Pharmacy Jurisprudence, L.L.C.

Our annual continuing education offering is written specifically for pharmacists and pharmacy technicians in all 50 states.

Index:

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Program Title: **FDA MedWatch Alerts - 2018**

Target Audience: All Pharmacists and Pharmacy Technicians

ACPE Program No.: 0487-0000-18-002-H05-P and 0487-0000-18-002-H05-T (knowledge-based activity)

Release Date: March 5, 2018

Expiration Date: March 5, 2021

Accreditations: This CE activity is ACPE-accredited for 2.0 contact hours, or 0.20 C.E.U.'s, of patient safety topic CE (topic designator "05") for pharmacists and pharmacy technicians.

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Faculty: Patti Nussle, R.Ph., J.D., is 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. Robyn Satterfield, PharmD, is our Peer Reviewer.

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Objectives: At the conclusion of this program, pharmacists should be able to list 8 drugs for which the FDA has issued MedWatch Alerts.

Objectives: At the conclusion of this program, pharmacy technicians should be able to list 8 drugs for which the FDA has issued MedWatch Alerts.

Important Note: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority.

Contact Us: By phone (614) 481-8711 or email at patti@selectce.org.

Thank you! We truly enjoy serving you!

Introduction

MedWatch® is a service of the U.S. Food and Drug Administration (FDA). The FDA says its MedWatch Alerts are designed to be "*your FDA gateway for clinically important safety information and reporting serious problems with human medical products*".[1] MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contain actionable information that may impact both treatment and diagnostic choices for health care professionals and patients.

In this CE activity, we bring you selected recent FDA MedWatch Alerts. The information is taken directly from the FDA's website, where you can look for additional information.

Question 1:

The FDA MedWatch Alerts contain:

a. clinically important information;
b. regarding both human and veterinary medical products;
c. reports of mild, medium or serious problems;
d. all of the above are true.

Question 2:

The FDA MedWatch Alerts contain:

a. timely new safety information;
b. regarding human drugs, medical devices vaccines, other biologics, dietary supplements, and cosmetics;
c. that may impact both treatment and diagnostic choices;
d. all of the above are true.

[1] https://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm

Ocaliva (obeticholic acid): Drug Safety Communication - Boxed Warning Added To Highlight Correct Dosing[2]

ISSUE: FDA is warning that the liver disease medicine Ocaliva (obeticholic acid) has been incorrectly dosed daily instead of weekly in patients with moderate to severe primary biliary cholangitis (PBC), a rare chronic liver disease, increasing the risk of serious liver injury. To ensure correct dosing and reduce the risk of liver problems, FDA is clarifying the current recommendations for screening, dosing, monitoring, and managing PBC patients with moderate to severe liver disease taking Ocaliva. FDA is adding a new Boxed Warning, FDA's most prominent warning, to highlight this information in the prescribing information of the drug label. FDA is also requiring a Medication Guide for patients to inform them about this issue.

As a condition of approval, FDA required the manufacturer of Ocaliva, Intercept Pharmaceuticals, to continue studying the medicine in patients with advanced PBC. These clinical trials are currently ongoing and FDA expects to receive results in 2023. FDA is adding the additional warnings to the drug label after receiving reports that Ocaliva is being given to PBC patients with moderate to severe liver impairment more often than is recommended in the prescribing information, resulting in liver decompensation, liver failure, and sometimes death. FDA will continue to monitor this medicine and will update the public if new information becomes available.

BACKGROUND: This is an update to the MedWatch safety alert for Ocaliva (obeticholic acid) - Increased Risk of Serious Liver Injury, issued 09-21-2017.

RECOMMENDATION: Health care professionals should follow the Ocaliva dosing regimen in the drug label, which is based on calculating a Child-Pugh score in PBC patients with suspected liver cirrhosis before treatment to determine their specific classification and starting dosage (see Table for the Clarified Ocaliva Dosage Regimen and more detailed instructions). Dosing higher than recommended in the drug label can

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https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm594901.htm

increase the risk for liver decompensation, liver failure, and sometimes death. Routinely monitor all patients for biochemical response, tolerability, and PBC progression, and re-evaluate Child-Pugh classification to determine if dosage adjustment is needed. Close monitoring is recommended for patients at an increased risk of liver decompensation, including those with laboratory evidence of worsening liver function (e.g., total bilirubin, INR, albumin) or progression to cirrhosis.

Question 3:

Ocaliva (obeticholic acid):

a. has been incorrectly dosed daily instead of weekly;
b. is used in mild liver disease;
c. is not known to cause serious liver injury;
d. all of the above are true.

Question 4:

Ocaliva (obeticholic acid) dosing:

a. should follow the dosing regimen on the drug label;
b. is based in calculating a Child-Pugh score before initiating treatment;
c. at higher than recommended dosing can increase the risk for liver decompensation, liver failure, and sometimes death;
d. all of the above are true.

Imodium (loperamide) for Over-the-Counter Use: Drug Safety Communication - FDA Limits Packaging To Encourage Safe Use[3]

ISSUE: To foster safe use of the over-the counter (OTC) anti-diarrhea drug loperamide, FDA is working with manufacturers to use blister packs or other single dose packaging and to limit the number of doses in a package. FDA continues to receive reports of serious heart problems and deaths with much higher than the recommended doses of loperamide. These reports are primarily among people who are intentionally misusing or abusing the product, despite the addition of a warning to the medicine label and a previous communication.

Loperamide acts on opioid receptors in the gut to slow the movement in the intestines and decrease the number of bowel movements. It is safe at approved doses, but when much higher than recommended doses are taken, it can lead to serious problems, including severe heart rhythm problems and death.

BACKGROUND: Loperamide is FDA-approved to help control symptoms of diarrhea, including Travelers' Diarrhea. The maximum approved daily dose for adults is 8 mg per day for OTC use and 16 mg per day for prescription use. It is sold under the OTC brand name Imodium A-D, as store brands, and as generics.

FDA previously issued a Drug Safety Communication about this safety concern in 2016. Warnings about serious heart problems were added to the prescription drug label of loperamide and to the Drug Facts label of OTC loperamide products.

RECOMMENDATION: Health care professionals should be aware that using much higher than recommended doses of loperamide, either intentionally or unintentionally, can result in serious cardiac adverse events. These events may include QT interval prolongation, Torsades de Pointes or other ventricular arrhythmias, syncope, and cardiac arrest. In cases of abuse, individuals often use other drugs together with

3 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm594403.htm

loperamide in attempts to increase its absorption and penetration across the blood-brain barrier, inhibit loperamide metabolism, and enhance its euphoric effects. Some individuals are taking high doses of loperamide to treat symptoms of opioid withdrawal.

If loperamide toxicity is suspected, promptly discontinue the drug and start necessary therapy. For some cases of abnormal heart rhythms in which drug treatment is ineffective, electrical pacing or cardioversion may be required. Also, counsel patients to take loperamide only as prescribed or according to the OTC Drug Facts label and advise patients that drug interactions with commonly used medicines may increase the risk of serious cardiac events.

Question 5:

Regarding Imodium (loperamide), the FDA:

a. is working with manufacturers to limit the number of doses in a package;
b. continues to receive reports of serious heart problems and deaths with much higher than recommended doses;
c. states the drug is a safe drug when used as directed;
d. all of the above are true.

Question 6:

Imodium (loperamide):

a. acts on opioid receptors in the gut to slow the movement in the intestines and decrease the number of bowel movements;
b. in some cases is taken by individuals to treat symptoms of opioid withdrawal;
c. has a maximum approved daily dose for adults of 8 mg per day for OTC use and 16 mg per day for prescription use;

Varubi (rolapitant) Injectable Emulsion: Health Care Provider Letter - Anaphylaxis and Other Serious Hypersensitivity Reactions[4]

ISSUE: Anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions have been reported in the postmarketing setting, some requiring hospitalization. These reactions have occurred during or soon after the infusion of Varubi (rolapitant) injectable emulsion. Most reactions have occurred within the first few minutes of administration. Symptoms of anaphylaxis can include wheezing or difficulty breathing; swelling of the face or throat; hives or flushing; itching; abdominal cramping, abdominal pain or vomiting; back pain or chest pain; hypotension or shock.

See the Health Care Provider Letter[5] for important prescribing information to reflect the new safety information.

BACKGROUND: Varubi (rolapitant) injectable emulsion is approved to prevent delayed phase chemotherapy-induced nausea and vomiting (emesis). Varubi is approved in adults in combination with other drugs (antiemetic agents) that prevent nausea and vomiting associated with initial and repeat courses of vomit-inducing (emetogenic and highly emetogenic) cancer chemotherapy.

RECOMMENDATION: Healthcare professionals must be vigilant for signs of hypersensitivity or anaphylaxis in all patients receiving Varubi (rolapitant) injectable emulsion, both during and following its administration.

It is advised that Healthcare professionals consult with patients to determine if the patient is hypersensitive to any component of the product (including soybean oil). Furthermore, as cross reactions to other allergens is possible, patients with known allergies to legumes or other

4 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm592592.htm

5 https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM592573.pdf

related allergens should be monitored closely. Patients with a potential hypersensitivity should not be administered Varubi (rolapitant) injectable emulsion.

Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during treatment with Varubi (rolapitant) injectable emulsion.

If anaphylaxis or any other serious hypersensitivity/infusion reaction occurs,

- administration of Varubi (rolapitant) injectable emulsion should be stopped immediately;
- appropriate medical management (including epinephrine and or antihistamines) should be initiated; and
- Varubi (rolapitant) injectable emulsion should be permanently discontinued.

Question 7:

Regarding Varubi (rolapitant) injectable emulsion:

a. anaphylactic shock has been reported;
b. most often after a long delay from time of administration;
c. has been removed from the market due to serious reactions;
d. all of the above are true.

Question 8:

Varubi (rolapitant) injectable emulsion:

a. has soybean oil as a component;
b. should not be used in patients allergic to legumes;
c. should only be used when epinephrine and or antihistamines are readily available to treat infusion reactions;
d. all of the above are true.

Prescription Opioid Cough and Cold Medicines: FDA Requires Labeling Changes[6]

ISSUE: FDA is requiring safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years and older. FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the Boxed Warning, the most prominent warning, of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

FDA is taking this action after conducting an extensive review and convening a panel of outside experts. Both of these groups determined the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in children.

BACKGROUND: Codeine and hydrocodone are available in combination with other medicines, such as antihistamines and decongestants, in prescription medicines to treat coughs and symptoms associated with allergies or the common cold. Other non-opioid prescription and OTC medicines are available to treat these symptoms.

Question 9:

Prescription opioid cough and cold medicines:

a. are only indicated for people 18 years of age or older;
b. have a risk of abuse, addiction, overdose, and death;
c. have been deemed too risky for children by a panel of experts;
d. all of the above are true.

6 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm592053.htm

Kayexalate (sodium polystyrene sulfonate): Drug Safety Communication - FDA Recommends Separating Dosing[7]

ISSUE: FDA is recommending that patients avoid taking the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) at the same time as other medicines taken by mouth. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines. To reduce this likelihood, we recommend separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least 3 hours.

BACKGROUND: Sodium polystyrene sulfonate is used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. It works by binding with potassium in the intestines so it can be removed from the body. Too much potassium in the blood can cause problems with heart rhythm, which in rare cases can be fatal.

RECOMMENDATION: When prescribing sodium polystyrene sulfonate, health care professionals should advise patients to separate dosing from other orally administered medicines by at least 3 hours. That time should be increased to 6 hours for patients with gastroparesis or other conditions resulting in delayed emptying of food from the stomach into the small intestine.

Question 10:

Kayexalate (sodium polystyrene sulfonate):

a. should be given at the same time as other oral medications;
b. has a risk of abuse, addiction, overdose, and death;
c. is used to treat hyperkalemia;
d. all of the above are true.

7 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574763.htm

Gadolinium-based Contrast Agents (GBCAs): Drug Safety Communication - Retained in Body; New Class Warnings[8]

ISSUE: FDA is requiring a new class warning and other safety measures for all gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging (MRI) concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and FDA has concluded that the benefit of all approved GBCAs continues to outweigh any potential risks.

To date, the only known adverse health effect related to gadolinium retention is a rare condition called nephrogenic systemic fibrosis (NSF) that occurs in a small subgroup of patients with pre-existing kidney failure. FDA received reports of adverse events involving multiple organ systems in patients with normal kidney function. A causal association between these adverse events and gadolinium retention could not be established.

BACKGROUND: This is an update to the May 22, 2017 MedWatch safety alert "Gadolinium-based Contrast Agents for Magnetic Resonance Imaging (MRI): Drug Safety Communication - No Harmful Effects Identified With Brain Retention".

There are two types of GBCAs based on their chemical structures: linear and macrocyclic (see Table 1 in Drug Safety Communication). Linear GBCAs result in more retention and retention for a longer time than macrocyclic GBCAs. Gadolinium levels remaining in the body are higher after administration of Omniscan (gadodiamide) or OptiMARK (gadoversetamide) than after Eovist (gadoxetate disodium), Magnevist (gadopentetate dimeglumine), or MultiHance (gadobenate dimeglumine). Gadolinium levels in the body are lowest after administration of Dotarem (gadoterate meglumine), Gadavist (gadobutrol), and ProHance (gadoteridol); the gadolinium levels are also similar across these agents.

8

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm589580.htm

RECOMMENDATION: Healthcare professionals should consider the retention characteristics of each agent when choosing a GBCA for patients who may be at higher risk for gadolinium retention (see Table 1 listing GBCAs)[9]. These patients include those requiring multiple lifetime doses, pregnant women, children, and patients with inflammatory conditions. Minimize repeated GBCA imaging studies when possible, particularly closely spaced MRI studies. However, do not avoid or defer necessary GBCA MRI scans.

Question 11:

Gadolinium-based contrast agents (GBCAs):

a. can remain in a person's body for months to years;
b. can remain in a person's brain for months or years;
c. can cause NSF in patients with normal kidney function;
d. both a and b are true.

Question 12:

Regarding gadolinium-based contrast agents (GBCAs), the FDA advises:

a. that gadolium levels remaining in the body are higher after Omniscan than after Dotarem or Gadavist or ProHance;
b. all people should avoid necessary MRI scans;
c. pregnant women and children should avoid MRI scans;
d. patients with inflammatory conditions should avoid MRI scans.

[9] https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm

Keytruda (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement - Two Clinical Trials on Hold[10]

ISSUE: Based on data from two recently halted clinical trials, the U.S. Food and Drug Administration today (August 31, 2017) is issuing this statement to inform the public, health care professionals, and oncology clinical investigators about the risks associated with the use of Keytruda (pembrolizumab) in combination with dexamethasone and an immunomodulatory agent (lenalidomide or pomalidomide) for the treatment of patients with multiple myeloma. Keytruda (pembrolizumab) is not approved for treatment of multiple myeloma.

The FDA statement is based on review of data from two clinical trials (KEYNOTE-183 and KEYNOTE-185) evaluating the use of Keytruda (pembrolizumab) combined with other treatments in patients with multiple myeloma. On July 3, 2017, the FDA required that all patients in these trials be discontinued from further investigation with this drug, because interim results from both trials demonstrated an increased risk of death for patients receiving Keytruda (pembrolizumab) when it was combined with an immunomodulatory agent as compared to the control group (see statistical analysis section below)[11]. Merck & Co., Inc. was made aware of the issue through an external data monitoring committee recommendation and suspended the trials on June 12, 2017.

BACKGROUND: This does not apply to patients taking Keytruda (pembrolizumab) for an approved indication. Patients on Keytruda (pembrolizumab) for an approved use should continue to take their medication as directed by their health care professional.

Keytruda (pembrolizumab) is currently approved by the FDA for treatment of: Melanoma, Lung Cancer, Head and Neck Cancer, Classical Hodgkin Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High (MSI-H) Cancer.

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10 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574347.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

11 https://www.fda.gov/Drugs/DrugSafety/ucm574305.htm

For a summary of the statistical analysis and findings, please refer to the FDA Statement.

RECOMMENDATION: Other multiple myeloma clinical trials of Keytruda (pembrolizumab), other PD-1/PD-L1 cancer drugs and other combinations are currently undergoing clinical evaluation. The FDA will be working directly with sponsors of Keytruda and other PD-1/PD-L1 cancer drugs, as well as clinical investigators conducting clinical trials in patients with multiple myeloma, to determine the extent of the safety issue. The agency will communicate any new information to the public as soon as it is able.

Question 13:

Regarding Keytruda (pembrolizumab) the FDA tells us in its August 2017 MedWatch Alert that:

a. there are significant risks associated with the use of Keytruda alone;
b. two clinical trials were recently halted;
c. Keytruda is approved for the treatment of multiple myeloma;
d. both a and b are true.

Question 14:

Regarding Keytruda (pembrolizumab) the FDA tell us:

a. patients taking Keytruda for FDA-approved indications should stop taking their medication;
b. patients taking Keytruda should call their doctor;
c. the FDA determined that interim results from clinical trials demonstrated an increased use of death for patients receiving Keytruda plus dexamethasome plus an immunomodulatory agent;
d. all of the above are true.

Viberzi (eluxadoline): Drug Safety Communication - Increased Risk of Serious Pancreatitis In Patients Without A Gallbladder[12]

ISSUE: FDA is warning that Viberzi (eluxadoline), a medicine used to treat irritable bowel syndrome with diarrhea (IBS-D), should not be used in patients who do not have a gallbladder. An FDA review found these patients have an increased risk of developing serious pancreatitis that could result in hospitalization or death. Pancreatitis may be caused by spasm of a certain digestive system muscle in the small intestine. As a result, FDA is working with the Viberzi manufacturer, Allergan, to address these safety concerns.

See the FDA Drug Safety Communication for a Data Summary[13].

BACKGROUND: Viberzi is a prescription medicine used to treat irritable bowel syndrome in adults when the main symptom is diarrhea (IBS-D). IBS-D affects the large intestine and causes cramping, stomach-area or abdomen pain, bloating, gas, and diarrhea. The cause of IBS-D is not known. Viberzi works by decreasing bowel contractions, which leads to less diarrhea. In patients with IBS-D, Viberzi can help ease stomach-area or abdomen pain and improve stool consistency.

From May 2015, when Viberzi was first approved, through February 2017, FDA received 120 reports of serious cases of pancreatitis or death.[14] Among the 68 patients who reported their gallbladder status, 56 of them did not have a gallbladder and received the currently recommended dosage of Viberzi. Seventy-six patients were hospitalized, of which two patients died. These two patients did not have a gallbladder. Some cases of serious pancreatitis or death also reported sphincter of Oddi spasm (n=6) or abdomen pain (n=16) (see Data Summary).

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12 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm546771.htm

13 https://www.fda.gov/Drugs/DrugSafety/ucm546154.htm

14 *The cases were reported to the FDA Adverse Event Reporting System (FAERS).

RECOMMENDATION: Health care professionals should not prescribe Viberzi in patients who do not have a gallbladder and should consider alternative treatment options in these patients. Hospitalizations and deaths due to pancreatitis have been reported with Viberzi use in patients who do not have a gallbladder. Symptoms of pancreatitis have occurred with just one or two doses of Viberzi at the recommended dosage for patients who do not have a gallbladder (75 mg), and who do not consume alcohol

Question 15:

Regarding Viberzi (eluxadoline), the FDA tells us:

a. this is a medicine used to treat IBS-D;
b. patients without a gall bladder who take this have an increased risk of developing serious pancreatitis that can result in death;
c. it is working with the drug manufacturer to address this safety concern;
d. all of the above are true.

Question 16:

Regarding Viberzi (eluxadoline), the FDA tells us:

a. it has received at least 120 reports of serious cases of pancreatitis or death;
b. it has received at least 2 reports of death and neither of those patients had a gall bladder;
c. symptoms of pancreatitis have occurred with just 1 or 2 doses of the recommended dosage;
d. all of the above are true.

Canagliflozin (Invokana, Invokamet): - Increased Risk of Leg and Foot Amputations[15]

ISSUE: Based on new data from two large clinical trials, the FDA has concluded that the type 2 diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations. FDA is requiring new warnings, including the most prominent Boxed Warning, to be added to the canagliflozin drug labels to describe this risk.

Final results from two clinical trials – the CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus) – showed that leg and foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo, which is an inactive treatment. Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred. Some patients had more than one amputation, some involving both limbs. See the FDA Drug Safety Communication for additional information, including a data summary.[16]

BACKGROUND: This information is an update to the May 18, 2016 MedWatch safety alert. Canagliflozin is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin lowers blood sugar by causing the kidneys to remove sugar from the body through the urine. It is available as a single-ingredient product under the brand name Invokana and also in combination with the diabetes medicine metformin under the brand name Invokamet.

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15 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm558605.htm

16 https://www.fda.gov/Drugs/DrugSafety/ucm557507.htm

RECOMMENDATION: Health care professionals should, before starting canagliflozin, consider factors that may predispose patients to the need for amputations. These factors include a history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers. Monitor patients receiving canagliflozin for the signs and symptoms described above and discontinue canagliflozin if these complications occur.

Question 17:

Regarding Canagliflozin (Invokana, Invokamet), this:

a. is a medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes;
b. causes the kidneys to remove sugar from the body through the urine;
c. causes an increased risk of leg and foot amputations;
d. all of the above are true.

Question 18:

Regarding Canagliflozin (Invokana, Invokamet), final results from 2 clinical trials shows:

a. leg and foot amputations occurred about three times as often when compared to those patients treated with placebo;
b. amputations of the heel were the most common;
c. amputations involving the leg did occur;
d. all of the above are true.

Opioid Addiction Medications in Patients Taking Benzodiazepines or CNS Depressants: Careful Medication Management Can Reduce Risks[17]

ISSUE: Based on additional review, FDA is advising that the opioid addiction medications used for medication-assisted treatment (MAT), buprenorphine and methadone, should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care professionals can reduce these risks.

BACKGROUND: Many patients with opioid dependence may also use benzodiazepines or other CNS depressants, either under a health care professional's direction or illicitly. Although there are serious risks with combining these medicines, excluding patients from MAT or discharging patients from treatment because of use of benzodiazepines or CNS depressants is not likely to stop them from using these drugs together. Instead, the combined use may continue outside the treatment setting, which could result in more severe outcomes.

RECOMMENDATIONS: Health care professionals should take several actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. These include:

- Educating patients about the serious risks of combined use, including overdose and death, that can occur with CNS depressants when used as prescribed or when used illicitly.
- Developing strategies to manage the use of prescribed or illicit benzodiazepines or other CNS depressants when starting MAT.
- Tapering the benzodiazepine or CNS depressant to discontinuation if possible.
- Verifying the diagnosis if a patient is receiving prescribed benzodiazepines or other CNS depressants for anxiety or

17 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm576755.htm

insomnia, and considering other treatment options for these conditions.

- Recognizing that patients may require MAT medications indefinitely and their use should continue for as long as patients are benefiting and their use contributes to the intended treatment goals.
- Coordinating care to ensure other prescribers are aware of the patient's buprenorphine or methadone treatment.
- Monitoring for illicit drug use, including urine or blood screening.

Question 19:

Regarding opioid addiction medications buprenorphine and methadone, the FDA tells us:

a. these medications should be withheld from patients who take benzodiazepines or other CNS depressants;
b. the risk of CNS depression when taken with other drugs outweighs the harm causes by untreated opioid addiction;
c. to discharge from MAT treatment anyone taking another CNS depressant;
d. none of the above are true.

Question 20:

Regarding opioid addiction medications buprenorphine and methadone use with concomitant benzodiazepine or CNS depressant use, the FDA tells healthcare professionals to:

a. increase any benzodiazepine or CNS depressant use, if possible;
b. report the patient's diagnosis to the FDA;
c. coordinate care to ensure other prescribers are aware;
d. stop all urine and blood testing.

Return this ANSWER SHEET with the $20.00 Program Fee payable to:

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ANSWERS: FDA MedWatch - 2018

(Expiration Date: March 5, 2021)

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

1.	a	b	c	d	11.	a	b	c	d
2.	a	b	c	d	12.	a	b	c	d
3.	a	b	c	d	13.	a	b	c	d
4.	a	b	c	d	14.	a	b	c	d
5.	a	b	c	d	15.	a	b	c	d
6.	a	b	c	d	16.	a	b	c	d
7.	a	b	c	d	17.	a	b	c	d
8.	a	b	c	d	18.	a	b	c	d
9.	a	b	c	d	19.	a	b	c	d
10.	a	b	c	d	20.	a	b	c	d

21. After completing this program, I am able to list 8 drugs for which the FDA has issued MedWatch Alerts: Yes No
22. This CE activity met my educational needs: Yes No
23. The author was organized in the written materials: Yes No
24. The learning material was useful: Yes No
25. The teaching and learning methods (case format, questions embedded in the program) fostered active learning and were effective: Yes No
26. The learning assessment (the post-test) was appropriate: Yes No
27. The test questions were relevant to the goals of the CE activity: Yes No
28. The test questions were at an appropriate level of difficulty: Yes No
29. The CE activity was presented in a fair and unbiased manner: Yes No
30. If you perceived any bias or commercialism, please describe:

_____

31. Thank You! Other comments are welcome: _____

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Program Title: **DOJ Cases Against Pharmacists - 2016**

Target Audience: All Pharmacists and Pharmacy Technicians

Release Date: February 1, 2017

Expiration Date: February 1, 2020

ACPE Program No.: 0487-0000-16-001-H03-P knowledge-based activity or 0487-0000-16-001-H03-T knowledge-based activity

Accreditations: This CE activity is ACPE-accredited for 1.0 contact hour, or 0.10 C.E.U.'s, for pharmacists and pharmacy technicians under our trade name Select CE®.

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Media: Enduring print material and interactive test-taking at **www.selectce.org.**

Fee Information: $15.00

Estimated Time to Complete the Activity: 60 minutes

Procedures: To receive a credit for this CE activity, you must supply your CPE Monitor ID (also known as the NABP eProfile ID) and month/day of birth. Other procedures are to read this program, complete the post-test questions and evaluation questions on the Answer Sheet, and either:

i) mail the Answer Sheet and the program fee to us. You will receive an Assessment Feedback mailed to you within 2 weeks. Checks or money orders are encouraged. Mail to: Select CE, P.O. Box 21186, Columbus, Ohio 43221- 0186;
or
ii) use the online test-taking website www.selectce.org. Follow the instructions on the website, using any major credit card to pay the

program fee. Upon passing the test, you will receive immediate confirmation via email, and your Assessment Feedback will be sent within 5 days. Refunds are not generally provided, unless you mistakenly make too many online payments or some such other snafu.

A minimum score of 70% on the post-test is also required to earn credit.

Faculty: Patti Nussle, R.Ph., J.D., is 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. Robyn Satterfield, PharmD was our Peer Reviewer for this activity. Thanks Robyn!

Disclosure of Commercialism, Unlabeled Uses, Bias, Conflicts of Interest: Prior to the delivery of the content, we will disclose any commercial support, and we do so here: No commercial support was used for developing or presenting this program. **All development, printing, mailing and internet costs, as well as ACPE accreditation fees, come solely from your program fees**. No unlabeled uses of drugs are discussed in this program. Brand names are not used, unless the Department of Justice used the brand name of the drug in its publication and hence the brand name is used here too. Faculty Patti Nussle, Robyn Satterfield, and Select CE have no real, apparent, or potential conflicts of interest or financial relationships to disclose.

Objective: At the conclusion of this program, pharmacists should be able to describe at least 5 consequences of failing to comply with federal drug laws.

Objective: At the conclusion of this program, pharmacy technicians should be able to describe at least 5 consequences of failing to comply with 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.

Contact Us: By phone (614) 481-8711 or email at patti@selectce.org.

Thank you! We truly enjoy serving you!

Introduction

In this CE activity, we bring you 8 reports about pharmacy violations from the U.S. Department of Justice (DOJ). We tried to choose cases that are of interest to the practicing pharmacy professional. In a few cases, a nurse or physician was involved in the pharmacy violation.

It has been said that most fraud starts by accident. That is, by some lack of oversight either medication or money was not properly handled, and nothing happened. Nobody seemed to notice. Then the next time it happened, and again nobody noticed. And then, somehow, as time passed the oversight became a regular occurrence. From Girl Scout fundraising to pharmacy dispensing, the stories of fraud often start with an innocent oversight. We have no way to know how or why the pharmacists in the following DOJ cases first started in what the DOJ says are illegal activities. Yet these cases remind us to be vigilant in our pharmacy dispensing activities and not let a lack of oversight lead to fraudulent activity.

Northwest Alabama Pharmacy Owner Agrees to Plead Guilty to Obstructing Medicare Audit[18]

Pledges to Pay $2.5 Million Penalty

BIRMINGHAM – The owner of two northwest Alabama pharmacies has agreed to plead guilty to obstructing a Medicare audit and to pay a $2.5 million penalty to the government.

The U.S. Attorney's Office for the Northern District of Alabama charged RDL, 63, of Muscle Shoals, with one count of obstructing a 2012 federal audit of Medicare claims submitted by a pharmacy he owned. RDL, a registered pharmacist, owned Leighton Pharmacy Inc., which did business as Sheffield Pharmacy and Homecare in Sheffield, and Russellville Pharmacy in Russellville. At various times, according to the charge, RDL was the lead pharmacist at both Sheffield and Russellville. Prosecutors filed the charge by information in U.S. District Court, along with a plea agreement reached between RDL and the government.

[18] https://www.justice.gov/usao-ndal/pr/northwest-alabama-pharmacies-owner-agrees-plead-guilty-obstructing-medicare-audit

“This case revolves around the falsification of documents in an effort to defraud Medicare, which exists to provide health care services for the elderly,” U.S. Attorney Joyce White Vance said.

"Obstructing a Medicare audit is something the OIG takes very seriously," OIG Special Agent Derrick Jackson said. "Submitting documentation to Medicare to substantiate that tablets or capsules were utilized when, in fact, bulk pharmaceutical powders were actually used is straight-up fraud."

The Sheffield and Russellville pharmacies operated as both compounding and retail pharmacies. A compounding pharmacy is one that prepares customized medications for individual patients, usually by mixing ingredients in order to create a prescription. The two pharmacies sold compounded prescriptions to patients in Alabama and other states.

According to the information and plea agreement, RDL obstructed a 2012 audit of the Sheffield pharmacy’s claims for Medicare reimbursement on compounded prescriptions as follows:

CVS/Caremark Inc. administered prescription drug claims for Medicare Part D and served as an auditor on Medicare’s behalf. Part D prohibited reimbursement to pharmacies for compounded medications made using bulk pharmaceutical powders. Russellville and Sheffield nonetheless sought Part D reimbursement after February 2009 for compounded medications, primarily topical pain creams, made from bulk powders. The pharmacies, however, used the billing code for the tablet or capsule form of the ingredient.

In response to the 2012 audit, RDL caused Sheffield to submit falsified and misleading documents stating that medications in tablet or capsule form were used as ingredients for the compounded prescriptions.

The maximum penalty for obstructing a federal audit is five years in prison and a fine of $250,000 or twice the amount improperly gained through the defendant’s conduct.

Question 1:

Using the billing code for the tablet or capsule form of the ingredient, rather than the bulk powder that was actually used in compounding a pain cream, can result in:

a. a charge of obstructing a federal audit;
b. 5 years in prison and a fine of $250,000;
c. 5 years in prison and a fine of twice the amount improperly gained by the wrongful conduct;
d. all of the above can be true.

Wisconsin Pharmacist Charged with Health Care Fraud & Identity Theft[19]

Madison, Wis. - John W. Vaudreuil, United States Attorney for the Western District of Wisconsin, announced that MJ, 55, Janesville, Wis., was arrested without incident by agents from the U.S. Department of Health and Human Services and the U.S. Postal Inspection Service.

MJ was charged in a 46-count indictment returned by a grand jury in Madison. The indictment charges MJ with health care fraud, making false statements in a health care fraud audit, and identity theft. Each of the 39 health care fraud charges carries a maximum penalty of 10 years in federal prison; the false statements charge carries a maximum penalty of five years in federal prison; and the six identity theft charges each carries a mandatory penalty of two years in federal prison.

The indictment alleges that MJ devised a scheme to defraud Medicare and Medicaid from approximately January 2008 to March 2014. During this time period, MJ was a licensed pharmacist, and the owner and president of Kealey Pharmacy and Home Care, Inc. Kealey Pharmacy was a retail pharmacy providing, among other things, prescription drugs to customers. Kealey Pharmacy was reimbursed for these prescriptions

[19] https://www.justice.gov/usao-wdwi/pr/janesville-pharmacist-charged-health-care-fraud-identity-theft

in a number of ways, including reimbursement payments under Medicare and Medicaid.

The indictment alleges that MJ submitted false and fraudulent claims to Medicare and Medicaid obtaining reimbursement for medication that was not, in fact, provided to beneficiaries. The indictment also alleges that MJ created false prescription orders for medication and submitted claims for reimbursement for medication pursuant to these false prescription orders. The indictment alleges that MJ caused the payment of approximately $1,000,000 by Medicare and Medicaid to him during the time period of the fraud.

The indictment also alleges that MJ lied in August 2013 in his responses to an audit being conducted by the Wisconsin Department of Health Services of paid Medicaid claims for the period from January 2010 to December 31, 2011. Finally, the indictment charges that MJ used the

Question 2:

An _____ is merely an accusation and a defendant is presumed innocent until and unless proven guilty.

a. acquittal;
b. indictment;
c. indication;
d. exoneration.

Question 3:

Using the DEA number and National Provider Identifier of two physicians to create false physician prescription orders to support claims to Medicaid and Medicare can result in a charge of:

a. grand theft;
b. identity theft;
c. theft in office;
d. prescription theft.

DEA number and National Provider Identifier of two physicians to create false and fictitious physician's prescription orders to support the submission of false claims to Medicare and Medicaid.

The reader is reminded that an indictment or charge is merely an accusation and that a defendant is presumed innocent until and unless proven guilty.

New York Pharmacist Sentenced to 43 Months For Medicare And Tax Fraud[20]

Defendant Caused $2.7 Million in Losses to Government Health Care Programs and Underreported His Income By Over $2.6 Million

AB, a New York pharmacist who operated pharmacies in Bronx, Queens, and Rockland counties, was sentenced to 43 months' imprisonment to be followed by three years of supervised release. As part of the sentence, he was ordered to forfeit $2.7 million in criminal proceeds, pay $2.7 million in restitution to Medicare and Medicaid, and pay $736,000 in restitution to the Internal Revenue Service.

On May 25, 2016, AB pleaded guilty to committing a health care fraud scheme and filing false tax returns. From January 2011 to December 2012, he fraudulently billed Medicare and Medicaid approximately $2.7 million for prescription medications that he never dispensed to patients. AB used some of these proceeds to buy pharmaceutical products for his pharmacies. He also falsely claimed over $2 million in personal expenses as business expenses on his tax returns. Through this scheme, he caused a tax loss of $736,192.80.

To prove its case, the government used AB's computer hard drives, seized during two audits of his pharmacies, and compared the dispensing records on the pharmacy hard drive to the wholesaler's records of purchases.[21]

E.D.N.Y. Docket No. 15-CR-103

[20] https://www.justice.gov/usao-edny/pr/new-york-pharmacist-sentenced-43-months-medicare-and-tax-fraud

[21] https://casetext.com/case/united-states-v-barrett-56

Question 4:

To prove that a pharmacy billed for prescription medications that were never dispensed, the U.S. government can:

a. seize computer hard drives of a pharmacy's dispensing records;
b. compare the pharmacy's dispensing records to the pharmacy wholesaler's records of medication purchased;
c. both a and b;
d. neither a or b.

Palm Harbor Oncologist Convicted of Buying Cancer Medications From Foreign Sources and Defrauding Medicare[22]

Tampa, Florida – A federal jury today found AN (age 61 of Palm Harbor) guilty of 17 counts of receipt and delivery of misbranded drugs, 12 counts of smuggling goods into the United States, 11 counts of health care fraud, and 5 counts of mail fraud. She faces a maximum penalty of 20 years in federal prison for each mail fraud and smuggling offense, 10 years' imprisonment for each health care fraud count, and 3 years for each count of receipt and delivery of misbranded drugs. Her sentencing hearing is scheduled for February 16, 2017.

According to testimony and evidence presented at trial, AN, a licensed physician in Florida, was the head doctor, owner, and operator of East Lake Oncology ("ELO"), a cancer treatment clinic. Beginning in at least May 2009, she ordered, and directed others at ELO to order, drugs from foreign, unlicensed distributors, including Quality Specialty Products ("QSP"). The drugs sold to ELO by QSP and other foreign, unlicensed distributors were not FDA-approved. In fact, QSP had reportedly sold counterfeit versions of a chemotherapy medication that did not have the key ingredient in the drug. AN learned of this news from other sources

[22] https://www.justice.gov/usao-mdfl/pr/palm-harbor-oncologist-convicted-buying-unapproved-cancer-medications-foreign-sources

yet continued to have QSP drugs administered to patients. When QSP shut down, AN switched to buying drugs from another foreign, unlicensed distributor. Many of the drugs were shipped directly to ELO from a location outside the United States, usually from the United Kingdom. The packaging and documents shipped with the drugs showed that they were manufactured and packaged for distribution in foreign countries, such as Turkey, India, and Germany. Additionally, some of the packaging for the drugs was in foreign languages, without any English translation.

Unbeknownst to patients, these misbranded drugs were then administered at ELO. After administering these drugs to patients, ELO submitted claims for reimbursement to Medicare. In submitting those claims, AN falsely represented that the FDA-approved versions of the drugs had been administered, when she knew that unapproved and misbranded versions had been given to patients. In so doing, AN intended to generate profits from the difference between the Medicare reimbursement rates for the FDA-approved drugs and the discounted prices of the misbranded versions of those drugs purchased from foreign distributors.

Question 5:

Purchasing medications manufactured and distributed in foreign countries, from a distributer that is not licensed to distribute the medications in the United States, means that:

a. the use of the medication will definitely harm a patient;
b. the medications are not FDA-approved;
c. the medications should not be billed to Medicare or Medicaid;
d. both b and c are true.

CleanSlate Addiction Treatment Centers Settle Allegations of Unlicensed Prescribing and Improper Suboxone® Billing[23]

BOSTON – The U.S. Attorney's Office reached a $750,000 civil settlement with CleanSlate Centers, Inc. and Total Wellness Centers, LLC d/b/a CleanSlate, to resolve allegations that the two companies, which together operate opioid addiction treatment centers in Massachusetts and other states, improperly prescribed buprenorphine (Suboxone®) for addiction treatment and improperly billed Medicare.

CleanSlate operates 17 clinics, offering treatment to individuals addicted to opioids, including heroin and prescription painkillers, through medication and counseling. The medication, buprenorphine, is a Schedule III controlled substance that also can be used to treat pain.

Until recently, only a physician could prescribe buprenorphine for addiction treatment. Congress modified the law in July 2016, allowing nurse practitioners and physician assistants to prescribe buprenorphine for addiction treatment, provided they meet certain training and state-law licensing requirements. In Massachusetts, those requirements have not yet been established.

"We are committed to investigating healthcare providers engaged in improper billing and prescribing," said Special Agent in Charge Phillip Coyne of the U.S. Department of Health and Human Services – Office of Inspector General (HHS-OIG). "Working closely with the DEA, the Office of Inspector General will continue the fight against the deadly and destructive opiate epidemic to protect public safety as well as the federal health care programs intended to care for vulnerable Americans."

The settlement resolves two sets of allegations. First, the government alleged that, from March 2012 to February 2014, CleanSlate clinics routinely contacted pharmacies representing that physicians had prescribed buprenorphine for patients when, in fact, only midlevel practitioners had seen the patients. Days later, after patients had already picked up their medication from the pharmacies, part-time physicians employed by CleanSlate for as little as six hours per month accessed the

[23] https://www.justice.gov/usao-ma/pr/cleanslate-addiction-treatment-centers-settle-allegations-unlicensed-prescribing-and

patients' electronic medical records. After reviewing the patient visit information, the part-time physicians signed the prescriptions, backdating them to the visit dates. These actions violated the Controlled Substances Act and regulations issued by the DEA.

Second, the government alleged that, from June 2010 to April 2016, CleanSlate repeatedly billed Medicare for patient visits using physicians' identification numbers when, in fact, the patients saw midlevel practitioners and no physicians were on clinic premises to supervise those practitioners. Had CleanSlate properly billed under the midlevel practitioners' identification numbers, Medicare would have paid less. These actions violated HHS's rules for billing Medicare and violated the False Claims Act.

Upon learning of the prescribing and billing violations, CleanSlate cooperated fully with the federal investigation. It has appointed a new management team and has begun the process of hiring at least one full-time physician at each of its clinics. In addition, CleanSlate has implemented a new system under which only doctors can prescribe buprenorphine, and they do so electronically, thereby ensuring that no prescription is issued until after a doctor has reviewed the patient visit information.

Question 6:

A physician who signs buprenorphine prescriptions written by mid-level practitioners and back-dates his/her prescription signatures to match the dates of the patient visits days earlier is guilty of:

a. violating the Controlled Substances Act;
b. violating the Narcotic Substances Act;
c. harming the patient;
d. harming the mid-level practitioner.

Question 7:

Billing Medicare under a physician's identification number in situations in which the physician is offsite and the patient is not seen by the physician but instead is seen by a mid-level practitioner:

a. results in Medicare paying more than it would have;
b. results in a violation of the False Claims Act;
c. violates Medicare billing instructions;
d. all of the above are true.

Pharmacist Sentenced to 4 Years for Illegally Distributing Approximately 100,000 Oxycodone Tablets, Medicare Fraud, and Money Laundering[24]

LJ was sentenced November 29, 2016 by U.S. District Judge Jed Rakoff to four years in prison for illegally distributing 100,000 tablets of oxycodone, Medicare fraud, and money laundering. LJ pled guilty on July 28, 2016.

Manhattan U.S. Attorney Preet Bharara said: "Through her pharmacies in Queens and Brooklyn, [LJ] dumped 100,000 illegally diverted oxycodone pills into the City's streets. Driven by greed, [LJ] abused her pharmacy license, helping to fuel the opioid abuse epidemic that is ravaging too many of our communities. For her crimes, [she] will spend four years in prison and forfeit her ill-gotten gains."

According to the allegations in the Indictment and the civil Complaint, and other information in the public record:

[24] https://www.justice.gov/usao-sdny/pr/pharmacist-sentenced-4-years-illegally-distributing-approximately-100000-oxycodone

Between about March 2010 and October 2015, LJ owned and operated two pharmacies in Queens and Brooklyn doing business as "Chopin Chemists." During that time period, at these pharmacies, LJ knowingly distributed approximately 100,000 tablets of oxycodone based on fraudulent prescriptions, including prescriptions made out in the names of famous luxury brands, such as Coach and Chanel. In addition, LJ used the proceeds of that illegal narcotics trade to help finance the purchase of a multimillion-dollar home. Finally, LJ deliberately overbilled Medicare by more than $500,000, submitting reimbursement claims for medication that she never actually distributed to patients. In addition to the prison term, LJ was also directed to forfeit $800,000 and to pay restitution of $520,000.

Question 8:

LJ was guilty of illegally distributing oxycodone and Medicare fraud because she:

a. filled prescriptions for oxycodone made out in the names of luxury brands such as Coach and Chanel:
b. billed those prescriptions to Medicare;
c. neither of the above are true;
d. both of the above are true.

Former Owner of Miami Based Pharmacy Convicted at Trial of $700,000 Medicare Fraud Scheme[25]

The former owner of a Miami based retail pharmacy was convicted, following a three-day trial, for his participation in a scheme that involved the fraudulent submission of approximately $700,000 dollars in false billing to Medicare.

[25] https://www.justice.gov/usao-sdfl/pr/former-owner-miami-based-pharmacy-convicted-trial-700000-medicare-fraud-scheme

AA, 54, of Miami, was convicted of three substantive counts of health care fraud. AA faces a maximum possible sentence of ten years in prison for each count of conviction. AA is scheduled to be sentenced on January 27, 2017, by United States District Judge James I. Cohn in Fort Lauderdale.

Evidence presented at trial showed that, for less than six months in 2014, AA owned a retail pharmacy called La Gloria Pharmacy, in Miami. During that time, AA stole approximately $700,000 from Medicare Part D, by stealing the identities of doctors and Medicare beneficiaries and billing for prescription drugs he never purchased nor dispensed. The beneficiaries testified at trial that, although La Gloria Pharmacy had submitted claims for prescription drugs in their names, they had never heard of La Gloria Pharmacy, never received the drugs for which the pharmacy had submitted claims, and had never been treated by the doctor listed in the claim. The doctors testified that, although their names were listed as the prescribing physician in La Gloria Pharmacy's claims submissions, they had never treated, nor prescribed medication for, any of those beneficiaries.

Related court documents and information may be found on the website of the District Court for the Southern District of Florida at www.flsd.uscourts.gov or on http://pacer.flsd.uscourts.gov.

Question 9:

AA owned a pharmacy for less than 6 months, and was found guilty of submitting claims to Medicare Part D for prescriptions that doctors said they never wrote and patients said they never received. AA faces:

a. up to 2 years in prison on each count;
b. up to 5 years in prison on each count;
c. up to 10 years in prison on each count;
d. up to 20 years in prison on each count.

Former Walgreens Clinical Pharmacy Manager Pleads Guilty to $4.4 Million TennCare Fraud Scheme[26]

> *Author's Note: In a departure from the cold, hard facts that we typically aim to deliver to you, I will admit this case breaks my heart. It does so because it is easy to imagine how this pharmacist could well have had the patient's best interests in mind, but did not understand how serious her actions were. Also, once a pharmacist or technician deviates from her employer's standard operating procedures, then the typical employer does not support its pharmacist or technician. He/she is then often terminated from employment and left to defend themselves alone in court. Finally, in a twist of fate, CMS now advises state Medicaid agencies to do some of what this pharmacist did for her patients, and that is to disregard liver scarring as a criterion for reimbursing for this class of drugs[27].*

GREENEVILLE, Tenn. – On Oct. 25, 2016, AR, 33, pleaded guilty to one count of healthcare fraud contained in a federal information, before the Honorable J. Ronnie Greer, U.S. District Judge. AR was the former Clinical Pharmacy Manager at the Walgreens Specialty Pharmacy located in the Holston Valley Hospital in Kingsport, Tenn.

Sentencing has been set for Jan. 30, 2017. AR faces a potential sentence of up to 10 years in prison, a fine of up to $250,000, and supervised release of up to three years.

In a detailed plea agreement on file with the U.S District Court, AR admitted that between October 2014 and April 2016, she falsified prior authorizations, medical lab reports, and drug test results for at least 51 Hepatitis C patients who had prescriptions for the expensive Hepatitis C drugs of Sovaldi®, Harvoni®, Viekira Pak®, or Daklinza®. These patients had health insurance through TennCare, which does not pay for Hepatitis C prescriptions for patients who abuse illicit substances or who

[26] https://www.justice.gov/usao-edtn/pr/former-walgreens-clinical-pharmacy-manager-pleads-guilty-44-million-tenncare-fraud

[27] https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf

have limited or no scarring of the liver. The patient's authentic medical lab reports and drug tests showed that they failed to meet TennCare eligibility requirements. However, AR admitted to replacing disqualifying information regarding levels of liver scarring and illicit substance abuse on the authentic records with qualifying information, and then submitting the altered records to TennCare. She also admitted to fabricating allergies on the prior authorization forms of some of these patients so they could receive the most expensive Hepatitis C drug, Harvoni®.

As a result of AR's conduct, TennCare paid at least $4,400,000 to purchase Sovaldi®, Harvoni®, Viekira Pak®, and Daklinza® prescriptions for these 51 patients, which TennCare would not have paid if true and accurate prior authorizations, drug test results, and medical lab reports pertaining to these patients had been submitted.

Question 10:

AR pled guilty to falsifying the prior authorizations, lab reports, and/or drug tests for 51 patients to enable them to meet clinical criteria for expensive drugs to treat chronic hepatitis C. The effect of her actions includes:

a. the Medicaid agency paid at least $10 million to purchase hepatitis C medications for these patients;
b. AR faces a potential prison sentence of up to 10 years in prison;
c. AR caused significant harm to her patients;
d. AR faces a potential fine of up to $1 million.

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

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

NAME:	Pharmacist? Yes/No
ADDRESS:	Technician? Yes/No
CITY, STATE and ZIP:	
EMAIL:	
NABP e-Profile #:	Month and Day of Birth:

ANSWERS: DOJ Cases Against Pharmacists - 2016

Expiration Date: February 1, 2020

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

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

11. For Pharmacists: After completing this program, I am able to describe at least 5 consequences of failing to comply with federal drug laws: Yes No
12. For Pharmacy Technicians: After completing this program, I am able to describe at least 5 consequences of failing to comply with federal drug laws: Yes No
13. This CE activity met my educational needs: Yes No
14. The author was organized in the written materials: Yes No
15. The learning material was useful: Yes No
16. The teaching and learning methods (case format, questions embedded in the program) fostered active learning and were effective: Yes No
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18. The test questions were relevant to the goals of the CE activity: Yes No
19. The test questions were at an appropriate level of difficulty: Yes No
20. The CE activity was presented in a fair and unbiased manner: Yes No
21. If you perceived any bias or commercialism, please describe:

_____

22. How long did it take you to complete this program?_____
23. Thank You! Other comments are welcome, including any gaps in your knowledge regarding pharmacy law or patient safety that we can help fill in with our next CE activity:_____

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Our annual continuing education offering is written specifically for pharmacists and pharmacy technicians in all 50 states.

Index:

ACPE Program Number.: 0487-0000-18-001-H03-P knowledge-based activity or 0487-0000-18-001-H03-T
Contact Hour(s): 2.0 (or 0.2 C.E.U.'s)
Release Date: March 5, 2018
Expiration Date: March 5, 2021
Program Fee: $30.00

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Program Title: **More DOJ Cases Against Pharmacists - 2018**

Target Audience: All Pharmacists and Pharmacy Technicians

ACPE Program No.: 0487-0000-18-001-H03-P knowledge-based activity or 0487-0000-18-001-H03-T knowledge-based activity

Release Date: March 5, 2018

Expiration Date: March 5, 2021

Accreditations: This CE activity is ACPE-accredited for 2.0 contact hours, or 0.20 C.E.U.'s, of pharmacy law CE (topic designator "03") for pharmacists and pharmacy technicians.

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Estimated Time to Complete the Activity: 120 minutes

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i) mail the Answer Sheet and the program fee to us. You will receive an Assessment Feedback mailed to you within 2 weeks. Checks or money orders are encouraged. Mail to: Select CE, P.O. Box 21186, Columbus, Ohio 43221- 0186;

or

ii) use the online test-taking website www.selectce.org. Follow the instructions on the website, using any major credit card to pay the program fee. Upon passing the test, you will receive immediate confirmation via email, and your Assessment Feedback will be sent within 5 days. Refunds are not generally provided, unless you mistakenly make too many online payments or some such other snafu.

A minimum score of 70% on the post-test is also required to earn credit.

Faculty: Patti Nussle, R.Ph., J.D., is 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. Robyn Satterfield, PharmD, is our Peer Reviewer.

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Objective: At the conclusion of this program, pharmacists should be able to describe at least 5 consequences of failing to comply with federal drug laws.

Objective: At the conclusion of this program, pharmacy technicians should be able to describe at least 5 consequences of failing to comply with 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.

Contact Us: By phone (614) 481-8711 or email at patti@selectce.org.

Introduction

In this 2-hour CE activity, we bring you 11 cases about pharmacy violations from the U.S. Department of Justice (DOJ). We chose cases that should be of interest to a wide variety of practicing pharmacists and technicians.

There are several reasons we focus on DOJ cases, which include some cases in which the DOJ worked with a state's attorney general's office. First, you have said in past comments to us that these are interesting and useful to you and that you want more. Second, we get our information directly from DOJ published reports and we cite the case for you. This means you have a specific identified resource if you want more information about a particular case. Also, in these DOJ summaries we find it easier to abbreviate peoples' names rather than use their full legal name. While all of parties' names are a matter of public record, we want you to focus on the facts of the case and how the law applies to the facts.

With that said, read on and learn!

NY Pharmacy Case - New York Announces Indictment Against Pharmacy Owner, Pharmacist, And Three Pharmacies For Allegedly Defrauding Medicaid Of Over $3 Million[28]

Pharmacy Owner Allegedly Stole Over $3 Million By Falsely Billing HIV Medications That Were Never Dispensed

NEW YORK – Attorney General Eric T. Schneiderman announced the indictment of HTW, 49, of Manhattan, MG, 58, of the Bronx, and three pharmacies. The indictment charges HTW, the owner of three Manhattan pharmacies – New York Pharmacy Inc. ("NY Pharmacy"), NYC Pharmacy Inc. ("NYC Pharmacy"), and New York Healthfirst Pharmacy Inc. ("NY Healthfirst") – for defrauding several government-funded healthcare programs, including Medicaid and Medicare, by falsely billing prescription refills and stealing over $3 million in reimbursement for medication they did not dispense. HTW was indicted for Grand Larceny in the First Degree, a class "B" felony, and other crimes. In addition,

[28] https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-against-pharmacy-owner-pharmacist-and-three

MG, a pharmacist at NYC Pharmacy, was indicted for Grand Larceny in the Second Degree and other related crimes.

"Pharmacists' most important duty must be to the welfare of their patients – not lining their own pockets," said Attorney General Schneiderman**.** "The blatant theft and abuse of Medicaid is reprehensible and will not be tolerated by my office."

Following up on a tip from Amida Care Inc., a Medicaid Managed Care Organization, the Attorney General's Medicaid Fraud Control Unit (MFCU) conducted several undercover operations at NY Pharmacy, NYC Pharmacy, and NY Healthfirst Pharmacy. HTW, a licensed pharmacist, and MG, the supervising pharmacist of NYC Pharmacy, allegedly paid undercover agents posing as Medicaid patients cash for HIV prescriptions and for referring other Medicaid patients to bring their prescriptions to NY Pharmacy and/or NYC Pharmacy.

The defendants thereafter allegedly submitted false claims for reimbursement to various insurers, including Medicaid, for prescription refills HTW nor her staff ever dispensed. HTW, NY Pharmacy, NYC Pharmacy, and NY Healthfirst are charged with allegedly receiving over $60,000 for prescription refills dispensed just to undercover agents.

The indictment further alleges that HTW's pharmacies did not purchase enough medication to support their substantial billings to Medicaid and other insurers. Between January 1, 2014 and August 1, 2017, HTW's pharmacies billed Medicaid and other insurers over $11 million for medications they allegedly dispensed, but purchased only a fraction of the amount of drugs necessary to fill those prescriptions.

If convicted, HTW faces up to twenty-five years in state prison and MG faces up to fifteen years in state prison; each of HTW's pharmacies can be ordered to pay a fine double what it gained from its criminal conduct, as well as restitution to those victimized by its conduct.

The Attorney General also thanks Medicaid managed care companies Amida Care and Wellcare; pharmacy benefit managers CVS Caremark and Optum RX; and pharmaceutical wholesalers HD Smith and

Question 1:

In the NY Pharmacy case, the alleged overbilling of Medicaid was first brought to the attention of the state's Medicaid fraud unit by:

a. a tip from one of the store's pharmacy technicians;
b. a tip from one of the state's Medicaid managed care plans;
c. a disgruntled customer;
d. the state Medicaid agency's billing department.

Question 2:

In the NY Pharmacy case, after the initial tip, the next step that we know of to determine what was going on at the pharmacy was:

a. the state pharmacy board conducted a store inspection;
b. undercover agents posed as patients;
c. undercover agents raided the store;
d. the state Medicaid agency conducted a survey.

Question 3:

In the NY Pharmacy case, the investigators were able to determine that the pharmacy did not buy enough medication to support their billings by working with:

a. PBM's;
b. wholesalers;
c. managed care plans;
d. all of the above.

Question 4:

In the NY Pharmacy case, the alleged overbilling of Medicaid can result in:

a. a prison sentence of 25 years for the pharmacy owner;
b. a prison sentence of 15 years for the dispensing pharmacist;
c. the pharmacies paying a fine double what it gained from its criminal conduct, as well as restitution to those victimized by its conduct;
d. all of the above are true.

McKesson for their cooperation throughout the investigation.

The charges against the defendants are merely accusations. The defendants are presumed innocent unless and until proven guilty in a court of law.

FL Pharmacy Case - St. Augustine Pharmacist Pleads Guilty To $2 Million Compound Pharmacy Fraud Scheme[29]

Jacksonville, FL – Acting United States Attorney W. Stephen Muldrow announces that DA (40, St. Augustine) has pleaded guilty to healthcare fraud in connection with his role in a fraudulent compound pharmacy scheme. He faces a maximum penalty of 10 years in federal prison.

According to the plea agreement, DA was the operator of Wellness Pharmacy in St Augustine. He performed various jobs, including marketing prescriptions, recruiting physicians to write and fill prescriptions at Wellness Pharmacy, and other jobs.

DA also relied on marketers to help recruit patients to get prescriptions filled at his pharmacy. One of these marketers brought his family in to

[29] https://www.justice.gov/usao-mdfl/pr/st-augustine-pharmacist-pleads-guilty-2-million-compound-pharmacy-fraud-scheme

become “patients” of Wellness Pharmacy. The pharmacy filled numerous prescriptions for the marketer’s family and received nearly $200,000 in government reimbursement. DA admitted paying the marketer almost $50,000 for the referral of work, in violation of the Anti-Kickback statute.

DA also recruited patients himself. For example, he offered patients access to “anything in the store” if they agreed to receive compound prescription drugs. At other times, he offered gift baskets, with chocolate, deodorant, nuts, and other accessories, to patients that

Question 5:

In the FL Pharmacy case, the pharmacist violated the Anti-Kickback statute when he:

a. paid almost $50000 to a "marketer" in return for the filling prescriptions for the marketer's family;
b. offered patients access to “anything in the store” if they agreed to receive compound prescription drugs;
c. offered gift baskets to patients that accepted compound prescriptions;
d. all of the above are true.

accepted compounded prescriptions all in violation of the Anti-Kickback statute.

In 2016, TRICARE developed suspicions regarding the legitimacy of these compound prescriptions. Because the vast majority of Wellness Pharmacy’s claims were purportedly written by a doctor who had never separately billed for these patient visits, TRICARE asked Wellness Pharmacy to complete an audit. During the course of the audit, DA and others made a variety of false and misleading statements. Among other things, DA noted that all patients paid co-pays, no patient was offered anything of value to receive prescriptions, and that Wellness Pharmacy called the doctor prior to dispensing the prescriptions.

Question 6:

In the FL Pharmacy case, what tipped off TRICARE that something was amiss at the Wellness Pharmacy was:

a. all of the patients received chocolate, deodorant or nuts;
b. many patients received multiple prescriptions;
c. the vast majority of Wellness Pharmacy's claims were written by a doctor who had never separately billed for these patient visits;
d. all of the above are true.

Despite his false and misleading statements to TRICARE, or maybe because he made false and misleading statements to TRICARE, prior to trial DA agreed to plead guilty to healthcare fraud.

Pharmacist Pleads Guilty in Scheme to Re-use Medications Left over from Nursing Homes[30]

PITTSBURGH - A resident of Butler County, Pennsylvania, pleaded guilty in federal court to a charge of conspiracy, Acting United States Attorney Soo C. Song announced.

GC, 47, of Mars, PA, pleaded guilty to one count before United States District Judge Arthur J. Schwab.

In connection with the guilty plea, the court was advised that according to Pennsylvania Board of Pharmacy, pharmacists are not permitted to restock medications that have left the pharmacy's control. These must be destroyed. According to the FDCA (Food Drug and Cosmetic Act), if a prescription or a container of stock drugs falsely describes the lot numbers, expiration dates or manufacturers, then the drugs are rendered/deemed misbranded. For example, when pills that left the

[30] https://www.justice.gov/usao-wdpa/pr/pharmacist-pleads-guilty-scheme-re-use-medications-left-over-nursing-homes

pharmacy are returned and comingled with stock drugs instead of being destroyed, and the required labeling on stock containers does not accurately state the actual manufacturer, date of expiration and lot number, then the drugs in the stock container or prescription package are misbranded.

The evidence would show that at all times relevant to the charges, GC, a pharmacist, was the supervisor over a chain of about nine pharmacies known as MedFast Pharmacies. He reported directly to its owner.

MedFast Institutional Pharmacy supplied nursing home chains with individualized medication packages for the patients/residents. If the nursing home had unused pills from prescriptions filled by MedFast or other pharmacies from, for example, a resident passing or a change in medications, MedFast delivery drivers were instructed to collect the unused medications and return them to MedFast. Once these drugs were returned to MedFast, the drugs would be removed from their packaging and returned to stock. As a result, pills with different lot numbers, different expiration dates and different manufacturers were comingled. These comingled pills were thereafter used to fill new prescriptions.

This conduct was initially directed by the defendant. The immediate supervisor of the MedFast Institutional Pharmacy, CP, who reported directly to the defendant, was responsible for carrying out this policy on a day-to-day basis. The evidence would establish that the defendant was a leader and organizer of the criminal conduct under 3B1.1 (a) of the United States Sentencing Guidelines.

In addition to the crime charged, the parties have agreed to a two-point enhancement under the sentencing guidelines for obstruction of justice, pursuant to Section 3C1.1. The government would prove that the defendant became aware that narcotic drugs were being stolen from the MedFast, and that pharmacy technician JG was suspected of stealing the drugs and providing them to her boyfriend, a drug dealer named DB. In October 2011 the defendant arranged for a surveillance technician to focus a camera in her area in an attempt to catch the technician JG stealing. A day after the camera was moved, the defendant reviewed the recording and did not see anything suspicious, but noted that JG was the one who unpacked a shipment of drugs. Between 1 p.m. and 2 p.m. that day, the defendant conducted an inventory and realized there was a

shortage of Opana ER 40 mg. The defendant took JG to a back room and questioned her about the theft. She eventually admitted to this theft as well as additional thefts that had taken place in the past. She told the defendant that she gave the Opana prescription to her boyfriend, DB. The defendant told technician JG that he wanted the drugs back and told her to call her boyfriend to ask him to return them. JG made the call, but her boyfriend would not bring them back for fear of getting arrested. The defendant told DB he would contact the police if DB did not agree to return the stolen Opana.

After about two hours, DB showed up at the pharmacy but did not have the drugs in his possession. DB told his girlfriend technician JG where he had hidden the drugs down the street. The defendant took JG and drove to the location where DB said he had hidden the drugs. The drugs were recovered by JG from a bush in front of a convent. The defendant took the Opana pill vial from JG and observed that the seal had been broken on the prescription vial and opened the vial to see that the cotton was still in the vial. He returned to the pharmacy with it. The drugs had been out of the possession of the pharmacy from between two and six hours. Knowing that the drugs had been stolen, had been in the hands of a drug dealer, that they were recovered from a bush after being gone from the pharmacy from between two and six hours, the defendant thereafter ordered another pharmacist to restock the Opana. The Schedule II log of the pharmacy reflects that 79 Opana pills were restocked. Technician JG was fired that day by the defendant for stealing Opana.

The defendant was interviewed by a DEA special agent. The special agent asked the defendant if there had ever been any diversion of pharmaceutical or disciplinary problems of any current or former employees. The defendant stated there were "none that he knew of." This statement was not true.

The special agent then asked the defendant about any former employees and he stated JG worked there as a pharmacy technician for a while and that her boyfriend had drug issues. The defendant stated JG quit awhile back claiming she was "stressed out." The defendant stated JG quit her job but was not fired or let go. This statement was not true.

The special agent asked the defendant pointedly if there were any instances of any current or former employees where the employee had

stolen controlled substances and then was asked to return the controlled substances to the pharmacy. The defendant stated that he was not aware of any instances. This statement was not true.

The special agent also asked if there were any current or former employees that had been fired or asked to resign as a result of the diversion of controlled substances and the defendant stated, "no." This statement was not true.

There is no evidence that any patient was harmed in any way as a result of any of the conduct described herein.

Judge Schwab scheduled sentencing for April 16, 2018. The law provides for a maximum total sentence of 5 years in prison, a fine of $250,000 or both. Under the Federal Sentencing Guidelines, the actual sentence imposed would be based upon the seriousness of the offenses and the prior criminal history, if any, of the defendant.

Question 7:

If a prescription or a container of stock drugs falsely describes the lot numbers, expiration dates or manufacturers, then the drugs are rendered/deemed:

a. misbranded;
b. expired:
c. harmful to patients;
d. returnable to the wholesaler.

Question 8:

Knowing that Opana had been stolen, had been in the hands of a drug dealer, was recovered from a bush after being gone from the pharmacy from between two and six hours, the defendant thereafter ordered another pharmacist to restock the Opana. Failing to admit this to the investigators resulted in the defendant:

a. agreeing to a 2-point sentencing enhancement for obstruction of justice;
b. causing actual harm to future patients;
c. billing the patient for drugs never dispensed;
d. getting a lighter sentence from the judge.

Med-Fast Pharmacy Inc. and Iserve Technologies, Inc. and its Former Exec and Manager Plead Guilty[31]

PITTSBURGH – Individuals and entities associated with Med-Fast Pharmacy, Inc. ("Med-Fast") have resolved criminal and civil charges associated with Med-Fast's improper submission of claims to the Medicare and Medicaid programs, Acting United States Attorney Soo C. Song announced.

Iserve Technologies, Inc., a company co-located with and operated out of Med-Fast, participated in a conspiracy to fill prescriptions for nursing homes with recycled unused drugs that were commingled with drug stocks on hand at Med-Fast's Institutional Pharmacy. The court sentenced it to pay $400,000 in forfeiture, $44,600 in a criminal fine and a $400 special assessment. Iserve was also ordered by the court to pay to the United States $1,555,000, in accordance with a Civil Settlement Agreement to reimburse the Medicare and Medicaid Programs for overbilling. The Iserve criminal charges follow the earlier guilty plea on

[31] https://www.justice.gov/usao-wdpa/pr/med-fast-pharmacy-inc-and-former-exec-agree-resolve-criminal-and-civil-charges

related charges against the former Vice President of Store Operations for Med-Fast, pharmacist GC, 47, of Mars, Pennsylvania, and the former manager of the Med-Fast Institutional Pharmacy, CP, 37, of Monaca, Pennsylvania.

Med-Fast Pharmacy, Inc., its owner DK, and related entities also have agreed to pay the United States additional monies to settle civil False Claims Act allegations. The total amounts paid, including the above sums, total $2,666,300. The civil settlement resolves allegations in two separate whistleblower lawsuits filed in federal court in Pittsburgh, Pennsylvania. The settled claims contended that Med-Fast violated the False Claims Act by distributing and submitting claims to Medicare for medication that it had either recycled from long-term care facilities serviced by its institutional pharmacy, or that otherwise differed from the medications identified as part of the claims submitted to the United States. The settlement also resolves allegations that Med-Fast violated the False Claims Act by submitting claims to Medicare and Pennsylvania Medicaid that sought reimbursement for the retail-packaged version of diabetes testing strips, while actually supplying patients with cheaper mail-order-packaged version of the same strips.

Question 9:

The Med-Fast Pharmacy case resolves claims that the pharmacy:

a. recycled medication from its long-term care facilities;
b. dispensed different medications than what it billed Medicare for;
c. sought reimbursement for retail-packaged versions of diabetes test strips while actually supplying patients with cheaper mail-order-packaged versions of the same strips;
d. all of the above are true.

The claims resolved by the civil settlement are allegations only, and there has been no determination of liability.

Safeway Pharmacies Pay $3 Million to Resolve Allegations Chain Failed to Timely Report Drug Diversion[32]

Investigation began with Pharmacies in North Bend, WA and Wasilla, AK

The Department of Justice and Safeway (a division of Albertson's Companies, Inc.) have reached a civil settlement of allegations the company failed to timely report controlled substances that were missing from pharmacies, announced U.S. Attorney Annette L. Hayes. Safeway will pay the United States $3 million and implement a compliance agreement reached with the Drug Enforcement Administration (DEA) to ensure such notification lapses do not happen again.

According to the settlement agreement, the investigation began in April 2014, when the DEA learned that Safeway pharmacies in North Bend, Washington and Wasilla, Alaska did not notify DEA of losses of tens of thousands of hydrocodone tablets until months after Safeway discovered the pills were pilfered by employees. DOJ's investigation was later widened to review practices at all Safeway pharmacies nationwide between 2009 and 2014. The investigation revealed a widespread practice of Safeway pharmacies failing to timely report missing or stolen controlled substances. Today's settlement resolves the allegations with Safeway acknowledging and accepting responsibility for failing to report the missing medications in a timely fashion.

DEA Special Agent in Charge Keith Weis was pleased with the settlement adding, "At this crucial juncture in our efforts to combat abuses of prescription drugs, it is imperative that pharmacies notify DEA immediately when drugs are stolen or missing. A quick response to such reports is one of the best tools DEA has in stopping prescription drug diversion."

By law, pharmacies and other drug providers are required to notify the appropriate Field Division of the DEA of the theft or significant loss of any controlled substance within one business day of the discovery of the theft or loss.

[32] https://www.justice.gov/usao-wdwa/pr/safeway-pharmacies-pay-3-million-resolve-allegations-chain-failed-timely-report-drug

This is the third DOJ settlement in the last year in the Western District of Washington involving lax pharmacy controls and inconsistent adherence to DEA requirements. In January 2017, DOJ reached an $11.75 million settlement with Costco and in July 2016 DOJ reached a settlement with Seattle Cancer Care Alliance over pharmacy control failures.

Question 10:

In the Safeway Pharmacies case, what Safeway allegedly did not do was:

a. discipline its employees who pilfered controlled substances;
b. discipline its executives who covered up for pilferers;
c. report the theft or significant loss of any controlled substances within one business day of the discovery of the loss or theft;
d. all of the above are true.

North Carolina Pharmacist Sentenced to Prison For Medicare and Medicaid Fraud[33]

GREENVILLE – The United States Attorney's Office for the Eastern District of North Carolina announced that in federal court, JLD, 35, of Fayetteville, North Carolina**,** was sentenced to 12 months and a day in federal prison and 3 years of supervised release following his prior guilty plea to Health Care Fraud Conspiracy. JLD was also ordered to make restitution of $1,961,176.56 to the Medicare program and $479,923.50 to the North Carolina Medicaid program.

United States Attorney Robert J. Higdon, Jr. stated, "This was a case of a corrupt pharmacist who mixed and sold non-covered pain cremes to the public, but who billed federal taxpayers millions for expensive pain pills

[33] https://www.justice.gov/usao-ednc/pr/north-carolina-pharmacist-sentenced-prison-medicare-and-medicaid-fraud

through the Medicare and Medicaid programs. I am happy to report not only that this pharmacist will be reporting to federal prison as punishment, but more importantly, that he has surrendered his pharmacy license and has already paid back $2 million of the money he stole. JLD will never again be in a position to defraud patients, or taxpayers, using his pharmacy license."

North Carolina Attorney General Josh Stein said, "Cheating Medicaid wastes tax dollars, and it's unacceptable. My office will continue our work to protect taxpayers and hold the healthcare providers who commit fraud accountable."

The Criminal Information to which JLD pleaded guilty, as well as information provided at the sentencing hearing, provided that between 2011 and 2015, JLD owned and operated Old Main Pharmacy, Inc. ("Old Main") located in Pembroke and Rowland, North Carolina. During that time period, JLD directed his staff to fraudulently bill the Medicare program and the North Carolina Medicaid Program for ketoprofen extended release capsules that his pharmacy did not use when creating a compounded pain-relief cream sold by Old Main.

In addition to being sentenced to federal prison and serving a term of supervised release, JLD surrendered his North Carolina pharmacist's license. Prior to sentencing, JLD paid $2,000,000 to the court in anticipation of the sizable restitution judgment.

Question 11:

In the ketoprofen pain crème case, the pharmacist:

a. dispensed pain creams without a prescription;
b. compounded dirty pain creams;
c. billed Medicare and Medicaid for ketoprofen extended release capsules that he did not use in compounding;
d. all of the above are true.

Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering[34]

Defendant and other executives allegedly bribed doctors and pharmacists to prescribe fentanyl spray meant for breakthrough cancer pain

The founder and majority owner of Insys Therapeutics Inc., was arrested and charged with leading a nationwide conspiracy to profit by using bribes and fraud to cause the illegal distribution of a Fentanyl spray intended for cancer patients experiencing breakthrough pain.

JNK, 74, of Phoenix, Ariz., a current member of the Board of Directors of Insys, was arrested in Arizona and charged with RICO conspiracy, as well as other felonies, including conspiracy to commit mail and wire fraud and conspiracy to violate the Anti-Kickback Law.

The superseding indictment, unsealed in Boston, also includes additional allegations against several former Insys executives and managers who were initially indicted in December 2016.

The superseding indictment charges that JNK; MLB, 40, of Scottsdale, Ariz., former CEO and President of the company; AB, 42, of Charlotte, N.C., former Vice President of Sales; RMS, 46, of Seal Beach, Calif., former National Director of Sales; former Regional Sales Directors SL 36, of Bryant City, Mich., and JAR, 43, of Panama City, Fla.; and former Vice President of Managed Markets, MJG, 53, of Scottsdale, Ariz., conspired to bribe practitioners in various states, many of whom operated pain clinics, in order to get them to prescribe a fentanyl-based pain medication. The medication, called "Subsys," is a powerful narcotic intended to treat cancer patients suffering intense breakthrough pain. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for the patients, most of whom were not diagnosed with cancer.

The indictment also alleges that JNK and the six former executives conspired to mislead and defraud health insurance providers who were

[34] https://www.justice.gov/opa/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering

reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up the "reimbursement unit," which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

"In the midst of a nationwide opioid epidemic that has reached crisis proportions, JNK and his company stand accused of bribing doctors to overprescribe a potent opioid and committing fraud on insurance companies solely for profit," said Acting United States Attorney William D. Weinreb. "Today's arrest and charges reflect our ongoing efforts to attack the opioid crisis from all angles. We must hold the industry and its leadership accountable - just as we would the cartels or a street-level drug dealer."

"As alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers," said Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division. "The allegations of selling a highly addictive opioid cancer pain drug to patients who did not have cancer, make them no better than street-level drug dealers. Today's charges mark an important step in holding pharmaceutical executives responsible for their part in the opioid crisis. The FBI will vigorously investigate corrupt organizations with business practices that promote fraud with a total disregard for patient safety."

"Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it," said DEA Special Agent in Charge Michael J. Ferguson. "DEA pledges to work with our law enforcement and regulatory partners nationwide to ensure that rules and regulations under the Controlled Substances Act are followed."

The charges of conspiracy to commit RICO and conspiracy to commit mail and wire fraud each provide for a sentence of no greater than 20 years in prison, three years of supervised release and a fine of $250,000, or twice the amount of pecuniary gain or loss. The charges of conspiracy to violate the Anti-Kickback Law provide for a sentence of no greater

than five years in prison, three years of supervised release and a $25,000 fine. Sentences are imposed by a federal district court judge based upon the U.S. Sentencing Guidelines and other statutory factors.

Question 12:

In the Subsys pain spray case, the company executives allegedly:

a. bribed pharmacists to dispense Subsys without a prescription;
b. bribed physicians to prescribe Subsys;
c. set up a "reimbursement unit" to approve prior authorizations for Subsys;
d. both b an c are true.

Question 13:

In the Subsys pain spray case, the DEA stated that:

a. use of Subsys for non-cancer pain is always wrong;
b. use of Subsys always leads to addiction;
c. pharmaceutical companies whose products include controlled substances have a special obligation to operate in a trustworthy, transparent manner;
d. both b an c are true.

DaVita Rx Agrees to Pay $63.7 Million to Resolve False Claims Act Allegations[35]

DaVita Rx LLC, a nationwide pharmacy that specializes in serving patients with severe kidney disease, agreed to pay a total of $63.7 million to resolve False Claims Act allegations relating to improper billing practices and unlawful financial inducements to federal healthcare program beneficiaries, the Justice Department announced.

The settlement resolves allegations that DaVita Rx billed federal healthcare programs for prescription medications that were never shipped, that were shipped but subsequently returned, and that did not comply with requirements for documentation of proof of delivery, refill requests, or patient consent. In addition, the settlement also resolves allegations that DaVita paid financial inducements to Federal healthcare program beneficiaries in violation of the Anti-Kickback Statute. Specifically, DaVita Rx allegedly accepted manufacturer copayment discount cards in lieu of collecting copayments from Medicare beneficiaries, routinely wrote off unpaid beneficiary debt, and extended discounts to beneficiaries who paid for their medications by credit card. These allegations relating to improper billing and unlawful financial inducements were the subject of self-disclosures by DaVita Rx and a subsequently filed whistleblower lawsuit.

"Improper billing practices and unlawful financial inducements to health program beneficiaries can drive up our nation's health care costs," said Civil Division Acting Assistant Attorney General Chad Readler.

DaVita Rx has agreed to pay a total of $63.7 million to resolve the allegations in its self-disclosures and the whistleblower lawsuit. DaVita Rx repaid approximately $22.2 million to federal healthcare programs following its self-disclosure and will pay an additional $38.3 million to the United States as part of the settlement agreement. In addition, $3.2 million has been allocated to cover Medicaid program claims by states that elect to participate in the settlement.

[35] https://www.justice.gov/opa/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations

"Providers should not make patient care decisions based upon improper financial incentives or encourage their patients to do the same," said U.S. Attorney Erin Nealy Cox for the Northern District of Texas.

The lawsuit resolved by the settlement was filed by two former DaVita Rx employees under the *qui tam*, or whistleblower, provisions of the False Claims Act, which permit private parties to sue on behalf of the government when they discover evidence that defendants have submitted false claims for government funds and to receive a share of any recovery.

Question 14:

In the DaVita Rx case, the company was accused of:

a. billing for prescriptions that were never shipped;
b. billing for prescriptions that were shipped and then returned;
c. billing for prescriptions that did not comply with documented proof of delivery, refill requests or patient consent;
d. all of the above are true.

Question 15:

In the DaVita Rx case, the company was accused of paying financial inducements to Medicare/Medicaid beneficiaries including:

a. accepting manufacturer copayment discount cards in lieu of collecting copayments;
b. routinely writing off unpaid beneficiary debt;
c. extending discounts to beneficiaries who paid for their medications by credit card;
d. all of the above are true.

Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks[36]

Pharmaceutical company United Therapeutics Corporation (UT), based in Silver Spring, Maryland, has agreed to pay $210 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking UT's pulmonary arterial hypertension drugs, in violation of the False Claims Act, the Justice Department announced.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a copayment, coinsurance, or deductible (collectively "copays"). These copay obligations may be substantial for expensive medications. Congress included copay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs—including the prices that pharmaceutical manufacturers can demand for their drugs. Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering or paying, directly or indirectly, any remuneration—which includes money or any other thing of value— to induce Medicare patients to purchase the company's product.

UT sells a number of pulmonary arterial hypertension drugs, including Adcirca, Remodulin, Tyvaso, and Orenitram (the "Subject Dugs"). The government alleged that UT used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the copay obligations of thousands of Medicare patients taking the Subject Drugs. In particular, from 2010 to 2014, UT allegedly made donations to the foundation, which, in turn, used those donations to pay copays for the Subject Drugs to induce patients to purchase these drugs. The government alleged that UT routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug and that this data was used by UT to decide how much to donate to the foundation. The Government also alleged that UT had a policy of not permitting needy Medicare patients to participate in its free drug program, which was open to other financially needy patients, and instead referred Medicare patients to the foundation, which allowed claims to be submitted to Medicare.

[36] https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability

"While we support efforts to provide patients with access to needed medications, such assistance must comply with federal law. Today's settlement shows that the government will hold accountable drug companies that attempt to use illegal kickbacks to defeat mechanisms Congress designed to act as a check on drug pricing and healthcare costs," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division.

UT has also entered into a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The five-year CIA requires, among other things, that UT implement measures designed to ensure that arrangements and interactions with third-party patient assistance programs are compliant with the law. In addition, the CIA requires reviews by an independent review organization, compliance-related certifications from company executives and Board members, and the implementation of a risk assessment and mitigation process.

"Our corporate integrity agreement requires United Therapeutics to implement controls and monitoring designed to promote true independence from any patient assistance programs to which it donates," said Gregory E. Demske, Chief Counsel to the Inspector General for the U.S. Department of Health and Human Services. "Without true independence, a drug company can use a foundation as a conduit for improper payments that expose the taxpayer-funded Medicare program to the risk of abuse."

"UT used a third party to do exactly what it knew it could not lawfully do itself," said Acting United States Attorney William D. Weinreb. "According to the allegations in today's settlement agreement, UT understood that the third-party foundation used UT's money to cover the co-pays of patients taking UT drugs. UT's payments to the foundation were not charity for PAH patients generally, but rather were a way to funnel money to patients taking UT drugs. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these that leave Medicare holding the bag for the costs of expensive drugs."

The government's resolution of this matter illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement, can be reported to the Department of Health and Human Services at 800-HHS-TIPS (800-447-8477).

The claims resolved by the settlement are allegations only; there has been no determination of liability.

Question 16:

In the United Therapeutics case, the company was accused of:

a. billing for prescriptions that were never shipped;
b. billing for prescriptions that were shipped and then returned;
c. using a third party to do exactly what it knew it could not lawfully do itself;
d. all of the above are true.

Question 17:

In the United Therapeutics case, the company was accused of:

a. using a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the copay obligations of thousands of Medicare patients;
b. routinely writing off unpaid beneficiary debt;
c. extending discounts to beneficiaries who paid for their medications by credit card;
d. all of the above are true.

Wellford Woman Pleads Guilty to Forging Prescriptions[37]

She filled ten different prescriptions forged in the names of her children and had Medicaid pay for them

Columbia, South Carolina ---- United States Attorney Beth Drake announces that FLP, age 41, of Wellford, South Carolina, pled guilty to Aggravated Identity Theft, a violation of Title 18, United States Code, § 1028A; and, Obtaining a Controlled Substance by Fraud, a violation of Title 21, United States Code, § 843(a)(3). Chief Judge Terry L. Wooten presided at the hearing and will sentence FLP on February 27, 2018.

Evidence presented at the change of plea established that FLP filled ten different prescriptions forged in the names of her four children and had Medicaid pay for them. The conduct occurred between July 2016 and April 2017. The investigation revealed that these prescriptions were for Schedule II opioids, such as oxycodone, hydrocodone, and Adderall.
U.S. Attorney Drake stated the statutorily mandated penalty faced by FLP for a violation of Title 18, United States Code, § 1028A is imprisonment for two years, with a potential fine up to $250,000. The maximum penalty for a violation of Title 21, United States Code, § 843(a)(3) is four years in prison and a fine of $250,000.

Question 18:

In the forged prescriptions case, the forger:

a. filled prescriptions in the names of her 4 children;
b. filled prescriptions for some Schedule II controlled substances;
c. had Medicaid pay for the forged prescriptions:
d. all of the above are true.

[37] https://www.justice.gov/usao-sc/pr/wellford-woman-pleads-guilty-forging-prescriptions

Question 19:

In the forged prescriptions case, the forger's penalty will be:

a. statutorily mandated penalty of imprisonment for 2 years;
b. potential fine of up to $250,000;
c. maximum penalty of 4 years in prison and a fine of $250,000;
d. all of the above are true.

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Former Pharmacy Compliance Director Pleads Guilty to Introducing Adulterated Drugs into Interstate Commerce and Conspiracy to Defraud the United States[38]

The former compliance director of an Indiana compounding pharmacy pleaded guilty to introducing adulterated drugs into interstate commerce and conspiracy to defraud the United States by obstructing the Food and Drug Administration's (FDA) lawful functions.

CRB, 63, of Carmel, Indiana, pleaded guilty in the Southern District of Indiana to one count of conspiracy to defraud the United States, three misdemeanor counts of introducing an adulterated drug in interstate commerce, and six misdemeanor counts of adulterating drugs while held for sale after shipment of a drug component in interstate commerce. CRB was the Director of Compliance for Pharmakon Pharmaceuticals Inc. (Pharmakon). Pharmakon compounded drugs at a facility in Noblesville, Indiana, for customers in various states.

"This defendant distributed serious drugs to hospitals in Indiana and around the country, knowing that the drugs were significantly under or over the strength they were supposed to be," said Josh Minkler, United States Attorney for the Southern District of Indiana.

[38] https://www.justice.gov/opa/pr/former-pharmacy-compliance-director-pleads-guilty-introducing-adulterated-drugs-interstate

As part of her plea agreement, CRB acknowledged that during 2014 and 2016 FDA inspections, she lied about Pharmakon's never having received any out-of-specification drug potency test results. CRB also acknowledged that she knowingly conspired with another individual to defraud the United States by obstructing the lawful functions of the FDA. In addition, she acknowledged that it was the purpose of the conspiracy to prevent the loss of revenue that would result from customers' and FDA's knowledge of Pharmakon's having distributed numerous compounded drugs that were not the strength purported on the drugs' labeling.

"This is an egregious example of how harmful conduct can result in risk to patients. The disregard for the law resulted in the injury of infants from poorly compounded, super potent morphine products," said FDA Commissioner Scott Gottlieb, M.D.

The conspiracy charge to which CRB pleaded guilty carries a statutory maximum sentence of five years in prison and a fine of $250,000 or twice the gross gain or gross loss from the offense. The misdemeanor charges of distributing an adulterated drug in interstate commerce and adulterating drugs while held for sale after shipment of a drug component in interstate commerce each carry a statutory maximum punishment of one year in prison and a fine of $100,000 or twice the gross gain or gross loss from the offense.

Question 20:

If you tell the FDA during an inspection that your compounding pharmacy never received any out-of-specification drug results, yet it did, and you sell those drugs to customers, you can expect:

a. to be charged with introducing adulterated drugs into interstate commerce;
b. to be charged with conspiracy to defraud the United States;
c. a potential sentence of 5 years in prison and a $250,000 fine;
d. all of the above are true.

Return this ANSWER SHEET with the $30.00 Program Fee payable to:

Select CE, P.O. Box 21186, Columbus, Ohio 43221-0186

NAME:	**Pharmacist? Yes/No**
ADDRESS:	**Technician? Yes/No**
CITY, STATE and ZIP:	
EMAIL:	
NABP e-Profile #:	**Month and Day of Birth:**

ANSWERS: More DOJ Cases Against Pharmacists - 2018

(Expiration Date: March 5, 2021)

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

1.	a	b	c	d	11.	a	b	c	d
2.	a	b	c	d	12.	a	b	c	d
3.	a	b	c	d	13.	a	b	c	d
4.	a	b	c	d	14.	a	b	c	d
5.	a	b	c	d	15.	a	b	c	d
6.	a	b	c	d	16.	a	b	c	d
7.	a	b	c	d	17.	a	b	c	d
8.	a	b	c	d	18.	a	b	c	d
9.	a	b	c	d	19.	a	b	c	d
10.	a	b	c	d	20.	a	b	c	d

21. After completing this program, I am able to describe at least 5 consequences of failing to comply with federal drug laws: Yes No
22. This CE activity met my educational needs: Yes No
23. The author was organized in the written materials: Yes No
24. The learning material was useful: Yes No
25. The teaching and learning methods (case format, questions embedded in the program) fostered active learning and were effective: Yes No
26. The learning assessment (the post-test) was appropriate: Yes No
27. The test questions were relevant to the goals of the CE activity: Yes No
28. The test questions were at an appropriate level of difficulty: Yes No
29. The CE activity was presented in a fair and unbiased manner: Yes No
30. If you perceived any bias or commercialism, please describe:

_____

31. Thank You! Other comments are welcome: _____

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