



A PHARMACY CONTINUING EDUCATION PROGRAM

W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

Jan 2006 Pharmacy Law: Drug Labeling Requirements 707-000-06-001-H03



THIS MONTH
"Pharmacy Law
2006"

HAS EVERYONE RECEIVED YOUR 2005 CE CREDITS? IF YOU HAVE QUESTIONS, PLEASE CONTACT US.

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IT'S A NEW YEAR. WHEN YOU SEND IN QUIZZES, ALWAYS KEEP A COPY. YOU MAY EMAIL OR FAX THEM. FAX # IS 847-945-5037. OR SEND A CONVENTIONAL EMAIL WITH YOUR ANSWERS. (INFO@WFPROFESSIONAL.COM).

HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US.

Drug labeling is an issue that is not often regarded by practitioners. There can be serious considerations. This lesson provides 3.0 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings.

**The program ID # for this lesson is 707-000-06-001-H03.
Pharmacists completing this lesson by January 31, 2009 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. List the components of a drug package insert & describe the significance of each component.
2. Discuss the regulatory implications of off label drug use.
3. Describe the significance of the "black box" warning.
4. Identify the regulatory significance of drug product labeling.
5. List the factors that can cause a drug to be considered misbranded.
6. Discuss the legal requirements for patient directed drug labeling.
7. Describe legal cases in which pharmacists & others associated with drug use have been held accountable for improper labeling.
8. Describe the responsibility of pharmacists to supplement patient counseling with written information for patients.

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.

INTRODUCTION

Pharmaceuticals are among the most highly regulated of all products in American commerce. Tremendously beneficial when used correctly, drugs can be very harmful when taken incorrectly. A safe drug can be used unsafely to the tragic detriment of the patient. It is not that patients want to use drugs incorrectly. They simply lack the expertise necessary to make decisions that result in correct drug use. This is because drugs are generally considered to be post-experience goods.

There are many ways to classify products and services. One of the traditional methods is to recognize differences based on a person's ability to experience the effects of the products and services. Some products can be easily evaluated before they are used. One simply visualizes the product and applies one's own previous experience to what can be seen in the product. For example, a painting or a knife can be seen to be of little or of great value before even using them. The purchaser is at no risk because the evaluation can be done ahead of time. Products like these that can be effectively evaluated before using them are called "pre-experience" goods. There are other products and services that are considered to be "experience" goods because they can be evaluated effectively only while using them. A meal at a restaurant or a movie is experience goods. Once you eat the meal or see the movie you know immediately that it is good or bad, but you cannot have known that ahead of time. The experiences of others may be relevant in a decision to use a product, but the value to a specific individual will be known only after that individual has used the product. The most difficult type of good or service is what is known as the "post-experience" good or service. These products cannot be evaluated until well after they have been used. A drug is an example of a post-experience good.

Because drugs are so difficult to evaluate, the federal Food, Drug and Cosmetic Act (FDCA) has implemented requirements designed to provide information to drug users to better inform the decisions made by users. In effect, the experience of others is made known to those who are considering the use of a drug, so that a more careful and knowledgeable decision about use can be made. The purpose of providing information is to increase the likelihood that a safe drug will be used safely. Drug information is made available both to health care providers (principally physicians and pharmacists), to patients, and to family caregivers of patients. The provision of information can convert a post-experience good into an experience good, or even a pre-experience good.

Drug labeling is the primary means of official information provision under the FDCA. A drug product that is not appropriately labeled is considered "misbranded" under the act, and the party who commits a misbranding violation can be severely punished. The basic document that establishes the parameters of required information provision from manufacturers to the public, under the auspices of the federal Food and Drug Administration (FDA), is the package insert. Written in technical language, the package insert is primarily intended to inform decisions made by health care providers. Less complex documents are generated based on information in the package insert, and they may be written in lay terms to enable patients or family caregivers of patients to make informed decisions. Pharmacists play a significant role in distributing information about drugs to other health care providers and to patients.

DRUG LABELING

Under the FDCA, the terms "label" and "labeling" are specifically defined. A drug "label" is considered to be "a display of written, printed, or graphic matter upon the immediate container of any article." "Labeling" refers to "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers,

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or (2) accompanying such article." The spoken word and video or audio programs would not be considered to be labeling, because they are not written, printed, or graphic matter. A distributor of written material need not have authored it for it to be considered labeling. Printed matter that is used in conjunction with the sale of a drug may be considered labeling, even if it was written by someone other than the seller. For example, reprints of journal articles distributed with a drug would be considered labeling. Newsletters published by third parties and distributed with a drug will also be considered labeling. But the mere placement of a book near a product will not justify classification of the book as labeling. The "common origin" test is usually applied, leading to classification as labeling any printed matter that came from the party who distributed a drug mentioned in the printed matter, regardless of who wrote the printed matter.

In recent years there has been concern expressed about the label on the stock bottle of prescription medication, and the volume of information required to be placed on it. Prescription drug labels are necessarily small in size because they must be affixed to the drug manufacturer's container. A large amount of information placed on a small label will create confusion and may lead to error. Patient safety is affected when a stock bottle's label contains so much information that the name of the drug and a description of it are so small that they are difficult to see. To prevent dispensing errors caused by confusing labels, there has been discussion of simplifying labels on drug stock bottles so they boldly state what is contained in the bottle, without diluting that message through the inclusion of voluminous information of little relevance.

MISBRANDING

A misbranding violation occurs in one of two ways. There can be misbranding based on something stated in a labeling, and there is misbranding based on something not stated (but required) in the labeling. When a misbranding violation occurs, either the violator has made a statement that is untruthful or misleading, or the violator has failed to make a required labeling disclosure. Herein lies the "gotcha" of the misbranding provisions. A clever (but uninformed) person might think that by stating very little in drug labeling there is little likelihood of making a statement that is false or misleading. So there could be no violation of the prohibition against making untruthful or misleading statements, this person would correctly conclude. But by saying little, the person would probably fail to comply with the adequate disclosure requirements, and the product would still be misbranded. Increasing labeling information to meet the full disclosure requirement would bring with it the risk that something disclosed would be either false or misleading. The bottom line is that to avoid a misbranding violation, a large volume of information must be disclosed, and it must be neither false nor misleading.

Pharmacists who dispense a medication pursuant to a prescription, and who affix a standard prescription label to the medication vial do not need to adhere to the full disclosure requirement, because they are exempt from it. Pharmacists may not place false or misleading statements on a prescription label, but the extensive information required for manufacturer stock bottles need not be placed on the vial dispensed by the pharmacist to the patient.

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CASE LAW IN PRODUCT LABELING

In a Tennessee case from 1990, the allegation against the defendant pharmacist was that the pharmacist should not have removed the manufacturer's product labeling from a container of eye drops dispensed to the plaintiff. The plaintiff contended that the pharmacist had not filled the plaintiff's prescription correctly because a prescription for eye drops means not only the eye drops themselves but the entirety of the product sold in a sealed package, including the manufacturer's labeling. In other words, the plaintiff's position was that a prescription for eye drops means the sealed box and everything within the sealed box. Since the pharmacist has opened the box and removed the package insert, and then dispensed the eye drops, the plaintiff argued that the pharmacist had inaccurately filled the prescription. The court affirmed dismissal of the case against the pharmacist, ruling that the manufacturer's labeling is directed to health care providers and not to patients. Moreover, the prescription did not direct the pharmacist to dispense the labeling to the patient; it directed only that the eye drops themselves be dispensed.

The significance of manufacturer labeling was also considered in a 1994 case from Tennessee. The plaintiff alleged that the patient who was dispensed an oral hypoglycemic medication should have been warned about the hazards of overusing it. In absolving the manufacturer from liability, the court referred to the product labeling in which a section titled "Information for Patients" instructed as follows: "The risks of hypoglycemia, its symptoms and treatment, and the conditions that predispose to its development should be explained to patients and responsible family members." This statement was sufficient to shift the responsibility for warning from the manufacturer to the physician and pharmacist.

THE PACKAGE INSERT

The standard means of communication from the pharmaceutical manufacturer to the health care provider, under the auspices of the FDA, is the drug package insert. Lengthy and packed with information, these documents, sent along with every drug provided to a pharmacist for dispensing, bring new meaning to the advice that one should "check the small print." Hidden in these documents, among the literally hundreds of standard cautionary statements, are important pieces of advice that can improve the safety and efficacy of drugs.

The purpose of the package insert has been described by the FDA:

"The major objective of the drug provisions of the Federal Food, Drug and Cosmetic Act is to assure that drugs will be safe and effective for use under the conditions of use prescribed, recommended, or suggested in the labeling thereof. When a new drug is approved for marketing, the conditions of use that have been approved are required to be set forth in detail in the official labeling. This labeling must accompany the drug in interstate shipment and must contain adequate information for safe and effective use of the drug. It presents a full disclosure summarization of drug use information, which the supplier of the drug is required to develop from accumulated clinical experience, and systematic drug trials consisting of preclinical investigations and adequate well-controlled clinical investigations that demonstrate the drug's safety and effectiveness it purports or represented to possess."

The headings in the package insert have specific meanings under FDA regulations.

Under "Indications and Usage," the agency instructs that "all indications shall be supported by substantial evidence of effectiveness based on adequate and well-controlled studies." This means that the package insert will not list under "indications" all uses to which a drug is actually put in medical practices, or all uses that are recognized as standard within medicine. Only those uses that have been subjected to clinical trials and for which clinical trials have supported a conclusion of safety and efficacy will be listed under "indications."

The section labeled "Contraindications" must describe "those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." The DEA regulation states that: "These situations include administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction." This is the section that the agency can use if they want to restrict prescribing of a drug to a particular type of patient or for a particular length of time. A drug can be contraindicated in young or old patients. It can be contraindicated in patients with a particular disease or who have had a certain laboratory value documented. A drug can be contraindicated for use beyond several weeks, months or years. It can be contraindicated for use

with another drug. This is the strongest of the categories in the package insert. It is the only one that completely restricts drug use. When a drug is prescribed in a way that is contraindicated in the package insert, there must be a very, very good reason for dispensing it. Otherwise, the drug should not be dispensed.

At this point it is important to note the distinction between the presence of a contraindication and the absence of an indication. A drug may not be indicated for use in patients who suffer from a particular disease. But unless the drug is contraindicated for use in patients with that disease, the package insert does not restrict its use in that disease. Likewise, a drug may not be indicated for pediatric patients. But it is not restricted from use in such patients unless the contraindications section of the package instructs that it is not to be used in this way. Sometimes pharmacists become confused about restrictions, thinking that simply because a drug is not indicated in a particular way it is necessarily contraindicated for use in that way. This is not a correct interpretation of FDA regulations. Only contraindications restrict the use of a medication. Indications, or the lack thereof, do not restrict use.

An equally important, but less restrictive, section of the drug package insert is labeled as "Warnings." Under this section heading, "the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." Rather than imposing limitations on use, as do contraindications, the warnings included in a drug package insert serve as an alert to problems that may occur and they provide guidance on how to manage those problems when they do occur. Within the section heading describing "warnings," there is a special note regarding "special problems." The note indicates that such special problems, "particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box." The regulation indicates that "If a boxed warning is required, its location will be specified by the Food and Drug Administration."

The so-called "black box warning" is a special kind of warning, but it is a warning nonetheless. It is not a contraindication. Usually placed at the top of the package insert, a black-box warning directs attention to a concern that might otherwise be missed if "hidden in plain sight" within the small print somewhere in the middle of the package insert. Black-box warnings have become far more commonplace in recent years than they once were. In fact, the presence of a black-box warning has become so common that the significance of the warning has been eroded. Once considered of great import, these warnings are now largely ignored. This is unfortunate, because the FDA may one day look for more restrictive distribution systems to control drug use, since the agency's key method of control using the package insert has become of little value.

The "Precautions" section of the package insert contains "information regarding any special care to be exercised by the practitioner for safe and effective use of the drug." These precautions include warnings about use of the drug in pregnancy, and a categorization of teratogenic hazard using the letters A, B, C, D, and X. The higher the letter in the alphabet, the less likely the drug is to cause teratogenic effects. Drugs categorized in pregnancy category X are those in which the "risk of use of the drug in pregnant women clearly outweighs any possible benefit." It is the precautions section of the package insert in which information about pediatric use will be listed. If there have been findings to support a pediatric indication or a pediatric use of a drug, then there will be extensive discussion of that use in the precautions. If no such findings have been made for pediatric use, then that lack of evidence will be noted. For such drugs that do not carry a labeled pediatric indication, if use in the pediatric population has been associated with a specific hazard, then that specific hazard will be noted in precautions. The absence of a specified hazard connotes that no such problem is known in pediatric use.

OFF-LABEL USE

Because the requirements for product labeling are strict, and because a high level of scientific evidence is necessary to support a labeling claim, not every accepted use of a medication is noted in the package insert. There are some widely accepted uses of medications that have not been subjected to clinical trials and never will be, because the cost to demonstrate what is already known is too high. Physicians prescribe drugs "off-label" and pharmacists dispense them "off-label" because it is necessary to do this if patients are to be cared for properly under the standard of care.

The FDA has consistently instructed that off-label use is permissible under the FDCA. Although the labeling requirements of the FDCA apply to the manufacturer and distributor, the prescriber and dispenser need not be constrained by the language within the package insert. The FDA instructs as follows:

"If an approved new drug is shipped in interstate commerce with the approved package insert, and neither the shipper nor the recipient intends that it be used for an unapproved purpose, the requirements of the Act are satisfied. Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration."

Circumstances may arise in which the agency becomes concerned about a widespread off-label use, and the agency has made it clear that the results will be administrative action aimed at the manufacturer; not at the prescriber or pharmacist. This is how the agency describes its role under such circumstances:

"Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. Several alternative courses of action are available to the Food and Drug Administration under these circumstances, depending upon the specific facts of each case. These actions include: Requiring a change in the labeling to warn against or to approve the unapproved use, seeking substantial evidence to substantiate the use, restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases."

Traditionally the agency has viewed manufacturer promotion of off-label uses as strictly illegal. Although that perspective has softened somewhat in the past several years, permitting information about some off-label uses to be shared by manufactures with health care professionals, the hard-line attitude continues to be the general rule. That attitude is reflected in this FDA statement:

"Where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly."

CASE LAW IN OFF-LABEL USE

Even with the FDA's reassurance that an off-label drug use will not cause problems for pharmacists, the possibility exists that courts will impose a duty to stay on-label, regardless of what has been established as a rule by the FDA. There have been many court cases to date involving the off-label use issue, and in most cases the courts have sided with the health care professional whose contention has been that the off-label use was appropriate. In those cases resulting in opposite conclusions, the use of the medication has been so egregious and willfully inappropriate that the off-label use issue has been largely overshadowed by other significant concerns about improper care. There are two classic cases that inform an understanding of the off-label use issue in litigation.

In *United States v. Evers*, the FDA sought to prevent the defendant, a physician, from using calcium disodium versenate in the treatment of arteriosclerosis because the labeling of this approved drug indicated that it was useful for the treatment of heavy metal poisoning, but no other conditions. Dr. Evers argued that the use of the drug for arteriosclerosis was not contraindicated in the package insert and that he had the right to use drugs in accordance with his best judgment as a physician. The court agreed with him and stated that once a drug is in a local pharmacy, the physician may choose how to use the medication in patient care. However, the court left open the question of whether the FDA could prevent the prescribing of approved drugs for uses that are contraindicated in the product labeling, suggesting that such a prohibition may be possible under the law. Also left unanswered was the question of whether the dispensing of a contraindicated drug by a pharmacist pursuant to a prescription would be an act of misbranding.

The use of an unapproved drug in a way that is not specifically suggested in the drug's official labeling may serve as the basis for a claim against a health care provider. In *Ramon v. Farr*, a physician was sued for damages allegedly caused by the injection of a drug as a paracervical block when that use was not recommended by the manufacturer. The physician countered that the package insert language did not contraindicate the use of the drug for paracervical blocks, but simply stated that the manufacturer was not recommending the use of the drug without further testing. The court reviewed a number of cases from different jurisdictions in which different positions on the issue had been adopted. The court ruled that a drug's official labeling, as represented by its manufacturer's package insert, does not by itself set the standard of care. A manufacturer's recommendations

are, however, evidence that the finder of fact may consider, along with expert testimony, on the standard of care. Although package inserts may provide useful information, they are not designed to establish a standard of medical care.

PATIENT-DIRECTED LABELING

Providing information to health care professionals may be insufficient if patients are heavily involved with decisions about medication use. Federal regulations require for some drugs that a medication leaflet be given directly to the patient at the time of dispensing. This information is considered labeling, because it is printed matter that accompanies the product. Written information for patients differs from the package insert for health care providers, both in content and in format. It is not as scientifically complex, and it is easier to understand. A pharmacist who fails to dispense a legally mandated patient leaflet has misbranded the product.

The federal government has a long history of programs designed to get information directly in the hands of patients. A comprehensive and controversial program of patient package inserts (PPIs) for all drugs was promulgated during the Jimmy Carter presidency, and would have become effective had he won a second term. It was a massive program, requiring manufacturers to send pharmacists stacks of leaflets accompanying drug stock bottles, and requiring pharmacists to then include a leaflet with each dispensing of the drug to a patient. When Ronald Regan became president, his administration rescinded all promulgated rules that had not yet gone into effect. This action was the death knell for comprehensive patient package inserts. The idea has never been seriously reconsidered.

What remains is a mere vestige of what could have been. A limited federal PPI program continues to be in effect, but it applies only to estrogens, progestational drugs and oral contraceptives. Bulk leaflets are sent by the manufacturer to the pharmacy, and the pharmacy must distribute the leaflets to patients. For outpatients, the requirement applies with each dispensing. For inpatients, the requirement applies with the first dispensing, and every 30 days thereafter.

More recently, a small but important program has been the focus of FDA activities in the area of patient-directed labeling. Since 1999, the FDA has been authorized to require a patient-directed document known as a Medication Guide (MedGuide) to be distributed directly to patients with a limited number of drugs (those that pose a "serious and significant" concern to public health). Various means of accomplishing this distribution have been discussed, but the primary means continues to be through the pharmacy at the point of sale. MedGuides are written in lay language but they convey much of the same information as the drug's package insert. MedGuides are often required as part of an FDA developed "risk management" program that permits the marketing of drugs that would otherwise be off the market, as long as patients are taught how to use the drugs correctly to manage their risks. Some examples of MedGuide drugs include Accutane®, Lotronex®, Lariam®, and Lindane Lotion and Shampoo.

Federal regulations are not the only source of patient-directed labeling. Some pharmaceutical manufacturers have voluntarily provided patient-directed labeling for drugs, either included within the stock packaging or in some other way accompanying the packaging, when it is distributed to pharmacists. Not all such labeling is truly voluntary. The FDA may have expressed grave reservations about the approval of a product, and only become convinced of the product's safety when the manufacturer offered to voluntarily include patient directed labeling with each unit. Regardless of the motivation in creating this labeling, pharmacists have a responsibility to provide it to patients, and this sometimes requires inventiveness in dispensing.

Pharmacists have increased the amount of written information they have provided to patients. The most common type of patient-directed labeling is the computer-generated information sheet that pharmacists routinely give to patients with their medication. Almost every computerized pharmacy has a program that creates a brief listing of advice for the patient. This information is not approved by the FDA and it may not reconcile completely with the package insert. For this reason, the FDA has expressed concerns about it. Under an exemption in federal law, most misbranding provisions do not apply when a pharmacist is dispensing medication pursuant to a prescription. As long as the pharmacy-generated information is truthful and not misleading, it is unlikely that a misbranding violation would occur.

CASE LAW IN PATIENT-DIRECTED LABELING

Hospitals and other institutions in which patients receive a drug for which there is a PPI share with the attending physician the responsibility to ensure that patients receive patient-directed labeling prior to administration of the first dose of medication and every 30 days thereafter. In the case of *Schlieter v. Los Alamos Medical Center*, the plaintiff alleged that the defendant hospital had failed to meet its responsibility to give her a leaflet regarding estrogen prior to administering that drug to her. The hospital contended that its policy was to delegate this responsibility to attending physicians who were not employees of the hospital, and that it could not be helped that the patient's physician had not provided a federally mandated leaflet. Referring to the federal regulation, which does not include an exception for hospitals, the court ruled that an independent duty to provide leaflets rests with the pharmacists at hospitals, and this duty cannot be delegated to physicians.

The plaintiff in *Farkas v. Saary* was a woman who was prescribed progesterone during pregnancy and who later gave birth to a child suffering from left-sided microphthalmia. This is a condition in which the eye socket and eye are abnormally small resulting in blindness to the affected eye. The defendant pharmacy allegedly did not provide the patient-directed information leaflet about progesterone required by FDA regulations. However, the court noted that the written information in the leaflet contained warnings solely related to genital abnormalities that might occur in children born to a woman who used the drug during pregnancy. No side effects related to vision were included in the leaflet's warnings. Therefore, the court held that the failure to provide the mandated leaflet could not have been the cause of the child's birth defect because this would not have been mentioned even if the leaflet had been provided by the pharmacist.

Litigation against pharmacists may be based on the failure to distribute manufacturer-supplied leaflets, even if the leaflets are not mandated by the FDA. In the case of *Santiago v. Bare National, Inc.*, the court described allegations by a woman who claimed that medication dispensed by the defendant pharmacy had harmed her child. The specific allegation was that the pharmacy had failed to give the mother a handout leaflet provided by the manufacturer to the pharmacist. The leaflet instructed on the proper use of the medication and cautioned against improper use. The child developed serious neurological damage which the mother claimed would not have occurred had the pharmacy provided the leaflet that was designed to accompany the drug product when dispensed. Although this particular case report dealt with allegations against the manufacturer, it refers to a \$700,000 settlement entered into with the pharmacy.

CONCLUSION

Pharmacists and prescribers have responsibilities to patients that depend on accurate and complete information. Information is provided to pharmacists and prescribers by manufacturers, primarily through the drug package insert. This information must be truthful and not misleading. It must also be complete, including full disclosure of required information. A drug is misbranded if the labeling requirements are not met. Additional labeling is directed to patients, to assure that they understand how to maximize the benefits and minimize the detriments of medications. Failure to provide this patient-directed information to patients falls below the standard of care for pharmacists.

UPCOMING TOPICS FOR 2006

Pharmacy Law Update 2006
New Drugs for Erectile Dysfunction
Jaundice
HIV/AIDS Update
Medication Errors Update
Diarrhea & Constipation

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to:
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CHECK IF NEW ADDRESS **ARE YOU LICENSED IN FLORIDA? IF YES FL LIC** _____

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LESSON EVALUATION

Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

List components of a drug package insert	Yes	No		
Discuss regulatory implications of off label drug use	Yes	No		
Describe significance of the 'black box' warning	Yes	No		
Identify the regulatory significance of drug product labeling	Yes	No		
List the factors that can cause a drug to be considered misbranded	Yes	No		
Discuss the legal requirements for patient directed drug labeling	Yes	No		
Describe legal cases in which pharmacists have been held accountable for improper labeling	Yes	No		
Describe the responsibility of pharmacists to supplement counseling with written information	Yes	No		

2. Was the program independent & non-commercial?

	Poor		Average		Yes	No
	1	2	3	4	5	6
						Excellent
						7

3. Relevance of topic to your practice

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

(WATCH OUR WEBSITE FOR RESULTS OF PARTICIPANT EVALUATIONS)

Quiz—Please Select the Most Correct Answer

1. A drug is an example of which type of 'good'?
 - A. Non-experience
 - B. Experience
 - C. Pre-experience
 - D. Post-experience
2. Under the FDCA, what word is used to describe written, printed, or graphic matter accompanying the container of a drug?
 - A. Packaging
 - B. Label
 - C. Labeling
 - D. Branding
3. A misbranding violation on a manufacturer's stock bottle of meds occurs when:
 - A. Statements are untruthful
 - B. Statements are misleading
 - C. Statements fail to meet full disclosure requirements
 - D. All of these
4. Which category signifies the least danger of a drug when used in pregnancy?
 - A. A
 - B. B
 - C. C
 - D. X
5. In the package insert, the term *Precautions* refers to information regarding any special care to be exercised by the practitioner for safe & effective use of the drug.
 - A. True
 - B. False
6. Which term is used to refer to those situations when the drug should not be used if the risk of use clearly outweighs any possible benefit?
 - A. Contraindications
 - B. Precautions
 - C. Warnings
 - D. Adverse Effects
7. The manufacturer may have an action aimed at them, if the FDA learns of widespread off label use of a medication.
 - A. True
 - B. False
8. When a drug for which a PPI is required, & is dispensed to a hospital inpatient, the leaflet must be dispensed upon the 1st administration of the drug & every 30 days thereafter during the hospitalization.
 - A. True
 - B. False
9. If a pharmacist's computer generates an information leaflet for a patient, & if the leaflet contains untruthful information, this is a violation known as misbranding.
 - A. True
 - B. False
10. A black-box warning in a package insert should be interpreted as what type of information from the manufacturer to the health care provider?
 - A. Precaution
 - B. Contraindication
 - C. Warning
 - D. Adverse effect

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