Essentials of Pharmacology for Health Professions 10th edition Colbert Solutions Manual

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Solution and Answer Guide

COLBERT, JAMES & KATRANCHA, ESSENTIALS OF PHARMACOLOGY FOR HEALTH PROFESSIONS, 10E, 2026, 9798214116068; CHAPTER 1: CONSUMER SAFETY AND DRUG REGULATIONS

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CHAPTER REVIEW QUIZ ANSWERS

1. The first major U.S. drug law was passed in the year _____ and was called the _____.

   Answer: 1906; Pure Food and Drug Act

   Feedback: The Pure Food and Drug Act was passed in the U.S. in 1906. It was the first government attempt to establish consumer protection in the manufacture of drugs and foods.

2. USP stands for _____

   Answer: United States Pharmacopeia

   Feedback: The United States Pharmacopeia (USP) is a reference that specifies the official U.S. standards for making individual drugs.

3. NF stands for _____

   Answer: National Formulary

   Feedback: The National Formulary (NF) is a reference that specifies the official U.S. standards for making individual drugs. It has been combined with the United States Pharmacopeia (USP) into one reference book, the USP/NF

4. Which drug law established the USP and NF (which are now one)?

   Answer: The Pure Food and Drug Act

   Feedback: The 1906 Pure Food and Drug Act established two references of officially approved drugs: the USP and NP, which were subsequently combined into one single reference source.

5. The agency that requires you to keep a record of each controlled substance transaction is the _____

   Answer: Drug Enforcement Administration (DEA)

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Feedback: The Drug Enforcement Administration enforces security and accountability related to controlled substances. Anyone who dispenses, receives, sells, or destroys controlled substances must keep on hand special DEA forms, indicating the exact current inventory and a two-year inventory of every controlled substance transaction.

6. Schedule C-_____ has the lowest potential for abuse.

   Answer: Schedule C-V has the lowest potential for abuse

   Feedback: The 1970 Controlled Substances Act classified abused and addicting drugs into five levels, or schedules, according to their medical value, harmfulness, and potential for abuse or addiction: C-I, C-II, C-III, C-IV, and C-V, with class C-I being the highest potential for abuse, and C-V with the lowest potential for abuse.

7. How long must you keep an inventory record of each controlled substance transaction at your office? _____

   Answer: Two years

   Feedback: The Drug Enforcement Administration (DEA) enforces security and accountability related to controlled substances, including a two-year inventory of every controlled substance transaction (see also feedback to question 5).

8. Three responsibilities of the FDA include:
   _____

   Answer: Three responsibilities of the FDA include any of the following:

   - Overseeing testing of all proposed new drugs before they are released into the U.S. market
   - Inspecting plants where foods, drugs, medical devices, or cosmetics are made
   - Reviewing new drug applications and petitions for food additives
   - Investigating and removing unsafe drugs from the market
   - Ensuring proper labeling of foods, cosmetics, and drugs

   Feedback: The increase in the number of drugs produced for marketing brought dangers to the public. The federal FDA was established to ensure that some basic standards would be followed. Its responsibilities include the five listed in the answer above.

9. What types of drugs are listed in the C-V schedule?
   _____

   Answer: Drugs that have the lowest abuse potential among the five classes or schedules of controlled substance; these consist primarily of cough suppressants containing codeine and antidiarrheal preparations such as diphenoxylate

   Feedback: Schedule C-V consists primarily of preparations for cough suppressants containing codeine and preparations for diarrhea (e.g., diphenoxylate). Examples include promethazine with codeine, Cheratussin AC, and Lomotil.

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10. What method is recommended for securing the controlled substances at your office? _____.

    Answer: The drugs should be kept inside a locked safety box, which is then placed within in a cupboard that is also locked.

    Feedback: The Drug Enforcement Administration enforces security and accountability related to controlled substances; this includes keeping all controlled substances inside a locked safety box, which is then placed within a cupboard that is also locked.

11. If a patient calls to request a refill of a Percocet (C-II) prescription, how would you reply? _____

    Answer: A refill for a C-II substance cannot be called into a pharmacy as a new prescription is required by law.

    Feedback: The 1970 Controlled Substances Act set regulations governing which schedules may have prescriptions phoned in to the pharmacy. A refill for a C-II substance cannot be called into a pharmacy; a new written prescription is required.

12. A patient has a rare disease that requires medication for only a small population of patients. Which act has allowed their drug to be produced even though it is not profitable to the pharmaceutical industry?

    Answer: The Orphan Drug Act of 1983

    Feedback: The 1983 Orphan Drug Act provides pharmaceutical companies financial incentives to develop medications for diseases that affect only a small number of people, so that orphan drugs that would otherwise be of low profitability would be available to patients with rare diseases.

13. A patient calls into the office asking for a new prescription for a narcotic medication that they have been taking for six months. You bring up their chart and notice that whereas they have been requesting new prescriptions every 23 days, the medication should last 30 days. Additionally, the patient also mentions that they feel that they are in need of a higher dose, and they become agitated and irritable when you tell them that they will need an appointment. What do you think of this? What should you do?

    Answer: The medication taking behavior suggests a potential pattern of drug abuse. Nevertheless, the most appropriate action should be to notify the patient's physician so that they can assess the real need for an increase in the dose and/or frequency of administration.

    Feedback: The prescription fill record indicated that the patient is getting the narcotic more frequently than what is allowed by their physician for their medical condition. Given the high potential of narcotic abuse, such requests need to be addressed by the physician.

14. Each drug is given a _____ number to identify the manufacturer, the drug, and the package size.
    a. FDA
    b. USP
    c. DEA
    d. NDC

    Answer: d

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Feedback: The National Drug Code (NDC) is a directory of numerical codes that allow identification of a drug, as well as the package size and the manufacturer. This directory provides a list of all drugs manufactured for commercial distribution. The NDC is comprised of three parts: the first part is five numbers and identifies the manufacturer, the second part is four numbers and identifies the drug, and the third part is two digits and identifies the package size.

15. Answer the questions concerning the following three drug labels:
    a. Which drug(s) requires a prescription?

    Answer: Morphine Sulfate and Procardia (nifedipine)

    Feedback: Both Morphine and Procardia (nifedipine) require a prescription and cannot be purchased over the counter.

    b. Which drug(s) can be bought without a prescription?

    Answer: Acetaminophen

    Feedback: Acetaminophen can be obtained over the counter from any pharmacy without a prescription.

    c. Which drug(s) require(s) a DEA number?

    Answer: Morphine Sulfate

    Feedback: Morphine is a controlled substance that requires not only a prescription but also that the ordering and dispensing, respectively, needs to be by a physician and a pharmacist that have a DEA number indicating their proper registration with the agency.

16. Drug standards ensure consistency in all the areas EXCEPT
    a. strength
    b. purity
    c. quality
    d. size

    Answer: d

    Feedback: Drug standards assure consumers that the drugs they take are of uniform strength, purity, and quality.

17. The Federal Food, Drug, and Cosmetic Act of 1938 established which agency?
    a. NDC
    b. DEA
    c. FDA
    d. USP

    Answer: c

    Feedback: The Federal Food, Drug, and Cosmetic Act of 1938 established the Food and Drug Administration (FDA) under the Department of Health and Human Services to enforce the provisions of the Act.

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18. The earliest recorded use of drugs occurred during which civilization?
    a. Egyptian
    b. Roman
    c. Greek
    d. Aztec

    Answer: a

    Feedback: The first documented use of drugs was in ancient Egypt.

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Purpose and Perspective of the Chapter

The purpose of this chapter is to provide a comprehensive overview of key concepts and regulations in pharmacology, including drug standards, historical milestones, and the evolution of drug laws in the United States. It begins by explaining drug standards and tracing the historical development of pharmacology. This chapter outlines significant legislation, such as the Federal Food, Drug, and Cosmetic act of 1938—the first U.S. drug law for consumer safety—and the Controlled Substances Act of 1970, clarifying their provisions and impact. It explains the roles of the FDA and DEA, the meaning of USP/NF, and the classification of controlled substance schedules (C-I through C-V). Additionally, it addresses orphan drugs and emphasizes the responsibilities associated with administering medications under these laws.

Chapter Objectives

The following objectives are addressed in this chapter:

1. Explain what is meant by drug standards.
2. Summarize the historical development of pharmacology.
3. Name the first drug law passed in the United States for consumer safety and give the year it was passed.
4. Summarize the provisions of the Federal Food, Drug, and Cosmetic Act of 1938 and its amendments.
5. Interpret what is meant by *USP/NF*.
6. Summarize the provisions of the Controlled Substances Act of 1970.
7. Contrast the responsibilities of the FDA and DEA.
8. Define *orphan drug*.
9. Differentiate between controlled substance schedules C-I through C-V.
10. State several responsibilities you have in administering medications as a direct result of the three major drug laws described in this chapter.

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CHAPTER OUTLINE

I. Drug History (LO 2, PPT Slides 5–8)
   i. From the very first documented use of "pharmacology" in ancient Egypt, where they used substances such as berries, beer, poppies, salt, and even crushed precious stones to treat ailments, it was clear that humans were determined to overcome diseases by any means necessary.

II. Pharmacology Timeline (LO 2, PPT Slides 9–14)
   i. 16th century BCE: Earliest documented pharmacologic examples found recorded on papyri from ancient Egypt.
   ii. 2nd century BCE: Earliest evidence of actual "prescriptions"
   iii. 1st century BCE: Greek physician Dioscorides writes the *De Materia Medica*, which is considered the most influential work in the history of Western pharmacology.
   iv. 1885
      a) Pasteur develops precursor to rabies vaccine.
      b) Oswald Schmiedeberg, known as the founder of modern pharmacology, publishes *Outline of Pharmacology*.
   v. 1897–1899: Aspirin discovered and first marketed for use.
   vi. 1905: German chemist Alfred Einhorn discovers procaine, giving it the trade name Novocaine (aka Novocain).
   vii. 1906: The Pure Food and Drug Act passed in United States.
   viii. 1922: Insulin first used to treat diabetes.
   ix. 1928: Alexander Fleming discovers penicillin.
   x. 1936: Chemotherapy first used to treat cancer.
   xi. 1937: Over 100 people die in the United States of a sulphanilamide elixir, leading to passage of the Federal Food, Drug, and Cosmetic Act in 1938.
   xii. 1953: Watson and Crick describe the structure of DNA.
   xiii. 1960: First contraceptive pill.
   xiv. 1958–1960 Thalidomide crisis where approximately 10,000 babies were born with deformities after thalidomide was used to treat morning sickness; this led to passage of a drug amendment act establishing the Food and Drug Administration in 1962.
   xv. 1969: Ibuprofen developed in Great Britain.
   xvi. 1991: FDA approves the first-ever treatment for hepatitis C (interferon alpha-2b).
   xvii. 2000: First draft of the human genome released to public; this sets the stage for genetically targeted drugs.
   xviii. 2017: Shingrix, the vaccine to treat shingles, approved.

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xix. 2020–2021: Several vaccines developed in an attempt to mitigate the COVID-19 global pandemic.
xx. 2023–2024: First respiratory syncytial virus (RSV) vaccine approved.

III. Drug Laws (LOs 1, 2, 4, 5, 6, 8, 9; PPT Slides 15–29)
i. During the 1900s, laws were passed that specifically addressed the matter of safely dispensing drugs in the United States.
ii. Drug standards are rules set to assure consumers that they get what they pay for. The law says that all preparations called by the same drug name must be of *uniform strength, quality, and purity*.

a. 1906 Pure Food and Drug Act
i. First government attempt to establish consumer protection in the manufacture of drugs and foods.
ii. Required all drugs marketed in the United States to meet minimal standards of strength, purity, and quality.
iii. Demanded that drug preparations containing dangerous ingredients have a labeled container indicating the ingredient.
iv. Established two references of *officially* approved drugs:
a) *United States Pharmacopeia (USP)*
b) *National Formulary (NF)*

b. 1938 Federal Food, Drug, and Cosmetic Act and Amendments of 1951, 1962, and 1972
i. Established the Food and Drug Administration (FDA) under the Department of Health and Human Services to enforce the provisions of the Act.
a) All labels must be accurate and must include a listing of all active and inactive ingredients.
b) All new products must be approved by the FDA before public release.
c) “Warning” labels must be present on certain preparations.
d) Legend drugs must be labeled as “Caution—federal law prohibits dispensing without a prescription.”
e) Certain drugs must be labeled with the legend (inscription) “Caution—federal law prohibits dispensing without a prescription.” Thus, the term *legend drug* refers to such preparations. The act also designated which drugs can be sold without a prescription.
f) Prescription and nonprescription drugs must be shown to be *effective* as well as *safe*.

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g) In 1972, the National Drug Code (NDC) Directory was established. This provided the FDA with a list of all drugs manufactured for commercial distribution.
    1. The first part is five numbers and identifies the manufacturer.
    2. The second part is four numbers and identifies the drug.
    3. The third part is two digits and identifies the package size.

ii. The five schedules of controlled substances are arranged with those with the highest potential for abuse at level I and those with the lowest abuse potential at level V (Refer to Table 1-1 in the text.).

c. 1970 Controlled Substances Act
    i. Established the Drug Enforcement Administration (DEA) as a bureau of the Department of Justice to enforce the provisions of the Act.
    ii. The Act:
        a) Isolated the abused and addicting drugs into five levels, or schedules, according to their medical value, harmfulness, and potential for abuse or addiction: C-I, C-II, C-III, C-IV, and C-V.
        b) Demanded security and accountability related to controlled substances; anyone (e.g., pharmacists, hospitals, physicians, and drug companies) who dispenses, receives, sells, or destroys controlled substances must keep on hand special DEA forms, indicating the exact current inventory and a two-year inventory of every controlled substance transaction.
        c) Set limitations on the use of prescriptions; guidelines were established for each of the five schedules of controlled substances, regulating the number of times a drug may be prescribed in a six-month period as well as for which schedules prescriptions may be phoned in to the pharmacy and so on.
        d) Demanded that each prescriber of these substances register with the DEA and obtain a DEA registration number, to be present on their prescriptions of controlled substances; drug manufacturers must also be registered and identified with their own DEA numbers, as must pharmacists, physicians, veterinarians, and so on.

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d. Additional Drug Legislations
    i. The 1983 Orphan Drug Act
        a) Gives financial incentives to develop medications for diseases that affect a small number of people and are of low profitability.
    ii. Omnibus Budget Reconciliation Act (OBRA) of 1990
        a) This Act mandates that all OTC drugs a patient is taking must be documented as part of the medical record. OBRA also mandates that pharmacists provide drug use review and patient counseling before dispensing prescriptions to a patient.

IV. FDA and DEA (LO 7, PPT Slides 30–34)
    i. Responsibilities of FDA:
        a) Overseeing testing of all proposed new drugs before they are released into the U.S. market.
        b) Inspecting plants where foods, drugs, medical devices, or cosmetics are made.
        c) Reviewing new drug applications and petitions for food additives.
        d) Investigating and removing unsafe drugs from the market.
        e) Ensuring proper labeling of foods, cosmetics, and drugs.
    ii. Responsibilities of DEA:
        a) Concerned only with controlled substances.
        b) Enforces laws against drug activities, including illegal drug use, dealing, and manufacturing.
        c) Monitors need for changing the schedules of abused drugs.

V. Health Care Professionals and the Law and Ethics (LO 10, PPT Slides 35–39)
    i. The following guidelines should be followed by the health care professional involved in dispensing medications:
        a) Keep a current drug reference source available at all times. You should be able to readily identify substances that are controlled by the DEA.
        b) Keep controlled substances locked securely. Double-locking is required in most situations. This means:
            1. Placing the drugs in a locked safety box
            2. Placing the locked box in a cupboard that is also locked.

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c) Conceal and secure prescription pads at your office, clinic, or facility. Do not leave pads out in the open, especially in patient examination rooms.
d) Keep accurate records of each controlled substance administered, received, or destroyed at your facility. These records, as well as the records from the previous two years, must be available at all times.
e) Be responsible for keeping up to date with current news of the activities of the FDA and the DEA. If working for a physician, monitor the DEA registration renewal date. Keep informed of any changes in the scheduling of controlled substances.
f) Establish a working rapport with a pharmacist. A local pharmacist is an excellent resource for you when you are unsure of your legal responsibilities with drugs or have any uncertainties about drug therapy.
g) If you work in an office, maintain a professional rapport with the pharmaceutical representatives who leave drug samples there. As part of the Affordable Care Act, the Sunshine Act now requires reporting of compensation and gifts paid to physicians by pharmaceutical representatives.

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Discussion Questions

You can assign these questions several ways: in a discussion forum in your LMS; as whole-class discussions in person; or as a partner or group activity in class.

Discussion: Drug Safety. Duration 60 minutes.

In the United States, the use of marijuana has gained social acceptance, with some states *legalizing* the drug for recreational use or medicinal purposes. At the federal level, marijuana remains a Schedule 1 controlled substance by the United States Drug Enforcement Administration (DEA) and has not gained approval from the Food and Drug Administration (FDA) for medicinal use.

i. What would be the benefits to the consumer if this substance were to gain FDA approval?
    1. Answer: The discussion response answers need to include assurance of consumer safety because manufacturers going through FDA approval will have demonstrated effectiveness and safety of their product.

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ii. What are the risks of not having FDA approval for marijuana medicinal use?
    1. Answer: The answer needs to include unwanted deaths or harm as seen with sulfanilamide and thalidomide.

iii. What are the implications to the DEA schedule classification of marijuana if this substance obtains FDA approval?
    1. Answer: Because of the dynamic nature in medication use, the DEA classifications have been revised or changed to incorporate those changes.

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      a) Pasteur develops precursor to rabies vaccine.
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        d) Investigating and removing unsafe drugs from the market.
        e) Ensuring proper labeling of foods, cosmetics, and drugs.
    ii. Responsibilities of DEA:
        a) Concerned only with controlled substances.
        b) Enforces laws against drug activities, including illegal drug use, dealing, and manufacturing.
        c) Monitors need for changing the schedules of abused drugs.

V. Health Care Professionals and the Law and Ethics (LO 10, PPT Slides 35–39)
    i. The following guidelines should be followed by the health care professional involved in dispensing medications:
        a) Keep a current drug reference source available at all times. You should be able to readily identify substances that are controlled by the DEA.
        b) Keep controlled substances locked securely. Double-locking is required in most situations. This means:
            1. Placing the drugs in a locked safety box
            2. Placing the locked box in a cupboard that is also locked.

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c) Conceal and secure prescription pads at your office, clinic, or facility. Do not leave pads out in the open, especially in patient examination rooms.
d) Keep accurate records of each controlled substance administered, received, or destroyed at your facility. These records, as well as the records from the previous two years, must be available at all times.
e) Be responsible for keeping up to date with current news of the activities of the FDA and the DEA. If working for a physician, monitor the DEA registration renewal date. Keep informed of any changes in the scheduling of controlled substances.
f) Establish a working rapport with a pharmacist. A local pharmacist is an excellent resource for you when you are unsure of your legal responsibilities with drugs or have any uncertainties about drug therapy.
g) If you work in an office, maintain a professional rapport with the pharmaceutical representatives who leave drug samples there. As part of the Affordable Care Act, the Sunshine Act now requires reporting of compensation and gifts paid to physicians by pharmaceutical representatives.

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Discussion Questions

You can assign these questions several ways: in a discussion forum in your LMS; as whole-class discussions in person; or as a partner or group activity in class.

Discussion: Drug Safety. Duration 60 minutes.

In the United States, the use of marijuana has gained social acceptance, with some states *legalizing* the drug for recreational use or medicinal purposes. At the federal level, marijuana remains a Schedule 1 controlled substance by the United States Drug Enforcement Administration (DEA) and has not gained approval from the Food and Drug Administration (FDA) for medicinal use.

i. What would be the benefits to the consumer if this substance were to gain FDA approval?
    1. Answer: The discussion response answers need to include assurance of consumer safety because manufacturers going through FDA approval will have demonstrated effectiveness and safety of their product.

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ii. What are the risks of not having FDA approval for marijuana medicinal use?
    1. Answer: The answer needs to include unwanted deaths or harm as seen with sulfanilamide and thalidomide.

iii. What are the implications to the DEA schedule classification of marijuana if this substance obtains FDA approval?
    1. Answer: Because of the dynamic nature in medication use, the DEA classifications have been revised or changed to incorporate those changes.

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