

SOLUTIONS MANUAL

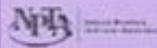
THE PHARMACY TECHNICAL SERIES

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Fundamentals of Pharmacy Practice



Mike Johnston



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Pharmacy Law and Ethics

LEARNING OBJECTIVES

After completing this chapter, students should be able to:

- Describe the purpose of the Food, Drug, and Cosmetic Act (FDCA).
- List the major amendments and acts related to the FDCA.
- Compare and contrast adulteration and misbranding.
- List the requirements of the FDCA pertaining to legend and over-the-counter (OTC) drugs.
- Describe the Controlled Substances Act (CSA).
- List and provide examples of the various schedules of controlled substances.
- Describe special requirements of Drug Efficacy Amendments (DEA) registrants.
- Describe and define Health Insurance Portability and Accountability Act (HIPAA).
- Discuss the moral principles involved with ethics.
- Contrast ethical theories and their possible outcomes in a pharmacy setting.
- Describe the Code of Ethics for Pharmacy Technicians adopted by the American Association of Pharmacy Technicians (AAPT).

CHAPTER OVERVIEW

Before introducing the actual operations of pharmacy practice, Chapter 2 builds a solid foundation for the student regarding the regulations, legalities, responsibilities, and ethical decisions he will face in pharmacy. This chapter begins with ethics—the grey area—and then moves on to the laws and regulations pertaining to pharmacy—the black and white areas. Chapter 2 covers the major laws and amendments that regulate the practice of pharmacy on a national level. It does not, however, cover state-specific regulations as these vary greatly from state to state.

Chapter Outline

Learning Objectives

Introduction

Ethics and the Pharmacy Technician

Defining Ethics

Moral Philosophy

Practicing Ethics

Ethical Theories

 Consequentialism

 Nonconsequentialism

 Social Contracts

 The Ethics of Care

 Rights-Based Ethics

 Principle-Based Ethics

 Virtue-Based Ethics

 Law

 Codes of Ethics

Pharmacy Technician Code of Ethics (1996)

 Preamble

Overview of Pharmacy Law

 FDCA—Food, Drug, and Cosmetic Act

 Durham–Humphrey Amendment of 1951

Kefauver–Harris Amendments of 1962

Drug Abuse Control Amendments of 1965

Comprehensive Drug Abuse Prevention and Control Act of 1970

Medical Device Amendment of 1976

Legend Drugs—Prescribing and Dispensing

OTC Drugs

PPPA

Adulteration versus Misbranding

Adulterated Drugs

Misbranded Drugs

New Drugs

Samples

Medical Devices

CSA—Controlled Substances Act

Schedule I

Schedule II

Schedule III

Schedule IV

Schedule V

The DEA

Activities Requiring DEA Approval

Prescribing and Dispensing Controlled Substances

Ordering

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Record Keeping

Reporting

Inspections

Omnibus Budget Reconciliation Act of 1990

HIPAA

Conclusion

Chapter Review Questions

Resources and References

TOPICS FOR DISCUSSION

- reasons why major pharmacy laws are introduced, such as the sulfonamide disaster
- the impact of HIPAA and patient confidentiality
- the liability of pharmacy technicians

SUGGESTED ACTIVITIES

- Provide each student with an ethical case study. Allow students to research their topic and then present it to their classmates, along with what their decision would have been and why.
- Provide each student with a lawsuit case study. Allow students to research their case and then present their findings to their classmates.
- Have students research liability insurance options for pharmacy technicians, including providers, cost, coverage, and so forth.

CHAPTER REVIEW ANSWERS

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| 1. d | 5. a | 9. d |
| 2. a | 6. a | 10. b |
| 3. b | 7. d | |
| 4. b | 8. a | |

