Pharmacy Practice and the Law

Richard R. Abood
David B. Brushwood

AN ASPEN PUBLICATION

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Richard R. Abood, BS Pharm, JD
Professor
Pharmacy Administration
School of Pharmacy
University of the Pacific
Stockton, California

David B. Brushwood, BS Pharm, JD
Professor
Pharmacy Health Care Administration
College of Pharmacy
University of Florida
Gainesville, Florida

AN ASPEN PUBLICATION®
Aspen Publishers, Inc.
Gaithersburg, Maryland
1994

Library of Congress Cataloging-in-Publication Data

Abood, Richard R.
Pharmacy practice and the law/Richard R. Abood, David B. Brushwood.
p. cm.
Includes bibliographical references and index.
ISBN 0-8342-0321-9
1. Pharmacists—Legal status, laws, etc.—United States.
2. Pharmacy—Law and legislation—United States.
3. Drugs—Law and legislation—United States. I. Brushwood, David B. II. Title.
[DNLM: QV 33 AA1 A2p 1994]
KF2915.P4A93 1994
344.73'0416—dc20
[347.304416]
DNLM/DLC
for Library of Congress
94-11751
CIP

Editorial Resources: Ruth Bloom
Library of Congress Catalog Card Number: 94-11751
ISBN: 0-8342-0321-9

Printed in the United States of America

1 2 3 4 5

The authors dedicate this book
to their spouses, Jeri and Chris;
and to their children,
Aaron, Meredith, Chuck, Paul and John.

Preface

Pharmacy Practice and the Law reflects the premise that a pharmacy law course should acquaint pharmacy students with much more than the laws and regulations that govern dispensing practices. Such a course should also provide pharmacy students with an in-depth exposure to legal and ethical issues. Because pharmacists now have greater authority and responsibilities for drug therapy decision making and patient care outcomes, they need to understand a broad array of complex legal and ethical issues that affect the profession and the drug distribution system. The authors have designed this book primarily as a textbook for use in pharmacy law courses, but practitioners will also find the information applicable and instructive.

The chapters in this book have been structured to conform to the approach taken in many pharmacy law courses. Chapter 1 contains a general discussion of the law, the sources of law, and the structure and process of the legal system. It provides a background to students which can relate the substantive information and discussions that follow.

Chapters 2, 3, and 4 contain all the information about federal pharmacy laws that a student needs to pass a state pharmacy board examination; however, the chapters were not written with that objective. Conforming to the premise of the text, these chapters address what pharmacists should know in their role as clinicians, decision makers, and leaders. Because of their current importance to pharmacy practice, many issues (e.g., pharmacy compounding and the dispensing of controlled substances for legitimate medical purposes), have been discussed in more detail. Knowing that many pharmacy law professors like to refer directly to the statutes and regulations, the authors have liberally quoted or summarized them in the text and have included explanations when necessary.

An entire chapter (Chapter 5) is devoted to the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) because of its profound effect on professional practice standards. Chapter 5 forms the bridge between the discussion of federal control

of the drug product that appears in the early chapters and the discussion of the state's control of the pharmacy profession that appears in Chapter 6. The purpose of Chapter 6 is to provide a general knowledge of state pharmacy laws. With such a background, students can better understand their own state practice act and can appreciate the differences and similarities in several other state practice acts.

Because many current, controversial legal issues involve drug advertising and promotional activities, Chapter 7 is devoted to this subject.

Chapters 8, 9, and 10 address the very important issues of professional liability and drug product liability. Chapter 8 focuses on the manner in which pharmacists have traditionally faced negligence liability. Chapter 9 provides a more theoretical examination of pharmacist liability in light in OBRA-90, professional standards of pharmaceutical care, and pharmacists' expanded responsibility to perform discretionary functions. Chapter 10 differentiates product liability from professional liability and introduces the concept of strict liability.

Chapter 11 stands apart as a unique discussion. It distinguishes some of the legal issues that hospital pharmacists and hospitals face from those that community pharmacists and pharmacies experience.

Chapter 12 and 13 are closely related. Chapter 12 describes the antitrust laws, which play a major role in pharmacy practice and economics. Chapter 13 specifically addresses the antitrust laws, as well as other laws, case law, and important legal events, that affect third-party plans.

Chapter 14 contains a discussion of employment law. The chapter raises several legal issues in this area of law that are of frequent concern to pharmacists.

Chapter 15 bridges the subjects of law and ethics by distinguishing law from ethics and demonstrating how they sometimes merge. Chapter 16 describes ethical dilemmas and alternatives that pharmacists may choose. Chapter 17 supplements Chapters 15 and 16 by providing ethics cases for classroom discussion.

The authors recognize that each instructor has his or her own way of teaching a pharmacy law course and have organized the materials within the chapters to accord some flexibility. Instructors can structure assignments from the chapters to reflect their own unique approach to learning. Furthermore, if the pharmacy law course cannot accommodate all the subject matter, certain chapters can be useful in other courses. For example, the chapters on employment, unfair competition, and third-party legal issues would easily fit into a pharmacy management or business law course. The chapters that focus on ethics could be part of an ethics course, and the chapter on hospital law could be part of a hospital pharmacy course. Some pharmacy curriculums include a course in contemporary pharmacy issues, and the chapters on professional liability, product liability, and ethics could be useful in such a course.

Throughout *Pharmacy Practice and the Law,* the authors have attempted to show that the law is a fluid entity subject to challenge and interpretation; it is not

a set of permanent black and white rules. To demonstrate this point, the authors have incorporated actual legal cases into the discussions whenever possible. Readers who want more information about a particular area of law should read the actual cases summarized or cited in the discussions and should refer to the statutes and regulations that have been extensively cited.

The authors wish to thank *Bruce D. Weinstein, PhD,* Adjunct Assistant Professor of Behavioral and Administrative Pharmacy and Associate Director of the Center for Health Ethics and Law at West Virginia University, Morgantown, West Virginia, for his contribution, "Ethical Issues in Pharmacy" (Chapter 16).

The authors also wish to thank those individuals who reviewed the first manuscripts and provided valuable suggestions. Thanks also to our departmental colleagues who endured our ever constant excuse of "I have to work on the book." Special thanks to our families, who are unquestionably the happiest that this book has finally been published.

Table of Contents

1

The Law and the Legal System

Chapter Objectives

Upon completing this chapter the reader will be able to:

- Identify the reasons why society regulates medications and the limits on this regulation.
- Distinguish the sources and types of law in the United States.
- Understand generally the federal and state legislative process.
- Understand generally the structure and function of the judicial system.
- Distinguish between federal authority and state authority to regulate medications and pharmacy practice.

The law directly affects every member of society. It affects pharmacists more profoundly than it does most other segments of society, since pharmacy is the most regulated of all health care professions. The extensive regulation and control of pharmacy is understandable. In view of the fact that patients entrust their health, safety, and lives to pharmacists, society has a right to expect and demand that pharmaceutical products and services meet well-defined standards and requirements. Pharmacy laws specify society's expectations of pharmacists. No pharmacist should engage in any type of practice without a thorough knowledge and understanding of the law as it relates to pharmacy practice.

NATURE AND ROLE OF LAW

Laws may generally be defined as rules of 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 or process by which people in society can resolve their disputes and problems in a way that does not involve force and consistently yields decisions acceptable to most of society. It is a socially prescribed process through which people declare their collective will and express their norms and values. Therefore, the law attempts both to be fluid and to maintain a reasonable degree of certainty. To achieve this certainty, the law assumes the existence of a decision maker, such as a legislature, an administrative agency, or a court, whose function is to resolve disagreements by providing definitive, final answers that reflect society's expectations.

Answers in law are not often easily derived or black and white in nature. Many times, an attorney's reply to a legal question is, "It depends." Many laws are necessarily vague and variable because they deal with human relationships. It is impossible for lawmakers to foresee all the countless, ever-changing human relationships that may occur. Courts can often reach decisions in law only after considerable reasoning based on several factors, including

- 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 inherent in the law is important 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 conjures up images of an overbearing, paternalistic bureaucracy that forces people to behave in certain ways. If it is assumed that people tend to act in their own self-interest by making decisions that will increase their happiness (e.g., higher income, more free time, improved health status), then why does the government need to make decisions for people? The answer is that the free market does not always act efficiently to promote

happiness-maximizing behavior. Such market inefficiency, called a "market failure," serves as justification for government regulation.

Four types of market failures are relevant to drug use: (1) public goods, (2) externalities, (3) natural monopolies, and (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.

Public goods are those necessary and beneficial goods 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. 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 can 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. Vaccines, on the other hand, are beneficial to a great number of patients, but carry a tremendous risk of product liability lawsuits that could bankrupt the manufacturer. Thus, although orphan drugs and vaccines have enormous social value, government regulation is required to ensure their availability.

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. The parties who are directly involved in using the good do not consider the indirect impact of the production or consumption of the good on a party who 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. Utilities that provide electricity, water, and natural gas are natural monopolies, for example, 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 prior to purchase (e.g., a chair or a tablet of paper). Consumers can evaluate other goods only after purchasing them (e.g., a used car or 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 is often difficult for untrained individuals to understand these benefits and detriments. To minimize the possibility of market failure due to 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 action. 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.

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.

Human relationships, to the extent that they are well defined by society, are usually best left alone by legal institutions. In families, professions, and religious groups, for example, 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 accept a legal pronouncement.

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" (1986, 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. Yet, 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.

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. Most persons say that the legislative branch of government makes the laws, while 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 the law—together with what can be considered a fourth branch of government, administrative agencies.

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 in such a short document is quite remarkable and illustrates the timeless manner in which the Constitution was written.