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January 2008 "Legal & Regulatory Update 2008" 707-000-08-001-H03-P

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"Pharmacy Law  
2008"

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During the early & mid 1970s, we provided CE programs on audio cassettes. Those programs, called Edutapes, were well received in the days before most states had mandatory CE requirements.

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In this lesson we discuss a number of legal & regulatory challenges that we face as pharmacists. 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 707-000-08-001-H03-P. Pharmacists completing this lesson by January 31, 2011 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.

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

1. Discuss current legal & regulatory challenges facing pharmacists.
2. Describe the legal status of drug reimportation in the U.S.
3. Discuss the status of currently marketed drugs that have been FDA approved.
4. List FDA factors considered to determine if a pharmacy is a manufacturer or a compounder.
5. Explain the status of the DEA rule permitting multiple same day C-II prescriptions with "DNF until" instructions.
6. Discuss the advantages & disadvantages of electronic prescription monitoring programs

**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.**

## BACKGROUND

The legal and regulatory environment of pharmacy practice continues to play a significant role in determining how pharmacists provide services and products to patients. The federal government oversees pharmacists indirectly through the regulation of the product that pharmacists control. State regulators establish rules for individual licensure, the equipment and resources necessary at a practice site, and for standards of practice in the provision of services and products to patients.

Sometimes these state and federal rules are inconsistent with each other. The general approach to inconsistencies between state and federal laws and regulations is that the stricter of the two is the rule that must be followed by a pharmacist. For example, if a state legalizes the sale of marijuana for medical purposes (as several states have done), it is still illegal to sell marijuana in those states, because each state is a part of the United States, and federal law enforcement officials will arrest and prosecute those who sell marijuana in any state. The stricter federal law would be the law that pharmacists should follow, even though state law enforcement personnel would have no quarrel with the sale of marijuana for medical purposes in states where that activity is legal.

On the other hand, some states have made it illegal to prescribe and dispense appetite suppressant medications unless very specific requirements have been met. Federal law imposes no such requirements. If a prescriber or dispenser were to authorize the acquisition by a patient of an appetite suppressant to treat obesity, without meeting the state-imposed requirements, then the federal authorities would have no problems. But state authorities could enforce the stricter state laws.

Sometimes federal-state conflicts are not as clear as the above two examples. When that occurs, pharmacists are often placed in a quandary as to what they should do and how they should do it. The purpose of this lesson is to provide updated information about federal agencies that regulate pharmacy, and guidance on how to handle situations that present potential conflicts between state and federal laws.

## RECENT FOOD AND DRUG ADMINISTRATION ISSUES

The FDA rarely inspects pharmacies, and the regulatory activities of that federal agency are focused primarily on manufacturers and distributors upstream from the final distribution to patients. Nevertheless, FDA regulation reaches the dispensing level, so pharmacists must be mindful of the requirements impacting them under the Food, Drug and Cosmetic Act (FDCA) and the regulations promulgated by the FDA pursuant to the authority of the Act. A pharmacist who violates the FDCA can be federally prosecuted and can also be disciplined by the Board of Pharmacy in most states, because most state pharmacy acts permit discipline by the licensing agency for violations of federal laws.

## DRUG REIMPORTATION

Seldom does a week go by without the media reporting concerns about the prices of pharmaceuticals in the United States and emphasizing the disparity in pricing between the U.S. market and the market overseas. The comparison is usually made between the United States and Canada, where price controls make it possible to purchase pharmaceuticals significantly lower than in the U.S. Patients sometimes express alarm to U.S. pharmacists because it seems so unfair that the prices for pharmaceutical should be so much higher here, since most of the pharmaceuticals were developed and produced in the U.S. Some state governments have developed policies of allowing reimportation of pharmaceuticals either for personal or commercial use. Because of these policies, pharmacists may get mixed messages from state and federal regulatory authorities, with the state

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regulators supporting the reimportation of pharmaceuticals and the federal authorities advising against it. Unless the U.S. Congress passes new legislation, it is clear that the reimportation of pharmaceuticals from other countries is strictly illegal. Here is what the FDA has to say in a guidance document it has issued:

### **GENERAL GUIDANCE**

*The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.*

*FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.*

### **Commercial or Promotional Shipments**

*Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment. In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations:*

- 1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or*
- 2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;*  
*b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue;*  
*c) the product is considered not to represent an unreasonable risk; and*  
*d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.*

This guidance provides clear instruction to pharmacists that the reimportation of pharmaceuticals from foreign countries for commercial purposes is illegal under any circumstances. Pharmacists may not be involved in this activity at all. Actually, the reimportation of pharmaceuticals by patients for their own personal use is illegal as well, but the FDA has decided to "look the other way" when this is done, as long as the quantities are for no more than a 3 month supply. Even then, the guidance requires that certain criteria be met, such as the drug not presenting an unreasonable risk and the patient being able to identify a doctor who is responsible for his or her treatment. Until the matter of reimportation is resolved by federal legislation, pharmacists who involve themselves in it for commercial purposes risk regulatory action.

### **UNAPPROVED NEW DRUGS**

For many years a large number of drugs have been marketed without FDA approval because conventional wisdom was that they did not need FDA approval. Only "new drugs" require FDA approval before they can be introduced into interstate commerce. A "new drug" is a drug that scientific experts do not generally rec-

ognize as safe and effective under the conditions for which the drug is prescribed, suggested or recommended in the drug's labeling. Drugs that are generally recognized as safe and effective are referred to as GRASE drugs, and are sometimes said to have achieved a "state of GRASE." This is different from so-called grandfathered drugs that were marketed prior to 1938 and are still labeled in the same way as they were in 1938 (prior to the enactment of the FDCA). Most people believe that there are no true grandfathered drugs, because all pre-1938 drugs currently on the market have labeling that differs from the pre-1938 labeling. The drugs that are unapproved and are currently being marketed are GRASE rather than grandfathered.

On June 8, 2007, the FDA changed the rules from those that had previously been in effect, through a guidance document that announced the intent to require all drugs to be approved by the agency. In effect, the agency ruled that all drugs are "new drugs." Here is what the agency had to say in a press release describing the guidance:

*The Food and Drug Administration (FDA) announced the strengthening of its efforts against unapproved drug products. The activity will begin with prescription products containing the antihistamine carbinoxamine because of safety concerns regarding their use in children less than 2 years of age.*

*The agency is issuing a final guidance document outlining its approach to addressing other medicines that are marketed without FDA approval.*

*The first action under the new guidance, "Marketed Unapproved Drugs—Compliance Policy Guide," concerns carbinoxamine-containing products. Carbinoxamine-containing products require FDA approval to be marketed, but numerous products containing carbinoxamine, either alone or in combination with other active ingredients, are marketed without FDA approval. To date, FDA has approved two carbinoxamine products for various allergic symptoms. Many unapproved carbinoxamine products are labeled for treatment of cough and cold symptoms, an indication for which carbinoxamine has not been found safe and effective by FDA. Many companies are selling carbinoxamine drops and syrups that are specifically labeled for use in children as young as one month of age. Carbinoxamine has never been studied in very young children, and FDA cannot predict how they will respond to it. However, children under 2 years of age are more susceptible to drug-related adverse events, in part due to the immaturity of their systems.*

*FDA estimates that there are several hundred different unapproved active ingredients in prescription drugs on the market. The agency estimates that less than 2 percent of prescribed drugs are unapproved.*

*"Right now, many unapproved drugs represent a public health threat because consumers wrongly assume that these widely marketed and available drugs are approved and have been found to be safe and effective by the FDA," said Acting FDA Commissioner Dr. Andrew von Eschenbach. "While we want to ensure continued patient access to necessary treatments, as a physician I feel strongly that patients expect and deserve all their prescription medicines to be FDA approved. These unapproved drugs have bypassed the agency approval process through which FDA ensures, based on reliable scientific data, that marketed drugs are safe, effective, properly manufactured, and accurately labeled."*

*Many of the unapproved drugs affected by today's final guidance, including the antihistamine carbinoxamine, are medicines that were developed and marketed before successive changes to the drug approval process that is established in the Federal Food, Drug, and Cosmetic Act. FDA approval guarantees that a product has been reviewed and will be consistently monitored for safety, effectiveness and adherence with manufacturing quality standards.*

*Unapproved drugs may not meet modern standards for safety, effectiveness, quality, and labeling. Clearly this is a problem we intend to fix," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research.*

*Health care providers are often unaware of the unapproved status of some drugs and have continued to unknowingly prescribe unapproved drugs because the drugs' labels do not disclose that they lack FDA approval. Often these drugs are advertised in reputable medical journals or are included in widely used pharmaceutical references such as the Physicians' Desk Reference (PDR).*

*Under the guidance issued today, FDA is encouraging companies to comply with the drug approval process and seek approval for their products, as well as safeguarding consumer access to important medicines. The guidance identifies as the highest priority for agency enforcement action those unapproved products that are most likely to pose a risk to public health. The guidance explains that FDA intends to continue to give prior-*

ity to enforcement actions involving unapproved drugs (1) with potential safety risks, (2) that lack evidence of effectiveness, and (3) that constitute health fraud. It also explains how the agency intends to address those situations in which a company obtains FDA approval to sell a drug that other companies have long been selling without FDA approval. Those manufacturers that do not comply with drug approval requirements may be subject to enforcement action.

Today's actions are part of FDA's broader initiative, launched last year, to ensure that consumers and the health care community are provided with established and emerging drug safety information so that they can make the best possible medical decisions about the safe and effective use of drugs.

The agency is committed to working with companies to facilitate the process of ensuring that products are safe and effective and meet appropriate standards for manufacturing and labeling. It is noted that some unapproved drugs may provide benefits. However, since these unapproved drugs are not approved by the FDA, the agency recommends that patients and health care professionals carefully consider the medical condition being treated, the patient's previous response to the drug, and the availability of approved alternatives for treatment.

As a consequence of this shift in policy by the FDA, pharmacists are now in a position that requires them to dispense unapproved new drugs (for example, immediate release morphine products are unapproved new drugs), because there are no suitable alternatives to them. Yet the FDA has declared that these drugs violate the law. As the FDA works with manufacturers to solicit new drug applications and approve those applications, pharmacists may be placed in situations where two products of a drug are available, and one is approved by the FDA but the other is not. Pharmacists who wish to dispense only approved drugs should refer to the Online Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations), available at <http://www.fda.gov/cder/orange/default.htm>. This reference, usually used to determine whether two generically equivalent products are rated as therapeutically equivalent by the FDA, is also a useful reference for pharmacists who need to know the fundamental approval status of a particular product.

## PHARMACIST COMPOUNDING

Perhaps the most challenging issue for state and federal regulatory authorities is the question of what pharmacist activities should be classified as compounding and what activities should be classified as manufacturing. In the late 1990s, the issue seemed to have been resolved with federal legislation that provided clear guidelines. That federal legislation effectively classified large scale pharmacy operations that were not patient-specific as manufacturing, and small scale pharmacy operations focusing on individual patients as compounding. It was a compromise that met the need of the FDA to clamp down on what it perceived to be unauthorized manufacturers masquerading as pharmacies, while at the same time permitting traditional pharmacy compounding to continue uninterrupted. That federal legislation was held unconstitutional due to a provision that violated freedom of speech (the law forbade certain types of pharmacy advertising). In the absence of clear legislative guidelines, the FDA has now reissued a compliance policy guide (CPG) that is not the law but is guidance on how the law will be enforced.

In 2006, a federal district court in Texas caused quite a stir when it ruled that the FDA has no authority to regulate compounding. This ruling stood in stark contrast with the position advocated by some in the FDA, which is that all pharmacy compounding is illegal. The ruling is being appealed and it is likely that some balance will be struck between the two polarized "FDA can't regulate anything" and "FDA can regulate everything" positions. In the meantime, the CPG is the best guidance pharmacists have on what they can and cannot do. Here is what the CPG says:

*Generally, FDA will continue to defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states. However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any*

of the following acts:

1. *Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.*
2. *Compounding drugs that were withdrawn or removed from the market for safety reasons.*
3. *Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.*
4. *Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.*
5. *Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.*
6. *Using commercial scale manufacturing or testing equipment for compounding drug products.*
7. *Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.*
8. *Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.*
9. *Failing to operate in conformance with applicable state law regulating the practice of pharmacy.*

The foregoing list of factors is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

Note that this list is simply a description of factors that the FDA will take into consideration in deciding whether to investigate a pharmacy that the agency believes may be engaging in manufacturing. Simply because a pharmacy practices contrary to one of these factors does not mean that the pharmacy has broken the law. State laws may provide that one or more of the above listed factors are legal. If this is the case, then the FDA has suggested that compliance with state laws would be considered favorably, just as the failure to comply with state laws would be considered unfavorably.

## **RECENT DRUG ENFORCEMENT ADMINISTRATION ISSUES**

The Federal Drug Enforcement Administration (DEA) has been very active in recent years, confronting pharmacists and pharmacies when the agency believes they have been involved in some way with the diversion of controlled substances. The perceived crisis over OxyContin, and the national data showing that there is an increase in the abuse of pharmaceutical controlled substances, has led to a shift in the agency perspective from one of almost complete focus on street drugs to one of increasing emphasis on the diversion of pharmaceuticals. This emphasis on pharmaceutical diversion prevention has led to rulemaking and enforcement actions that have a chilling effect on the availability of medications for patients who legitimately need them.

### **MULTIPLE SAME-DAY C-II DNF PRESCRIPTIONS**

For many years pharmacists and physicians have engaged in a practice through which physicians have written several original prescriptions on the same day for patients who do not need to be seen every month because their condition is stable. Since all prescriptions must be dated on the date of issue, post-dating prescriptions is illegal. So the prescribers have instead dated every prescription with the date of issue, but on some of them have written the instruction "do not fill until [a firm date in the future]." These prescriptions are often referred to as "do not fill" or DNF prescriptions. For many years the DEA instructed that this was the correct way to authorize a continued supply of C-II medication for a patient whose need was well documented and who would be wasting money and be caused an unnecessary inconvenience to visit the physician more often than necessary.

In August, 2004, the DNF approach to patient care was reiterated in a DEA document that was posted to the DEA website. Six weeks later the document was withdrawn. Although the law had not changed in that time period, the agency said that it had made a "misstatement" by indicating that DNF prescriptions can be filled.

The medical and pharmacy professions, and patient advocacy groups, cried foul, and two years later the agency admitted it had been wrong. The agency has now finalized a rule that clearly provides that DNF prescriptions are legal. The final rule says this:

**Sec. 1306.12 Refilling prescriptions; issuance of multiple prescriptions.**

- (a) *The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.*
- (b)(1) *An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:*
- (i) *Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;*
  - (ii) *The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;*
  - (iii) *The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;*
  - (iv) *The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and*
  - (v) *The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.*
- (2) *Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.*

While this is a welcome development from the perspective of health care providers and the patients who they serve, the rule contains perplexing language that must eventually be clarified. For example, what is an "undue risk of diversion or abuse"? (See paragraph (B)(1)(iii) above) The phrase itself suggests that some risk of diversion or abuse is expected and is acceptable, but how much? When does a risk become so great that it is "undue"? Also, the requirement that DNF prescriptions be issued only "in accordance with established medical standards" is perplexing. (See paragraph (B)(2) above). The fact is that there are no established medical standards for DNF prescriptions, other than the standard that they are acceptable for use in medical care. Is the DEA suggesting that there are limits that medical standards place on DNF prescriptions? If so, what are those limits and where can a description of them be found? Hopefully these questions will be clarified as additional interpretive information is developed. For now, the DEA has made it clear that DNF prescriptions are not illegal, although there are certain criteria that must be met when DNF prescriptions are used.

## **ELECTRONIC PRESCRIPTION MONITORING PROGRAMS**

About half of the states have enacted some sort of program that establishes a statewide electronic prescription monitoring program (ePMP). Although all of the programs differ somewhat from each other, the basic idea is that pharmacies periodically upload their controlled substance dispensing data to a centralized database somewhere and these data are aggregated into a single database. The database can then be queried to determine whether certain patients are doctor shopping, and those patients can be denied medications that they do not deserve. Pharmacists and physicians who have the responsibility for providing services and products to a particular person may query the system about that person. Usually, law enforcement personnel are not permitted to go on a "fishing expedition" in the database. The official DEA position on ePMPs is that they are hugely successful. The DEA has this to say:

*Prescription monitoring programs are being used to deter and identify many types of illegal activity including prescription forgery, indiscriminate prescribing and "doctor shopping" -which is a felony in some states. Most programs provide patient specific drug information upon request of the patient's physician or pharmacist. Some state programs proactively notify physicians when their patients are seeing multiple prescribers for the same class of drugs. This assists health care professionals in enhancing patient care by allowing them to intervene on the patient's behalf and assist them in obtaining appropriate treatment. It has been an extremely suc-*

*cessful program to thwart diversion in a number of states.*

This optimistic assessment belies problems that those in the field have detected with ePMPs. The primary problem is patient identification. With so many patients having the same or similar names, and the same or similar birthdates, reports to health care practitioners from the programs are either too inclusive or too exclusive. The reports either include people who should not be included or they exclude people who should be included. Physicians and pharmacists are left to figure out whether the report they receive about a patient accurately reflects medication acquisition by that patient. To confuse the analysis, it is not difficult for drug diverters to acquire false identification for a fraction of the cost of the medication that can be acquired in one fraudulent prescription.

Pharmacists who live in states with ePMPs should be mindful of the limitations of these programs. The programs are subject to error, and the content of a report should not be assumed to be accurate. A report from an ePMP is a beginning, and not an ending. The report may, for example, indicate that a patient has been receiving medication from other prescribers and at other pharmacies, but the report may reflect information about another person who has the same name and a similar birth date. Any patient who has a plausible explanation for why a report may contain inaccurate information deserves to have that report verified as accurate through additional investigation. The pharmacist at the other pharmacy may be able to clarify that the person listed on the report is not the person who is seeking medication from the pharmacy that requested the report.

### CONCLUSION

Pharmacists are health care providers first, but under many circumstances, they must be legal experts second. The ability of a pharmacist to provide safe and effective pharmaceutical products and services to patients depends to a certain degree on the ability of the pharmacist to interpret the laws that permit certain activities and forbid others. The legal landscape is constantly changing, and the successful pharmacist must stay up-to-date with those changes.

Asthma	Medication Errors Update
HIV/AIDS Update	BPH
New Standards on Cholesterol	New Standards on BP
OTC Antihistamines—New Concerns for Pharmacy Practitioners	Which Cancers (If Any) Are We Gaining Control Of?
Review of New Drugs	Review of Popular Natural Supplements

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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?

- |   |     |    |
|---|-----|----|
| Discuss current legal & regulatory challenges facing pharmacists                  | Yes | No |
| Describe legal status of drug reimportation in the U.S.                           | Yes | No |
| Discuss status of currently marketed FDA approved drugs                           | Yes | No |
| List FDA factors that determine if pharmacy is a manufacturer or compounder       | Yes | No |
| Explain DEA rule regarding multiple same day "DNF until" prescriptions            | Yes | No |
| Discuss advantages & disadvantages of electronic prescription monitoring programs | Yes | No |
| 2. Was the program independent & non-commercial                                   | Yes | No |

	Poor		Average		Excellent
3. Relevance of topic	1	2	3	4	5 6 7

4. What did you like most about this lesson? \_\_\_\_\_

5. What did you like least about this lesson? \_\_\_\_\_

**Please Select the Most Correct Answer**

- |  |   |
|--|---|
| 1. When a state law & a federal law conflict, which should be followed?<br>A. State law<br>B. Federal law<br>C. Stricter law<br>D. Either federal or state law   | 6. Commercial importation of drugs into the U.S. by pharmacists is permitted as long as the quantity does not exceed:<br>A. 1 month supply<br>B. 2 month supply<br>C. 3 month supply<br>D. Commercial importation not permitted                                       |
| 2. If a state legalizes medical marijuana, then federal law is irrelevant & a pharmacist may dispense medical marijuana in that state without fear of state or federal prosecution.<br>A. True<br>B. False | 7. FDA recommends that healthcare professionals who dispense unapproved drugs carefully consider the medical condition being treated, the patient's previous response to the drug & the availability of approved alternatives for treatment.<br>A. True      B. False |
| 3. Federal regulation reaches the dispensing level, so pharmacists must be mindful of the requirements of them under the FDCA.<br>A. True<br>B. False  | 8. Under the current DEA rule, DNF prescriptions may be issued for up to how many days supply of C-II medications?<br>A. 30<br>B. 60<br>C. 90<br>D. 120   |
| 4. So-called "Grandfathered" drugs are those that were marketed prior to:<br>A. 1938<br>B. 1952<br>C. 1962<br>D. 1985  | 9. Reports from ePMPs should be considered a beginning & not an ending.<br>A. True<br>B. False  |
| 5. What percent of currently prescribed drugs does the FDA estimate are unapproved?<br>A. 1 %<br>B. 2 %<br>C. 3 %<br>D. 4 %  | 10. How many states have ePMP programs?<br>A. None<br>B. Just a few<br>C. About half<br>D. Almost all   |

**Contributing Author**

David D. Brushwood, RPh, JD  
Professor, Healthcare Administration  
University of Florida College of Pharmacy  
Gainesville, FL

**Executive Editor**

William J. Feinberg,  
BS Pharm, MBA

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