pharmacy technicians. Some courts have interpreted enabling legislation quite liberally. In *Rite Aid of New Jersey, Inc. v. Board of Pharmacy*, 304 A.2d 754 (N.J. Super. 1973), the court upheld a regulation passed by the New Jersey Board of Pharmacy to require that pharmacies maintain patient profile record systems. The board cited as the enabling law a state law requiring pharmacists to keep prescription records on file. Although the law made no mention of patient medication records (as this was prior to OBRA '90), the court found that the regulation was valid because it furthered the objective of the state law requiring pharmacists to keep records to protect the public. The court stated that the legislature could not be expected to anticipate every possible problem when it wrote the law.

As another example, the North Carolina Board of Pharmacy proposed a regulation limiting the number of continuous hours a pharmacist may work to 12 and requiring pharmacists be given one 30-minute and one 15-minute break if working longer than 6 continuous hours. Chain drug stores argued against the proposed regulation and the Rule Review Commission (RRC), which must approve state agency regulations, vetoed the rule on the basis that the Board lacked statutory authority to regulate pharmacists' working conditions. The Board sued to force publication, but the trial court and state court of appeals, in a split decision, found for the RRC, concluding that the pharmacy board did not have the authority to regulate work conditions because it is a function of the North Carolina Department of Labor. The appellate court majority also concluded that setting limits on work hours and requiring breaks does not concern filling prescriptions. On appeal, the North Carolina Supreme Court reversed the court of appeals and sided with the dissenting appellate court judge that the Board did have the statutory authority to issue the regulation and that there is a relationship between continuous hours of work and accuracy in filling prescriptions (*North Carolina Board of Pharmacy v. Rules Review Com'n.*, 620 S.E. 2d 893 (N.C. Ct. App. 2005); reversed 637 S.E. 2d 515 (N.C. 2006)).

The third legal requirement for a regulation is that it must bear a reasonable relationship to public health, safety, and welfare. Thus, regulations that

specify a dress code for pharmacists or that require the front door of a pharmacy to face the north or south side of a street are likely to be invalid.

## **Judicial Function**

An administrative agency exercises its judicial function through its enforcement activities. The decision to institute proceedings is discretionary with the agency. Hearings conducted by administrative agencies resemble civil or criminal court proceedings—evidence is presented, arguments made, and a decision rendered. The results favor either the agency or the regulated party, perhaps creating new law by interpreting the existing law. At one time, it was common to create new law through case-by-case enforcement (i.e., regulated parties discover that they have committed a violation only through an adjudicative proceeding), but notice and comment rulemaking has largely replaced that inefficient and unfair approach.

Agency decisions are usually subject to “judicial review,” but only after the individual has availed him or herself of every available administrative option, legally called “exhaustion of remedies.” On judicial review, a court usually examines the record of the administrative hearing. If the record shows that the agency's decision was based on “substantial evidence,” the court often simply reviews the appropriateness of the decision in light of the evidence. If the court finds that the agency's decision was not based on substantial evidence, it may decide to hear the case *de novo*, meaning that the court will pay no heed to the hearing findings but instead will conduct an entirely new trial.

## **The Federal Register and Code of Federal Regulations**

Administrative agencies exercise considerable authority over pharmaceutical distribution and pharmacy practice, and pharmacists must be aware of the proposed and final regulations that affect their professional lives. Congress has prescribed that federal agency regulations be recorded in a specific manner so the public will have notice. This notice occurs primarily through two sources:

1. The *Federal Register*
2. The *Code of Federal Regulations* (CFR)

These two publications can be found at many public libraries, university and law school libraries, county courthouse libraries, and several government websites, including the U.S. Government Printing Office website (<https://www.gpo.gov/>).

The *Federal Register* is a daily publication that lists various federal actions, including proposed regulations, final regulations, and various government notices. The CFR is an annually revised compilation of final regulations divided and indexed by subject matter. There are 50 titles (i.e., divided subject areas) in the CFR, and each title is further divided into chapters, subchapters, parts, subparts, and sections.

To pass a regulation that would add a labeling requirement for prescription drugs, for example, the FDA would first publish in the *Federal Register* the proposed regulation, a notice of the intent to enact this regulation, and its reasons for proposing the regulation. A number would be included to identify exactly where the regulation, if enacted, would be placed in the CFR. (All FDA regulations are contained in Title 21 of the CFR.) The notice would invite public comment within a certain time frame. At the conclusion of the comment period, the FDA would review the comments, draft a final regulation, and publish this final regulation along with the agency's comments and the effective date in the *Federal Register*. Simultaneously, this regulation would be inserted into its appropriate location within Title 21 of the CFR.

## Law Made by the Courts: Common Law

When two or more parties cannot settle a dispute or controversy among themselves, they are likely to ask a court to settle the issue. The duty of the court is to apply the proper law to the facts before it and resolve the matter through judicial opinions (decisions). Although legislatures make law through statutes and administrative agencies make law through regulations and hearings, courts make law through judicial “opinions.” The word opinion is potentially misleading. When a court issues an opinion, the rules of law stated within it are not merely a point of view, subject to debate but with no general applicability. Rather, these rules are enforceable as law—they are binding on lower courts within the same jurisdiction and are persuasive in other jurisdictions. Judicial opinions establish enforceable legal principles either by expanding the common law (i.e., a body of judge-made law with its roots in centuries of resolved disputes) or by interpreting statutes and regulations.

The subject matter considered by a court varies a great deal from one day to the next. Thus, a court that is resolving a controversy relating to drug use today may have been presiding over a divorce yesterday and may be facing a dispute over securities

tomorrow. Given the vast differences in subject matter, it is remarkable that courts are consistently able to resolve conflicts in a way that makes contextual sense, and it is inevitable that a court's ruling will sometimes reflect a misunderstanding of the subject matter. There have been periodic calls for “science courts,” in which experts in both law and science work to resolve legal controversies relating to drug risks and other complex scientific issues. To date, however, no coordinated effort toward that end has materialized, and the judiciary continues to lack scientific expertise.

The term “common law” refers to law developed from judicial opinions. Much of the common law in the United States is based on law developed in England during the 200–300 years that followed the Norman conquest of England in 1066. Because the English kings in this period wanted to establish a uniform set of national laws, judges recorded and followed court decisions made previously. The result was a body of legal rules, many of which courts still follow today.

The English colonists retained the common law legal system when they came to North America. Each new state, except for Louisiana (whose law is based on French and Spanish law), then adopted common law into its system. Although many common law principles are uniformly applicable in all states, each state does have its own common law, and some common law principles differ from state to state. In some instances, common law principles have become so accepted and recognized that legislatures have codified them as statutes.

### **Stare Decisis**

The essence of the common law system is the recording of judicial opinions and the reliance of courts on those previous opinions. This practice is called *stare decisis*, meaning “to abide by decided cases.” In practice, a court's establishment of a certain rule of law based on a particular set of facts becomes a precedent that all lower courts in that jurisdiction must follow. *Stare decisis* serves two purposes:

1. Establishing continuity of decisions
2. Expediting judicial decision making

*Stare decisis* applies only to lower courts within the jurisdiction in which the precedent has been established. Thus, lower courts in one state need not follow a state supreme court ruling from another state. Similarly, a federal court of appeals in one circuit need not follow an opinion rendered in another circuit.



Often, however, courts carefully consider opinions from other jurisdictions.

Stare decisis is not an inflexible principle. A court may vary from precedent, primarily for two reasons. First, there may be factual distinctions between the case before the court and previous decisions on which the court relies. For example, a court may find that a pharmacist has a duty to warn patients of the drowsiness associated with an antihistamine drug, but may later find that a pharmacist has no duty to warn patients of possible teratogenic effects associated with a sulfa drug. Lawyers commonly single out factual differences between cases in an attempt to convince a court that the present case is different from the precedent relied on by the other party in the lawsuit.

Second, courts may vary from a precedent because of changing times or circumstances since the precedent was established. A legal principle that was appropriate when the precedent was established may not be the best rule of law for society today. Thus, even if a court ruled in 1965 that pharmacists have no duty to warn a patient of adverse drug reactions, the court may be convinced to reverse that decision today, based in part on the different educational background of pharmacists in 1965 and today and the difference in societal expectations.

### **Relationship of Common Law to Statutory Law**

Common law and statutory law merge when courts are required to interpret the meaning of statutes. It is virtually impossible for any legislature to write a law that is not ambiguous, vague, or confusing in some manner when applied to specific controversies. In fact, many statutes are deliberately written in very general language to provide flexibility. If a statute is too ambiguous or vague, however, courts may invalidate all or part of the statute as unconstitutional. For example, in an attempt to make it illegal to sell and possess devices for illicit drug use, some states in the late 1960s and early 1970s passed laws so broad and imprecise that even items like household teaspoons could have been considered illegal. In those states, the courts either invalidated all or parts of these laws. Courts do not commonly invalidate statutes unless they have no choice; they prefer to presume the constitutionality of a statute and make every attempt to interpret the statute in a way that results in a reasonable and fair application of the law to the facts of a case.

In numerous cases, a court has had to interpret statutes and decide if the set of facts before it is

subject to a particular law. What principles do courts apply when interpreting legislation? In conjunction with the rule of stare decisis, the most important approach that courts apply when interpreting statutes is to determine the legislative intent. In other words, the court attempts to put itself in the mind of the legislature and ask, “Did the legislature mean for the law to apply to the specific fact situation that the court is now considering?” Especially with respect to federal statutes, the court looks to legislative committee reports and any written legislative history to guide it in its interpretation. Often, the legislative history is of no assistance because the legislature never anticipated the type of situation that is the subject of litigation. In this event, the court looks to the overall intent and purpose of the legislation, asking, “Why did the legislature pass this law? What is the law attempting to accomplish? How does this particular situation apply to the law’s purpose?”

For example, a state may pass a law that requires pharmacies to offer counseling to patients but does not require the pharmacist to actually provide the service if the patient refuses it. In one pharmacy, a clerk informs all patients that they may receive counseling from the pharmacist but will have to wait 30–60 minutes. As a result, nearly all patients refuse the counseling. The state board charges the pharmacist with violating the statute, but the pharmacy contends that it has complied with the law. If this case goes to court, the pharmacy’s actions may be ruled more as an attempt to avoid the intent of the statute than an effort to accomplish the intent.

Although a determination of legislative intent generally prevails, courts often combine this analysis with other approaches to interpret a statute. One such other approach is to give the words in a statute their ordinary (commonly understood) meaning. Another is to support the position that best exemplifies current social policy. Yet another consideration that courts must heed is an individual’s constitutional right of due process. In this context, due process means that a reasonable person would be expected to know that this law applies or does not apply to the particular activity in question. It is unfair to hold someone accountable for a law that the person could not know was applicable.

### **Distinguishing Criminal, Civil, and Administrative Law**

A pharmacist’s wrongful act may subject the pharmacist to a criminal, civil, or administrative action, or perhaps all three at the same time. The government

may initiate a criminal action if the pharmacist has violated a statute. For example, a pharmacist who sells a prescription-controlled substance without a prescription may be subject to a criminal action by the state and/or federal government. A person can be charged with a crime only if there is a statute prohibiting the conduct. The sanctions are usually a fine, a prison sentence, or both, depending on the severity of the crime and the penalties specified in the statute. The objectives of criminal statutes and prosecutions are to deter an undesirable activity as well as to punish and rehabilitate the wrongdoer.

A civil action is a lawsuit in which one private party sues another private party alleging an injury. If, for example, the pharmacist in the criminal case just discussed sold the controlled substance to a patient who was allergic to the drug and the pharmacist had knowledge of that allergy but simply forgot, the patient injured from ingesting the drug may sue the pharmacist for the injury. Civil actions

may be based on common law, statutory law, or both. The objective of a civil action is to compensate the injured party for the damages caused by the wrongdoer.

An administrative action may occur when a pharmacist has violated a statute or regulation or has committed an act that, in the opinion of the agency, warrants an investigation. As discussed previously, such administrative actions are called “hearings.” Depending on the statutes and the nature of the violation, they may lead to sanctions, including:

- Warnings
- Fines
- License revocation
- License suspension
- Probation

The pharmacist in the situation discussed is likely to be subject to a state pharmacy board disciplinary hearing.



### Take-Away Points

- The U.S. Constitution is the supreme law of the country.
- Legislatures make law by enacting laws or statutes.
- Administrative agencies make law by enacting regulations and by making enforcement decisions through hearings.
- Federal agencies publish their regulations and other information chronologically in the *Federal Register* and publish final regulations at the appropriate location in the *Code of Federal Regulations*.
- Courts make law by issuing judicial opinions, which is known as common law.
- The practice of courts relying on prior judicial opinions is called *stare decisis*.
- Common law and statutory law intersect when courts must interpret statutes.
- A pharmacist's wrongful act could subject him or her to either or all criminal, civil, or administrative actions.



### Study Scenarios and Questions

1. Assume the Board of Pharmacy passed a regulation prohibiting any pharmacy from accepting any third-party insurance plan whose dispensing fee is less than \$2. You are the owner of a pharmacy that wants to accept a plan offering a fee of \$1. On what basis might you challenge this regulation in court?
2. Assume the Board of Pharmacy passed a regulation that pharmacists may not wear facial jewelry (from piercing). You are a pharmacist who has a number of rings in your eyebrows, nose, and lips. On what basis might you challenge this regulation in court?
3. Apply the principle of *stare decisis* and precedent to the following related fictional cases:

#### 1990 Case

Assume it is 1990 and a patient has been dispensed a prescription antihistamine. The pharmacist did not counsel or provide any warnings. The patient became drowsy while driving, had an accident, and was seriously injured. The patient sued the pharmacist for failing to warn him of the drowsiness. Assume no counseling statute or regulation is in effect in 1990.

There is a 1975 case decision in this same jurisdiction where a patient was dispensed Valium. The pharmacist did not counsel or provide any warnings. The patient took the drug and later, while standing on a

ladder fixing his roof, fell off the ladder and broke his back. The patient sued the pharmacist for failing to warn him that Valium could cause drowsiness and dizziness. The court found for the pharmacist and determined that the legal obligation a pharmacist owes a patient does not include warning the patient of a drug's dangers but only to fill the prescription correctly, exactly as written. During the trial:

- What arguments will the defendant pharmacist's lawyer make?
- What arguments will the plaintiff's lawyer make?

### 2004 Case

Now, assume the plaintiff won the 1990 case and the court held that the pharmacist had a legal obligation to warn the patient of the drowsiness. In this 2004 case, the patient is dispensed an antibiotic. The pharmacist provided counseling and warnings but did not warn of myocardial infarction (MI), a relatively uncommon adverse effect. The patient suffered an MI and sued the pharmacist for failure to warn. Assume the state counseling statute or regulation is in effect.

- What arguments will the plaintiff's lawyer make?
- What arguments will the pharmacist's lawyer make?

### 2018 Case

Now, assume a similar situation to the 1990 case occurred, except with the following differences: The patient taking the antihistamine ran her car into another car, injuring the occupants. The state counseling regulation or statute was in effect. The injured occupants of the other car are suing.

- What arguments will the plaintiff's lawyer make?
  - What arguments will the pharmacist's lawyer make?
4. The state has a law mandating that pharmacists must counsel patients under certain circumstances. Your pharmacy is simply too busy to provide counseling personally and keep up with the volume; so, being the tech wizard you are, you program computers to provide counseling to the patients. The computers are in a private area where a patient can simply enter the name of the drug and a pharmacist, who has been videotaped, comes on screen, and provides all of the required information. The board of pharmacy finds that you have violated the counseling law. You contend otherwise and take your case to court, representing yourself.
- What would be critical to the court's analysis? In other words, how would you argue your case to the court? Conversely, what would the board argue?

## The Legislative Process

Enacting or amending federal or state laws is the role of the federal or state legislative branch. The federal legislative branch and the state legislative branch have similar legislative processes.

### Federal Level

At the federal level, the U.S. Congress, composed of the Senate and the House of Representatives, is the basis of legislative power. The Senate has 100 members and the House has 435 members. The primary function of the Congress is to enact statutes through vote of the full membership. Statutes are usually general in scope, establishing a framework within which the expressed intent of the law is to be achieved.

Ideas for bills originate from several sources, including lobbying groups, citizens, government officials, and the president. The sponsor of the bill, who

must be a senator or representative, introduces the bill in Congress. After introduction, the bill moves to the particular congressional committee that has jurisdiction over that subject. The committee stage of a bill's life is by far the most important to its success or failure. The committee holds public hearings, conducts investigations, and works with the sponsor to ensure that special interests are accommodated to the extent possible. Advocates and proponents of a bill concentrate their activities on the committee level because a bill cannot proceed to a vote by the Senate or House without the consent of a majority of the committee members.

If the committee votes favorably on the bill, it issues a report detailing the purpose of the bill, the reasons the committee approved it, any amendments, and the changes the bill would create in the existing law. Often, individual committee members file supplemental opinions or views with the majority's report. Courts and administrative agencies may

use the committee report to ascertain the legislative intent of the law.

After a bill has cleared the committee, the majority leadership places it on a calendar. This is a strategic step. If not impressed by a particular bill, the majority leadership may place it so late on the calendar that it will not come to a vote before Congress adjourns for the year. Once the bill is called for discussion in the Senate or House, it is usually extensively debated and amended.

After one chamber passes a bill, it goes to the other chamber's appropriate committee for further consideration. Again, hearings are held, and opponents and proponents do their best to influence committee members to vote for or against the bill. There are often differences between the version of a bill passed by the Senate and the version passed by the House. In this case, a conference committee rectifies the differences between the two. After the identical bill has been agreed on by both sides, it is signed by the president of the Senate and the Speaker of the House and sent to the President of the United States. The bill becomes law on the signature of the President of the United States or if the president fails to return the bill to Congress within 10 days. If the president disapproves of the bill, the president may veto it; in this case, the president must return it with the reasons for disapproval to the chamber where the bill originated. Congress can override a presidential veto only by a two-thirds vote in favor of the bill. The president also can prevent a bill from becoming a law by means of a pocket veto, which occurs when the president fails to act on a bill within a 10-day period and Congress adjourns within that time period.

In addition to enacting statutes, Congress is responsible for overseeing the federal bureaucracy. Because Congress has a say in appointments to administrative agencies and appropriations for these agencies, congressional influence over substantive agency policy is significant. Congressional committee investigations, committee hearings, and statutorily required agency reports keep members of Congress informed of agency activities. Members of Congress often are able, either individually or as members of a committee, to influence administrative agencies.

## State Level

Legislatures at the state level are modeled roughly after the U.S. Congress, although some differ from the federal body in one or more characteristics. For example, the Congress meets almost continuously, but some state legislatures meet in full session for only a few months of the year, usually every other year (with limited budget sessions during the off year).

State legislative committees differ from congressional committees at the federal level, in that they are generally less prone to hold full hearings and do not usually issue fully informative committee reports on bills. Communication is sometimes poor on the state level, making it difficult for legislators to know the true nature of proposed bills, their status, and amendments. Thus, a statute's legislative history (i.e., early drafts, committee reports, relevant statements made on the floor), which usually plays a significant role in determining the meaning of a federal statute when a dispute arises, may be virtually nonexistent at the state level.



### Take-Away Points

- Congress is composed of the Senate and the House of Representatives.
- The committee stage of a bill is the most important to a bill's success or failure.
- State legislatures are generally modeled after Congress; however, there is usually not a well-documented, written history of a bill as in Congress.

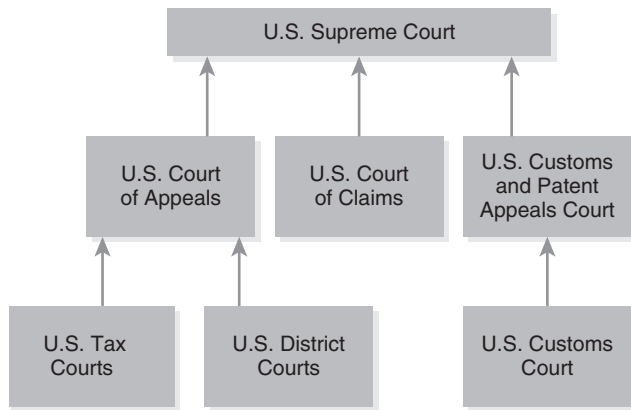
## The Judicial Process

The judicial process includes the series of steps for disputes to be resolved through an established system of courts. There is a federal court system and a state court system that have similar judicial processes.

## The Federal Court System

Article 3 of the U.S. Constitution provides that there shall be a Supreme Court, and it authorizes Congress to establish additional federal courts as necessary (**Figure 1-1**). At the trial court level, Congress has





**Figure 1-1** Federal court system.

established district courts. Each state has at least one U.S. district court; more populated states have two or more. District courts have jurisdiction over controversies that involve:

- The U.S. Constitution or a federal law
- Ambassadors or consuls
- Admiralty and maritime issues
- The United States as a party
- A state as a party against another state
- A state as one party and a citizen of another state as the other party
- A citizen of one state against a citizen of a different state

There are 12 circuit courts of appeals, one for each judicial circuit and the District of Columbia. An appeal from a district court goes to the court of appeals in the circuit that includes both courts. Most cases before appellate courts are those on appeal from the district courts, but these courts can also directly review certain administrative agency decisions.

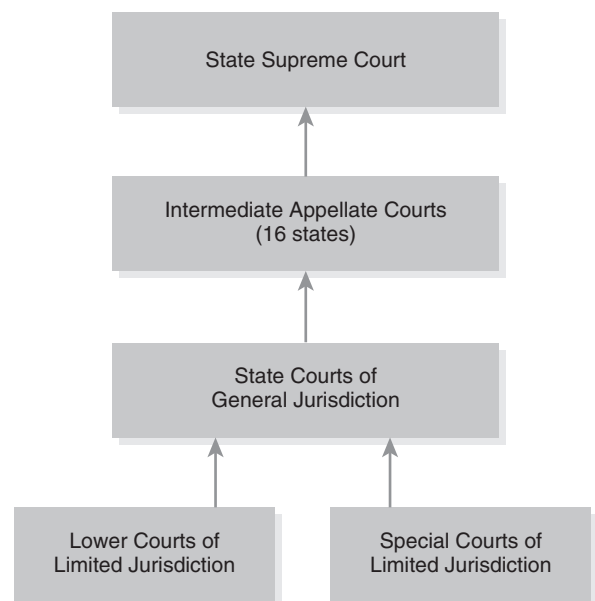
The U.S. Supreme Court has nine justices who hold lifetime appointments from the president, subject to Senate confirmation. As specified in the Constitution, the Supreme Court has “original” jurisdiction in all cases that affect ambassadors, other public ministers, and consuls as well as in all cases in which a state is a party. In most other cases, the Supreme Court has “appellate” jurisdiction. The Supreme Court primarily reviews cases from federal appellate courts, three-judge district court decisions, and final judgments from the highest court in a state when a federal question is involved. Although the Supreme Court is obligated to hear certain cases on appeal, most cases must be submitted through a *writ of certiorari*, meaning essentially that the Court has the

discretion to hear whichever cases it chooses by granting or denying certiorari.

The federal court system also includes special courts, such as tax courts for tax disputes, a customs court for issues involving imported goods, and a customs and patent appeals court that hears appeals from the customs court and from the patent and trademark office. A court of claims hears disputes lodged against the United States, although district courts also may have jurisdiction.

## The State Court System

Although each state has its own court system, there are many similarities among the states (**Figure 1-2**). Every state has one highest review court, usually called the state supreme court. Many of the more densely populated states, such as California, Florida, and New York, have intermediate appellate courts. Below the appellate courts, all states have trial courts with very broad jurisdiction; these may be called county courts, superior courts, district courts, or circuit courts, depending on the state. In addition, most states have limited jurisdiction trial courts such as probate courts, juvenile courts, and family courts. Below the trial courts are courts with very limited jurisdiction such as police courts, traffic courts, small claims courts, and justice of the peace courts. Disputes in these courts often involve relatively small amounts of money or minor statutory violations. No record of the proceedings is kept, and the individuals involved often represent themselves.



**Figure 1-2** Typical state judicial court system.

## Civil Court Procedures

Controversies are resolved in court through an adversarial process. Each attorney has the obligation to present the best legal arguments possible on behalf of a client while also attempting to refute the other party's arguments. The intent of the adversarial process is to bring out all possible legal arguments and rationale that are relevant to the issue so an impartial judge or jury may apply the best ones.

Every party in a court case must follow specific procedures as prescribed by statutes and court rules. The procedures differ somewhat, depending on:

- Whether the action commences in a federal court or a state court
- Whether the action is civil or criminal

Many of the procedures in the following hypothetical civil action are generally applicable to criminal actions as well:

Gail Bond has delivered a baby with birth defects. During the pregnancy, her physician prescribed a benzodiazepine drug for her. Sally Walker, a pharmacist and owner of Walker Pharmacy, dispensed the drug. Bond believes the drug caused her baby's birth defects and sues Walker Pharmacy for not warning her that this could happen.

### Selection of a Court

To start this lawsuit, Bond's attorney must first file the case in the proper court. An action can be filed in a court only if that court has jurisdiction over both the subject matter of the dispute and the parties involved. Occasionally, the jurisdiction issue is so complicated that the parties must spend considerable time and money to resolve it before the case can proceed. In this hypothetical case, there are no jurisdictional problems, and the case is filed in a state trial court. Filing in a federal court would not likely be an option because both Bond and Walker are citizens of the same state and there is no federal law in question.

### The Parties

The person who brings the lawsuit is called a "plaintiff." The person against whom the lawsuit is brought is called a "defendant." The plaintiff's name appears first in the name of the case. Thus, the title of the hypothetical case would be *Bond v. Walker Pharmacy*.

A party bringing a lawsuit must prove "standing"; that is, the plaintiff must show that the challenged conduct has caused the plaintiff injury and that the plaintiff's interest is a legally protectable interest. In *Bond v. Walker Pharmacy*, there would be no dispute that Bond has standing. If Bond did not wish to bring a lawsuit against the pharmacist but a friend of hers did—someone who believed that such a suit was necessary to establish the social policy that pharmacists must warn of these types of dangers—the friend would likely not have standing to bring the lawsuit because Walker's conduct did not harm the friend. Similarly, courts have often maintained that pharmacists do not have standing to sue a state on behalf of Medicaid patients who may be denied quality services because of state policy. The Medicaid patients must bring the lawsuit.

### Statute of Limitations

Bond cannot wait too long before filing a lawsuit against Walker. All states have "statutes of limitations" requiring that lawsuits be brought within a certain period of time after the injury. The period of time in which the suit must be brought usually depends on the nature of the lawsuit and the state in which the lawsuit is brought. In most states, the statute of limitations is 2 years for this type of case.

### The Complaint, Summons, and Answer

To initiate the lawsuit, the plaintiff, Bond (herself or through her attorney), would file a "complaint" that contains all of the material facts of her case and the remedy requested with the clerk of the court. The clerk of the court would then issue a document called a "summons," and the sheriff of the county or a deputy would likely serve the summons, together with a copy of the complaint, to the defendant. The summons would command Walker to file an "answer" to Bond's complaint within a specific period of time, usually about 30 days. Walker's answer may admit or deny any of Bond's allegations. If Walker fails to submit an answer within the required time period; however, the court would probably issue a "default judgment" in favor of Bond. A defendant must never ignore a summons and should notify his or her insurance company or an attorney the instant a complaint is received.

Often called the "pleadings" of the case, the complaint and answer serve two purposes:

1. They provide the defendant with the constitutional due process right of notice.
2. They constitute the basis on which the trial is built.

No facts or legal issues not stated in the pleadings may be admitted in court, unless the court allows amendments to the pleadings. Thus, the complaint and answer must be drafted very thoroughly and carefully.

### **Discovery**

Contrary to widespread public beliefs, surprise evidence and witnesses are unusual during a trial (civil or criminal). Nearly all courts allow the parties to use the pretrial process called “discovery.” Each party must give the other party all of the facts, evidence, and names of witnesses on which that party relies. Each lawyer generally questions the key witnesses who will testify for the opposing party. This questioning takes place in a “deposition,” a procedure in which the opposing party’s lawyer interrogates a witness in the presence of the other party’s lawyer outside of a courtroom. A court-approved stenographer records the deposition. There are three major purposes for a deposition:

1. It allows the attorneys to know in advance what the witnesses will say at trial.
2. If a witness cannot appear at trial, the deposition may be admitted to serve as the witness’s testimony.
3. The deposition can be used to impeach the credibility of a witness whose testimony on the witness stand deviates from that in the deposition.

If it is not practical or necessary to depose a witness, the lawyers may use an “interrogatory.” An interrogatory requires the witness to respond in writing under oath to written questions.

### **Pretrial Motions**

At the pleadings stage, either party may file various “motions” with the court. For example, Walker might file motions of objection against Bond’s complaint, pointing to errors in the complaint or in the procedure process or asserting that there are no legal grounds for a lawsuit. If the court grants the motions, either the case would be dismissed or the court would allow Bond to correct the errors.

### **Jury Selection and Role**

The parties must decide whether to have a jury trial or to allow the judge to decide the case. If they want a jury trial, the clerk of the court requires a number

of potential jurors to appear at the courthouse. The attorneys then question each potential juror through a process known as voir dire examination to determine if they want that person on the jury. Ultimately, they accept the required number of jurors, and the trial proceeds.

The jury’s role is to determine all questions of fact presented at the trial. In the hypothetical case, the jury would have to decide, for example, if Walker provided the warnings. The judge’s role is to determine the law involved in the case (e.g., does the pharmacist have a legal duty to warn patients of these types of drug dangers?) and to instruct the jury regarding what law to apply to the facts. If there is no jury, the judge both determines the facts and applies the proper law.

### **Witnesses**

As discussed earlier, the witnesses for both sides are generally identified and depositions taken before the trial. As an additional precaution to ensure a witness’s presence, either party’s attorney may choose to *subpoena* one or more witnesses. A subpoena is an order to appear in court at a specified time and place. Failure to appear in court can result in a contempt of court citation. Subpoenas serve valuable functions, even for a party’s own witnesses. If a subpoenaed witness cannot appear in court, the trial may be postponed. A subpoena may also ease the conscience of a witness who must testify against a friend or relative because an order to appear may reduce the witness’s sense of betraying the party.

When certain factual subject matter is beyond the scope of knowledge of jurors, “expert witnesses” are used to explain the technical facts to a jury and to render professional opinions. For example, in *Bond v. Walker Pharmacy*, pharmacists could be called expert witnesses to testify about pharmacists’ functions when they dispense prescriptions. The expert witnesses would be allowed to render opinions regarding whether a reasonable pharmacist has a duty to warn patients of a drug’s side effects, particularly its potential teratogenicity. The jury would then have to decide whether it agreed with the expert witness’s assessment of the case.

### **The Trial**

Before or during the trial, either side may ask the judge to decide the case without trying the facts. This is called a motion for “summary judgment.” One party attempts to convince the judge that the other party’s claim or defense has no merit,

even if all of the facts are correct. For example, in *Bond v. Walker Pharmacy*, Walker might make a motion for a summary judgment. By doing so, she concedes that the facts are not in dispute and she did not warn Bond but that it does not matter because she has no legal duty to do so, and thus there is no substance to Bond's claim.

Assuming summary judgment is denied before the trial, each party usually makes an opening statement at the trial. The plaintiff's attorney begins by highlighting the issues involved and the reasons that the jury should ultimately decide in the plaintiff's favor. The witnesses for the plaintiff are then sworn, examined (i.e., questioned under oath) by the plaintiff's attorney, and cross-examined by the defense attorney. After all the plaintiff's witnesses have testified and all the plaintiff's evidence has been introduced, the focus of the trial shifts to the defendant. At this point, the defendant's attorney may make a motion for a "directed verdict," on the basis that the plaintiff did not introduce sufficient evidence to justify the complaint. If granted, the defendant wins; if not, the defense then presents its witnesses and evidence. After the presentation of the defendant's case, the plaintiff may also make a motion for a directed verdict on the ground that a defense has not been established.

At any time during the trial, either side may voice "objections" to certain testimony or evidence. The judge must decide whether to overrule or to sustain each objection. Timely objections are crucial. A party that fails to object to evidence or testimony at the proper time cannot later issue an objection. A failure to object to evidence properly can be devastating to a party's case at the trial level because objections can sometimes block the introduction of damaging evidence. The failure to object can also be damaging on appeal because the appellate court cannot consider if the introduction of evidence was proper unless objections had been raised at trial.

In the absence of a directed verdict, each side provides its closing arguments and summation to the jury. The judge then instructs the jury about what law to apply to the determined facts. For example, assume the judge instructs the jury that the law states that a pharmacist only has a duty to warn patients of those adverse effects that are highly probable to occur. After being instructed, the jury would retire to another room and deliberate the probability of teratogenicity occurring with a benzodiazepine drug and if it is a risk of which a reasonable pharmacist would warn. Any

time before or during the trial and before the jury reaches its verdict, the parties can agree to settle the case. Settlements are common and encouraged by the court. Assuming a settlement is not reached, the jury would then return with the verdict.

### **The Verdict**

The jury's verdict may not end the controversy. If the jury has clearly reached the wrong verdict, the losing party may ask the judge to rule contrary to the jury, called a "judgment notwithstanding the verdict." Alternatively, if an egregious error was made during the trial (e.g., a juror talking to a witness outside of the courtroom and then influencing other jurors with information thus obtained), the losing party may ask for a "mistrial" and have the verdict thrown out. If the verdict is final, the disgruntled party may "appeal" the case to a higher court.

### **The Appeal**

In most cases, the dissatisfied party has a right to "appeal" the decision of the trial court. The party bringing the appeal is known as the "appellant," whereas the party defending the appeal is known as the "appellee." The appellant's name appears first. Thus, if Walker lost in the hypothetical *Bond v. Walker Pharmacy* at the trial level and appealed, the case would become *Walker Pharmacy v. Bond* at the appellate level. Notice of the intent to appeal must usually be filed within a 30-day period after the trial court's decision. The appeal documents usually include a transcript of the trial court proceedings for review by the appellate court judges.

To succeed on appeal, the appellant must convince the appellate court that the trial court committed an "error of law" that was material to the decision in the case. Generally, only questions of law are considered on appeal because the appellate court, which usually consists of three judges, does not second-guess the trial court on questions of fact. Every time a judge rules on an objection or instruction to the jury, this ruling creates a question of law on which a party may base an appeal. The appellant's attorney attempts to convince the appellate court of the trial court's legal errors and the significance of the errors by means of a written legal document called a "brief." The brief not only provides the reason for the appeal but also specifies the alleged errors of law committed by the trial court and cites the legal principles and cases that support the appellant's arguments. The appellee's attorney also files a brief with the court, refuting the appellant's claim and citing legal principles and



cases in the appellee's favor. If Walker lost at the trial level, her lawyer's brief might contend that the judge improperly allowed certain testimony by a witness or improperly instructed the jury as to the law in that jurisdiction; the attorney would cite previous cases in support of these contentions.

At the appellate hearing, the attorneys for each party present their oral arguments and answer questions from the judges. Presumably, the judges will have read the briefs and be quite familiar with the case. After hearing oral arguments, the court is likely to move on to hear other cases; it may not render a judgment for weeks or months.

Although attorneys can file various motions for rehearing, the judgment of an appellate court is usually final. However, the losing party has the option to file an appeal to the highest state court, if the appeal had been to an intermediate court. After the highest state court hears the appeal, there is likely to be no further review, unless one of the parties has raised a constitutional or federal law issue that may entitle the case to be reviewed by the U.S. Supreme Court.

## Criminal Court Procedures

Some important differences exist between criminal and civil court procedures. As is true of civil cases, criminal procedures vary somewhat, depending on the statutes and court rules in a particular jurisdiction. Nonetheless, some general observations can be made. A defendant can be charged with a crime in different ways but most often either by an "indictment" or by "arrest." An indictment is issued by a "grand jury," called such because it normally has more jurors than an ordinary trial jury. The grand jury hears evidence presented by the government to determine if a trial should be held. If enough evidence ("probable cause") exists, the grand jury will issue an indictment leading to an arrest and trial.

Alternatively, the government may arrest an individual for a crime directly. In this case, it must afford the defendant a preliminary hearing before a judge to determine if probable cause exists for the arrest. If probable cause exists, the defendant will face an arraignment, where, in front of a judge, the defendant will be given the right to enter a plea of guilty or not guilty. In most jurisdictions, the defendant also has the right to plead "nolo contendere" ("I do not wish to contend"). Although this is a guilty plea, it might not bind the defendant in other proceedings such as an administrative hearing or civil case.

Defendants in a criminal trial have considerable rights that the government must not violate, ranging from the right to not self-incriminate to the legality of the arrest. This provides the defendant with the opportunity to make various types of pre-trial motions to challenge nearly every aspect of the government's case. Also, the defendant may wish to negotiate a "plea bargain." In a plea bargain, the defendant agrees to plead guilty to a lesser offense instead of risking the results of a jury trial and being found guilty of a greater offense. Plea bargains benefit the government by saving considerable expense and resources.

The burden of proof in a criminal trial is much higher than in a civil trial. In a civil trial, the plaintiff must establish proof by a "preponderance of the evidence." In a criminal trial, the government must prove its case "beyond a reasonable doubt." Thus, evidence that would result in a victory for a plaintiff in a civil trial might not be enough evidence to convict a defendant in a criminal trial.

## Case Citation and Analysis

Trial court opinions at the state level are not usually reported (published). Most state and federal appellate opinions and many federal trial court opinions are reported, however. These are the opinions that courts use as precedents. When a case is reported, it is titled with the names of the parties involved and a citation to indicate which court decided the case and where its record can be found. For example, the case citation *United States v. Guardian Chemical Corporation*, 410 F.2d 157 (2nd Cir. 1969), means that this is a Court of Appeals for the Second Circuit decision issued in 1969 and can be found in volume 410 of the second Federal Reporter series, starting on page 157. All case citations containing F, F.2d, or F.3d are federal courts of appeal opinions. Any case citation containing F. Supp. is a federal district court opinion and any case citation containing U.S. or S. Ct. is a U.S. Supreme Court opinion. Citations containing the abbreviation of a state (e.g., 145 N.M. 322) or the abbreviation of a region of the country (e.g., 323 P.2d 445) are state court opinions. Regional reporter abbreviations include P. (Pacific), N.W. (Northwestern), N.E. (Northeastern), A. (Atlantic), S.E. (Southeastern), and So. (Southern).

Studying actual court cases is an excellent method of learning law, and is used by nearly all law schools and in many undergraduate and graduate programs. Any law librarian can help a person find published cases.



## Take-Away Points

- The federal court system consists of district courts, circuit courts of appeal, the U.S. Supreme Court, and specialty courts, and has jurisdiction over certain specified controversies.
- Every state has a highest review court and trial courts, and more populous states also have intermediate appellate courts.
- A plaintiff in a lawsuit must have “standing” in order to bring a case.
- Lawsuits must be filed within a specified period of time, called the “statute of limitations.”
- The pleadings of a case include the complaint and answer.
- The pretrial process of discovery allows each side to know the witnesses and evidence upon which each side will rely.
- The jury selection process is known as voir dire.
- Witnesses may be ordered to appear in court by means of a subpoena.
- At any time before or during a trial, either side may ask the judge for summary judgment, meaning that the other side’s claim or defense has no merit.
- At the conclusion of each side’s trial presentation, the other side may ask for a directed verdict, meaning the party has not produced enough evidence to prevail.
- Objections to evidence or testimony are critical to preserving questions of law on appeal.
- Only questions of law may be appealed.
- A defendant can be charged with a crime by means of either an indictment or an arrest.
- The burden of proof in a criminal trial (beyond a reasonable doubt) is much higher than that of a civil trial (preponderance of the evidence).
- Case citations enable a person to find a particular judicial opinion and to know which court issued the opinion.



## Study Scenarios and Questions

A patient, Molly, contends that Bill, a pharmacist for DrugEm Pharmacy, dispensed the wrong drug to her and that she suffered serious injury as a result. Bill denies this claim and believes that Molly somehow transferred the wrong drug to the container at her home. Molly plans to sue Bill and DrugEm Pharmacy jointly as codefendants.

- Is this a civil and/or criminal case and why?
- Can the patient sue in either federal or state court and why?
- How would Bill know he is being sued?
- Could Bill ask for a summary judgment at the beginning of the trial and, if so, would the judge grant it?
- Could Bill ask for a directed verdict at the beginning of the trial and, if so, would the judge grant it?

During the trial, Molly introduced a surprise witness who testified she saw the tablets in the vial when Bill dispensed them to Molly and that they were the wrong tablets that Molly contended she received.

- What process might prevent Molly from introducing this surprise witness and why might it prevent a surprise witness?
- Assume the jury concluded that Bill dispensed the wrong drug and found for Molly. Can Bill appeal and, if so, on what basis?

## Federal vs State Law

The practice of pharmacy and the distribution of drug products are subject to both federal and state regulation. As a general rule, a state has the authority to regulate in most areas that Congress has regulated, as long as there is no conflict between state and federal law. If a conflict exists, federal law always prevails over state law under the Supremacy Clause of the Constitution. This principle of federal law also is known as the “preemption doctrine.”

Most conflicts occur when state law is less strict than federal law and compliance with a state law

could lead to the violation of federal law. For example, federal law provides that a pharmacist can refill prescriptions for some controlled substances only 5 times within a 6-month period. If a state were to pass a law permitting 10 refills, the law would directly conflict with federal law and, if legally challenged, would be preempted. A pharmacist who complies with state law by dispensing a 6th refill during the 4th month would be in violation of federal law. On the other hand, if a state passed a law allowing no refills of the controlled substances that are refillable under federal law, this stricter law would not conflict with federal law. A pharmacist who complies with

state law by refusing all refills would not be in violation of federal law.

## Federal Authority to Regulate

The U.S. Congress and federal administrative agencies derive their authority to regulate drug distribution from the Interstate Commerce Clause of the Constitution. The courts have liberally interpreted this clause on several occasions to give Congress considerable power to regulate commerce among the states. Technically, the federal government regulates drug distribution through the Interstate Commerce Clause and reserves for the states the authority to regulate the practice of pharmacy. In actuality, however, regulation of drug distribution often results in professional regulation as well.

The reach of the federal government's authority under the Interstate Commerce Clause was put to the test in a landmark Supreme Court case, *United States v. Sullivan*, 332 U.S. 689 (1948). In *Sullivan*, a community pharmacist contended that the federal FDCA did not apply to transactions between his pharmacy and his customers because these were entirely intrastate transactions. The facts of the case showed that a pharmaceutical manufacturer in Chicago, Illinois, shipped properly labeled bottles of sulfathiazole tablets to an Atlanta, Georgia, wholesaler. The label stated that the drug was to be sold by prescription only. Sullivan, a pharmacist in

Columbus, Georgia, purchased the drug from the wholesaler and proceeded to sell the drug without prescription and without the labeling required under the FDCA. Finding against the pharmacist, the Court held that the Act extends to even these intrastate transactions because its intent is to protect the public and that intent would be subverted by a narrow definition of interstate commerce.

## State Authority to Regulate

State government receives the authority to regulate pharmacy practice and the distribution of drugs through the Tenth Amendment of the Constitution, which, as noted earlier, gives the states all powers not delegated to the federal government or prohibited by the Constitution. States also have the authority to regulate drugs and the professions through the common law concept of "police powers," which allow the state to enact laws promoting the health, safety, and welfare of its people. State laws are considered valid as long as they do not conflict with the U.S. Constitution or federal laws, and as long as they bear a reasonable relationship to the protection of the public health, safety, and welfare. For example, if a state passed a law that all over-the-counter drugs must be sold only in licensed pharmacies, opponents could challenge this law on the ground that the law does not bear a reasonable relationship to the protection of the public health, safety, and welfare.



### Take-Away Points

- The practice of pharmacy and distribution of drug products are subject to both state and federal law.
- Federal authority to regulate drug distribution comes primarily from the Interstate Commerce Clause.
- State authority to regulate pharmacy practice and drug distribution comes primarily from the Tenth Amendment and the inherent authority of a state's police powers.
- State laws that conflict with federal law are preempted.



### Study Scenarios and Questions

1. Makeit Laboratories in New Jersey shipped one of its prescription drugs to a wholesaler in Sacramento, California, which sold it to a pharmacy in Stockton, California. The pharmacy in Stockton sold it to a Stockton patient without a prescription. The FDA charged the pharmacy with violating federal law pursuant to the FDCA. The defendant pharmacy argued that the FDCA does not apply to this situation.
  - On what basis would the defendant make this argument?
  - What would the court likely decide and why?
  - Does the FDA have jurisdiction to charge the pharmacy or is this a state law issue?
2. A state passed a law that a pharmacist could refill a schedule II prescription two times when the patient requires continual use of the medication. Federal law states that a schedule II prescription may not be refilled. If you were a pharmacist in that state, which law would you follow and why?

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## Case Studies

### Case 1-1 *People v. Stuart*, 302 P.2d 5 (Cal. 1956)

#### Issue

Whether a pharmacist should be held criminally liable for having inadvertently made a mistake in dispensing a medication to a patient.

#### Overview

In criminal law, the state takes action against an individual who has committed an act so unacceptable that all of society is offended by it. Theft and assault are examples of crimes that harm all of society, not just their immediate victims. Reprehensible crimes such as these threaten to degrade the moral fiber of an entire society. Reaction to them is not left only to their immediate victims but also society collectively reacts to crime because everyone is harmed by it.

After a crime has been committed, a prosecutor representing either a locality, the state, or the entire country files charges against the perpetrator. If found guilty, a convicted criminal will usually serve time in jail. Criminal law isolates a criminal who might otherwise continue to act unacceptably and harm others. It deters unacceptable conduct by others who prefer not to face the same consequences as the criminal who has been made an example. Criminal law also provides vengeance for a society that feels the need to strike back at a person who has broken well-established rules of conduct.

In the case presented here, a pharmacist has been charged with both manslaughter (a relatively serious crime) and misbranding (a relatively minor crime). As you read this case, ask yourself what the purpose of criminal law is and if that purpose is being met by this prosecution. Also, ask yourself what the consequences might be if pharmacists were to be held criminally liable for an error in order processing. If any pharmacist who makes a mistake in filling a prescription is a criminal, how many pharmacists are criminals at some point during their decades-long careers?

The court opinion began by describing the facts of the case:

Defendant was charged by information with manslaughter (Pen. Code, § 192) and the violation of section 380 of the Penal Code. He was convicted of both offenses by the court sitting without a jury. His motions for a new trial and for dismissal (Pen. Code, § 1385) were denied, sentence was suspended, and he was placed on probation for 2 years. He appeals from the judgment of conviction and the order denying his motion for a new trial.

Defendant was licensed as a pharmacist by this state in 1946 and has practiced here since that time. He holds a BS degree in chemistry from Long Island University and a BS degree in pharmacy from Columbia University. In April 1954, he was employed as a pharmacist by the Ethical Drug Company in Los Angeles.

On July 16, 1954, he filled a prescription for Irvin Sills. It had been written by Dr. D. M. Goldstein for Sills' 8-day-old child. It called for "sodium phenobarbital, grains eight. Sodium citrate, drams three. Simple Syrup, ounces two. Aqua peppermint, ounces one. Aqua distillate QS, ounces four." Defendant assembled the necessary drugs to fill the prescription. He knew that the simple syrup called for was unavailable and therefore used syrup of orange. The ingredients were incompatible, and the syrup of orange precipitated out the phenobarbital. Defendant then telephoned Dr. Goldstein to ask if he could use some other flavoring. Dr. Goldstein told him that since it was midnight, if he could not find any simple syrup "it would be just as well to use another substance, elixir Mesopin, P.B." Defendant spoke to a clerk and learned that there was simple syrup behind the counter. He mixed the prescription with this syrup, put a label on the bottle according to the prescription, and gave it to Sills. Sills went home, put a teaspoonful of the prescription in the baby's milk and gave it to the baby. The baby died a few hours later.

Defendant stipulated [admitted] that there was nitrite in the prescription bottle and that "the cause of death was methemoglobinemia caused by the ingestion of nitrite." When he compounded the prescription, there was a bottle containing sodium nitrite on the shelf near a bottle labeled sodium citrate. He testified that at no time during his employment at the Ethical Drug Company had he filled any prescription calling for sodium nitrite and that he had taken the prescribed three drams of sodium citrate from the bottle so labeled.



On August 11, 1954, another pharmacist employed by the Ethical Drug Company filled a prescription identical with the Sills' prescription. He obtained the sodium citrate from the bottle used by defendant. The prescription was given to an infant. The infant became ill but recovered. In the opinion of Dr. Goldstein, it was suffering from methemoglobinemia. An analysis of this prescription by a University of Southern California chemist disclosed that it contained 5.4 grams of sodium nitrite per 100 cc's and 4.5 grams of sodium citrate per 100 cc's.

An analysis made by the staff of the head toxicologist for the Los Angeles County coroner of contents of the bottle given to Sills disclosed that it contained 1.33 grams of sodium citrate and 1.23 of sodium nitrite. An analysis made by Biochemical Procedures, Incorporated, a laboratory, of a sample of the contents of the bottle labeled sodium citrate disclosed that it contained 38.9 milligrams of nitrite per gram of material. Charles Covet, one of the owners of the Ethical Drug Company, testified that on the 17th or 18th of October 1954, he emptied the contents of sodium citrate bottle, washed the bottle but not its cap, and put in new sodium citrate. A subsequent analysis of rinsings from the cap gave strong positive tests for nitrite. Covet also testified that when he purchased an interest in the company in April 1950, the bottle labeled sodium citrate was part of the inventory, that no one had put additional sodium citrate into the bottle from that time until he refilled it after the death of the Sills child; he had never seen any other supply of sodium citrate in the store.

There was testimony that at first glance sodium citrate and sodium nitrite are identical in appearance, that in form either may consist of small colorless crystals or white crystalline powder, that the granulation of the crystals may vary with the manufacturer, and that there may be a slight difference in color between the two. The substance from the bottle labeled sodium citrate was exhibited to the court, but no attempt was made to compare it with unadulterated sodium citrate or sodium nitrite. A chemist with Biochemical Procedures, Incorporated, testified that the mixture did not appear to be homogeneous but that from visual observation alone he could not identify the crystals as one substance or the other. Defendant testified that he had no occasion before July 16th to examine or fill any prescription from the sodium citrate bottle.

No evidence whatever was introduced that would justify an inference that defendant knew or should have known that the bottle labeled sodium citrate contained sodium nitrite. On the contrary, the undisputed evidence shows conclusively that defendant was morally entirely innocent and that only because of a reasonable mistake or unavoidable accident was the prescription filled with a substance containing sodium nitrite.

The court then reviewed the necessary elements of criminal misconduct, noting particularly that "intent" is a necessary element of virtually any crime. In other words, one cannot usually be held criminally liable for that which one unintentionally did.

Section 20 of the Penal Code makes the union act and intent or criminal negligence an invariable element of every crime unless it is excluded expressly or by necessary implication. Moreover, section 26 of the Penal Code lists among the persons incapable of committing crimes "[persons] who committed the act or made the omission charged under an ignorance or mistake of fact, which disproves any criminal intent" and "[persons] who committed the act or made the omission charged through misfortune or by accident, when it appears that there was no evil design, intention, or culpable negligence." The question is thus presented if a person can be convicted of manslaughter or a violation of section 380 of the Penal Code in the absence of any evidence of criminal intent or criminal negligence.

The answer to this question as it relates to the conviction of manslaughter depends on if the defendant committed an "unlawful act" within the meaning of section 192 of the Penal Code when he filled the prescription. The attorney general contends that even if he had no criminal intent and was not criminally negligent, the defendant violated section 26280 of the Health and Safety Code, and therefore committed an unlawful act within the meaning of section 192 of the Penal Code.

The court described the elements of the crime of manslaughter, noting that there are two types of conduct that may lead to conviction of this crime; one type is voluntary, based on killing in the "heat of passion," and the other type is involuntary, based on killing during the commission of an unlawful act.

Manslaughter is the unlawful killing of a human being, without malice. It is of two kinds:

1. Voluntary—upon a sudden quarrel or heat of passion.
2. Involuntary—in the commission of an unlawful act, not amounting to felony; or in the commission of a lawful act that might produce death, in an unlawful manner, or without due caution and circumspection; provided that this subdivision shall not apply to acts committed in the driving of a vehicle. . . .

The court considered if the misbranding violation by the defendant pharmacist was an unlawful act sufficient to form the basis of an involuntary manslaughter charge.

Section 26280 of the Health and Safety Code provides "The manufacture, production, preparation, compounding, packing, selling, offering for sale, advertising or keeping for sale within the State of California of any drug or device which is adulterated or misbranded is prohibited." In view of the analysis of the contents of the prescription bottle and the bottle labeled sodium citrate and defendant's stipulation, there can be no doubt that he prepared, compounded, and sold an adulterated and misbranded drug.

Because of the great danger to the public health and safety that the preparation, compounding, or sale of adulterated or misbranded drugs entails, the public interest in demanding that those who prepare, compound, or sell drugs make certain that they are not adulterated or misbranded, and the belief that although an occasional nonculpable offender

may be punished, it is necessary to incur that risk by imposing strict liability to prevent the escape of great numbers of culpable offenders, public welfare statutes like section 26280 are not ordinarily governed by section 20 of the Penal Code, and therefore call for the sanctions imposed even though the prohibited acts were committed without criminal intent or criminal negligence.

So-called “strict liability” or liability without fault may apply to some activities of pharmacists and lead to minor criminal liability for acts such as misbranding because this is the best way to protect the public health. However, misbranding violations do not fit within the realm of unlawful acts that may form the basis of an involuntary manslaughter charge.

It does not follow, however, that such acts, committed without criminal intent or criminal negligence, are unlawful acts within the meaning of section 192 of the Penal Code, for it is that this section is governed by section 20 of the Penal Code.

It follows, therefore, that only if defendant had intentionally or through criminal negligence prepared, compounded, or sold an adulterated or misbranded drug would his violation of section 26280 of the Health and Safety Code be an unlawful act within the meaning of section 192 of the Penal Code. When, as in this case, the defendant did not know, and could not reasonably be expected to know, that the sodium citrate bottle contained nitrite, those conditions are not met, and there is therefore lacking the culpability necessary to make the act an unlawful act within the meaning of section 192.

The judgment and order are reversed.

### **Notes on *People v. Stuart***

1. Criminal prosecutions of healthcare providers based on harm caused by inadvertent errors have been rare in American law. This is, of course, contrasted with prosecutions for flagrant disregard of professional responsibilities, such as the sale of prescription narcotic medications without a prescription. Controlled substance diversion is frequently prosecuted as a criminal violation, and pharmacists should be aware that they cannot expect to commit such illegal acts and be free of legal consequences. The difference between these two types of conduct, of course, is that although one is volitional, the other is not. As the *People v. Stuart* case suggests, there is no point in punishing people for things they nonvolitionally do because only volitional conduct can be controlled. To criminally punish a pharmacist for merely making a mistake would be to criminalize the human condition of fallibility. All pharmacists would be criminals because all pharmacists make mistakes. As this case illustrates, such a result would be absurd and it is not the law. Nonetheless, in 2007, an Ohio hospital pharmacist was indicted for involuntary manslaughter for failing to check an IV erroneously compounded by a technician that caused the death of a 2-year-old girl. The pharmacist ultimately pleaded no contest in 2009 and was sentenced to 6 months in jail, 6 months of house arrest, 3 years' probation, a \$5,000 fine, and 400 hours of community service. The technician was not charged.
2. The effect of criminal liability for honest error would probably be to cause pharmacists to be extremely cautious and risk averse in their practice. Those prescriptions or medication orders that presented a potential risk to the patient might be avoided by pharmacists, simply because the possibility of criminal liability would exist if an error were to occur; better to play it safe when prison or a stiff fine is a possibility. Caution of this kind could prevent patients from receiving necessary medications under extreme circumstances of need simply because their prescribed medication posed a risk of harm (that, to them, was acceptable but to the pharmacist might seem unreasonable). The threat of criminal liability might cause pharmacists to focus their attention on risks to themselves rather than on risks to patients. The threat might also chill pharmacists from documenting errors, a critical component to any pharmacy continuous quality improvement program.
3. In this case, the court ruled that intent is a necessary element of a serious criminal violation such as manslaughter; however, intent is hard to see in a person. It exists primarily in the mind of an individual and only, perhaps, for a fleeting period of time. One may intend to do harm to another, but that intent will never be known to anyone unless some act accompanies it. Thus, the law usually requires for criminal liability that there be both intent to do harm and some act in furtherance of that intent. Fortunately, we are not criminals simply for thinking occasional bad thoughts about harm to others. As the court notes, there are some minor crimes (such as the misbranding and adulteration in this case) that are so-called strict liability or no-fault crimes. These crimes require no proof of intent because there is a strong social purpose in deterring them, and it would be virtually impossible to prove them if proof of intent were required.

## Case 1-2 *Cohen v. Missouri Board of Pharmacy*, 967 S.W.2d 243 (Mo. App. 1998)

### Issue

Whether the Missouri Board of Pharmacy exceeded the scope of its statutory authority by imposing a penalty against a pharmacist.

### Overview

This case explored the limits of the authority of a state board of pharmacy to discipline a pharmacist for obviously inappropriate conduct. There was no question that the pharmacist described in this case violated the law, but the board of pharmacy did not follow the rules it was given by the legislature. Boards of pharmacy are created by the legislature, and they are limited by the authority the legislature gives them. In most states, a pharmacy act describes how the board of pharmacy will function and the limits of what it can do. Simply because a pharmacist has committed a violation of the law does not mean the board of pharmacy can do anything it pleases to discipline the pharmacist. In most states, specific penalties are prescribed for specific violations. The board of pharmacy may punish pharmacists only in the ways it is authorized to do so under the enabling legislation.

As you read this case excerpt, ask yourself if the board of pharmacy should be given wider latitude in determining the disciplinary actions it may use for a pharmacist who has violated the law. Are the rules so difficult to understand that pharmacies will inevitably violate them, or are they possible to understand and easy to apply? To what extent should "legal technicalities" be permitted to stand in the way of disciplinary action that is clearly warranted?

The court opinion began by describing the facts of the case:

Sylvan H. Cohen has been a registered pharmacist in Missouri since 1965. In August of 1976, he was convicted in the United States District Court, on a plea of guilty, of one felony count of "devising and intending to devise a scheme to defraud and obtain money and property by false pretenses" from Venture Stores, Inc. As a result, on July 24, 1978, his pharmacist license was suspended for 1 year by the Missouri Board of Pharmacy (the "Board"). Although the record does not reflect the date, the Board at some point filed another complaint against the appellant based upon a charge related to his addiction to Demerol. On April 18, 1988, based upon this complaint and pursuant to a "Joint Stipulation of Facts, Waiver of Hearings Before the Administrative Hearing Commission and the State Board of Pharmacy, and Consent Order," the Board suspended the appellant's license for 1 year, to be followed by 5 years of probation.

On April 27, 1993, while on probation, an inspection of the appellant's pharmacy by the Bureau of Narcotics and Dangerous Drugs revealed 24 dispensing infractions in violation of CSR 220-2.110(1). On April 20, 1994, the appellant's 5-year probation expired. On June 28, 1994, the Board filed a "Complaint in Violation of Disciplinary Order," which alleged that 24 dispensing infractions violated the terms of the appellant's probation. On August 5, 1994, the Board conducted a "Violation of Disciplinary Order Hearing" to determine whether discipline should be imposed based upon these violations of probation. On September 20, 1994, the Board issued its "Findings of Fact, Conclusions of Law and Disciplinary Order," which provided that the appellant's probation was to be "extended" for 1 year beginning on October 20, 1994.

In August of 1995, while on probation, the appellant suffered a relapse of his chemical dependency. As a result, on October 18, 1995, the Board filed a "Complaint in Violation of Disciplinary Order," alleging that appellant violated the terms of his probation imposed by the Board's 1994 disciplinary order and was subject to further discipline. The complaint reflected that a staff pharmacist reported that the appellant had diverted approximately 400 hydrocodone/acetaminophen tablets from the pharmacy. After this violation was reported, the appellant self-reported that he had suffered a relapse of his chemical dependency. The complaint also reflected that, after being confronted by an employee concerning missing drugs, the appellant wrestled with the employee, and that, at the time, he possessed two concealed weapons. As to this complaint, on January 30, 1996, the appellant and the Board entered into a "Joint Stipulation of Facts, Waiver of Hearings Before the Administrative Hearing Commission and the State of Pharmacy, and Consent Order," wherein appellant stipulated that all of the facts alleged in the October 18, 1995, complaint were true.

On February 1, 1996, the Board held a hearing on the violations of the appellant's probation as alleged in the Board's October 18, 1995, complaint to determine whether his probation should be revoked, and what discipline, if any, should be imposed. At the hearing, the appellant again admitted to the allegations in the complaint and explained his illness and progress to the Board. On February 22, 1996, the Board issued its "Findings of Fact, and Conclusions of Law and Disciplinary Order," revoking the appellant's license for a violation of his probation imposed by the Board's 1994 disciplinary order.

It is undisputed that the February 22, 1996, order, revoking the appellant's pharmacist license based upon alleged violations by the appellant of the September 20, 1994, probation order, extended his original 1988 5-year probation for another year. The alleged violations of the 1994 probation order, professional misconduct and inaccurate controlled substance recordkeeping, were set forth in the Board's "Complaint in Violation of Disciplinary Order."

The court then described the contention by the pharmacist that he was being disciplined in a way the pharmacy act did not permit. Specifically, his license was being revoked because he had violated conditions of a probation that was longer than the statute permitted the board of pharmacy to extend a probationary period.

The appellant claims that the Board lacked the authority to revoke his license for a violation of the 1994 probation order because the order was void. Because we agree with the appellant that, if the probation order was void, the 1996 order revoking the appellant's license based on a violation and revocation of the same would be void as well, then the issue we must decide is whether the Board had the authority to enter its 1994 probation order.

The appellant's claim that the Board's September 20, 1994, probation order was void is premised upon his assertion that the Board's authority to enter the order was based on a violation and revocation of the appellant's 5-year probation ordered in the Board's April 20, 1988, disciplinary order, and that its authority to enter the 1994 probation order for a violation of the 5-year probation had expired on April 20, 1994, prior to the entry of the 1994 order. The record reflects that the 1988 disciplinary order imposed a 1-year suspension of the appellant's license to be followed by a 5-year probation, the maximum allowed. As such, the appellant's 5-year probation would have expired on April 20, 1994. Thus, the appellant contends that because his 5-year probation had already expired at the time of his revocation and entry of the September 20, 1994, probation order, the Board lacked authority to enter a disciplinary order based on a violation and revocation of his 5-year probation, rendering the 1994 order void.

Based upon the 1988 complaint, the appellant entered into a "Joint Stipulation of Facts, Waiver of Hearings Before the Administrative Hearing Commission and the State Board of Pharmacy, and Consent Order." As a result, on April 20, 1988, pursuant to § 338.050.3, the Board suspended the appellant's license for 1 year, which was to be followed by a 5-year probation. Unlike the 1988 disciplinary order, which was entered in accordance with § 338.055 authority and procedures, the 1994 probation order and the 1996 order revoking the appellant's license were entered based upon violations and revocations of the 1988 and 1994 probation orders, respectively, which resulted from the original 1988 complaint. Thus, the issue becomes whether the Board had the authority to enter its 1994 and 1996 disciplinary orders based upon violations of the 1988 and 1994 probation orders, which sprang from the original 1988 complaint.

In assessing the persuasiveness of the pharmacist's argument, the court noted the well-recognized principle that administrative agencies may exercise only the powers given them in their enabling statutes. The court then applied that fundamental concept to the facts of the case.

A key principle of administrative law "is that administrative agencies—legislative creations—possess only those powers expressly conferred or necessarily implied by statute." In this regard, the authority which allows the Board to take disciplinary action against a pharmacist licensed in Missouri and the procedures by which such must be done are contained in § 338.055. As such, it is clear that for each complaint filed pursuant to § 338.055, on which the administrative hearing commission (AHC) finds that the grounds for disciplinary action are met, the Board has the authority to: (1) censure the person named in the complaint; (2) impose up to 5 years probation on him or her; (3) suspend his or her license for up to 3 years; or (4) revoke his or her license. In this regard, the 1988 order, which was entered as a result of a § 338.055 complaint, imposed the maximum 5-year term of probation. Although § 338.055.3 expressly authorizes the Board to impose up to 5 years of probation for a substantiated complaint filed pursuant to § 338.055.2, it does not expressly authorize it to discipline a licensee based upon an alleged violation of such probation. In the absence of express statutory authority to discipline a licensee based upon an alleged violation of such probation, the issue is whether the Board has the inherent authority to do so.

Logically, the Board would be limited to those dispositions provided for in § 338.055.3, which would include extending the term of the probation which was violated. However, even assuming the Board has the authority in the case of a probation revocation to impose discipline on a licensee pursuant to § 338.055, including extending the term of probation, the question arises as to whether the Board could extend a term of probation beyond the maximum term of 5 years provided for in § 338.055.3. The answer to this question is significant to the case at bar because, if we assume the Board did not have the authority to extend the appellant's probation beyond the 5-year term originally ordered in the 1988 disciplinary order, the 1994 probation order extending the appellant's probation for another year would be void, which, as discussed, would render the 1996 order revoking the appellant's license, based upon a violation of the 1994 probation order, void as well. Thus, we must decide whether the Board had the authority in 1994 to extend by 1 year the appellant's 5-year probation ordered in 1988, which had expired prior to the entry of the 1994 probation order, for an alleged violation of that probation.

Because the Board was prohibited by § 338.055.3 from extending the appellant's probation beyond the original 5 years, we find it had no authority to enter its 1994 order extending the appellant's probation for one more year. Thus, the 1994 order was void.

Having decided that the board of pharmacy was without authority to extend the probation beyond the 5 years authorized by the statute and having decided also that the license revocation was void for having been based on the violation of an unauthorized probation, the court then took care to describe the narrowness of its ruling.

In holding as we do, we do not decide whether the Board, after revoking the appellant's probation, could have ordered him censured, or his license suspended or revoked as provided in § 338.055.3, rather than extending his probation beyond the maximum term of 5 years. We also do not decide whether the Board could have sought to discipline the appellant pursuant to a new § 338.055 complaint based on the alleged violations of probation, rather than revoking and extending



his probation. We only decide that in revoking the appellant's 5-year probation ordered pursuant to § 338.055, the Board was prohibited by § 338.055.3 from extending his probation for another year.

The judgment of the circuit court affirming the order of the Missouri Board of Pharmacy revoking the appellant's pharmacist license is reversed, and the cause is remanded to the circuit court for it to order the Board to reinstate the appellant's pharmacist license in accordance with this opinion.

### **Notes on *Cohen v. Missouri Board of Pharmacy***

1. All citizens have a right to know what the rules are before they engage in activity that may expose them to government punishment. It is not fair; thus it is a denial of due process for a governmental agency to "make up the rules as it goes." In this case, it is a stretch to suggest that the pharmacist was unfairly treated by the board of pharmacy because he obviously knew he was violating the law and that punishment was a very real possibility. However, the protections of the law extend to those who deserve them as well as to those who do not. The obvious culpability of this pharmacist was irrelevant to the core issue in the case; the board of pharmacy had exceeded the scope of its statutory authority.
2. At first blush, it may appear that this pharmacist was let off on a trivial technicality. Although he may have been the beneficiary of a technicality, it is important to note that the law is full of similar technicalities, all of them designed to protect citizens from arbitrary government action. Society's interest in removing incompetent pharmacists from practice is a compelling reason to "let it slide," if a board of pharmacy fails to adhere to the letter of the law. However, even more compelling is the interest in protecting citizens from arbitrary government action. The state board of pharmacy may discipline pharmacists only because it is authorized to do so by the legislature through its enabling legislation, and in this case, that authority was clearly exceeded.
3. It is interesting to note that the court provided a not-too-subtle primer on appropriate administrative enforcement for the board of pharmacy. Just to make sure there were no misunderstandings of the meaning of this legal opinion, the court specified that it would have been fully acceptable for the board of pharmacy to have used one of the other enforcement mechanisms available to it under the statute. Boards of pharmacy have undoubtedly heeded this advice.

### **Case 1-3 *Malan v. Huesemann*, 942 S.W.2d 424 (Mo. App. 1997)**

#### **Issue**

Whether a pharmacist's admission of errors in a state board of pharmacy administrative action may be admitted into evidence in a subsequent malpractice case to show a propensity of the pharmacist to commit errors.

#### **Overview**

This case is a lawsuit within a lawsuit. The primary case was a malpractice lawsuit brought by a patient against a pharmacist who had allegedly dispensed to her an incorrect medication. The judge in that lawsuit ruled that evidence from a previous board of pharmacy disciplinary action could be used in the malpractice case. The pharmacist then filed an action against the judge who issued that ruling, seeking to have the ruling set aside by the appellate court on review.

As you read this case, reflect on the differing purposes of administrative actions brought by the board of pharmacy against a licensee and of malpractice cases brought by patients against their pharmacist. In the former, the purpose is to protect the public in the future, whereas in the latter, the purpose is to award compensation for a problem of the past. Might admissions made in one type of action be inappropriate for consideration in the other type of action on the basis of the difference in character of the two proceedings? On the other hand, why should a person who has made an admission in one legal proceeding not be forced to live with that admission in another, albeit different, proceeding? How might practical matters such as the availability of funding to support litigation, the relatively slight punishment one expects, and the confidentiality of a disciplinary action influence pharmacists to admit to charges that they would prefer to contest?

The court opinion began by describing the facts of the case:

Mary Malan is a registered pharmacist, practicing in Clinton, Missouri. In September 1990, the Missouri Board of Pharmacy seized Ms. Malan's bulk chemicals because it believed that her process of compounding drugs from them was illegal. On October 19, 1990, the Board also informed Ms. Malan that it was not renewing her pharmacy permit. Ms. Malan petitioned the Administrative Hearing Commission (AHC) for relief. The AHC subsequently ordered the Board to reinstate Ms. Malan's permit.

On February 4, 1991, the Board filed a 16-count Expedited Complaint against Ms. Malan with the AHC, alleging that she had compounded drugs from bulk chemicals and had made dispensing errors or illegal substitutions that endangered

the health of her customers. The Board requested an expedited hearing and asked the AHC to immediately suspend Ms. Malan's license until a full hearing could be held to determine whether cause existed to discipline her.

The AHC held a hearing on March 20, 1991. In its order, the AHC denied the Board's request to suspend Ms. Malan's license and dismissed the Board's complaint. It found that most of Ms. Malan's compounding was not illegal, and in those instances that may have been illegal there was no clear and present danger to public health or safety because Ms. Malan testified that she had stopped this compounding. The AHC also noted that the Board's seizure of her bulk chemicals was done without authority and the Board's 5-month delay between the seizure and filing the complaint indicated there was not a present danger.

Regarding the alleged dispensing errors, the AHC found that Ms. Malan had a low error rating and the instances were mere mistakes. Although there was evidence of one serious incident, the AHC did not believe this warranted suspension of her license. The AHC did state, however, that it would have been willing to restrict her from dispensing anything other than acceptable commercial products if the Board had requested this relief.

Thereafter, the Board refiled its complaint with the AHC, seeking a full hearing. Before a hearing was held, however, the parties settled the dispute by entering into a "Joint Stipulation of Facts, Waiver of Hearings Before the Administrative Hearing Commission and State Board of Pharmacy, and Consent Order with Joint Proposed Findings of Fact and Conclusions of Law" on October 10, 1991. Ms. Malan suggests in this Court that she entered into the settlement because defense of the Board's prior unsuccessful actions against her had taken all of her funds. In any event, the Joint Stipulation stated in numerous places it was solely for the purposes of settlement that Ms. Malan did not contest the Board's allegations. The Joint Proposed Findings of Fact similarly recited that, on specified occasions, Ms. Malan agreed, again for settlement purposes only, that she had filled prescriptions by compounding bulk chemicals and had substituted drugs other than those prescribed.

Pursuant to the terms of the settlement, Ms. Malan's pharmacist's license and pharmacy permit were placed on probation for 5 years beginning on November 6, 1991.

On May 12, 1995, the Pharmacy Board issued a Complaint of Violation of Disciplinary Order against Ms. Malan alleging she had incorrectly filled prescriptions and made improper substitutions. This second Board complaint was not filed with the AHC, however. Instead, on August 4, 1995, Ms. Malan and the Board again entered into a settlement in the form of a Joint Stipulation extending Ms. Malan's probation. The Findings of Fact in this Joint Stipulation stated that Ms. Malan agreed, again solely for the purposes of settlement and not as an admission of liability, that she incorrectly filled prescriptions and substituted drugs for a person designated as "Patient I." The Joint Stipulation also recounted incidents involving other patients.

The Executive Director of the Board executed a Consent Order, purporting to find that the facts the Board had itself alleged, and which were stipulated to by Ms. Malan for purposes of settlement only, were true and that Ms. Malan was subject to discipline. No hearing was held on this order and neither it nor the Joint Stipulation on which it was based were ever filed with the AHC. The AHC issued no order at all in regard to the 1995 complaint.

After this lengthy description of the protracted problems between the pharmacist and the board of pharmacy, the court then described the lawsuit that served as the basis of the action brought by the patient against the pharmacist.

Also on May 12, 1995, Lois Ruth Kalberloh, the person identified as "Patient I" in the 1995 Joint Stipulation, filed a Petition against Ms. Malan alleging pharmaceutical malpractice. Ms. Kalberloh alleged that Ms. Malan filled Ms. Kalberloh's prescription for Eldepryl with the drug Prednisone. In her amended Petition, Ms. Kalberloh made a claim for punitive damages, alleging that Ms. Malan had repeatedly demonstrated willful, wanton, and malicious conduct in her practice as a pharmacist. As support, Ms. Kalberloh included as exhibits copies of the 1991 and 1995 Joint Stipulations between Ms. Malan and the Board. She sought to read portions of these stipulations to the jury.

Punitive damages are awarded when a defendant is determined to have acted with willful disregard of the interests of the plaintiff. The only way in which the plaintiff in this case could claim willful disregard would be if there was a pattern of pharmacy errors and if this pattern showed willful, wanton, and malicious conduct toward the public. To show such a pattern, the plaintiff sought to introduce evidence of the pharmacist's admissions of other errors made within the administrative action.

Judge Raymond T. Huesemann ruled that portions of the settlement agreements dealing with misfilling of other prescriptions were admissible and could be read to the jury, and that the fact they are settlements went only to their weight, not to their admissibility.

We hold that the court below erred in ruling that Ms. Kalberloh could read or introduce portions of the joint stipulations during the trial of her suit against Ms. Malan. Each explicitly states that it is being entered into solely for the purposes of settling the dispute, and not as any admission of liability by Ms. Malan. Each forms a part of a settlement between Ms. Malan and the Board of Pharmacy. As such, it is not admissible in evidence nor may the jury be informed about the fact of the prior settlements.

The court reviewed the policy of courts toward settlements generally, noting that out-of-court settlements are favored under the law because there is no purpose in using judicial resources when no real controversy exists. Courts are usually quite happy to let parties iron out their own disagreements, without resort to litigation.

In order to further the public policy favoring the settlement of disputes, it is well established that settlement offers are not admissible in a subsequent trial. This is because settlement negotiations "should be encouraged and a party making an offer of settlement should not be penalized by revealing the offer to the jury if the negotiations fail to materialize."

The danger of admitting evidence of settlements is that the trier of fact may believe that the fact that a settlement was attempted is some indication of the merits of the case. As a result, "if offers of settlement were admitted in evidence, they would have the natural tendency with the jury to denigrate the position at trial. No one would make offers if the risk of their being before the jury were a necessary corollary of the offer."

The desire to encourage settlements is fully applicable to settlement of administrative actions. This policy rationale supporting exclusion of evidence of settlements fully applies here. Ms. Malan had twice successfully defended against actions taken by the Board. The third action involved similar issues, and she nowhere admitted that her conduct had been improper. For practical reasons, however, she claims, she desired to settle, as did the Board. In any event, the settlements stated repeatedly that the facts stated therein were admitted solely for purposes of settlement. To now admit the stipulations contained in the settlement in this civil action would clearly be contrary to the intent of the settling parties, and would discourage further settlements in future cases, in derogation of the policy favoring settlements. For these reasons, no evidence of the settlement agreements may be admitted below.

### **Notes on *Malan v. Huesemann***

1. The court in this case was quite clearly considering the public policy implications of its actions. Although every case has as its main purpose the settlement of a dispute between two or more parties, the ruling of any case has the potential to set precedent that will extend beyond the confines of the parties to the case. The court recognized that if it had ruled in favor of admitting into evidence in a malpractice case the admissions from an administrative case, there would be a deterrent to the settlement of administrative cases in the future. Why should a person admit error in an administrative hearing if the admissions are going to come back to haunt that person in a later malpractice case? The best approach might be to refuse to admit everything and force the administrative agency to prove its case, and then continue with the denials in any subsequent malpractice case. The obvious problem with this result would be that administrative actions would continue long after they could have been settled, expending scarce resources and wasting the time of all involved. The court considered that a bad policy for the public and ruled in a way that would avoid such a problematic result.
2. In a pharmacist malpractice case such as this one, based on an alleged misfill of a prescription with one drug instead of another, the plaintiff is obligated to prove the facts alleged. Although evidence of past errors is irrelevant to prove a present error, evidence of past errors may be relevant to prove carelessness, sloppiness, and recklessness. Should these undesirable characteristics be proven for a pharmacist, a finding of willful disregard with attendant punitive damages may be supported. Of course, the plaintiff may be able to prove such facts and receive punitive damages, but this case stands for the principle that the plaintiff will not be permitted to use admissions from an administrative hearing as proof. Other means of developing evidence must be used to support an award of punitive damages.
3. The difficulties that can occur for a pharmacist who is noticed by the board of pharmacy are quite evident in this case. Most pharmacists hope to complete their entire career of years of pharmacy practice without, at any time, ever coming to the attention of the board of pharmacy. Because this pharmacist had attracted so much attention from the board of pharmacy, she had apparently expended significant financial resources in defending charges against her. It just seemed best to admit her mistakes and get on with her life. Although the board of pharmacy could revoke a license, the penalty in this case was evidently much less severe. However, the penalties of a malpractice case, especially punitive damages that usually are not paid for by insurance, are more significant and worth defending.

## **Case 1-4 *Heckler v. Chaney*, 470 U.S. 821 (1984)**

### **Issue**

Whether an administrative agency has the discretion to decide not to enforce rules it is authorized to enforce, even though there is a possibility that the law would permit such an enforcement.

### **Overview**

This case attracted national attention when it was appealed to the Supreme Court of the United States, but the attention was because of the controversial subject matter and not the important legal question it addressed. It was a dark case brought by condemned prisoners who contended that the drugs used for the execution of people under circumstances such as theirs were not approved by the FDA for this purpose, and, therefore, were unlawful when

used for execution by lethal injection. The prisoners sought a ruling to that effect by the FDA, but the FDA refused to even consider the issue.

As a general matter, administrative agencies have considerable discretion to choose when to enforce their rules and when not to. Rarely does an agency enforce every possible violation of the rules it is authorized to enforce. Rather, the agency prioritizes violations and enforces the rules against only those violations that are considered to be important enough to warrant agency attention. The FDA certainly functions in this way, with many trivial violations being ignored by the agency. In this case, the court was asked to force the FDA to take action against state governments that the prisoners believed were violating the FDCA.

The court opinion began by describing the facts of the case:

Respondents have been sentenced to death by lethal injection of drugs under the laws of the States of Oklahoma and Texas. Those States, and several others, have recently adopted this method for carrying out the capital sentence. Respondents first petitioned the FDA, claiming that the drugs used by the States for this purpose, although approved by the FDA for the medical purposes stated on their labels, were not approved for use in human executions. They alleged that the drugs had not been tested for the purpose for which they were to be used, and that, given that the drugs would likely be administered by untrained personnel, it was also likely that the drugs would not induce the quick and painless death intended. They urged that use of these drugs for human execution was the “unapproved use of an approved drug” and constituted a violation of the Act’s prohibitions against “misbranding.” They also suggested that the FDCA’s requirements for approval of “new drugs” applied, since these drugs were now being used for a new purpose. Accordingly, respondents claimed that the FDA was required to approve the drugs as “safe and effective” for human execution before they could be distributed in interstate commerce. They therefore requested the FDA to take various investigatory and enforcement actions to prevent these perceived violations; they requested the FDA to affix warnings to the labels of all the drugs stating that they were unapproved and unsafe for human execution, to send statements to the drug manufacturers and prison administrators stating that the drugs should not be so used, and to adopt procedures for seizing the drugs from state prisons and to recommend the prosecution of all those in the chain of distribution who knowingly distribute or purchase the drugs with intent to use them for human execution.

The FDA Commissioner responded, refusing to take the requested actions. The Commissioner first detailed his disagreement with respondents’ understanding of the scope of FDA jurisdiction over the unapproved use of approved drugs for human execution, concluding that FDA jurisdiction in the area was generally unclear but in any event should not be exercised to interfere with this particular aspect of state criminal justice systems.

Although the court could have spent significant time addressing the social issues surrounding capital punishment and the Constitutional prohibition against cruel and unusual punishment, the case instead was decided on the basis of principles of administrative law.

For us, this case turns on the important question of the extent to which determinations by the FDA not to exercise its enforcement authority over the use of drugs in interstate commerce may be judicially reviewed. This Court has recognized on several occasions over many years that an agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion. This recognition of the existence of discretion is attributable in no small part to the general unsuitability for judicial review of agency decisions to refuse enforcement.

The court explained that it is unusual for there to be judicial interference with a decision of an administrative agency because agencies usually have expertise that courts do not have, and the availability of this expertise is a sound basis for judicial deference to administrative authority.

The reasons for this general unsuitability are many. First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency’s overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities. Similar concerns animate the principles of administrative law that courts generally will defer to an agency’s construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute.

In addition to these administrative concerns, we note that when an agency refuses to act, it generally does not exercise its coercive power over an individual’s liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect. Similarly, when an agency does act to enforce, that action itself provides a focus for judicial review, inasmuch as the agency must have exercised its power in some manner. The action at least can be reviewed to determine whether the agency exceeded its statutory powers. Finally, we recognize that an agency’s refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch, inasmuch as it is the Executive who is charged by the Constitution to “take Care that the Laws be faithfully executed.”

The court considered the argument of the petitioners that, despite general deference to agency decisions, some enforcement actions were specifically mandated by the statute and thus were not discretionary.

To enforce the various substantive prohibitions contained in the FDCA, the Act provides for injunctions, 21 U.S.C. § 332, criminal sanctions, §§ 333 and 335, and seizure of any offending food, drug, or cosmetic article, § 334. The Act's general provision for enforcement, § 372, provides only that "[the] Secretary is authorized to conduct examinations and investigations." The section on criminal sanctions states baldly that any person who violates the Act's substantive prohibitions "shall be imprisoned or fined." Respondents argue that this statement mandates criminal prosecution of every violator of the Act but they adduce no indication in case law or legislative history that such was Congress' intention in using this language, which is commonly found in the criminal provisions of the United States Code. We are unwilling to attribute such a sweeping meaning to this language, particularly since the Act charges the Secretary only with recommending prosecution; any criminal prosecutions must be instituted by the Attorney General. The Act's enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised.

### **Notes on *Heckler v. Chaney***

1. Government agencies usually are criticized for what they do, not for what they fail to do. However, in this case, the FDA was accused of having failed to do its duty to protect individuals for whom approved drugs were used (although admittedly, a distinct and small class of individuals). The Supreme Court did not agree with the approach taken by the agency; it merely said that if the agency chose to take this approach, it was within its rights to do so. As a general matter, courts are highly deferential to administrative decisions.
2. The substantive claim in this case—that the FDA may forbid uses of medications in ways that fall outside their product labeling—has consistently been a losing argument. Product labeling is a guideline as to appropriate use, but it does not define the universe of appropriate use. So-called "off-label" uses, when physicians prescribe and pharmacists dispense in ways that are not fully supported by the product labeling, have generally been held not to violate the FDCA. Although the FDCA regulates drug distribution, it does not regulate professional practice. Even had the FDA exercised its discretion to consider the complaint by the prisoners, their claim would probably have failed on its merits.
3. In a 2012 case, *Beatty v. Food and Drug Admin.*, 2012 WL 102108 (D.D.C. March 27, 2012), plaintiff death row inmates sued the FDA, contending that the agency violated the FDCA by improperly allowing shipments of thiopental from foreign manufacturers for the purpose of being used in lethal injections. The court found for the plaintiffs, noting that the FDCA mandates the FDA to require registration of foreign drug manufacturers and to refuse entry to any drug that appears to be misbranded or unapproved. The court distinguished *Beatty* from *Heckler* by noting that *Heckler* centered on the FDA's discretion to decline to pursue enforcement actions contained in administrative rules. *Beatty*, however, deals with the agency's failure to carry out a statutory mandate. The court considered the FDA's failure to enforce the statute as arbitrary and capricious because it enforced this statute in other instances.



