Accreditations (Pharmacy): This continuing pharmacy education activity is accredited by ACPE for law-related continuing education for pharmacists (topic designator "03") in all 50 states. It is also approved by the Ohio State Board of Pharmacy for Ohio Board-approved jurisprudence.

Credit(s): 1.0 contact hours (0.1 C.E.U.)
Release Date: March 20, 2013
Expiration Date: January 28, 2015
Program Fee: $15.00
Program Title: 2013 Pharmacy Law Review - Recent Cases

Target Audience: All Pharmacists

Release Date: March 20, 2013

Expiration Date: January 28, 2015

Ohio State Board of Pharmacy Program No.: 036-350-13-001-H03

ACPE Program No.: 487-000-13-001-H03-P knowledge-based activity
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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 program, complete the post-test questions and evaluation on the Answer Sheet, and either:

i) mail the Answer Sheet (page 14) and the program fee of $15.00 to us. You will receive a Statement of Credit mailed to you within 2 weeks. Checks or money orders are encouraged. Mail to: Pharmacy Jurisprudence, P.O. Box 21186, Columbus, Ohio 43221-0186. Refunds are not provided.

or

ii) use our online test-taking website www.selectce.org. Follow the instructions on the website, using any major credit card to pay the $15 program fee. Upon passing the test, you will receive immediate confirmation via email, and your official Statement of Credit will be sent via U.S. mail within 5 days but in most cases within 2 days. Refunds are not provided, unless you mistakenly make too many online payments or some such other online snafu.
A minimum score of 72% is required to earn a Statement of Credit.

**Faculty**: Patricia A. Nussle, R.Ph., J.D., is the founder of Pharmacy Jurisprudence and Select CE. She is also a healthcare attorney who has written and published continuing education programs in pharmacy law and nursing law for over 200,000 healthcare professionals since 2001.

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**Objective**: At the conclusion of this program, **pharmacists** should be able to describe at least 3 violations of federal drug laws.

**Objective**: At the conclusion of this program, **pharmacy technicians** should be able to describe at least 3 violations of federal drug laws.

**Important Note**: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority. If you do have a legal problem or question, please consult an attorney experienced in pharmacy law matters to discuss your specific situation.

**Thank you! We truly enjoy serving you.**
Introduction

In this CE program offering, we highlight several types of violations, or alleged violations, of federal drug laws. Specifically, this program looks at real-life situations ranging from questionable couponing programs by a large retail chain to off-label drug promotion by multi-billion dollar pharmaceutical companies to billing for prescriptions never dispensed by a small independent pharmacy. Because so many of you are from Ohio or New Jersey, we also offer a highlight from each of these state Board of Pharmacy newsletters that is applicable to all.

Walgreens Pays $7.9 Million to Resolve Coupon Case

Walgreens, a company with over 7,000 drugstores and yearly sales of over $72 billion, learned the hard way that prescription couponing has its costs.

In May 2012, Walgreens paid the government $7.9 million in a settlement reached amid allegations that the drugstore chain illegally paid kickbacks so that prescriptions would be transferred to its pharmacies.

Federal agents had been looking into whether Walgreens had given patients enrolled in government-run health programs -- such as Medicare, Medicaid, Tricare (for military families) and FEHBP (for federal employees) -- gift cards and coupons ranging from $10 to $50 if they moved their prescriptions over to Walgreens' drugstores.

Such inducements violate federal law, says the U.S. Department of Justice.

Not so, said Walgreens, which admitted no wrongdoing. Yet, its lawyers apparently knew that giving gift cards to these types of patients violated federal law, because on Walgreens' coupons the company stated the gift cards did not apply to those insured via Medicaid, Medicare and other federal programs. Despite the exemptions on the coupons, the government believed that

Question 1:
Using coupons and gift cards to induce patients enrolled in government-run health programs to transfer their prescription to your pharmacy:

a. violates federal law;  
b. violates patients' privacy;  
c. cannot be easily captured by claims processing systems.

1 http://www.justice.gov/opa/pr/2012/April/12-civ-505.html  
2 http://www.cnn.com/2012/04/20/health/walgreens-prescription-settlement/index.html  
3 http://www.courthousenews.com/2012/04/24/45884.htm
"Walgreens employees frequently ignored the stated exemptions on the face of the coupons and handed gift cards to customers who were beneficiaries of government health programs."

As can so easily happen, transferring legal knowledge into daily practice proved to be difficult. It appears the cashiers and technicians at the drugstores were not trained, or not trained well enough, to know not to honor coupons and give gift cards to federally-insured patients.

The government learned of the allegations in lawsuits filed by two whistle-blowers: Cassie Bass, a pharmacy technician who worked at Walgreens in Detroit, and Jack Chin, an independent pharmacist in Florida.

All of this begs the question: why is honoring coupons and giving gift cards to federally-insured patients against the law?

Couponing to federally-insured patients is against the law because:

a. coupons are really kickbacks;
b. coupons do not provide real value to the patient;
c. formularies for federally-insured patients dictate which drugs to dispense.

Question 2:

Couponing to federally-insured patients is against the law because:

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b. coupons do not provide real value to the patient;
c. formularies for federally-insured patients dictate which drugs to dispense.

Question 3:

Couponing to federally-insured patients is against the law because:

a. the patient gets both a subsidized prescription and "free goods" from the drugstore;
b. it lures patients whose prescriptions are subsidized by the government;
c. both of the above are true.

The net effect to Medicare/Medicaid is that it pays full price to the drugstore for a patient's prescription, and the patient gets both his prescription and an additional $25 of "free goods" from elsewhere in the store. To make this right, either the pharmacy should report to Medicare/Medicaid that the patient received $25 in free goods, or the patient should report to Medicare or Medicaid that he received this extra $25 worth of free goods in addition to his prescription.
In the words of the government prosecutor in this Walgreens settlement: “The law prohibits pharmacies from using their retail clout to lure patients whose prescriptions are subsidized by the government,” says Barbara L. McQuade, U.S. Attorney for the Eastern District of Michigan. The U.S. government claims the coupons and gift cards caused it to pay for unneeded prescriptions, gave Walgreens an unfair competitive advantage, and encouraged patients to make choices based upon discounts, rather than legitimate health care needs.

“This settlement makes clear that corporations seeking increased profits over their patients' needs will pay a substantial price,” said Daniel R. Levinson, Inspector General for the Department of Health and Human Services. “Violating Federal health care laws, as Walgreens allegedly did by offering incentives for new business, cannot be tolerated.”

Back to prosecutor Barbara L. McQuade. She said in her press release: “Continuity with a pharmacist is important to detect problems with dosages and drug interactions. Patients should make decisions based on legitimate health care needs, not on inducements like gift cards.”

**Question 4:**

"Continuity with a pharmacist is important to detect problems with dosages and drug interactions" is:

a. enhanced by coupon programs which encourage prescription transfers between pharmacies;
b. a concern of the federal prosecutor in the Walgreens settlement;
c. both of the above are true.
Merck Pays Almost $1 Billion for Wrongful Vioxx® Marketing

Vioxx® (rofecoxib) was introduced in the market in 1999 and withdrawn from the marketplace in September 2004. During this time period, nearly 105 million prescriptions for Vioxx were dispensed to approximately 20 million patients in the United States.

In May 1999, the FDA approved Vioxx for three indications: for the treatment of primary dysmenorrhea, for the management of acute pain in adults, and for relief of the signs and symptoms of osteoarthritis. The FDA did not approve its use for rheumatoid arthritis until April 2002. In the interim, for nearly three years, Merck Sharp & Dohme (Merck) promoted Vioxx for rheumatoid arthritis, conduct for which it was admonished in an FDA warning letter issued in September 2001. In the warning letter, the FDA noted that Merck's promotional activities regarding Vioxx minimized serious cardiovascular findings, minimized the Vioxx / Coumadin (warfarin) drug interaction, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses such as for treatment of rheumatoid arthritis, the prevention of cancer and invasive cancer, and for the treatment of Alzheimer's disease and gout. These findings caused the FDA to state in its 2001 warning letter to Merck that its promotional materials were false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) and applicable regulations. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f), and (n), and 355 (a).

In 2004 the FBI began investigating these matters. In the spring of 2012 Merck pled guilty to a criminal charge of violating the FDCA for introducing a misbranded drug, Vioxx, into interstate commerce, and paid a fine of nearly $322 million. Merck's guilty plea was part of a global resolution involving illegal promotional activity. In late 2011, Merck entered into a civil settlement agreement under

Question 5:
The FBI's investigation of Merck's promotional activity of Vioxx:

a. likely was a surprise to Merck, because it has no warning that it might have done anything wrong;
b. likely was a surprise to Merck, because it had no hint that Vioxx was related to serious cardiovascular findings;
c. led to a criminal charge that Merck violated the FDCA.

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4 http://www.justice.gov/opa/pr/2012/April/12-civ-497.html
5 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1779871/
which it agreed to pay over $628 million to resolve additional allegations regarding off-label marketing of Vioxx and false statements about the drug's cardiovascular safety. These criminal and civil matters with the U.S. government are separate from the personal injury lawsuits from thousands of patients alleging harm from Vioxx.

The $628 million parallel civil settlement covered a broader range of allegedly illegal conduct by Merck. The settlement resolved allegations that Merck representatives made inaccurate, unsupported, or misleading statements about Vioxx’s cardiovascular safety in order to increase sales of the drug, resulting in payments by the federal government. It also resolved allegations that Merck made false statements to state Medicaid agencies about the cardiovascular safety of Vioxx, and that those agencies relied on Merck’s false claims in making payment decisions about the drug. Finally, like the criminal plea, the civil settlement also recovered damages for allegedly false claims caused by Merck’s unlawful promotion of Vioxx for rheumatoid arthritis.

Why is such promoting or marketing illegal? It is illegal because under the provisions of the FDCA, a company is required to specify the intended uses of a drug product in its new drug application to the FDA. Data from randomized well-controlled clinical trials must accompany the request for the intended uses, and the data must show that the drug is safe and effective when used as stated on the drug product label. Once approved by the FDA, the drug may not be marketed or promoted for so-called "off-label" uses - any use not specified in its

Question 6:
Wrongful promotion of Vioxx caused the following criminal penalties for Merck:

a. a guilty plea for introducing a misbranded drug into interstate commerce;
b. a nearly $322 million fine;
c. both of the above are true.

Question 7:
The U.S. government's allegations of inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety resulted in part in:

a. a nearly $628 million settlement with Merck;
b. an admission by Merck that it did this to increase the sales of its drug;
c. both of the above are true.
application and approved by the FDA - unless the manufacturer applies to the FDA for approval of additional use.

Promotion by the manufacturer for other uses, i.e., the off-label uses, renders the product misbranded.

Of course, physicians can prescribe a medication like Vioxx for a given patient for any indication they deem proper, once the drug is initially approved by the FDA. Thus any individual physician who prescribed Vioxx for rheumatoid arthritis, or other non-FDA approved use, would not face these same allegations of wrongdoing. That is because the wrongfulness in this case, and other cases of off-label promotion, is that the drug company marketed the drug for a non-FDA approved use. It is the marketing that is wrongful, not the prescribing.

Why is marketing a drug for a non-FDA approved use wrongful?

It is wrong because it makes unsupported safety claims. In the words of Carmen Ortiz, the U.S. Attorney for the District of Massachusetts, “Any marketing activity that ignores the importance of FDA approval, or that makes unsupported safety claims about a drug is unacceptable, and will be pursued vigorously in both the criminal and civil arena.”

Once again, we have a federal prosecutor informing the country that FDA drug approval for intended uses is necessary, and that making unsupported safety claims about a drug is not acceptable conduct. And once again, we know that any licensed pharmacist in the United States could tell the country's patients the same thing.

And yet, the judge in Merck's criminal sentencing said in substance that off-label promotion has become a substantial problem in the United States and that she has seen a barrage of off-label marketing cases. She essentially said that she hoped the size of the fine of $322 million and the fact that the government

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Question 8:

According to the judge in the criminal case against Merck for Vioxx marketing:

a. off-label marketing cases are becoming rare;
b. the government continues to press off-label marketing cases;
c. Merck might have simply made an honest mistake in its marketing plans, but she must enforce the law.
continues to press these cases will send a signal to the pharmaceutical industry that this is not acceptable conduct.

**Pharmacist Billed Medicaid for Rx's Never Dispensed**

It is a surprising day when your pharmacy gets raided by agents from the FBI, CMS, HHS's Office of Inspector General, and your state's attorney general.

That is just what happened to the Terre Haute Prescription Shop in Terre Haute, Indiana in 2011. Co-owner Lynn Hostettler was not charged with any wrongdoing, and the raid by the state and federal agents caused him as much surprise as anybody else.

Mr. Lynn Hostettler's pharmacist-partner was indicted and ultimately convicted of billing the state Medicaid department for medications that were never ordered from the pharmacy's wholesaler, and never dispensed to patients. It appears the pharmacist submitted claims for expensive drugs such as Copaxone® and Aranesp®, and then voided the prescription before any other employee of the pharmacy could notice a record for a prescription. The prescription was never filled, but the claim was accepted and paid. While it's unclear how or why the state Medicaid agency paid for a voided prescription, the agency did pay and the pharmacist did receive the monies for these prescriptions that he billed, such as:

- 1,317.4 units of Aranesp billed for a total of $1,677,554.50. During the same time period, the pharmacy only ordered six units of Aransep at a cost of $5,188.36.
- 172 units of Copaxone billed for $236,989.54. During the same time period the pharmacy only ordered 20 units of Copaxone at a cost of $29,265.87.
- 660 units of Epogen® billed for $126,732.80. During the same time period, the pharmacy only ordered ten units of Epogen at a cost of $2,545.69.
- 588 units of Humira® billed for $429,959.82. During the same time period, the pharmacy only ordered 98 units of Humira at a cost of $62,693.53.
- 1,488 units of Procrit® billed for $615,612.23. During the same time period, THPS only ordered 22 units of Procrit at a cost of $6,366.40.
- 2,630 units of Sandostatin® billed for $343,334.58. During the same time period, the pharmacy did not order any units of Sandostatin.

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From the New Jersey State Board of Pharmacy

A good number of New Jersey pharmacists take our CE programs, and here is a piece from the July 2012 New Jersey State Board of Pharmacy Newsletter. It is specifically applicable to pharmacists practicing in New Jersey, and is good advice for all pharmacists in all states:

**Documentation of Quantity Dispensed**

The New Jersey State Board of Pharmacy wishes to remind pharmacists of the importance of documentation when dispensing a lesser quantity of medication than that prescribed. N.J.A.C. 13:39-6.2(f)2 reads, “Accurate records of all prescription medication received and dispensed are maintained” and N.J.A.C. 13:39-6.2(f)3 reads, “Policies are in place regarding accurate dispensing and labeling of prescriptions and that such policies are followed.” The Board continues to receive complaints from consumers regarding the dispensing of inaccurate or incomplete prescriptions. To avoid confusion when the quantity in stock is less than that required to fill a prescription, the pharmacist should clearly describe the situation to the patient with complete instructions regarding when to return to the pharmacy to receive the remaining quantity. As an important follow-up to avoid any issues should the pharmacy be inspected by the Board, the pharmacist should add a concise yet clear description of the incident to the back of the prescription or in the computerized prescription record, which should be updated once the remainder of the prescription is dispensed.

From the Ohio State Board of Pharmacy

A good number of Ohio pharmacists take our CE programs, and here is a recent piece from the August 2012 Ohio State Board of Pharmacy Newsletter. It is specifically applicable to pharmacists practicing in Ohio but because it addresses e-prescribing of controlled substances it should be useful to all pharmacists.

**E-Prescribing of Controlled Substances Now Occurring in Ohio**

As you may know, Drug Enforcement Administration (DEA) finished their interim rule allowing e-prescribing of controlled substances (C2-C5) about two years ago. It has taken the computer system vendors some time, but finally there have been a few that have completed the certification process created by DEA. DEA is not actually “certifying” the systems, but they have approved a number of firms that do. The Board of Pharmacy is not one of these firms. It is also important to know that the Board of Pharmacy acknowledges this certification and thus this meets our state requirements.
for e-prescribing of controlled substances. And if the same process/method is used for non-controlled e-prescriptions, these systems also meet our requirements for e-prescribing non-controlled drugs. However, the Board has noticed some systems are using different processes and types of positive identification, depending on whether it is a controlled or non-controlled e-prescription. If the system does not use the same DEA-certified process for non-controlled e-prescriptions, the system must be approved by the Ohio State Board of Pharmacy.

Please note that both the sending prescriber system and the receiving pharmacy system must be certified and need to be re-certified every two years by one of the DEA-accredited firms. Currently, there are only a few prescribing and pharmacy vendors who have completed the DEA approval process for e-prescribing controlled substances.

Before filling these electronic controlled prescriptions, here are some things you should know:

♦♦ You must ensure your pharmacy system has been certified to accept controlled e-prescriptions. Your company or software vendor should indicate when this approval is completed. Also, if you utilize Surescripts (an intermediary switching station that directs electronic prescriptions and claims), you can check the Surescripts Web site for your system at www.surescripts.com/about-e-prescribing/e-prescribing-of-controlledsubstances.aspx, and click on “EPCS Certified Pharmacies and Pharmacy Software Vendors.”

♦♦ You must validate any e-prescriptions that fail due to a transmission error. This may involve calling the prescriber and/or calling other pharmacies.

♦♦ Part of the certification process forces these systems to print “copy,” or something to that effect, on the paper copy if the prescriber also tries to print the e-prescription for any reason. This should minimize the potential for multiple scripts from the same e-prescription.

♦♦ These controlled e-prescriptions shall not be e-faxed. They must be computer to computer.

♦♦ You must print these e-prescriptions for your files.

♦♦ Traditional paper controlled prescriptions and the regulations pertaining to them are still valid!
Traditional faxed controlled prescriptions (fax-fax) and the regulations pertaining to them are still valid! The main point to remember on these prescriptions is that a “wet” handwritten signature was applied to them, not a digital computer-generated signature.

For prescriptions handled by Surescripts:

Surescripts will ensure the prescribing systems that submit these controlled e-prescriptions are certified and will block those that are not on the certified list. Surescripts will also have on their Web site a list of all approved e-prescribing and pharmacy systems able to e-prescribe controlled substances. For more detail visit www.surescripts.com/about-e-prescribing/e-prescribing-of-controlled-substances.aspx, and click on “EPCS Certified Prescriber Software Vendors.”

If your pharmacy does not utilize Surescripts, or you have e-prescriptions prescribed via another intermediary, please contact your company and/or IT vendor for information on how to validate the prescribing systems are certified.

Any Concerns with E-Prescribing?

The Board of Pharmacy has been actively involved with Ohio Health Information Partnership (OHIP), which is an organization whose goal is to increase the utilization of e-prescribing and the adoption of health information exchanges in Ohio. The OHIP work groups, including Ohio Pharmacists Association and Board of Pharmacy staff, have concerns about the quality and types of errors that we are seeing in these electronic prescriptions. This group is also working on capturing the main safety issues that can go along with this change. Because as we all know even though some legibility issues may be resolved with e-prescribing, there are many other types of errors that e-prescribing may create. Potential errors include drop-down errors for wrong sig, drug, prescriber, and patient. Another common error includes free form sigs in the notes field, which may directly contradict the drop down chosen sig. If you notice these types of problems are occurring routinely, thus a system issue, please contact the Board and the Board will follow up with the vendor for corrective action.
Question 9:
If you dispense to the patient a lesser quantity than what is prescribed:

a. you should note what you have done on the prescription;
b. you should inform the patient why he/she is getting less than the amount prescribed, with instructions for when and how to pick up the remaining quantity;
c. both of the above are true.

Question 10:
Controlled substance e-prescriptions:

a. can always be e-faxed;
b. must be printed for your files;
c. make traditional paper prescriptions for controlled substances invalid.

Question 11:
Potential errors in e-prescribing include:

a. drop-down errors in which the wrong drug is selected;
b. use of the notes field for directions from the prescriber, which might even contradict the directions chosen from a drop-down choice;
c. both of the above are true.
Return this ANSWER SHEET with the $15.00 Program Fee payable to:

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

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**ANSWERS: 2013 Pharmacy Law Review - Recent Cases**  
Expiration Date: January 28, 2015

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

1. a b c  
2. a b c  
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11. a b c  

12. **For Pharmacists**: After completing this program, I am able to describe at least 3 violations of federal drug laws:  
   Yes No  

   (Please tell us your profession: ________________________________)  

13. **For Other Healthcare Professionals**: After completing this program, I am able to describe at least 3 violations of federal drug laws:  
   Yes No  

14. This program was an effective way for me to learn:  
   Yes No  

15. I liked the program’s format:  
   Yes No  

16. This program fostered my mental participation:  
   Yes No  

17. This was a “user-friendly” way for me to learn:  
   Yes No  

18. I could sense some commercialism in this program:  
   Yes No  

If yes, please describe:__________________________________________  

19. The faculty quality was: Great OK Needs to Improve  

20. The learning material quality was: Great OK Needs to Improve  

21. How long did it take to complete this program?__________________________________________  

22. What other topics would you like to see?__________________________________________  

23. We do listen to your comments:__________________________________________  

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Good for pharmacy law CE in states of
AZ, CT, MA, NJ, OH, and UT

As we have done in Ohio since 2001,
and nationwide since 2008,
we provide pharmacy law CE programs
with no commercial support.

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