# PHARMACY LAW
## Desk Reference


Delbert D. Konnor, PharmMS
Editor

# Pharmacy Law Desk Reference

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## ABOUT THE EDITOR

**Delbert D. Konnor, PharmMS, PharmBS, RPh,** is President of The Del Konnor Group, LLC, and DEA Solutions Group, LLC, which he established in 2001 after sixteen years as President and Chief Executive Officer of the Pharmaceutical Care Management Association. He served as official spokesperson for the PCMA on matters of legislation, healthcare benefits, and managed care pharmacy.

Mr. Konnor has served as Vice President of Professional Services at the American Association of Retired Persons (AARP) Pharmacy Service, head of the Drug Enforcement Administration's Voluntary Compliance Program, and Director of the White House Conference on Prescription Drug Misuse, Abuse, and Diversion. He has been Assistant to Executive Vice President and Director of Association Affairs at the National Association of Retail Druggists (now the National Community Pharmacists Association or NCPA), and is the author of "The Evolution of PBMs–An Overview: From Mail Order Pharmacy to Pharmacy Benefits Manager," which appeared in *Drug Injury: Liability, Analysis and Prevention, Second Edition.*

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# Foreword

Those of us who graduated from pharmacy school in the 1960s or 1970s have witnessed tremendous and exciting changes in the practice of our profession. As an attorney as well as a pharmacist, I know that the regulatory framework governing pharmacy has also changed dramatically over the past thirty-five years. Understanding those changes in pharmacy law, and how they affect the practice of pharmacy, will be critical to our profession's success in the coming years.

That's where this book comes in. It is designed to help pharmacists, leaders of the profession, healthcare decision makers, regulators, and lawmakers gain insight into what is expected of the profession by government and the courts.

Because the subject matter of this work is so comprehensive, it could not have been written by any one person. It is, rather, the product of the efforts of numerous respected authorities in various aspects of pharmacy law. While key chapters in the book address contemporary topics in pharmacy law, the focus of this work is on providing the reader with a framework for understanding how and why the profession is regulated.

I expect that this book will serve as required reading in pharmacy schools throughout the country. This book is more than a textbook. It is a foundation work that will serve widely as a desk reference for law offices, pharmacy boards, professional societies, and healthcare facilities across the country. As a past president of the American Society for Pharmacy Law, I understand the value and importance of this book and its inherent contribution to pharmacy literature.

This is a book that will influence our understanding of pharmacy law for a generation to come.

*Joseph G. Valentino, JD, RPh*
*Senior Vice President and General Counsel (Retired)*
*The United States Pharmacopeial Convention, Inc.*

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# Preface

No profession in America is more closely regulated than pharmacy—and for good reason. The decisions that pharmacists make every day, the medicines they select, and the counsel they provide to patients have the potential to heal the sick, alleviate pain, and extend our lives. But they also have the potential to do great harm.

As one who has served both as a practicing pharmacist and as a regulator of the profession, I know firsthand how important it is for people on both sides of the regulatory fence to understand each other's role. In that regard, I've always believed that our country's small but dedicated community of pharmacist-attorneys is in a unique position to serve as a critically important liaison between government and the profession.

This book is a collaboration involving many leading members of that community. A nationally recognized authority in one or more aspects of pharmacy law authors each chapter. Many of these authors are active in the American Society for Pharmacy Law—an organization in which I have held membership for many years.

This book, though, is also a product of the support and guidance I received from others, including my friend and colleague Dr. Peter A. Previte, Professor of Social and Administrative Sciences, Ohio Northern University, College of Pharmacy, who critiqued my original outline and book proposal. and my son, D. Daniel Konnor II, who was always willing to provide input, advice, and support. Most important, though, this book owes its existence to my friend and colleague Dr. Albert I. Wertheimer, Director, Center for Pharmaceutical Health Services Research, Temple University, School of Pharmacy, whose constant encouragement and assistance helped me carry this project through to completion.

I must confess, however, that the seed for this endeavor was planted many years before the first chapter was written. Indeed, it is the book I wish was available to my students when I taught pharmacy law years ago at Wayne State University, College of Pharmacy. I hope it will offer our next generation of pharmacy students a solid grounding in the legal and regula-

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tory issues that impact our profession. I am also hopeful that this work will serve as a valuable reference for the organizations representing America's pharmacists, for the state pharmacy boards and federal agencies that regulate the profession, and for others with a stake in improving the laws and regulations governing pharmacy to protect the public.

The more government administrators and lawmakers know about pharmacy practice, the more likely they will be to design and implement effective regulations that serve the public interest. And the better pharmacists understand the regulatory and legislative framework that shapes their practice, the better they will be able to carry out their responsibilities to patients.

It is this belief that has served as the inspiration for this book.

*Delbert D. Konnor*

Chapter 1

# The Function, Evolution, and Historical Development of the Law

Martha M. Rumore

## *GOVERNMENT ORGANIZATION AND FUNCTION*

There are three branches of government: executive, legislative, and judicial. Legislatures create statutory law by enacting bills which become laws. The judiciary makes common law, which is found in court decisions. However, it is impossible for the legislature to make all the necessary rules or for the judicial branch to handle all of the cases. Certain fields require nonlegal expertise. Therefore, Congress created the administrative agencies, often referred to as the fourth branch of government, which create administrative law. Agencies act like courts or legislatures by making rules or deciding cases. Administrative agencies may be called commissions, boards, bureaus, divisions, or agencies.

## *AGENCY ORGANIZATION AND FUNCTION*

Agencies protect us against false advertising, unfair trade practices, unwholesome food, mislabeled drugs, air and water pollution, fraud in the sale of securities or land, unsanitary restaurants and hospitals, unsafe products, and sale of narcotics. Agencies dispose of many times the number of court-handled cases. Agencies also promulgate regulations via a process known as "notice and comment" rulemaking.

The *United States Government Manual* provides detailed descriptions and organization charts for each federal administrative agency.[1] The Food and Drug Administration (FDA), for example, is composed of various "centers" such as the Center for Drug Evaluation and Research (CDER) and the

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Center for Biologics Evaluation and Research (CBER). Located within each center are various offices. For example, within CDER is the Office of Pharmaceutical Science, the Office of Generic Drugs, the Office of New Drugs, the Office of Compliance, and the Office of Drug Safety. The centers play an important role in both administrative and judicial enforcement activities. The FDA has enforcement power over manufacturing procedures for (and the finished) food, drug, cosmetic, medical device, and biologic products that are moved in interstate commerce, and it is responsible for enforcement of the Federal Food Drug and Cosmetic Act. The FDA shares or coordinates enforcement responsibility for certain products through established relationships often formalized in Memorandums of Understanding (MOUs) and other interagency agreements with other federal agencies such as the Drug Enforcement Administration and U.S. Customs Service. The FDA enforces the following acts, among others: the Federal Food, Drug, and Cosmetic Act; the Orphan Drug Act; the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments); the Federal Anti-Tampering Act; the Fair Packaging and Labeling Act; and the Prescription Drug User Fee Act. The addition, the FDA regulates the advertising of prescription drugs.[2]

Food and drug laws are located in Title 21 of the Code of Federal Regulations, as described in Table 1.1. The entire Title 21 may be keyword searched at the FDA's Web site. Examples of the wealth of information available at www.fda.gov include guidance documents and manuals, the *Regulatory Procedures Manual, Federal Register,* the *Orange Book* searchable by generic name, warning letters, and *The Handbook for Requesting Information and Records from FDA.* In addition to formal rulemaking, the FDA issues guidelines to help with compliance with the requirements of the regulations.[3] These guidelines are not a legal requirement; however, the

TABLE 1.1. Code of federal regulations.

| Code number range | Description of subjects |
|---|---|
| 1 to 99 | FDA, General |
| 100 to 169 | Food for Human Consumption |
| 170 to 199 | Food fo Human Consumption |
| 200 to 299 | Drugs, General |
| 300 to 499 | Drugs for Human Use |
| 500 to 599 | Animal Drugs, Feeds, and Related Products |
| 600 to 799 | Biologics |
| 800 to 1299 | Medical Devices and Radiological Health |
| 1300 to 1404 | Drug Enforcement Administration, Department of Justice |

FDA has stated that it will not recommend legal action against a person or product if the procedures in a current FDA guideline are followed. FDA interpretation of its own regulations or another statute are not regulations. FDA sources include more than twenty manuals that contain technical and compliance information. Some examples of manuals are the FDA Compliance Policy Guides Manual, which is used by field officers in interpreting regulatory policies, and the FDA Compliance Program Guidance Manual, which provides inspection details. A company can also seek an "advisory opinion" concerning the FDA's compliance posture on a certain matter.[4] Knowledge of these tools is invaluable in establishing voluntary compliance programs.

Other agency functions are also of interest to health professionals. The Consumer Product Safety Commission (CPSC) enforces the Consumer Product Safety Act of 1972, the Federal Hazardous Substances Labeling Act, and the Poison Prevention Packaging Act.[5] Although most FDA-regulated products are exempt from these statutes, medical devices are subject to the Federal Hazardous Substances Act, and all FDA-related products are subject to the Poison Prevention Packaging Act. The Drug Enforcement Administration (DEA) is responsible for placing controlled substances on the federal "schedule" and enforces the Federal Controlled Substances Act of 1970. The Federal Trade Commission (FTC) regulates the advertising of foods, over-the-counter (OTC) drugs, medical devices, and cosmetics. In addition, the FTC may take action to prevent unfair methods of competition and other unfair or deceptive acts or practices involving advertising, labeling, and other promotional practices. Within the FTC, the Bureau of Competition is responsible for enforcing antitrust laws such as the Sherman Antitrust Act and the Clayton Act.

Other agencies include the Environmental Protection Agency (EPA), aimed at protecting the environment, and the Occupational Safety and Health Administration (OSHA), which implements the Federal Occupation Safety and Health Act of 1970 that requires employers to provide safe working conditions for their employees.

## *THE COURT SYSTEM*

Court decisions are collected chronologically in volumes called case reporters and are summarized by subject matter in reference works called case digests. Federal courts have three levels: a trial level, an appellate level, and a final appellate level. At the federal level, the trial courts are called the U.S. District Courts. Trial courts are courts of original jurisdiction that make de-

terminations of law and of fact, with juries often making the determinations of fact.

Discovery enables one party to examine the evidence of the other party. A subpoena is a written document issued by the court, by the legislature, or by an agency if empowered to do so. A violation of a subpoena is considered "contempt." There are two types of subpoenas: *testificatum,* in which the individual is asked to testify at a particular time and place, and *duces tecum,* in which the individual is asked to produce records.

Documents prepared by the parties called pleadings (complaint, answer, interrogatories) and motions are filed before and during a trial; exhibits are submitted into evidence during the trial and a record (or transcript) is made. Pleadings, motions, exhibits, and transcripts are usually available only directly from the court in which the litigation was conducted.[6]

Federal intermediate appellate courts are known as the United States Court of Appeals. There are thirteen Federal Courts of Appeals, each of which covers a particular geographic area known as a circuit. Appellate courts are not trial courts, but rather review whether the trial judge correctly applied the relevant points of law to the facts. Appellate courts accept written briefs (statements prepared by the counsel arguing the case) and frequently hear oral arguments. Many appellate courts sit in panels smaller than the full court. When the full court meets, it is referred to as an *en banc* proceeding.[7]

The final appellate court in the United States is the Supreme Court. The Supreme Court is the highest authority in the United States on questions of federal law and constitutional law. State courts of last resort are the highest authorities on questions of state law. There are some matters over which a state or federal court has exclusive jurisdiction and some matters over which a state court has concurrent jurisdiction with the federal courts. Most libraries collect copies of the briefs and records filed in the Supreme Court and of the court of last resort of the state in which they are located.

The number and type of state courts vary with the individual state. In New York, the highest court is the New York Court of Appeals. It has jurisdiction in both criminal and civil matters, but appellate only. The court reviews only questions of law, except in two instances in which it reviews the facts: on appeal from a criminal judgment imposing the death penalty and from an appellate division decision reversing or modifying a judgment, finding new facts, and directing that a final judgment be entered on new facts.[8]

The intermediate appellate court in New York is called the Appellate Division of the Supreme Court. There is one in each of four judicial departments. The court reviews both the law and the facts and has some original jurisdiction in certain areas, i.e., admission and supervision of attorneys.[9]

Two rungs below New York State's highest court is the supreme court, a misnomer since it is not supreme. The supreme court is a single court of statewide jurisdiction, with a branch in each county. There is also a county court in each county outside New York City, a surrogate's court, family court, court of claims (reserved for claims against the state or by the state), New York City criminal court, New York City civil court, district courts, city courts, and town and village courts.[10]

Each level of the federal courts has at least one case reporter for its decisions.[11] Cases from the U.S. Supreme Court are found in the *United States Reports* ("U.S."), which is the official reporter. Supreme Court decisions are also found in unofficial reporters where helpful editorial features are added by the publishers: *Supreme Court Reporter* ("S. Ct.") and the *United States Supreme Court Reports Lawyers' Edition* ("L.Ed.").

U.S. Court of Appeals decisions from all circuits are found in the *Federal Reporter* ("F."-1880-1924; "F.2d"- 1924-present). From 1880 to 1932, U.S. District Court opinions were reported along with U.S. Court of Appeals decisions in the *Federal Reporter.* Since 1932, they have been published in the *Federal Supplement* ("F.Supp.").

Decisions of state courts are published in state cases reporters as well as regional reporters. For example, New York State cases appear in the *North Eastern Reporter* as well as reporters all the way down to its trial level courts. The *North Eastern Reporter* ("N.E. or N.E.2d") includes appellate opinions from Illinois, Indiana, Massachusetts, New York, and Ohio.

Case reporters are organized either by jurisdiction, by geography, or by subject. An example of cases reported chronologically by subject is the *United States Patent Quarterly.* The topical arrangements of court decisions are published in case digests. These digests, in effect, serve as indexes to the case reporters. A digest is a set of books that takes brief summaries (digests) of the legal principles in a case and lists each under the appropriate topic or heading. A single case may appear under several different subjects. Examples include the *Federal Practice Digests, Education Law Digest,* and the *U.S. Supreme Court Digest*. Digests are particularly useful in locating cases interpreting constitutions.[12]

A court case typically includes the following: name or title of the case (also called the "caption"); citation to the case; docket number (numerical designation assigned by a court); date of decision; prefatory statement (explains the nature of the case, its disposition in the lower court, and disposition in the appellate court), e.g., affirmed or reversed; syllabus or headnote (brief summaries of the rules of law or significant facts in a case); names of counsel; statement of facts; opinions of the court; and the decision, with judgment or decree.

The opinion of a court is the explanation of the court's decision. The "majority opinion" is written by one member of the court and represents the principles of law the majority on the court deem operative in a given decision. A member of the majority may also write a "concurring opinion" elaborating on individual reasoning. When more judges join a concurring opinion, but not yet a majority of the court, it is known as a "plurality opinion." The views of a minority are expressed as a "dissenting opinion." A *per curiam* opinion is an opinion of the entire majority, as distinguished from an opinion written by a specific judge. A "memorandum opinion" is a brief holding of the whole court in which the opinion is limited or omitted.

## *ORDER OF PRECEDENCE OF AUTHORITY*

Although people are equal before the law, not all laws are equal. Some laws are more important than others. In general, the order of precedence of authority is the U.S. Constitution, federal statutes, federal regulations, state constitutions, state laws, and local laws and ordinances. The Constitution is the supreme law of the land; the first ten amendments place limits on government power and are known as the Bill of Rights.

Legal authority is any published source of law setting forth legal rules, legal doctrine, or legal reasoning that can be used as a basis for legal decisions.[13] Legal authority can be categorized as primary or secondary. Primary authority includes case law, legislation, constitutions, and regulations and opinions of administrative agencies. Secondary authority includes treatises, law reviews and other scholarly journals, *American Law Reports Annotations* ("A.L.R."), and loose-leaf services. Only primary authority can be "binding" (also called mandatory), meaning that a court or other decision maker believes the authority applies to the case before it and must be followed. Secondary authority can be only persuasive, meaning that a decision maker can, if so persuaded, follow it.[14]

Under what has come to be called the doctrine of precedent, the decision of a common law court not only settles a dispute between the parties involved but also sets a precedent to be followed in future cases among other litigants.[15] The doctrine of precedent encompasses *stare decisis,* which is the principle that the decision of a court is binding authority on the court that issued the decision and on lower courts in the same jurisdiction for the disposition of factually similar controversies.[16] In contrast, *dictum* (or *obiter dictum*) is language in an opinion that is arguably not necessary to the opinion. Dictim refers to what is said "by the way." Although dictum is not binding on future courts, it might be persuasive.[17] It is important to be aware of the fact that commonly yesterday's dictum develops into today's doc-

trine. Further, courts have much leeway in interpreting cases. No two cases are exactly the same, and at some point every case can be distinguished from all others.

## *ENACTMENT OF LEGISLATION*

### *How a Bill Becomes a Law*

Congress is responsible for federal criminal law, all laws governing the operation of federal departments and agencies, treaty approval, power to declare war, investigative power (when aimed at the executive branch this is called "oversight"), confirming or rejecting the president's nominees, and impeachment for "high crimes and misdemeanors. Via "congressional oversight" Congress oversees the activities of particular agencies. Congress also allocates money for the operation of federal departments and agencies via the appropriations process.

The Senate and House of Representatives make up the Congress. A "bill" is proposed legislation, not yet passed and, therefore, not law. A bill must be introduced in either the Senate or House of Representatives by a member of those legislative bodies. House seats are apportioned on the basis of population, whereas each state, regardless of population, elects two members to the Senate. Much of the work of Congress is conducted by committees with jurisdiction over a particular area of public policy. Almost every bill is sent to a committee or several committees, which normally pass them on to subcommittees. Committees schedule public hearings on bills where testimony is taken from bill sponsors, administration officials, outside experts, and any special interest groups. Next the bill undergoes "mark-up" where committee members go over it section by section, voting on proposed changes and redrafting the bill in view of what they have learned about the subject.

The full committee may at this point adopt the bill as written, amend it, or kill it. If adopted, the bill is sent to "the floor," meaning for vote by the House and Senate. House bills go to the House Rules Committee. Time for debate is limited, and floor action is often completed in a timely fashion. In the Senate, however, debate is often extensive, with elaborate rules of decorum. Once a bill is passed in either the full Senate or House, it is sent to the other chamber for consideration. Frequently, the House and Senate pass different versions of a bill. The differences are resolved via a "conference agreement," i.e., a compromise version which must then be repassed by both houses before being sent to the president for signing. If the president signs, it becomes law. Alternatively, the president can veto the bill, where it

is then sent back to the Senate and House for another vote. If both chambers vote for it by at least a two-thirds majority, it becomes law despite the president's veto, thereby overriding the veto.

The *Congressional Record* is a verbatim transcript of the proceedings of the Senate and House. It includes the "Daily Digest" summarizing floor action, committee activities, committee meetings, and hearings scheduled. The Government Printing Office (GPO) was established to act as the "public printer" for the entire federal government, including Congress. Most federal publications are available at the GPO Web site.

### *Legislative History*

Unfortunately, not all laws are clearly written. The entire process of enacting a law creates a legislative history which often serves as an important guide in determining the legislative intent and clarifying vagarities. In interpreting the meaning of a law, one can review the changes resulting from the committee process via the committee report. Other important items of legislative history are statements made during debates and changes made to a bill while it worked its way through Congress. Almost every printing of a bill represents a distinct step in its progress toward enactment and may ultimately be a significant document in its legislative history. The full text of congressional bills can be reached over the Internet by taping into the bulletin board of the House of Representatives or via Thomas, an Internet site that provides access to a wide variety of congressional documents, including bills.

Hearings do not have to be held on every bill, but when they exist, they aid in interpreting the provisions of the bill. Hearings may be published in the *Monthly Catalog of U.S. Government Publications* and in *CIS/Index*. Since 1970, *CIS/Index* has provided abstracts of testimony and indexing under the name of each witness.

Committee reports reflect the committee's proposal after the bill has been studied, hearings held, and amendments made.[18] They frequently contain the revised text of a bill and analysis of its content and intent. There will be a report only for bills that make it out of committee. Committee reports are indexed in the *Monthly Catalog of U.S. Government Publications,* the *CIS/Index,* and, occasionally, the *Congressional Record*. Congressional debates are found more or less verbatim in the *Congressional Record*.

Other Congressional documents, such as special studies and reports, are indexed and listed in the *Monthly Catalog of U.S. Government Publications*. *CIS* stands for Congressional Information Service. This reference

separates the House and Senate into committees and subcommittees and divides publications for each into hearings, reports, and prints.

### *Finding Statutes*

Like regulations, laws are published immediately upon enactment. When a bill is enacted, it is assigned a Public Law Number, e.g., 105-2. The first three numbers indicate the session of Congress, and the number following this is the number of the bill passed during that session of Congress. A permanent collection of the laws of each session of Congress is published by the Government Printing Office and called the *United States Statutes at Large* (abbreviated as "Stat."). The statutes are a chronological arrangement of the laws published as they become law, in no logical subject order. The codified version published by the U.S. government is found in the *United States Code* ("U.S.C.") and in two commercially published editions, *United States Code Annotated* ("U.S.C.A.") and *United States Code Service* ("U.S.C.S."). Published every six years, the United States Code is a consolidation of statutes arranged according to subject matter. Between editions, a supplementary volume is issued annually as an update for that year. To find a statute in the U.S.C., you can use the index, the Table of Titles and Chapters, the Tables of Acts cited by popular name, and the conversion tables. The FDCA begins at 21 USC 321; to locate it you would look for United States Code, Title 21, section 321. These are available in the government documents sections of most libraries.

U.S.C.A. and U.S.C.S. are annotated versions of the U.S.C. Both have detailed indexes, references to regulations promulgated and published in the C.F.R., popular name tables, and other tables. Both are updated with annual pocket parts, freestanding supplements, and periodic pamphlets (called advance sheets). The biggest difference is that each set organizes the case annotations according to different subject headings and may not include the same cases as the competing set. For legal research, the easiest way to locate a law is via its U.S. Code number.

Individual states also routinely publish session laws and statutory codes but vary widely in organizing and publishing these laws.

## *CODE OF FEDERAL REGULATIONS*

Regulations are often the details to put statutes into effect. Regulations are also arranged chronologically in the *Federal Register* ("Fed. Reg.") and according to specific regulatory topics in *The Code of Federal Regulations* ("C.F.R."). FDA and DEA regulations are located in Title 21. The CFR is

divided into 50 titles from "Accounts" to "Wildlife." There are over 150 CFR volumes. Each title is further divided into chapters, subchapters, parts, subparts, and sections. Federal administrative agency decisions are available from the agencies themselves.

Ordinarily research into the regulations of a federal agency begins with the C.F.R., since the C.F.R. pulls all the regulations together into one place. However, since the C.F.R. is updated on an annual basis, it is necessary to check the *LSA: List of CFR Sections Affected*. The LSA indicates *Federal Register* pages of any proposed or new rules affecting the C.F.R. In addition, as the LSA does not bring C.F.R. completely up to date, it is necessary to consult the last *Federal Register* issue of each month not covered by the LSA to be assured that no changes in the regulation have been promulgated.

### *What Is a Regulation?*

Congress has delegated to agencies the power to promulgate "regulations" (also known as "rules") which are binding and can be legally enforced.[19] Regulations interpret and enforce statutes and must be consistent with the statute or risk being declared invalid by the federal courts.

In addition, regulations must be developed and issued in accordance with the Administrative Procedures Act or they are not enforceable.[20] In 1935, Congress enacted the Federal Register Act which provided for

1. filing of documents with the Office of the Federal Register,
2. placement of documents on public inspection, and
3. publication of documents in the Federal Register.

In 1946, the Administrative Procedures Act

1. introduced the right of the public to participate in the rulemaking process by commenting on proposed rules,
2. required that the effective date of a regulation not be less than thirty days from the date of publication unless in an emergency, and
3. provided for publication of agency statements.

### *Development of a Regulation*

Regulations begin with an "Advance Notice of Proposed Rulemaking" or "Intent to Publish" in the *Federal Register.* Then they appear as a "Proposed Rule," whereby comments are invited within a time limit of sixty days to possibly one year. A hearing may also be scheduled to obtain public

viewpoints. The agency analyzes all comments and arrives at an equitable decision. It is published in final form as a "Final Rule." Figure 1.1 provides an overview of this process. After a regulation is issued, it may be struck down by the courts.

Administrative law can be very complex to research. Not only must the regulations and decisions created by the administrative agency be found, but researchers must also find, interpret, and update the legislation the agency is administering and the judicial opinions interpreting the regulations, adjudications, and legislation.

### *What Is Not a Regulation*

Petitions are not regulations. An interested party can petition an agency to establish, amend, or revoke a rule or any part thereof. If the agency head finds the petition has reasonable merit, notice of its filing and availability is published in the *Federal Register,* with a request for comment within a time limit. Any agency may also publish its own version of such a proposal.

Interim or temporary rules are also not regulations. They are effective as of the day of enactment but for a short or definite period of time. They have

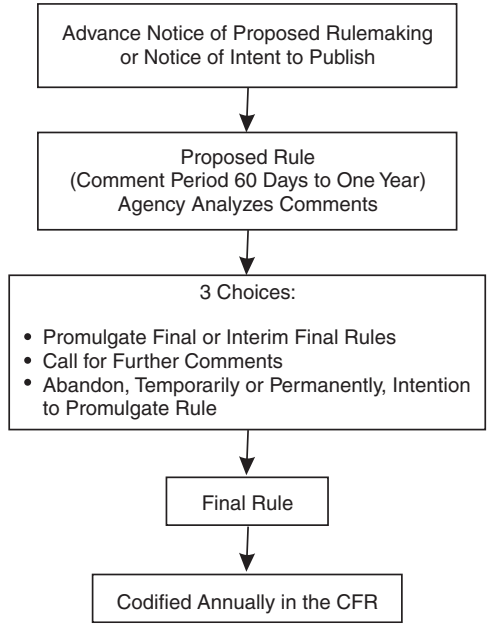


FIGURE 1.1. Regulation development process.

the same effect as a final rule in that they amend the CFR and give an effective date.

### *Adjudications*

Many agencies have the power to receive evidence and decide controversies via "administrative adjudications" presided over by administrative law judges (ALJ). Final adjudications are often published and available to review as agency interpretations. These adjudications can be appealed to the courts.

### *The Freedom of Information Request*

The Freedom of Information Act (FOIA) established the rights of private citizens to obtain information from federal government agencies. First passed in 1966 and strengthened in 1974, Congress enacted the FOIA which has opened thousands of government file cabinets to public scrutiny. The FOIA states that any person has the right to see and copy documents produced by any federal agency. The FOIA does not apply to the federal judiciary or elected officials of the federal government, private companies, persons who receive federal contracts or grants, tax-exempt organizations, or state and local governments. State and local governments have adopted their own versions of the FOIA, even though not federally mandated to do so.

Before enactment of the FOIA, the burden was on the individual to establish his or her right to examine government records. For those denied access there were no judicial remedies. Originally, the act was designed to establish more uniform procedures among the agencies in both rule making and adjudication, thus putting a new system of accountability into effect. In addition, the agency must reply within ten days of receipt of a FOIA inquiry. Delay is, nevertheless, common. Although the law states that an agency may receive a time extension only in exceptional or "unusual circumstances," agencies extend these deadlines regularly. Although the agency is mandated to reply within ten days of inquiry receipt, the actual information requested may take up to several months to be distributed. "Freedom of Information" must be stated on the request. Each request appears in a public log, which itself is available on request. There may be a fee for photocopying time or per page copied.[21]

Exhibit 1.1 lists the information that must be published in the *Federal Register* by each federal agency.[22] For example, under FOIA the FDA will

**EXHIBIT 1.1. Types of available general information.**

1. Central and field office locations, staff organizations
2. Methods by which the public can secure information
3. General methods by which its functions are channeled and determined
4. Rules of procedure, availability and description of necessary forms
5. Policy statements and substantive rulings of general applicability
6. Each agency must make the following available for public inspection and copying:
   - All final opinions whether concurring or dissenting, as well as orders given in the adjudication of cases
   - Those statements of policy and opinions which are informally adopted by the agency and not published in the *Federal Register*
   - Administrative staff manuals
   - All other records except those expressly exempted by law, upon request, within published rules for time, place, and fees
   - Agency proceedings

release information on test protocols, information relating adverse drug events, product experience and consumer complaints, approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs), administrative enforcement records such as recall letters, and manufacturing facility inspection reports.[23,24] Nondisclosable portions will be deleted prior to release. However, the FDA will uphold the confidential status of an IND. This information is considered nondisclosable under the trade secret exemption of the FOIA. Release of information may follow a sponsor's termination or withdrawal of the IND. In addition, under Executive Order 12958 which became effective October 15, 1995, there is automatic declassification of most U.S. government files more than twenty-five years old. Categories of information which are exempted from disclosure are found in Exhibit 1.2. The stamping of documents as "confidential" or "trade secret" by the person or company submitting said document does not obligate an agency to regard them as such.[25] Whenever an FOIA request is denied, the agency must inform the requestor of the reason for the denial and the right to appeal. Many agencies require that appeals be filed within thirty days. Whenever an administrative appeal is denied, the requestor may then file for judicial appeal in court.

**EXHIBIT 1.2. Exempted categories of information.**

- Classified national defense and foreign policy secrets
- Internal agency rules—agency personnel and medical records
- Trade secret and confidential business information
- Investigatory files for law enforcement purposes
- Information exempt under other laws
- Internal management matters
- Bank examination records
- Inter and intra agency memoranda
- Certain mineral, geological, and geophysical information

## *SECONDARY SOURCES OF THE LAW*

There are a number of legal encyclopedias on a wide variety of topics arranged alphabetically. Examples are *Corpus Juris Secundum* ("C.S.J.") and *American Jurisprudence, Second* ("Am. Jur. 2d"). Other secondary sources are treatises, book-length analyses of legal topics, and legal periodicals, which consist of law journals and law reviews. The *Index to Legal Periodicals and Books* is a primary finding aid for legal periodicals. Since 1993, it has indexed books. The *Current Law Index* is another primary finding aid for legal periodicals.

Of course, many of the aforementioned legal resources can be accessed with a computer and are searchable using key words and phrases. Examples include LEXIS and WESTLAW, which offer access to cases, statutes, secondary sources, law reviews, mass media, and other information and services that are constantly being expanded and updated. Moreover, many Internet sources are available for government information. See the Appendix for a compilation of these sources.

It is hoped that this overview of the function, evolution, and historical development of the law will assist pharmacists in developing a fundamental ability to use legal materials.

## *APPENDIX: ELECTRONIC RESOURCES*

**Supreme Court Calendar**
www.supremecourtus.gov/oral_arguments/argument_calendars.html

**Senate Calendar**
www.gpoaccess.gov/calendars/senate/index.html

**U.S. Senate**
www.senate.gov

**U.S. House of Representatives**
www.house.gov

**Congressional Record via GPO Access**
www.gpoaccess.gov/crecord/index.html

**Congressional Record via Thomas**
thomas.loc.gov

**Federal Register**
www.gpoaccess.gov/fr/index.html

**Food and Drug Administration**
www.fda.gov

**U.S. Code**
www.gpoaccess.gov/uscode/index.html

**Library of Congress**
www.loc.gov/index.html

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2. 21 U.S.C. §§ 352(n), 378.
3. 21 C.F.R. § 10.90(b).
4. 21 C.F.R. § 10.85.
5. *Compilation of Statutes Administered by the Consumer Product Safety Commission* (CPSC), Washington, DC, April 1992.
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17. Greenwalt K. Reflections on Holding and Dictim. *J. Legal Ed.* 39:431 (1989).

18. Berring RC. *Finding the Law.* 10th Edition. St. Paul, MN: West Pub. Co.; 1989, 168-186.

19. 5 U.S.C. §551(4).

20. 5 U.S.C. §553.

21. Nader R. *The Freedom of Information Act: A Users Guide.* Washington, DC: Freedom of Information Clearing House; 1992.

22. Freedom of Information Act, U.S.C. § 552, 309-312.

23. Pendergast WR. Problems and Opportunities Under the Public Information Regulation of the FDA. *Food, Drug Cosm L. J.* 30:326-337 (1975).

24. Marlene SB. Acquiring Food and Drug Administration Information Under the Freedom of Information Act. *Med. Ref. Serv. Quarterly* 7(4):19-29 (1988).

25. The Struggle Against Secrecy. *The New York Times.* 1996 Jan. 3: v145 PA 14(L) col. 1.

Chapter 2

# Forms of Business Organization

Francis B. Palumbo
George E. Rippel Jr.

## *INTRODUCTION*

When entering any type of business venture, many considerations must be taken into account. The type of business is quite important, in that it could be a small business, perhaps a community pharmacy, or it could be a large business, such as a major pharmaceutical manufacturer. In between are many other possible scenarios, including small group practices or consulting businesses. Each type of business has its own method of operation, its own financial needs, its own needs for governance such as a board of directors or shareholders, and its own expected profitability. In deciding what form of organization to use in conducting business, it is important to look at issues such as these and decide what is best for the short run, the medium run, and the long run. That is to say, when a small business is being put together the individuals might not have need for a regular corporate structure but may opt to enter into a partnership or some other form of organization. As the business grows and prospers, their organizational needs would be different and they may in fact need to take on the structure of a larger corporation. Many of our large corporations grew out of one individual's hard work and foresight.

There are, of course, tax considerations to be taken into account. As the organization becomes complex the tax situation would change considerably. For example, taxing a large corporation with thousands of shareholders is quite different from taxing a sole proprietor. One of the most important considerations in choosing a form of organization is liability. As this chapter develops, it will become clear that the personal financial exposure of a member of a business will vary, depending on the type of business organization under which that person operates. Limited liability is a very attractive

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motivator for entering into a corporate or similar structure. In a nutshell, when a member of a business relies on the concept of limited liability, he or she would not be liable personally for any more than has been invested in that particular business. Thus, personal assets, such as homes, automobiles, furnishings, jewelry, and so forth, are protected from business creditors.

## *FORMS OF ORGANIZATION*

### *The Sole Proprietorship*

The sole proprietorship is probably the simplest and least costly of all the forms of organization.[1] The sole proprietorship essentially costs nothing to establish, since an individual merely starts doing business, hopefully collecting revenues and keeping track of expenditures. There is a substantial tax advantage to operating as a sole proprietorship. The owner of a sole proprietorship pays taxes only once on the profits of the business. The profits are calculated differently depending on whether the business has inventory. For example, consider a pharmacy with annual sales of $2 million. The cost of goods sold, i.e., the amount of money paid for the inventory that was sold, is $1.54 million. This leaves a gross profit of $460,000. Out of this $460,000, all of the expenses of the pharmacy are paid, including rent, heat, other utilities, supplies, equipment, and salaries of the owner and employees. For this example that total amount is $372,000, leaving a net profit of $88,000 ($460,000 minus $372,000). The owner of the sole proprietorship would pay taxes on the $88,000 plus any salary that he or she took out of the business during the year. Both of these figures, however, would be lumped together and taxed only once. So if the owner had been paid $100,000 and the business generated a profit of $88,000, the total taxes would be calculated based on $188,000 and would be filed with the owner's 1040 form. One major disadvantage of the sole proprietorship is the fact that the owner of a sole proprietorship cannot enjoy the limited liability offered by corporate status. Thus, the owner of a sole proprietorship could be personally liable for all the losses of the business. This begs the question as to why anyone would wish to conduct business as a sole proprietorship. It may be much less expensive from an accounting and legal services standpoint. The owner may also have confidence that he or she is adequately insured to take care of any liability losses. And the business may be sufficiently healthy so that the owner does not feel that he or she needs any more than a sole proprietorship.

### *Partnerships*

The partnership is a more complex form of organization than the sole proprietorship, primarily because more than one party is involved. A partnership is defined as an association of two or more persons to carry on, as co-owners, a business for profit.[2] Thus, decision making is now spread across multiple individuals, and so are profits and losses. Like a sole proprietorship, the partnership does not enjoy limited liability. Thus, the partners can be personally liable for the obligations of the partnership itself. Under the law, each partner is presumed to be liable for the tort and contractual obligations of the other partners. Having said that, when entering into a partnership agreement, the partners may often specify the proportion of profits or losses to be enjoyed or borne by each individual of the partnership depending on each person's investment. Partners should be encouraged to have a written agreement when entering into a partnership, even though this is not absolutely required under the law. The agreement can serve to establish the expectations of the parties regarding many aspects of the business, not only the distribution of profits or losses. With regard to the issue of unlimited liability and partnerships, despite the fact that a partnership agreement might be in place, each partner may be jointly and severally liable if the partnership is on the losing end of a lawsuit. For example, if a court awards a large judgment to a plaintiff against a partnership, the partners are all jointly or severally (individually) liable to be sure that judgment is paid. So if one partner has very little in the way of income or assets and another partner has a great deal, the partner with the better ability to pay may end up paying all or most of the judgment despite what may be written in the partnership agreement. Generally speaking, the actions of any one partner will bind the entire partnership, in that that particular partner would be perceived as an agent of the partnership. Thus, except for extraordinary actions such as divestiture of partnership assets, any partner can bind the partnership.

The discussion thus far in this section has been about the concept of a general partnership. Another type of partnership, a limited partnership, also exists under the law and is something entirely different from a general partnership. A limited partnership is a partnership formed by two or more persons under a specific state statute, the Revised Uniform Limited Partnership Act.[3] Limited partners are basically mere investors. That is, someone can invest money in a limited partnership and enjoy the fruits of profits generated by that partnership, but their liability would be limited only to the extent of their investment in that partnership. Usually a limited partnership would have a managing partner who would be responsible for the day-to-day activities of the partnership and who could be liable for losses incurred

by the partnership. The limited partners would be investors only. However, if a limited partner were to engage in management or decision making in the partnership, his or her limited partnership status would no longer exist and the individual could be liable for obligations of the partnership beyond his or her particular investment in that partnership.

Taxes for a general partnership are somewhat different from those of a sole proprietorship with regard to the actual filing. Partnerships generally file a form 1065 partnership return, but it is information only. It is otherwise known as a pass-through return in that the partnership itself does not pay income taxes. All the profits or losses are passed on to the partners and are reported to those partners on an IRS form K-1. Each partner then takes the information from that K-1 form and incorporates it into his or her personal income tax return. Thus, the partnership profits are treated similarly to sole proprietorship profits from a tax standpoint.

### *Corporations*

The decision to incorporate can be based on a number of factors, which may include timing, the size of the business, the number of principals in the business, and the need for a limited liability.[4] Often corporations are formed at the inception of the business, but at other times the forming of the corporation represents a change of entity from another form of organization such as a sole proprietorship or a partnership.

A number of mechanics are involved in forming a corporation.[5] First, one must file articles of incorporation in his or her particular state. These articles would include the following:

1. *The name of the corporation*. The name should always end with a corporate designation such as Corp. or Inc. or some similar designation. This puts the public on notice that you are incorporated and entitled to limited liability.
2. *Specific purpose clause*. This basically details the reason for the existence of your corporation. For example, if your purpose is to conduct business as a pharmacy, then this should be listed in the specific purpose clause.
3. *General "catch-all" clause*. This more general clause would allow you to expand into other areas of business without having to refile your articles of incorporation with the state. It may say, for example, that this corporation can engage in any other business that is related to the specific purpose clause in any manner.
4. *The principal place of business of the corporation.*

5. *The name and address of the resident agent of the corporation*. This would be an individual within the state of incorporation who is authorized by the corporation to accept service of process and other legal notices on behalf of the corporation. So if a corporation is a defendant in a lawsuit, service on the resident agent would be considered service on the corporation. It should also be noted that anyone over the age of eighteen can generally serve as an incorporator. Often this may be the corporation's attorney or accountant, but it can also be a principal of the corporation.
6. *Authorization of capital stock*. This generally appears in the articles of incorporation and details the number of shares of stock that the corporation will be authorizing. This is a total number of shares and is not necessarily the number of shares that will actually be issued in the beginning years of the corporation.
7. *Board of directors*. In this section the initial board of directors will be listed by name. Otherwise the articles of incorporation may contain a provision waiving initial creation of a board of directors.
8. *Duration of the corporation*. A corporation can be perpetual, in which case there is no need to renew the charter. However, it may also have a limited duration, under which circumstance the charter would need to be renewed at the close of that period. If the corporation is to end at a certain time, it would be advisable to specify a limited duration in the articles of incorporation, thereby saving the members of the corporation money by not having to go through the corporation dissolution process.

After the articles of incorporation are filed with a particular state's version of the office of corporations or assessments, and after that office has accepted the articles of incorporation, the members (soon to be shareholders) of the corporation would hold an organizational meeting where the bylaws are adopted. At this meeting they would elect directors of the corporation and appoint the officers of the corporation, such as president, vice president, secretary, and treasurer. The duties of each of these would be generally spelled out in the bylaws at this meeting. Basically, the board of directors makes long-term decisions, and the officers of the corporation carry out the decisions of the board of directors. Ideally the board would not be involved in day-to-day management unless a board member is also an officer of the corporation.

At the organizational meeting, the board will also issue the stock in an amount and denomination necessary and appropriate for the initial capitalization of the corporation. Recall that in the articles of incorporation the

total number of shares was authorized or enumerated. At this organizational meeting, and at subsequent meetings of the board, shares may actually be issued. There are generally two prohibitions on issuance of stock. First, stock may not be issued in return for promises to do future services for the corporation. Second, stock may not be issued to an individual who signs a promissory note to acquire that stock.

There are different types of corporations. The first is a regular corporation, or C-corporation. This is generally reserved for larger companies where the entity may anticipate going public at some point in time. The major advantage of this type of corporation is that it provides for the potential infusion of capital for expansion at a later time. Of course, there are always disadvantages. In this case the disadvantage, depending on one's point of view, is that the corporation is now owned by the shareholders and there is less autonomy on the part of the individuals who established the corporation. A regular corporation is also subject to double taxation. Basically, when the corporation itself generates net profit, the corporation must first pay tax on the profit before any profits are distributed to the shareholders. Upon distribution of those profits (or dividends) to shareholders, the shareholders must also pay tax on those when filing their personal income tax. So, basically the net profit is taxed twice, once on the corporation and once to the shareholders.

Many states recognize an entity called a close corporation.[6] This is usually utilized by families who want to keep all the corporate assets and decisions inside the family or another small group of people. Generally a close corporation requires that all extraordinary transactions have unanimous consent of the members of the corporation. These would include merger with another corporation, consolidation, dissolution, or sale of substantially all the assets. Often there are restrictions on the transfer of stock. For example, a shareholder who wishes to sell must first offer the stock to the corporation and then to the other shareholders.[7] If a corporation is going to be formed as a close corporation this should be noted in the articles of corporation that are filed with the state. Often a close corporation is the next step for a sole proprietorship where the business is growing and where liability concerns become an issue. With a close corporation, there is also the necessity of a buy-sell agreement among the members in the event of the death or disability of one of them or in the event of some type of shareholder deadlock on a particular issue. With a close corporation, formalities of notice are dispensed with.

The next type of corporate entity is an S-corporation. These election to become an S-corporation is filed on an IRS form 2553. The election to become an S-corporation takes places at the time of the organizational meeting within seventy-five days of the creation of the corporation in order to be

valid for that particular tax year. An S-corporation cannot have more than seventy-five shareholders, and it requires IRS approval. As with a regular corporation (and a close corporation), S-corporation members enjoy limited liability. In addition, income in an S-corporation is treated the same as it is for a sole proprietorship or a partnership, that is, there is no double taxation.

A "professional corporation" is used widely by individuals who are members of certain recognized professions such as medicine, law, accounting, and other recognized service professions.[8] Individuals would need to refer to the statute on professional corporations for their particular state to determine whether they belong to a profession that is recognized by the legislature as one that would qualify for professional corporation status. A professional corporation's members enjoy limited liability for things such as contracts, leases, and other business types of obligations. However, membership in a professional corporation cannot insulate the professional from malpractice or professional liability claims. So, for example, merely because a physician is a member of a professional corporation, that physician is not insulated from personal liability for medical negligence.

### *Limited Liability Company*

The newest business entity in existence is the limited liability company (LLC). These are set up by specific statutes in various states and are different from regular corporations at the point of inception or creation. Individuals file articles of organization instead of articles of incorporation for a limited liability company. In addition, in lieu of officers, directors, and shareholders, this type of corporate entity has members. The business is governed by an "Operating Agreement" signed by all of the members. In addition to the limited liability feature of a corporate entity, the LLC offers further protection of the members from things such as shareholders' derivative suits, since there are no shareholders to bring suit. This type of entity is often desirable when a venture has a limited duration; however, it is not necessarily limited only to ventures with a limited duration. It has some of the trappings of both a corporation and a partnership. As in a corporation, there is the limited liability feature. However, the members of an LLC are taxed as if they were in a partnership,[9] that is, each member receives a K-1 and files it with his or her income taxes.

## *PIERCING THE CORPORATE VEIL*

It is very important for a corporation or an LLC to follow the laws and rules of its state very closely with regard to formation, meetings, notices, and other matters required by law. Plaintiffs or creditors are often anxious to try to get to a shareholder's or member's personal assets by "piercing the corporate veil." If they can show that your business entity is defective in some essential manner, your limited liability protection may dissipate and they may be able to reach your personal assets.

## *CONCLUSION*

Decisions as to the form of organization when conducting any business venture are often quite complex. In addition to legal issues, personality and relationship issues often play a major role. It is important for the professional or businessperson to secure appropriate and competent legal and accounting representation or advice in attempting to establish and maintain their particular form of organization under which they operate. It is also important to realize that forms of organization can be changed as the needs of the business venture dictate. For example, what may have started out as a sole proprietorship might blossom into a full-blown C-corporation with hundreds or thousands of employees. It is difficult, if not impossible, to delineate all of the situations in which a particular corporate entity would be ideal. Suffice it to say that this chapter has provided some general guidance to the reader to be able to sit down with the appropriate business and legal professionals and engage in an informed discussion on the issues.

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Chapter 3

# Federal Food, Drug, and Cosmetic Act

Larry R. Pilot

## *INTRODUCTION*

In 1906, the Pure Food and Drugs Act (the Act) was enacted into law.[1] The simple objective of this congressional initiative was to assure the purity of food and drugs distributed in the United States and provide existing federal government departments with the authority to assure compliance with this Act.* Since that time there have been many changes to the Act and considerable growth of the government agency responsible for the enforcement of applicable laws. This agency is the Food and Drug Administration (FDA), and its activities are followed so closely by the press that hardly a day passes when there is not some story which mentions the FDA.

Why is it important for pharmacists to know about the history, responsibility, and performance of the FDA? The state is responsible for the licensure of pharmacists and, to a limited extent, the articles that are made available to the consumer through pharmacists and pharmacies. However, it is the FDA that regulates these articles and evaluates whether those who manufacture, compound, distribute, clinically investigate, or dispense these articles are in compliance with federal law. The responsibilities of the FDA, as these may affect pharmacists, range from proper storage of drugs and devices through record keeping as part of the management of drugs or

*This Act described in five pages unlawful activities related to adulteration or misbranding of foods and drugs. The definition of "drug" and the identification of adulteration made explicit reference to the United States Pharmacopoeia and the National Formulary, a distinction that continues to the present.

*Pharmacy Law Desk Reference*

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devices used during clinical investigations. Any failure by the pharmacist to comply with a range of laws and regulations* administered by the FDA can subject the pharmacist to significant civil and/or criminal penalties, even though the pharmacist has no knowledge of or intent to commit a prohibited act.

The scope of federal government responsibility and authority expanded greatly during the twentieth century, in particular with reference to drugs, devices, biologics, certain food and dietary supplements, and radiological products. The contents of this chapter cannot condense the volumes of law and regulations that relate to the lawful commercial or investigational availability of articles subject to regulation by the FDA.† Within a typical chain pharmacy, the FDA has responsibility for the regulation of all prescription and over-the-counter (OTC) drugs, all cosmetics, packaged foods, infant formula, vitamins and minerals, dietary supplements, medical devices, and radiological products such as microwave ovens, cell phones, and televisions.

The history of what is generally known as "food and drug law" and the expansion of FDA responsibility reflects a century of public policy initiatives and decisions. Consequently, on a daily basis, consumers use or experience the use of a wide variety of goods and services that are directly subject to the authority of the FDA. From use of a toothbrush and toothpaste in the morning and prior to bedtime, the normal activities of the day are filled with examples of the benefits provided by a complex and diversified consumer and health industry. The pharmacist who practices in community or hospital pharmacy is a major player in the process of delivering many of these benefits to consumers. The pharmacist is also subject to various compliance responsibilities and the possibility of enforcement sanctions as these relate to the dispensing/discovery of drugs and devices.

Knowledge of the basics of food and drug law are important assets to every pharmacist who functions in the vast arena of activities that are subject to the pervasive regulatory authority of the FDA.

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*Congress has authorized the federal government (i.e., the FDA) to promulgate specific regulations that will have the force and effect of law. Development of these regulations requires publication of a proposal in the Federal Register (Fed. Reg.) inviting public comment. The comments are reviewed and analyzed by the FDA and could result in changes to, withdrawal of, or publication of a new proposed regulation. If the process is completed, a final regulation along with an explanatory preamble will be published in the Fed. Reg. identifying an effective date. The final regulation then appears in Title 21 of the Code of Federal Regulations (C.F.R.). For example, regulations relating to Investigational New Drugs (IND) appear in 21 C.F.R. Part 312.

†The FDA estimates that 25 cents of every dollar spent by consumers for goods is for articles subject to regulation by the FDA.

## *HISTORY*

From 1906 to 1938, there were no major developments in laws affecting the purity of foods and drugs. There was no authority to review the safety or effectiveness of drugs prior to commercial distribution. If the federal government believed that drugs or foods were adulterated or misbranded, the burden to prove such allegations in federal court was the responsibility of the federal government. Early efforts to amend the law were unsuccessful, until reports of severe injury and death associated with the consumption of a liquid sulfanilamide preparation were publicized. This preparation, as manufactured by the manufacturer, utilized diethylene glycol to form the solution. The toxicity of this medication and the reports of death or adverse incidents were sufficient to prompt Congress to agree on passage of the federal Food, Drug, and Cosmetic Act of 1938 (FFDCA). This major legislative accomplishment formed the basis for the present law. Numerous major amendments to this law have occurred because of deficiencies in existing provisions of the FFDCA and changes brought about by advances in technology or alterations in public policy.

Beginning with the 1938 FFDCA and moving to the present, some of these major changes are described as follows.

### *FFDCA—1938*

This comprehensive legislative initiative[2] identified and/or defined various articles subject to explicit requirements, prohibited acts, government inspectional authority, and various penalties for violations.

The terms *drugs, new drug, cosmetic, food,* and *device* were defined, and specific sections of the FDA applied to each of these articles. For example, any "new drug" was to be subject to prior approval for safety before it could be manufactured for distribution into interstate commerce. Medical devices and cosmetics were made subject to the provisions of FFDCA for the first time. Prohibited acts applicable to the various articles were identified, as well as the penalties to be applied to the articles and those responsible for committing the prohibited act.

Most of the prohibited acts revolved around the concept of expanded descriptions of adulteration and misbranding, and these concepts continue to represent the centerpiece for FDA allegations of violations. Penalties for violations included seizure of the article, injunctive relief to prevent continuation of a violation, and criminal prosecution as either a misdemeanor or felony. The government was authorized to make inspections of various types of facilities and collect samples for analysis. However, enforcement

of the FFDCA through application of penalties was the responsibility of the Department of Justice (DOJ). The government could refuse to approve a new drug that it considered to be unsafe; however, for drugs and devices that were in commercial distribution at the time of passage of the 1938 FFDCA, the DOJ had the burden to prove in federal court that there was interstate commerce, that a violation had occurred, and that appropriate penalties should be directed by the federal court.

### *Drug Amendments of 1962*

Between 1938 and 1962, the most notable amendments to the FFDCA related to food[3] and color additives.[4] Congressional efforts to amend the FFDCA relative to drugs were unsuccessful until publicity about the teratogenic effects of Thalidomide, a sedative drug used in Europe.

These major drug amendments of 1962[5] required FDA approval of any new drug for effectiveness, as well as safety. These amendments also required that the FDA review those new drugs approved since 1938 for effectiveness, a process which ultimately took more than a decade. In addition, the FDA undertook to evaluate the safety and effectiveness of various categories of over-the-counter drugs. This continuing process has resulted in the publication of specific monograph regulations identifying acceptable ingredients for use in OTC drugs.

### *Medical Device Amendments of 1976*

Because of the phenomenal growth of the medical device industry and a U.S. Supreme Court decision that confirmed FDA discretion to regulate some devices as new drugs, a major initiative began in 1969 to develop a legislative modification to the FFDCA that would apply to devices.* Representatives of industry, consumer, and healthcare groups, the federal government, and Congress agreed on an approach that would be enacted into law on May 28, 1976. This approach recognized the difference between drug and device premarket evaluation and established requirements applicable to investigational and commercially available devices that were significantly broader and more comprehensive than those applicable to drugs and new drugs.

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*The Supreme Court in 1969 considered *United States v. Bacto-Unidisk,* 89 S. Ct. 1410 (1969) and decided that the FDA had the authority to regulate antibiotic sensitivity discs used on agar petri dishes as drugs and new drugs. This decision reversed an earlier court decision that these discs, which were used for neither treatment nor diagnosis, were devices. Consequently, the FDA had discretionary authority to regulate devices as drugs in order to implement the broad "remedial" function of the FFDCA as determined by the FDA.

### *Infant Formula Act of 1980*

Except for certain specific types of infant products subject to regulation as drugs, infant formula products were subject to regulation as foods. However, in 1979 publicized incidents of death and injury that related to consumption of a defective infant formula manufactured by a pharmaceutical company prompted passage of amendments. These amendments[6] identified required nutrients for formulas, provided recall authority, and authorized the FDA to promulgate quality-control regulations.

### *Dietary Supplement Health and Education Act of 1994*

These amendments[7] were propelled by growing public interest about dietary supplements for claims that exceeded those normally associated with vitamins and minerals also subject to regulation under the FFDCA. As a result, manufacturers/distributors of such products were authorized to market these products with limited health claims after acceptable notification from the FDA for use as a dietary supplement or new dietary ingredient. Limited labeling claims were required to avoid regulation as new drugs.

Various other minor and major amendments to the FFDCA have been enacted since 1938, and new congressional initiatives are expressed with each session of Congress. The legislative process is necessarily dynamic because of national and international issues, some of which are prompted by new discoveries and needs for regulatory reform.

## *FOOD AND DRUG ADMINISTRATION*

The FDA is responsible for the premarket review or required notifications/submissions and enforcement of requirements that apply to various articles identified in the FFDCA.* The activities of those who manufacture, distribute, clinically investigate, and/or promote such articles are also subject to compliance with laws and regulations relating to these articles. The FDA is a component of the Department of Health and Human Services (HHS), and the Commissioner of Foods and Drugs reports to the HHS Secretary.

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*The terms *drug, new drug, device,* and *dietary supplement* are a few of the terms defined in the FFDCA in Section 201 of Title 21 in the United States Code ("U.S.C."). For example, the term *drug* is identified at 21 U.S.C. § 201(g).

The resources of the FDA are applied through headquarters in the Washington, DC, area and approximately twenty District Offices throughout the United States. The structure of the Office of the Commissioner is described in Figure 3.1.

The principal organizations within the FDA that report to the commissioner are the Office of Regulatory Affairs (ORA) and six different Centers. The ORA is responsible for management of field resources located in approximately twenty District Offices and scores of resident posts. These resources consist primarily of inspectors or laboratory personnel whose responsibilities are to assure compliance with laws and regulations administered by the FDA.* For example, inspectors will inspect facilities and, where objectionable conditions are observed, these will be communicated to management of the inspected facility. Inspectional observations conveyed on an official FORM FDA 483 are reviewed by District Office personnel to determine whether enforcement action is indicated. Generally if enforcement is indicated, a recommendation is forwarded to the responsible Center for review and concurrence.

Each of the six Centers is responsible for scientific review of data and establishment of policy relating to approval, clearance, market experience, and specific requirements of law applicable to the type of article subject to the jurisdiction of the Center. These are as follows.

### *Center for Drug Evaluation and Research (CDER)*

The CDER permits use of an Investigational New Drug (IND) upon acceptable review of submission by a sponsor. It approves new drugs through review of a New Drug Application (NDA) and generic drugs through review of an Abbreviated New Drug Approval Application (ANDA). They CDER also maintains establishment registration and drug-listing information, reviews adverse experience reports, provides surveillance over safety and effectiveness of drugs and labeling/advertising claims, and makes and/or confirms field recommendations for enforcement actions.

### *Center for Diseases and Radiological Health (CDRH)*

The CDRH permits use of device clinical investigations through acceptable review of an Investigational Device Exemption (IDE) by a sponsor. It

*The inspectional authority of the FDA inspectors and limitations are described in the FFDCA at 21 U.S.C. § 704.

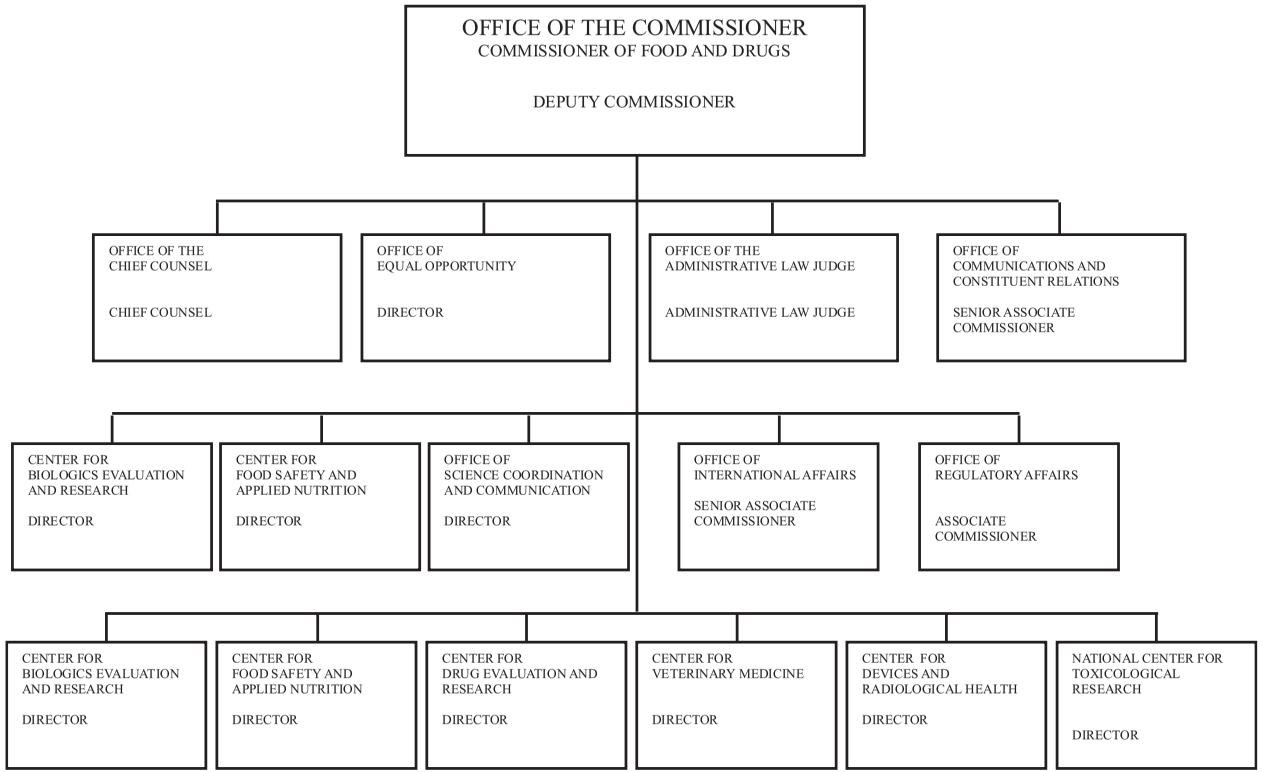


FIGURE 3.1. Department of Health and Human Services, Food and Drug Administration.

clears substantially equivalent devices for commercial distribution through acceptance of a premarket 510(k) notification and approves new devices through review and approval of a premarket approval (PMA) application. The CDRH assures safety of radiological products (e.g., TVs, microwave ovens, x-rays, laser establishment programs), and compliance with standards. The center also maintains registration and device listing information, provides surveillance over safety and effectiveness of devices and labeling/advertising claims, and makes and/or confirms field recommendations for enforcement actions.

***Center for Biological Evaluation and Research (CBER)***

The CBER administers provisions of the Public Health Service Act (PHSA)[8] relating to blood products, vaccines, and related products as well as some provisions of the FFDCA. It permits the use of new biological products through product and establishment licensure, maintains surveillance over safety of the nation's blood supply and related products, and makes and/or confirms field recommendations for enforcement action.

***Center for Food Safety and Nutrition (CFSAN)***

The CFSAN is responsible for safety and labeling of the packaged food supply; clearance of color additives for foods, drugs, and devices, and clearance of direct and indirect (e.g., packaging) food additives; recognition of lawful dietary supplements and new dietary ingredients; and safety of cosmetics. It makes and/or confirms field recommendations for enforcement action.

***Center for Veterinary Medicine (CVM)***

The CVM permits use of animal drugs through approval of New Animal Drug Applications (NADA) and is responsible for safety and effectiveness of animal drugs and devices as well as accuracy of labeling claims. It makes and/or confirms field recommendations for enforcement actions.

***National Center for Toxicological Research (NCTR)***

The CTR manages research activities relating to toxic substances and risk assessment related to the various articles subject to jurisdiction of the FDA. This Center is located in Arkansas, and unlike the other five Centers

has no specific product jurisdiction relating to clearance, surveillance, or compliance.

### *General Responsibilities of Centers and Districts*

Each of these Centers is responsible for a variety of activities that are to assure lawful commercial distribution of the various articles for which the FDA has jurisdiction. Premarket review of various types of required submissions will determine whether new articles or new claims for existing articles are lawful. Both the Center and the Office of Regulatory Affairs through its twenty District Offices cooperate in surveillance activities to assure continuous compliance of new and existing articles with a broad array of regulatory requirements.

District Office personnel are responsible for investigating complaints relating to performance and claims. This is accomplished through the use of inspectors and compliance officers who have authority to inspect facilities and gather information. A major function of the inspector is to inspect facilities to determine compliance with various regulations. For example, manufacturers of pharmaceuticals are expected to comply with regulations that define current Good Manufacturing Practice (cGMP). These regulations appear in Title 21 of the Code of Federal Regulations (CFR) at Parts 210 and 211 (i.e., 21 CFR Parts 210, 211). If the District Office believes that any person* has violated provisions of a law or regulation, it generally will present its recommendation as supported by evidence to the appropriate Center. Compliance personnel within the Center will review the recommendation and either accept or reject it. The recommendation could be limited to issuance of a Warning Letter† or could result in proceedings to apply civil and/or criminal penalties. Because these possibilities generally begin with the collection of evidence during an inspection and proceed through organizational components of the FDA and ultimately through the Department of Justice or local U.S. Attorney for resolution in a federal court, a brief description of this process as applied to drugs in interstate commerce is provided.

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*The term "person" as defined at 21 U.S.C. § 201(e) "includes individual, partnership, corporation, and association."

†The FDA exercises flexibility in its application of laws and regulations. Through publication of various procedures, policies, and guidance documents available to the public, the FDA expresses its intention. For example, the Warning Letter policy of the FDA is described to prompt voluntary compliance when the FDA believes that a violation of the FFDCA or other law has occurred and is continuing.

## *SURVEILLANCE, ENFORCEMENT, AND RESOLUTION*

### *The FDA Inspection*

The FFDCA authorizes FDA inspectors to inspect facilities where articles, in particular drugs and devices, are manufactured or held for sale in interstate commerce. These inspections begin with the appearance of the inspector and presentation of credentials along with a printed notice of inspection on a FORM FDA 482. The inspection is to occur at reasonable times, in a reasonable manner, and within reasonable limits as authorized by specific provisions of the FFDCA. During the inspection, those subject to the inspection have rights as well as responsibilities. Upon completion of the inspection, if the inspector has made observations of objectionable conditions these will be conveyed on a FORM FDA 483 and management of the facility will have the opportunity to discuss these with the inspector. The inspected facility can provide a written response to the observations in addition to discussing these during a conference with management. Generally, a report of the inspection and any management conference is prepared. This report is identified as the Establishment Inspection Report (EIR), and the content of the EIR often will determine whether the District Office will recommend an enforcement action to the appropriate Center.

### *The Center Review and Office of Commission Review*

When the District Office makes a recommendation to a Center, the recommendation is supported by the FORM FDA 483, any response from facility management, the EIR, and any other items of evidence gathered during the inspection. The compliance office in the Center will review the recommendation and either reject, accept, or request more information relating to the recommendation. If the recommendation for a Warning Letter is appropriate, then this is issued by the District Office or the Center for foreign inspections or other reasons.

A recommendation for seizure, injunction, or prosecution is referred to the Office of the Commissioner for acceptance or rejection. If accepted, the recommendation is forwarded to the FDA Office of Chief Counsel.

### *The FDA Office of Chief Counsel Review*

The Office of Chief Counsel is an organization within the Department of Health and Human Services Office of the General Counsel, and it exists to provide counsel to the FDA. Because the FDA has no authority to engage in

litigation on its own initiative, it must convey its recommendation to the Civil Division of the department or the local U.S. Attorney in the event of article seizure.

## *DEPARTMENT OF JUSTICE, CIVIL DIVISION*

This division will determine whether to accept or reject a recommendation or request more evidence. In the event that a recommendation for injunctive relief is accepted, attorneys for the Civil Division and the FDA Office of Chief Counsel will generally work together. If counsel for the defendant is known, there will be a contact to initiate a possible settlement, including execution of a consent decree. If a settlement cannot be accomplished, the matter must be resolved through a trial. It is the DOJ which must sustain the burden of proof during trial.

A recommendation for criminal prosecution may involve a notice to those who could be prosecuted for an informal hearing, but this is not required. However, the recommendation for prosecution is preceded by the review of a grand jury. Unlike the procedure for seizure or injunction, where discovery can occur prior to trial, there is no similar discovery opportunity prior to indictment. However, the DOJ is obligated to provide certain information and does have the responsibility to prove to the trial jury beyond a reasonable doubt the guilt of the defendant (i.e., individual and/or entity such as a corporation).

Once a verdict is rendered, either party has the opportunity to file an appeal with the Court of Appeals for the Federal District Court. The decision of the Court of Appeals can be appealed to the U.S. Supreme Court, which can either accept or reject the opportunity to render a final judgment. Numerous disputes involving the activities of pharmacists or pharmacies have been pursued on appeal, and a recent Supreme Court decision involved the right of pharmacists to compound medications.[9]

## *PROVISIONS OF FFDCA DIRECTLY APPLICABLE TO PHARMACISTS AND PHARMACIES*

### *General*

Pharmacists have the legal responsibility to dispense drugs on the order of a practitioner licensed by the state. Consequently, physicians, dentists, podiatrists, and other licensed practitioners can direct that a prescription drug, as identified by the FDA, an OTC drug, or one to be compounded by

the pharmacist be dispensed to a patient. Generally, the regulatory interest of the state and the FDA is to assure that patients are served and protected through the lawful activities of the pharmacist and the licensed practitioner. However, some provisions of the FFDCA or policies* established by the FDA have a direct impact on the practice of pharmacy. These include the Prescription Drug Marketing Act of 1987[10] and the Pharmacy Compounding provisions of the Food and Drug Administration Modernization Act of 1997.[11]

### *Prescription Drug Marketing Act of 1987 (PDMA)*

A by-product of the growth of the pharmaceutical industry was the opportunity to provide samples of prescription drugs to licensed practitioners. The objective of this practice was to provide samples of prescription drugs through pharmaceutical sales representatives in order to encourage licensed practitioners to prescribe a particular manufacturer's prescription drug for patients. This practice existed for decades without major incident. However, a committee of the U.S. Congress[12] undertook an investigation of these practices during the mid-1980s. This investigation identified a significant number of examples of questionable practices. These practices ranged from the adulteration of samples through repackaging and subsequent resale to questionable diversion, reimportation of previously exported drugs, and counterfeiting.

As a result, changes to the FFDCA were made through new subsections 502(c) and 503(d), and prohibited acts and penalties were also identified.[13] A primary objective of these changes was to apply controls to the distribution of samples in order to prevent varieties of abuse that could have a harmful effect on patients. Consequently, the distribution of samples became subject to extensive record-keeping requirements to reduce the possibility of diversions that were considered unlawful. Manufacturers, wholesalers/distributors, and pharmacists became subject to the additional burden of limiting distribution of samples and maintaining accurate records of such distribution. Recipients of lawful distribution of samples, such as pharmacists, must execute a written receipt to the manufacturer or distributor of record. The PDMA also imposed restrictions on the resale of prescription drugs by hospitals, charitable institutions, and other healthcare facilities.

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*The FDA maintains a number of documents, manuals, etc., which provide reference to FDA policy, procedures, etc. Many of these are also available to the public through the FDA Web site or through request under the Freedom of Information Act (FOIA). In addition, various "guidance" documents are prepared and available to give guidance to the FDA and those responsible for compliance with various provisions of the FFDCA.

Because these institutions often receive prescription drugs at reduced costs, the subsequent resale by these institutions raised issues about the integrity of the chain of control and unfair competition with wholesale distributors. Although these are exceptions, the restrictions applicable to these institutions greatly reduced the purchase for resale of prescription drugs.

The PDMA also required the FDA to promulgate regulations to establish minimum standards, terms, and conditions for the state licensing of wholesalers. On September 14, 1990, the FDA finalized "Guidelines for State Licensing of Wholesale Prescription Drug Distributors," which are located in 21 CFR Part 205. It is the responsibility of each state to apply these guidelines to their licensing of wholesalers.

### *Pharmacy Compounding—Food and Drug Administration Modernization Act of 1997*

Although the actual compounding of drugs to the order of a licensed practitioner diminished considerably soon after passage of the 1938 amendments, pharmacists continue to have the responsibility to compound when presented with a prescription order. Under some circumstances, community or hospital pharmacists may be in a position to compound a volume of a drug in anticipation of the prescription order that is likely to be issued for a patient. This practice has prompted the FDA to express the concern that such activities constitute manufacturing, for which the pharmacist is obligated to comply with FDA regulations describing current Good Manufacturing Practice.

For many years there has been tension between the FDA and the pharmacy profession over the distinction between compounding and manufacturing. The FDA did issue various statements of policy on this subject, including Compliance Policy Guides, but these statements do not have the force and effect of law.

The 1997 amendments created a new section 503A to the FFDCA which is applicable to pharmacy compounding. The objective of this section is to enable the pharmacist to engage in compounding activities that would not subject pharmacists to accusations that such compounding constituted manufacturing because of compounding in bulk for future dispensing in anticipation of the receipt of a prescription order. The FFDCA does provide explicit requirements as to permissible conduct and the FDA has documented a policy (Compliance Policy Guide 7132.16), but confusion and disagreement remain.

In 1999, a group of pharmacists that specialized in drug compounding filed a complaint against the FDA (i.e., HHS secretary) to prevent prosecu-