

Pharmacy Jurisprudence, L.L.C.



Our annual legal continuing education offering for all pharmacists and pharmacy technicians in the State of Ohio.

A publication for all members of the pharmacy profession.

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2 Drugs Under Federal Law

Accreditations: This continuing pharmacy education activity has been approved by the Ohio State Board of Pharmacy for Board-approved jurisprudence.

Ohio Program No.: 036-350-08-003-H03-P
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13 OTC, BTC, Rx and Dangerous Drugs in Ohio

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PHARMACY JURISPRUDENCE, L.L.C.

036-350-08-003-H03

Expires: August 6, 2010

Pharmacy Jurisprudence, a division of Select CE®, presents the following continuing pharmacy education (CPE) program for pharmacists and pharmacy technicians.

Drugs Under Federal Law

In the evaluation section of each of our law CPE programs, we here at Pharmacy Jurisprudence ask pharmacists: what topic would you like to see covered in the next law CPE program? We ask this for several reasons. First, it is strongly suggested by the national CPE accrediting body, Accreditation Council for Pharmacy Education (ACPE), that we ask participants this question. Second, we really do want to create programs that interest you.

Surprisingly, the most requested topics are “more law” and “controlled substances”. Really? Pharmacists want to know more about this? Aren’t you weary from worrying about compliance with the law? Aren’t you weary from dealing with controlled substance prescriptions, and that includes some of your patients who appear to be dependent on controlled substances?

Apparently not.

So, we create this series of CPE programs with you in mind. The first program discusses what a drug is under federal law. The second program discusses dangerous drugs in Ohio. The third program is still in development and will discuss controlled substances. Each program in this booklet is approved by the Ohio State Board of Pharmacy and also by ACPE for one (1) contact hour, and each costs \$15.00.

As always, we put our CPE programs together in bite-sized pieces so that you can complete this program standing up behind the counter, whether that is your retail pharmacy counter, your hospital counter, or your kitchen counter at home.

As always, let us know what you think. We thank you for reading our programs and using our services. We truly enjoy serving you.

Sincerely,
Patty Nussle, R.Ph., J.D.

Program Title: Drugs Under Federal Law
Ohio Program No.: 036-350-08-003-H03
ACPE Program No.: 487-000-08-003-H03-P or 487-000-08-003-H03-T
Target Audience: All Pharmacists and Pharmacy Technicians
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Fee Information: \$15.00

Estimated Time to Complete the Activity: 60 minutes

Procedures: To receive a Statement of Credit, read this booklet, complete the post-test questions and program evaluation on the Answer Sheet, and mail the Answer Sheet and the program fee of \$15.00 to us. Checks and money orders are encouraged. Mail to: Pharmacy Jurisprudence, P.O. Box 21186, Columbus, Ohio 43221-0186. A minimum score of 75% is required to earn credit.

Faculty: Patricia A. Nussle, R.Ph., J.D., is the founder of Pharmacy Jurisprudence. She is also a healthcare attorney who has written and published continuing education programs in pharmacy law and nursing law for over 375,000 healthcare professionals since 2001. Assistance was provided by Brynn Hannay, then-PharmD candidate, during her rotation with us.

Disclosure of Commercialism, Unlabeled Uses, Bias, Conflicts of Interest: Prior to the delivery of the content, we will disclose any commercial support, and we do so here: No commercial support was requested or accepted for developing or presenting this program. No unlabeled uses of drugs are

discussed in this program. Faculty Patricia A. Nussle, Pharmacy Jurisprudence, and Select CE have no real, apparent, or potential conflicts of interest or financial relationships to disclose, other than that Patricia A. Nussle is the owner of Pharmacy Jurisprudence and Select CE, and she warrants that she presents this information fairly and without bias.

Objectives: At the conclusion of this program, pharmacists should be able to:

1. define a drug under federal law; and
2. apply the drug definition to distinguish between a drug and a non-drug product.

Objectives: At the conclusion of this program, pharmacy technicians should be able to:

1. define a drug under federal law; and
2. apply the drug definition to distinguish between a drug and a non-drug product.

Important Disclaimer: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority. Laws and rules change often, and it is possible that some state and/or federal laws may have changed by the time you read this program. If you do have a legal problem or question, please consult an attorney experienced in pharmacy law matters to discuss your specific situation.

Questions? Please call Pharmacy Jurisprudence at (614) 481-8711.

Pre-test...just to get you thinking...

1. *What is an official compendia, and why is it important?*
2. *What is the USP-NF?*
3. *What standards-setting organizations deems an adulterant or contaminant as such?*
4. *What is a drug under federal law?*
5. *Why is a product's intended use important?*
6. *What is a cosmeceutical?*
7. *Why is a product's advertising important?*

Drugs Under Federal Law

Just what is a “drug”? What makes a drug different from other similar products? What makes a product subject to special laws and regulations regarding drugs in the United States? We will answer these questions in the following CPE program. As we do, we will use the phrase “drug” and “medication” interchangeably.

In the United States, the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a “drug” in this broad manner:

(g)(1) The term “drug” means:

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).¹

Food, devices, food additives, color additives, cosmetics, animal feed, infant formula and dietary supplements are different, and are defined separately in the FD&C Act.²

To help understand the drug definition, focus on the key words and think of a drug as anything:

- (A) recognized by an official compendium; and
- (B) intended for the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and
- (C) intended to affect the structure or function of the body of man or other animals; and
- (D) any component of the above.

Question 1:

Under federal law, a drug:

- a. is intended to be used to diagnose, cure, mitigate, treat or prevent disease;
- b. can be an infant formula, as long as it affects the structure or function of the body;
- c. includes medical devices.

¹ Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1). This can be found online at <http://www.fda.gov/opacom/laws/fdact/fdact1.htm>

² Id.

Official Compendia

First, let's think about what federal law means when it lists the "official compendia" in (A) of the drug definition.

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

The *USP*, or United States Pharmacopoeia, is the official public standards-setting authority for all prescription and over-the-counter medicines manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in more than 130 countries. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.³

As a practical matter, you can think of the *USP* and other official compendia as the reference books that tell you the exact characteristics of any particular drug. While these books do not set forth manufacturing processes, the *USP* monographs do provide the chemical name, packaging, storing and labeling requirements as well as testing and acceptance criteria that make the drug what it is.

Question 2:

The USP:

- a. is the sole determinant of whether a product is a drug under federal law;
- b. is the standards-setting authority for the quality of many drug products;
- c. determines whether a drug is Rx or OTC.

A practical implication of this is the story of contaminated heparin made in China and allegedly responsible for dozens of allergic reactions and deaths in the U.S. in the first part of 2008. Preliminary testing showed that some therapeutic heparin multi-dose vials and the heparin lock flush solution manufactured by Baxter Health Corporation and APP were adulterated with over-sulfated chondroitin. This adulterant can mimic the anticoagulant properties of heparin, and it is

possible that the testing assays and procedures described in the *USP* monograph for heparin did not pick up the adulterant over-sulfated chondroitin.⁴

³ See <http://www.usp.org/aboutUSP> for more information.

⁴ See <http://www.usp.org/pdf/EN/hottopics/heparinMediaStatement.pdf>

In the words of the USP: “[T]he adulterant oversulfated chondroitin could appear to be heparin in some of the tests described in the *USP* monograph. Thus the basis for adulteration would be commercial: substitution of a lower cost material (the over-sulfated chondroitin sulfate) for a higher cost material (heparin drug substance). It is unclear at this time whether the observed adverse events are due to the oversulfated chondroitin, to an impurity in this material, or to other factors.”

“USP’s laboratories are now assessing screening methods that could be used to detect the presence of oversulfated chondroitin sulfate in the heparin drug substance before it is made into heparin drug products. If this effort is successful, USP will add methods to the Identification test in *USP* heparin drug substance monographs to test for oversulfated chondroitin. *Under U.S. law, if a heparin drug substance tested positively for oversulfated chondroitin, it could not be called heparin and could not be used by a drug product manufacturer in heparin-containing drug products.*”⁵

Here we see the USP, official standards-setting body for what makes heparin able to be called heparin, adjusting its definition of heparin to exclude a new, threatening adulterant.

In recent years, the USP has teamed up with the standards-setters at the National Formulary (NF) which generally examines the higher level compounds which serve as the base for many drugs. Working collaboratively, they now publish their compendia together in the USP-NF. The USP–NF is a single–volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). A drug in the U.S. market should conform to the standards in USP-NF to avoid charges of adulteration and misbranding.

If you are thinking that you’ve seen the USP or USP-NF designation, you have. You see it quite often, because this official way to define a drug appears on every patient package insert (PPI) for a prescription medicine in the U.S., and in most drug information sources for non-prescription medicines. For example, if

Question 3:

Applying the information you’ve learned about USP, if lots of heparin are adulterated or contaminated, that means:

- a. it tested positively for an adulterant;
- b. it cannot be called heparin under federal law;
- c. it is adulterated and misbranded under federal law;
- d. all of the above are true.

⁵ See <http://www.usp.org/pdf/EN/hottopics/heparinMediaStatement.pdf>

you look at a PPI for Motrin, the first line will describe Motrin as “ibuprofen tablets, USP”.⁶ If you look up prescribing information for non-prescription Claritin-D 24 Hour Extended Release tablets, it will tell you the product contains “10 mg loratadine/240 mg pseudoephedrine sulfate, USP”.⁷ The “USP” designation means the ingredient meets the quality standards set forth by the United States Pharmacopoeia.

One final compendium merits discussion. The Homeopathic Pharmacopoeia of the United States (HPUS) is the publication of the standards-setting organization known as the Homeopathic Pharmacopoeia Convention of the U.S. It too is a non-governmental, non-profit scientific organization composed of experts in the fields of medicine, arts, biology, botany, chemistry and pharmacy who have had appropriate training and experience, but who have also demonstrated additional knowledge and interest in the principles of homeopathy. The Convention sets the standards for homeopathic medicines, which are those known to mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States (HPUS).

Question 4:

The official compendia which under federal law describe drugs are:

- a. USP;
- b. USP-NF;
- c. HPUS;
- d. all of the above.

The HPUS includes both prescription and over-the-counter medicines. And, a drug can be recognized by both the USP and HPUS.

An example of an HPUS recognized drug is belladonna. Belladonna is a group of alkaloids, which include atropine, scopolamine and hyoscyamine and is found in plants such as belladonna and jimson weed. It is also found in Hylands (Homeopathic) Teething Tablets®. Sold over-the-counter in 120-count bottles from large chain to independent pharmacies, each tablet contains:

- Calcarea Phosphorica 12X HPUS
- Chamomilla 6X HPUS
- Coffea Cruda 6X HPUS
- Belladonna 6X HPUS (0.0000003% Alkaloids)
in a base of Lactose (milk sugar) NF.

⁶ See http://www.pfizer.com/files/products/uspi_motrin.pdf

⁷ See <http://www.norxclaritin.com/claritin-seasonal-allergy-relief.htm>

The potencies of homeopathic drugs are specified in terms of dilution, i.e., 1x (1/10 dilution), 2x (1/100 dilution), instead of in milligrams or other metric unit.

Yet, you also know that belladonna is the term for a group of alkaloids found in Rx and OTC products. Atropine, scopolamine, and hyoscyamine from belladonna are found in products such as Donnatal® Elixir, Tablets, and Extendabs, the latter of which contains:

Phenobarbital, USP (3/4 gr.)48.6 mg
Hyoscyamine Sulfate, USP.....0.3111 mg
Atropine Sulfate, USP0.0582 mg
Scopolamine Hydrobromide, USP0.0195 mg

The belladonna alkaloids are examples of drug products in both the USP-NF and also the HPUS.

Intended to be Used to Diagnose, Cure, Mitigate, Treat or Prevent Disease

Next, let's think about the next section of 201(g)(1) of the Federal Food Drug and Cosmetic Act. This subsection makes clear that the intended use of the product determines whether or not it is a drug, because a drug is:

- (B) intended for the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
- (C) intended to affect the structure or function of the body of man or other animals;
- (D) any component of the above.

Using our Motrin example again, Motrin is intended to mitigate or treat a disease. The disease it intends to treat is for the “relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis”, and for the “relief of mild to moderate pain”, and for the “treatment of primary dysmenorrhea”.⁸

For another example of how “intended use” affects whether or not a product is a drug, consider the FDA’s example below.⁹

Question 5:

A product with an ingredient listing of “Belladonna 2X HPUS” is:

- a. not legitimate;
- b. referring to an official dilution of 1 part belladonna to 100 parts diluent;
- c. misbranded under federal law.

⁸ www.pfizer.com/files/products/uspi_motrin.pdf

⁹ See <http://www.cfsan.fda.gov/~dms/cos-218.html>

Is It a Cosmetic, a Drug, or Both? (or Is It Soap?)

The legal difference between a cosmetic and a drug is determined by a product's intended use. Different laws and regulations apply to each type of product. Companies or people can violate the law by marketing a cosmetic with a drug claim without adhering to requirements for drugs.

How does the law define a cosmetic?

The Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. Products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

How does the law define a drug?

The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

Can a product be both a cosmetic and drug?

Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

Question 6:

A cosmetic is:

- a. intended to be used for cleansing or beautifying the body;
- b. intended to be used for promoting attractiveness or altering appearance;
- c. is intended to be used for any of the above purposes.

Question 7:

Antidandruff shampoo is:

- a. a cosmetic;
- b. a drug;
- c. both.

Question 8:

Moisturizers that protect your skin from the harmful effects of the sun are:

- a. cosmetics;
- b. drugs;
- c. both.

Question 9:

A product's advertisement that it will restore hair growth makes that product a drug.

- a. True;
- b. False.

Question 10:

A product's advertisement that its aroma will help you sleep better makes the product a drug:

- a. True;
- b. False.

What about "cosmeceuticals"?

A product can be a drug, a cosmetic, or both, but the term "cosmeceutical" has no legal meaning.

How is "intended use" established?

Intended use may be established in a number of ways. Among them are:

- **Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials.** Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, or revitalize cells.
- **Consumer perception, which may be established by the product's reputation.** This means asking why the consumer is buying it and what the consumer expects it to do.
- **Ingredients that may cause a product to be considered a drug because they have a well known therapeutic use.** This principle also holds true for essential oils in fragrance products. A fragrance marketed for promoting attractiveness is a cosmetic. But a fragrance marketed with certain "aromatherapy" claims, such as assertions that the scent will help the consumer sleep or quit smoking, meets the definition of a drug because of its intended use.

Return this ANSWER SHEET with the \$15.00 Program Fee payable to:

*Pharmacy Jurisprudence, LLC
P.O. Box 21186
Columbus, Ohio 43221-0186*

NAME:	Pharmacist _____ or Technician _____
ADDRESS:	
CITY, STATE and ZIP:	
TELEPHONE:	
EMAIL:	

ANSWER SHEET: Drugs Under Federal Law

Ohio State Board of Pharmacy Program Number: 036-350-08-003-H03

Expiration Date: August 6, 2010

Circle the answer for each question (questions are imbedded in the program).

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

After completing this program, I believe I can:

- | | | | |
|--|-------|----|------------------|
| 11. <u>define</u> a drug under federal law: | Yes | No | |
| 12. <u>apply</u> the definition of a drug to distinguish between a drug and a cosmetic: | Yes | No | |
| 13. This program was an <u>effective</u> way for me to learn: | Yes | No | |
| 14. I liked the program's <u>format</u> : | Yes | No | |
| 15. This program made me <u>think</u> : | Yes | No | |
| 16. This was a " <u>user-friendly</u> " way for me to learn: | Yes | No | |
| 17. I could sense some <u>commercialism</u> in this program: | Yes | No | |
| 18. The <u>faculty</u> quality was: | Great | OK | Needs to Improve |
| 19. The <u>learning material</u> quality was: | Great | OK | Needs to Improve |
| 20. How long did it take to complete this program? _____ | | | |
| 21. If you sensed any <u>commercialism</u> , please tell us about it. What would you like to learn about in future CPE programs? Other comments welcome: _____ | | | |

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Objectives: At the conclusion of this program, pharmacists should be able to:

1. describe the relationship between OTC, BTC, Rx-only drugs and dangerous drugs;
2. apply the distinctions between OTC, BTC, Rx-only drugs and dangerous drugs.

Objectives: At the conclusion of this program, pharmacy technicians should be able to:

1. describe the relationship between OTC, BTC, Rx-only drugs and dangerous drugs;
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Pre-test...just to get you thinking...

1. What is a “drug” under federal law?
2. What makes a drug an OTC drug?
3. What makes a drug an Rx-Only drug?
4. What is a “dangerous drug” under Ohio law?
5. Is a dangerous drug always a prescription drug?
6. What are the most common Rx-Only drugs you dispense?
7. What is a “controlled substance” under federal law?

Dangerous Drugs in Ohio

A. What is a Drug?

In the previous lesson, you learned exactly what makes a product a drug under federal law. As a quick review, in the United States the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a “drug” in this broad manner:

(g)(1) The term “drug” means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).¹⁰

This drug definition section of the FD&C Act makes no distinction between an over-the-counter (often called non-prescription) and prescription drug. Any article that meets the above characteristics is a “drug” under federal law. Once the article is found to be a “drug”, the article must comply with other applicable sections of the FD&C Act.

B. What is an Rx Drug?

Rx, or Rx-only, or prescription drug, are the common terms for drugs that can only be sold pursuant to a prescription, i.e., it can only be sold on a patient-specific basis if a physician or other prescriber has first determined the patient has a medical need for the medicine and then issued an order, or prescription, for the particular medicine for the particular patient.

The federal government decides which drugs are Rx-only, and has delegated this job to the federal agency known as the Food and Drug Administration (FDA). Each state has the authority to add (but not remove) drugs to its own in-state prescription-only list. But states seldom exercise this authority, perhaps because it would create such confusion from state-to-state. Instead, most states, including Ohio, use the FDA’s list of prescription-only drugs.

¹⁰ Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1). This can be found online at <http://www.fda.gov/opacom/laws/fdact/fdact1.htm>

Question 1:

A product is a drug as a matter of federal law if:

- it is recognized in an official pharmacopoeia;
- it is intended to diagnose, cure, mitigate, treat, or prevent disease and affect the structure or function of the body in man or animals;
- it is intended to be used as a component of (b) above;
- all of the above.

Under section 503(b) of the FD&C Act, which is found in the federal law at 21 U.S.C. § 353(b), a **prescription drug** is:

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 (i.e., a new drug application) to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only -

(i) upon a written prescription of a practitioner licensed by law to administer such drug, or

(ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

(iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist.

The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

In short, a drug is a prescription drug because it is not safe for human use except under the supervision of a practitioner.

C. What is an OTC Drug?

Since Congress first enacted the FD&C Act in 1938, there has been a great deal of discussion about when drug products should be sold as prescription drugs as opposed to OTC drugs. Until 1951, the Act did not contain criteria for determining when to limit a drug's approval to prescription use. Consequently, different manufacturers made different decisions about whether to market a drug as prescription or OTC.

To eliminate this confusion and uncertainty, and to protect the public health, Congress enacted the Durham-Humphrey Amendments in 1951 (Public Law 82-215, 65 Stat. 648). Congress had two primary objectives in enacting the Amendments: (1) to protect the public from abuses in the sale of potent Rx drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without

the supervision of a physician.¹¹ To this end, the new legislation codified a statutory definition of prescription drug in §503(b) of the FD & C Act.

But, notably, the FD&C Act does not define “OTC drug”. Historically, the FDA uses this term “OTC drug” to describe a drug with these characteristics:

- their benefits outweigh their risks
- the potential for misuse and abuse is low
- consumers can use them for self-diagnosed conditions
- they can be adequately labeled
- health practitioners are not needed for the safe, effective use of it

D. OTC, BTC and Rx Drugs

Nearly all of the drugs in the U.S. fall into the OTC or Rx-only categories.

However, there is very small slice of behind-the-counter, or BTC, drugs available in the U.S.

In ten (10) states for a few selected drug products, and in all fifty (50) states for the oral contraceptive product known as Plan B, pharmacists have the ability to dispense from behind-the-counter to patients without a prescription. This has become known as the BTC category.

Question 2:

An Rx drug is:

- a. due to its toxicity or potential for harm, not safe for use except under the supervision of a practitioner;
- b. due to its toxicity or potential for harm, not safe for use in the United States;
- c. due to its high cost, should be used only in limited circumstances.

Question 3:

An OTC drug:

- a. is generally safe for use by the public for self-diagnosed conditions;
- b. has benefits that outweigh its risks;
- c. both of the above.

Question 4:

An OTC drug:

- a. is defined in section 503(b) of the FD & C Act;
- b. has a high potential for misuse and abuse;
- c. can be adequately labeled so that consumers understand how to use it.

¹¹ See S. Rep. No. 946, at 1 (1951), reprinted in 1951 U.S.C.C.A.N. 2454.

Interestingly, in many European and South American countries, the BTC category is the largest category of drugs. Walk into pharmacies in those places, and after talking to the pharmacist, you can purchase many drugs that are only available by prescription in the United States.

But, here in the United States, we take a lot of Rx and OTC drugs. A lot. Let's start by looking at OTC drug use in the United States.

The following chart shows a total of over \$16 billion in sales of OTC drugs in the U.S. in 2007, excluding Wal-Mart¹²:

OTC Category	Sales (in millions)
Acne Remedies	\$326
Analgesics, External	\$316
Analgesics, Internal	\$2,240
Anti-diarrheals	\$177
Anti-smoking	\$502
Cough/Cold Products	\$3,601
Eye Care	\$441
First Aid	\$627
Foot Care	\$354
Heartburn (incl. anti-gas)	\$1,263
Laxatives	\$761
Lip Remedies	\$410
Oral Antiseptics, Rinses	\$763
Sunscreens/ Sunblocks	\$415
Toothpaste	\$1,244
All Others	\$2,437

Remember that OTC medicines are indeed drugs. OTC's are the leading cause of overdose in children. OTC's can and do have side effects, and can and do interact with prescription drugs.

Question 5:

OTC medicines:

- are safe in any dose;
- have not been proven to be safe or effective;
- include medicines such as first aid products and toothpaste that can be purchased without a prescription.

Moving on to Rx drugs, we take even more Rx drugs than OTC drugs. Or at least we spend more money on Rx drugs. According to IMS Health, the leading provider of prescription data in the country, we spent \$286.5 billion on prescription medicines in 2007.¹³ That is over 40% of the world's sale of prescription medicines, which IMS Health puts at \$712 billion for 2007.

¹² From The Nielson Company; see <http://www.chpa-info.org/ChpaPortal/PressRoom/Statistics/OTCSalesbyCategory.htm>

¹³ The source for Rx sales and prescriptions dispensed, found on this page and the next, is attributed to IMS Health, Inc. and can be found at www.imshealth.com.

The top categories of sales of prescription medicines in the U.S. are:

RANK	THERAPEUTIC CLASS	2007 DOLLARS (IN BILLIONS)
1	Lipid Regulators	18.4
2	Proton Pump Inhibitors	14.1
3	Anti-psychotics	13.1
4	Anti-depressants	11.9
5	Seizure Disorders	10.2
6	Erythropoietins	8.6
7	Anti-neoplastic Monoclonal Antibodies	6.8
8	Angiotensin II Antagonists	6.6
9	Anti-arthritis, Biological Response Modulators	5.3
10	Biphosphonates	4.6

The top categories of number of prescriptions dispensed in 2007 in the U.S. are:

RANK	THERAPEUTIC CLASS	2007 SCRIPTS (IN MILLIONS)
1	Anti-depressants	232.7
2	Lipid Regulators	220.9
3	Codeine and Codeine-Combinations	186.1
4	ACE Inhibitors	157.9
5	Beta Blockers	132.5
6	Proton Pump Inhibitors	108.4
7	Seizure Disorders	101.8
8	Thyroid Hormone, Synthetic	101.4
9	Calcium Blockers	87.4
10	Benzodiazepines	82.9

Question 6:

Of the top ten (10) therapeutic classes of prescription drugs in terms of sales in 2007:

- a. all of them are controlled substances;
- b. only two (2) of them are dangerous drugs;
- c. none of them are controlled substances.

Why is this important? It is important because it helps put into perspective actual use of the types and amounts of prescription drugs dispensed and sold in pharmacies in the United States.

E. What is a Dangerous Drug?

The term “dangerous drug” is a legal term in Ohio law. It is arguably the most-often used term by Ohio law-makers and policy-makers when they discuss drug policy in Ohio.

The term “dangerous drug” has historically been used to describe any prescription drug. And that is partially correct, because all prescription drugs are dangerous drugs. But the term “dangerous drug” encompasses more than all prescription drugs. Ohio regulators wanted to be sure to include in its definition any miscellaneous drug found in Ohio’s other laws, and also ephedrine which is a Schedule V controlled substance that has been subject to special treatment over the years, and also insulin and other biological injectables.

Here is the language of the law in Ohio:

ORC 4729.01 Pharmacists, dangerous drugs definitions.

(F) “Dangerous drug” means any of the following:

(1) Any drug to which either of the following applies:

(a) Under the “Federal Food, Drug, and Cosmetic Act,” 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend “Caution: Federal law prohibits dispensing without prescription” or “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian” or any similar restrictive statement, or the drug may be dispensed only upon a prescription;¹⁴

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

Question #7:

A dangerous drug in Ohio:

- a. is any drug which under federal law is required to bear the legend “Caution: Federal law prohibits dispensing without a prescription” or similarly restrictive phrase;
- b. includes drugs intended for injection, such as insulin and biologicals;
- c. includes all schedule V controlled substances;
- d. all of the above

¹⁴ Note that as of 1998 the legend “Rx Only” is also an acceptable similarly restrictive statement in federal law. See 21 USC 503(b)(4), and FDA’s guidance to industry at <http://library.findlaw.com/1999/Mar/10/127997.pdf>

- (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply; or
- (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

In summary, in Ohio a “dangerous drug” is any drug that requires a prescription under federal law, plus any drug regulated by Chapter 3715 (Ohio’s Pure Food and Drug Act), plus any drug regulated by Chapter 3719 (Ohio’s Controlled Substances Act), plus any drug that is a Schedule V Controlled Substance, plus any drug intended to be administered by injection.

Question 8:

Of the top ten (10) classes of prescription drugs in terms of the number of prescriptions dispensed in 2007:

- a. all of them are controlled substances under Ohio law;
- b. only two (2) of them are dangerous drugs under Ohio law;
- c. only two (2) of them are controlled substances under Ohio law.

Question 9:

Which of the below is true?

- a. all dangerous drugs in Ohio are also prescription drugs;
- b. all prescription drugs in Ohio are dangerous drugs;
- c. insulin is a prescription drug under federal law.

Question 10:

Insulin is a:

- a. dangerous drug;
- b. prescription drug;
- c. controlled substance.

F. What is a Controlled Substance?

A *controlled (scheduled)* drug is one whose use and distribution is tightly controlled because of its abuse potential or risk. *Controlled* drugs are rated in the order of their abuse risk and placed in **Schedules** by the Federal Drug Enforcement Administration (DEA). The drugs with the highest abuse potential are placed in *Schedule I*, and those with the lowest abuse potential are in *Schedule V*. These schedules are shown as C-I, C-II, C-III, C-IV, and C-V.

Some examples of drugs in these Schedules are as follows:

Schedule I — drugs with a high abuse risk. These drugs have NO safe, accepted medical use in the United States. You will never see a prescription for this. Some examples are heroin, marijuana, LSD, PCP, and crack cocaine.

Schedule II — drugs with a high abuse risk, but also have safe and accepted medical uses. These drugs can cause severe psychological or physical dependence. Schedule II drugs include certain narcotic, stimulant, and depressant drugs. Some examples are morphine, cocaine, oxycodone (in combination with acetaminophen is known by the brand name Percocet®), methylphenidate (Ritalin®), and dextroamphetamine (Dexedrine®).

Schedule III, IV, or V — drugs with an abuse risk less than Schedule II. These drugs also have safe and accepted medical uses in the United States. Schedule III, IV, or V drugs include those containing smaller amounts of certain narcotic and non-narcotic drugs, anti-anxiety drugs, tranquilizers, sedatives, stimulants, and non-narcotic analgesics. Some examples of C-III's are acetaminophen with codeine (Tylenol® No.3) and hydrocodone with acetaminophen (Vicodin®); some examples of C-IV's are diazepam (Valium®), alprazolam (Xanax®), propoxyphene (Darvon®), and pentazocine (Talwin®); and examples of C-V's are buprenorphine, acetaminophen with codeine 120 mg/12mg per 5 ml (Tylenol® with Codeine Elixir), and some ephedrine-containing products.

To find a list of controlled substances CI-CV, look in the Ohio Revised Code section 3719.41, Controlled Substance Schedules.

We'll get into controlled substances in more detail in the next program. For this program, it is enough to know that controlled substances are those dangerous drugs that possess some degree of risk for abuse and are regulated by the DEA.

Return this ANSWER SHEET with the \$15.00 Program Fee payable to:

*Pharmacy Jurisprudence, LLC
P.O. Box 21186
Columbus, Ohio 43221-0186*

NAME:	Pharmacist _____ or Technician _____
ADDRESS:	
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ANSWER SHEET: OTC, BTC, Rx and Dangerous Drugs
Ohio State Board of Pharmacy Program No.: 036-350-08-004-H03
Expiration Date: August 6, 2010

Circle the answer for each question (questions are imbedded in the program).

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

After completing this program, I believe I can:

- | | | |
|---|-----|----|
| 11. <u>describe</u> the relationship between OTC, BTC, prescription drugs and dangerous drugs: | Yes | No |
| 12. <u>apply</u> the distinctions between OTC, BTC, prescription drugs and dangerous drugs: | Yes | No |
| 13. This program was an <u>effective</u> way for me to learn: | Yes | No |
| 14. I liked the program's <u>format</u> : | Yes | No |
| 15. This program fostered <u>active mental participation</u> : | Yes | No |
| 16. This was a " <u>user-friendly</u> " way for me to learn: | Yes | No |
| 17. I could sense some <u>commercialism</u> in this program: | Yes | No |
| 18. The <u>faculty</u> quality was: Great OK Needs to Improve | | |
| 19. The <u>learning material</u> quality was: Great OK Needs to Improve | | |
| 20. How <u>long</u> did it take to complete this program? _____ | | |
| 21. If you sensed any <u>commercialism</u> , what was it? What would you <u>like to learn</u> about in future CPE programs? Other comments welcome: _____ | | |

Pharmacy Jurisprudence, L.L.C.



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