PHARMACY EDUCATION SERIES

PHARMACY

What It Is and How It Works

Fourth Edition

WILLIAM N. KELLY

ROUTLEDGE

PHARMACY

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WILLIAM N. KELLY

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Foreword

At the time of the publication of this textbook, we find ourselves in the most dynamic, and simultaneously turbulent, moments in the evolution of healthcare, possibly since the early sixteenth and seventeenth centuries. It was during that time period that scientific methods and discovery gained firm traction, leading to advances in surgical interventions, improvements in human anatomical exploration, and enhanced understanding of medicinal agents for the curing of disease.

During that time period there existed the presence of intense skepticism of the "new" discoveries. Scientific discovery was viewed with doubt and cynicism; those individuals seeking new discoveries were subject to multiple levels of derision, or worse, bodily harm. Ultimately, their discoveries would be accepted, and establish a new platform for the translation and implementation of healthcare for many centuries to come. In this early part of the twenty-first century, we find ourselves at a new point of healthcare evolution. Exponential technological advancements will fundamentally, and permanently, change our approaches to the delivery of healthcare.

As healthcare systems have evolved, so has their complexity. Government-sponsored insurance versus private-pay insurance; single-payer systems and competitive healthcare markets; accountability for health outcomes; scrutinized reimbursement schedules for health providers; and equitable access to healthcare by persons from all communities. This complexity is not confined to the United States of America; many of these points touch on almost all communities across the world. Healthcare providers around the world face these facts, and still willingly dedicate their lives to assisting and treating people suffering from countless ailments. And therein lies the necessity of this textbook; the entire healthcare evolution that has occurred over many centuries has always focused on improving the human condition, to seek to improve and maintain the quality of life for people in communities through multiple medical means.

The profession of pharmacy is undergoing the same intense evolution that all of medical practice has endured. Pharmacy as a profession is complex, diverse, and very necessary. Differential diagnosis of patients is not enough to treat them adequately. I have often taught my students that once a diagnosis is made, the only interventions are (1) physical manipulation (surgery, therapy, etc.); (2) medication administration; (3) lifestyle modification; or (4) nothing. Of course, to do nothing is in direct violation of our professional oaths as clinicians. The profession of pharmacy, with all of its intricacies, has always been one of the most critical components of healthcare. This shall remain the case for many decades to come.

Medication management (including administration, distribution, therapeutic monitoring, safety monitoring, policy development, education, and innovation) is among the most important medical interventions to treat patients effectively and make earnest attempts to improve their condition. While physician practice is segmented into multiple specialties, pharmacy practice is multifaceted as well. In fact, there is almost no medical specialty that does not require a pharmacist to be knowledgeable about all aspects of that specialty. Dr. William Kelly has compiled the most comprehensive textbook outlining numerous facets of the pharmacy profession, all while establishing and maintaining concentration on the patient as the focal point of our professional efforts.

Healthcare has evolved from the sixteenth and seventeenth centuries to now include genomics, pharmacogenomics, analytics, informatics, big data, and artificial intelligence as

key emerging components for the delivery of care. I once saw on social media "Data and analytics may one day become more important than the clinician!" Despite these technological advances, the human body remains terrifically consistent with regard to drug receptors, organ systems, human emotions, and the basic necessities of food and shelter. This textbook by Dr. Kelly, with assistance from colleagues, makes the case for the profession of pharmacy to be its own sub-specialty, and describes how pharmacists interact with all of the aforementioned aspects of healthcare. The pharmacy profession must now morph and adjust to the ambiguity of healthcare, without vacating the core DNA of the pharmacy profession. Every reader will extract key components to augment their professional progression and understanding, which will lead to a higher quality of care provided to people in all communities.

I am sure the pharmacy community, along with medical and business communities, will embrace the efforts of Dr. William Kelly to carefully and thoroughly describe the pharmacy profession in fantastic detail. I congratulate him for his vision to move all of healthcare forward with this textbook.

Kevin Sneed
Dean of the University of South Florida College of Pharmacy

Preface

I was 8 years old when I fell in love with pharmacy. In the early 1950s, pharmacy was much different from today. The corner drugstore was the only place you could go to have your prescription dispensed. My corner drugstore was Barber's Drugstore. The large glass window in front of the store framed several "show globes"—large, clear glass containers dispensed with colored water—a symbol of pharmacy at the time. Some of the show globes sat in ornate stands or were hung from the ceiling. The window also had interesting displays of medical items and the latest merchandise to purchase. It was the job of the pharmacy intern to change the displays every several weeks.

The corner drugstore was more than a store and a pharmacy. It was a neighborhood asset. Barber's Drugstore had a soda fountain where you could purchase a Coke: 5¢ for a small one and 10¢ for a large one. It was a place where you would see and chat with your neighbors and friends, and for us kids, where we could "hang out."

There was no self-service at the drugstore. Products were stored behind the counters in glass cases. You had to ask for what you wanted. After purchasing an item, you waited as white paper was pulled off a roller, cut to size, and your package was neatly wrapped and tied with string.

I was intrigued with the pharmacist, Mr. Barber. He wore a crisp, clean, white druggist's jacket; was well respected in the community; and was everyone's friend. He always took time to say hello to everyone who came in the store. I asked Mr. Barber so many questions about pharmacy that he finally invited me behind the counter to watch him work with the medicine. I loved what I saw—all of the chemicals, bottles, and equipment. Mr. Barber compounded most of the medications, measuring and mixing the ingredients, pouring the medicine into tiny colored capsules, and then putting the capsules into small cardboard boxes that measured just 2 or 3 inches wide. He carefully placed a label on top of each box.

When Mr. Barber asked me to be the delivery boy and to do odd jobs around the pharmacy, I was delighted. I swept the sidewalk, washed the front window, took out the trash, and delivered medicine on my bike each day after school. When I could, I watched Mr. Barber prepare and dispense medication. I could not read the prescriptions because they were in Latin.

When I reflect on those days and think about what pharmacy is like today, I see tremendous change and progress. Fifty years ago, pharmacists earned a 4-year bachelor-of-science degree. Today, they earn a 6-year doctor of pharmacy degree. There were no residency programs, just internships—additional on-the-job apprenticeships.

Back then, pharmacists dispensed prescriptions as they were written unless the prescription was for an obvious overdose. Pharmacists were not to question the doctor about the patient or the intended use of the prescription. This interfered with the "doctor–patient" relationship. Today, pharmacists are taking responsibility for the patient and for the outcome patients receive from their medication. Some pharmacists are allowed to prescribe medication, monitor a patient's therapy, and recommend initial therapy for patients. Some doctors request pharmacists to perform complex mathematical calculations to dose critically sick patients with powerful drugs.

Patients' and doctors' respect for pharmacists has never been higher. Pharmacists in some community pharmacies work with patients, the patient's doctor, and the patient's insurance company to manage the patient's disease states. Some community pharmacists are providing immunizations for patients.

There are times I have been impatient with the profession not moving forward quickly enough. That changed when I reread the 2009 Whitney Award (the highest award in organized pharmacy practice) address by Paul Abramowitz, PharmD. Paul graduated shortly after me from the University of Michigan, so he has watched most of the same changes I have witnessed in pharmacy.

In explaining the metamorphosis of the profession, Dr. Abramowitz covered the period from 1978 to 2009. I was surprised at his documentation of so many changes, many of which I had forgotten. This long list of accomplishments changed my perception that the profession moves too slowly. When I stood back and looked, I could see how many changes have been made during my time as a pharmacist.

Doug Hepler, the chief architect of pharmaceutical care, in his 2010 Whitney Award address, "A Dream Deferred," discussed the issue of why, after 30 years, pharmaceutical care has not been universally implemented. Although the reasons for this are diverse, the dream is not dead, just deferred. At the end of his address, Dr. Hepler challenged new members to accept the legacy built by the many hard-working pharmacists before them and to keep pursing the dreams of the profession.

Since 2010, the profession has been plodding along, trying to determine how it can better explain its societal value, how it fits into the new era of healthcare reimbursement (accountable care), and if it can become a "paid provider" (paid for clinical services—those provided beyond dispensing).

Since the last edition of this book (2012), the major changes have been in: informatics, with some clinical pharmacists gaining more practice flexibility using collaborative practice agreements with physicians; medication therapy management (MTM); antimicrobial stewardship; pharmacogenomics; transitions in care; and 340B payment compliance.

This book is written to teach you about pharmacy but to encourage you to seize the vision, and to assert your professional autonomy on behalf of patients and for achieving the dream. After 50 years of practicing pharmacy, I can say confidently that your job as a pharmacist is to always (1) be patient-centered, (2) practice at the top of your license, (3) keep up-to-date on your drug knowledge, (4) practice autonomously (guard it against outside intrusion by non-pharmacists), and (5) improve the profession.

If you are reading this book because you are a student, please know you are about to become a member of one of the greatest professions, and that we are right on the cusp of achieving the goal of becoming a true clinical profession. If you are a student pharmacist reading this, I want you to know that I believe the highest and most dramatic improvements in the profession are going to occur during your lifetime. Writing the book has been a wonderful experience. This is the fourth edition, and I am still awed and proud of the rich history and accomplishments of pharmacy. Many pharmacists have worked hard to make pharmacy what it is today. After writing the book, I am more fascinated with pharmacy than ever before.

I hope you enjoy the book.

Acknowledgments

I could not have completed this edition of *Pharmacy: What It Is and How It Works* without the help of my wife Trudy, who is a superb reference librarian. She has worked on all four editions, doing the research, sending out the copyright permissions, and proofreading. This book is starting to feel like a third child of ours.

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Dr. Kelly is the author of *The Good Pharmacist: Characteristics, Virtues, and Habits*, published in 2011; *Prescribed Medication and the Public Health: Laying the Foundation for Risk Reduction*, published in 2006; and, co-author of *Leadership and Management in Pharmacy Practice* (2nd ed.), published in 2015.

He lives with his wife, Trudy, in Clearwater, Florida, and enjoys reading, swimming, golf, spending time with his children and grandchildren, stamp collecting, and serving as a medical missionary in Central America.

1 What Is Pharmacy?

INTRODUCTION

When asked about pharmacy, most people will say that a pharmacy is a drugstore or a place where you purchase medication. Some may talk about pharmacists (sometimes incorrectly referred to as druggists) and drugs. Most people do not think about pharmacy as a profession.

This chapter is a brief introduction to pharmacy. It considers four basic questions:

1. What is pharmacy?
2. What is the purpose of pharmacy?
3. What is the value of pharmacy?
4. What is its future?

To address these questions, this chapter begins with information on the nature of pharmacy as a profession. It then examines a brief history of pharmacy, what shapes it, and how it is still evolving as a profession. It ends with a discussion on the value of pharmacy and its future.

LEARNING OBJECTIVES

After reading this chapter, you should be able to:

- Provide at least five reasons why pharmacy is a profession.
- State the purpose of pharmacy.
- Provide three factors that control pharmacy.
- State at least three ways the pharmacy profession is shaped.
- Discuss how pharmacy is changing.
- Make a convincing argument that the pharmacy profession provides value to society.
- Define the term "provider status," and discuss (briefly) pharmacy's current efforts to achieve that status.
- Discuss briefly what the author believes the future is for pharmacy, along with your ideas.

PHARMACY

Pharmacy is a place, a profession, and sometimes a business. A pharmacy is a place where licensed pharmacists oversee the dispensing of medicine after receiving a valid *prescription* or *drug order* written or electronically transmitted (*e-prescribing*) by a legal prescriber. A pharmacy is not a drugstore. Some businesses today do not have pharmacies but do sell medicines bought without a prescription (over the counter [OTC] drugs) along with other nonmedical items such as cosmetics, hardware, and magazines. A pharmacy can be a free-standing building, or it may be found inside other places, such as a drugstore, a medical building, or a hospital.

The word *medicine* in defining pharmacy (as a place) is preferable to the word *drug*, as is the word *pharmacist* over the word *druggist.* In today's society, *drug* usually suggests an unlawful drug or drug abuse. The word *medicine* is more positive; its consumption usually improves health. The word *druggist* is derived from the negative word *drug*; thus, *druggist* is a less-acceptable term for pharmacist.

Pharmacists are registered by a board of pharmacy and therefore are designated *registered pharmacists* (RPh). However, this title is only conferred after passing rigorous national, state practice, and law examinations. The preferred term is *licensed pharmacist*.

The last part of defining pharmacy (as a place) includes the words *legal prescriber*. This is someone approved by the state legislature to prescribe drugs—a licensed physician, dentist, or veterinarian and sometimes a physician's assistant or nurse practitioner, depending on the state. *Note*: Pharmacists must always be vigilant for bogus prescriptions written by drug abusers who are trying to obtain narcotics and other controlled substances illegally.

Pharmacy also means the practice of pharmacy as a profession. To discuss this further, we need to explore what it means to be a profession and a member of a profession (a professional).

WHAT IS A PROFESSION?

A *profession* is a disciplined group of individuals who adhere to ethical standards and uphold themselves to and are accepted by the public. The individuals in the group possess special knowledge and skills in a widely recognized body of learning derived from research, education, and training at a high level. They are prepared to exercise this knowledge and these skills in the interest of others.[1]

There are three widely and commonly recognized characteristics of a profession: study and training, measure of success, and associations.[2]

Study and Training

Instruction and specialized training provided by a professional college over an extended period of time provide professional students with the knowledge and specific skills to practice their profession. In addition, professional students learn the history, attitudes, and ethics of the profession. They also must accept the duties and responsibilities of being a professional. Before being allowed to practice in the profession, a pharmacy graduate must submit to comprehensive national and state examinations. This is to assure the public that the applicant meets the minimum requirements to practice the profession.

Pharmacists must have 2–4 years of college education before being accepted into a 4-year Doctor of Pharmacy (PharmD) program at a college or university, for a total of 6–8 years. There is a trend by many pharmacy schools to require (such as medical schools) a four-year degree prior to being accepted into a pharmacy school.

They must then have 1000–2000 hours of internship training before eligibility to take licensure examinations on drugs, professional practice, and the law.

Measure of Success

Success in the profession is based on service to the needs of people, for which the professional usually receives a fee. However, the primary reward for a true professional is in providing service to the client. Note that in healthcare, the client is the patient. The focus of a pharmacist's

practice should be on the patient and the patient's needs. Counseling patients about their medication and disease without financial compensation has been a part of pharmacy practice since its beginning.

Associations

As a profession, each member works closely with other members and members of other professions. One of the mechanisms for close association is international, national, state, and local societies composed of members of the profession. Members network with one another, work on developing or improving standards of the profession, and attend educational sessions to improve their skills or learn new methods.

Pharmacists have many professional organizations at the local, state, national, and international level (see Chapter 16, "Pharmacy Organizations"). Generously sharing information with each other without hesitation is one of the strengths of the pharmacy profession.

The Business of Pharmacy

Pharmacy can also be a business. Pharmacists who own their own pharmacy or are managers of a pharmacy are business men and women as well as *practitioners*—patient care providers. Thus, they have two goals: (1) to care for patients and (2) to make enough profit to stay in business.

It is equally important for pharmacists, pharmacy interns, and other pharmacy workers in a pharmacy business to understand the goals of the business and to do all they can to help make the business successful. The more they do this, the more successful the business will be, and in turn, the more successful they will become.

A BRIEF HISTORY OF PHARMACY

Early Development

No one can be sure when pharmacy started.[3] However, early humans most likely discovered that applying water, mud, and some plants soothed the skin. By simple trial and error, humans slowly discovered things in nature that helped them.

The earliest known record of the art of the *apothecary*—the forerunner of the pharmacist—is in Babylon (today's Iraq), the jewel of ancient Mesopotamia (now Iran and previously Persia). Practitioners at this time (ca. 2600 BC) were priests, pharmacists, and physicians, all in one. The Chinese also contributed to early pharmacy (ca. 2000 BC).

From this point forward in history, the art of crude medicine preparation and pharmacy was increasingly refined by the Egyptians, the Greeks, and the Romans. One Roman in particular, Galen (130–200 AD), is of special note. He practiced and taught pharmacy and medicine in Rome and is revered by both professions today. His principles of preparing and *compounding* (mixing ingredients) ruled in the Western world for 1500 years.

Separation of pharmacy and medicine took place in about 300 AD and is portrayed by twin brothers of Arabian descent, Damian, the apothecary, and Cosmas, the physician. These twin brothers are considered the "patron saints" of pharmacy and medicine, respectively. The word *apothecary* (meaning "pharmacist") is of European origin and is the antecedent of the word *druggist*. There are still apothecaries in the United States today, and they restrict their community practices to prescriptions and specialty medical products.

Plants with medicinal value were cultivated in monasteries by monks between the fifth and twelfth centuries. The Arabs were the first to have privately owned drugstores called apothecary shops. These shops were open street stalls that sold wines, sweets, syrups, perfumes, and medicines.[4] Public pharmacies like these did not appear in Europe until the seventeenth century.

The first official compendium of drugs, or *pharmacopoeia*, originated in Florence, Italy. It was compiled in 1498 by the Guild of Apothecaries and the medical society. The Society of Apothecaries of London was the first organization of pharmacists in the Anglo-Saxon world. It was formed by pharmacists who broke away from the Guild of Grocers, which had jurisdiction over them. Early English apothecaries compounded and dispensed drugs and provided medical advice.[4]

Community Pharmacy in Early America

Apothecary shops in the United States first appeared in Boston, New York, and Philadelphia.[5] Apothecaries prescribed as well as dispensed drugs, as did some physicians. Few of these apothecaries were formally trained as pharmacists.

No one knows for sure who the first apothecary was in America. However, an Irish immigrant, Christopher Marshall, developed a pioneer pharmaceutical enterprise. The Marshall Apothecary in Philadelphia (Figure 1.1) was a leading retail pharmacy, a large-scale chemical manufacturer, a place for training pharmacists, and an important supply depot during

FIGURE 1.1 The Marshall Apothecary Shop in Philadelphia, 1729. (From Bender GA and Thom RA, *Great Moments in Pharmacy; The Stories and Paintings in the Series, A History of Pharmacy in Pictures, by Parke Davis & Company*, Detroit, MI: Northwood Institute Press, 1965. Courtesy of Pfizer Inc. and Northwood Institute Press.)

the American Revolution. Eventually, the apothecary shop was managed by Christopher Marshall's granddaughter, Elizabeth. She is considered to be America's first female pharmacist.

Most of the early American apothecaries sold various items, including crude drugs, chemicals, imported nostrums (secret cures), spices, teas, and coffees. Various European settlements (Dutch, German, Spanish, French, and English) and the American Indians made important contributions to the unique and developing *materia medica* in the American colonies.[6]

By 1721, there were 14 apothecary shops in Boston, and by 1840 some apothecaries were starting to become wholesalers, importing and buying large quantities of medicinal agents to be sold to other apothecaries. The terms *druggist* and *drugstore* may have had their beginnings here.[4]

Patents were first granted in 1790 by the newly founded United States of America. Such patents were granted for so-called secret cures. Patents granted protection of the knowledge of the ingredients for 17 years. The trade in English and American patent medicines became the backbone of American drugstores.[7,8]

Apothecaries made their own private-label *patent medicines*, and companies were formed to produce various curious mixtures.[9] Patent medicines flourished, and their popularity moved west with the settlers in the United States. Pioneers often used patent medicines before they went to a doctor for help.

America's first association of pharmacists, the Philadelphia College of Pharmacy, was founded in 1821 at Carpenter's Hall, the same place that birthed the country's Declaration of Independence. The reasons for forming this association were to improve the practice of pharmacy and the discriminatory classification by the University of Pennsylvania medical faculty in granting an unearned master of pharmacy degree to a number of "deserving apothecaries" in Philadelphia. William Proctor Jr., who served the college for 20 years, is considered by some to be the father of American pharmacy.

The American Pharmaceutical Association (APhA), now the American Pharmacists Association, began in 1852. It was started to improve communication among pharmacists, to develop standards for education and apprenticeship, and to improve the quality control of imported drugs.

The extraordinary financial demands of the Civil War resulted in patent medicines becoming taxed in 1862.[10] Revenue stamps had to be affixed on the patent medicines in such a way that the stamp was torn when the container was opened (see Figure 1.2). Although this helped make patent medicines the domain of large companies, drugstores flourished, and apothecaries (now called druggists) became managers as well as practitioners.

From early 1900 through the early 1940s, druggists continued to compound and prepare medicines for patients. However, drug manufacturers were starting to discover the active ingredients of various products derived from nature. Gradually, medicines were made with active ingredients and made available for druggists to dispense directly to patients.[11]

The abundance of drugstores made competing difficult. Shortly after World War II (1945), a young entrepreneur from Erie, Pennsylvania, named Jack Eckerd, made his mark by cutting prices and introducing self-service in the pharmacy.[12] Up until the late 1950s, all goods in drugstores were behind the counter in glass cases. Customers had to ask for the items they wished to buy. Eckerd also made sure each employee had a stake in the business. These principles paid off, and Eckerd expanded his business to a chain of drugstores in New York and Delaware. Other chain drugstores following Eckerd's business principles soon sprang up in other parts of the country.

FIGURE 1.2 Examples of tax stamps used on patent medicines in the late 1800s and early 1900s in the United States.

Hospital Pharmacy in Early America

The first hospital pharmacy (Figure 1.3) was established at the Pennsylvania Hospital, founded in 1752 by Benjamin Franklin, in Philadelphia.[13] The first hospital pharmacist was Jonathan Roberts. However, it was his successor, John Morgan, who made the biggest impact. Morgan, as a pharmacist and later as a physician, championed prescription writing and the separation of the two professions. By 1812, the New York Hospital also had a full-time pharmacy practitioner.[13]

Hospital pharmacy practice developed slowly. By 1921, it was estimated that only 500 of the 6000 hospitals in the United States had pharmacists on staff.[14] Most immigrants to the United States were Roman Catholic, and they built Catholic hospitals. The number of pharmacists was increased by the willingness of the Catholic Church to provide training in pharmacy for nuns.[13]

Between 1920 and 1940, an awakening came about because of hospital pharmacists' growing awareness of the problems and the potential of their specialty.[15] The first hospital pharmacy internship program was started by Harvey Whitney in 1927 at the University of Michigan Hospital in Ann Arbor, Michigan.

A section for hospital pharmacists within the APhA was established in 1936. The American Society of Hospital Pharmacists (ASHP) was formed in 1942 and ended joint membership with the APhA in 1972. In 1995, the organization changed its name to the American Society of Health-System Pharmacists since many of its members were practicing in organized healthcare settings rather than exclusively in hospitals.

Pharmacists made many contributions to the American Revolutionary War, World Wars I and II, and the Korean, Vietnam, and Gulf Wars. The contributions of pharmacists during World War II are documented by Worthen.[16,17]

For more information on the history of American pharmacy, consult the American Institute of the History of Pharmacy, located at the School of Pharmacy at the University of Wisconsin (http://www.aihp.org) in Madison.