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Our goal is to offer pharmacy CE activities in the areas of pharmacy law (ACPE topic designator "03") and patient safety (ACPE topic designator "05").

3 **FDA Drug Safety Communications -2019**
ACPE Program Number: 0487-0000-19-002-H05-P and 0487-0000-19-002-H05-T (knowledge-based activity)
Release Date: January 20, 2019
Expiration Date: January 20, 2022
Contact Hour(s): 2.0 **Program Fee**: $20.00

28 **FDA MedWatch Alerts - 2018**
ACPE Program Number: 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
Contact Hour(s): 2.0 **Program Fee**: $20.00

51 **DOJ Cases Against Pharmacists - 2019**
ACPE Program Number: 0487-0000-19-001-H03-P and 0487-0000-19-001-H03-T (knowledge-based activity)
Release Date: January 15, 2019
Expiration Date: January 15, 2022
Contact Hour(s): 1.0 **Program Fee**: $15.00

67 **More DOJ Cases Against Pharmacists - 2018**
ACPE Program Number: 0487-0000-18-001-H03-P and 0487-0000-18-001-H03-T (knowledge-based activity)
Release Date: March 5, 2018
Expiration Date: March 5, 2021
Contact Hour(s): 2.0 **Program Fee**: $30.00

Select CE® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Ohio State Board of Pharmacy - CE Reporting Changes

Effective September 16, 2018, the Ohio State Board of Pharmacy changed the reporting requirements for pharmacists to align the CE reporting period to the biennual license renewal cycle.

Specifically, pharmacists are required to obtain a minimum of **4.0 CEUs (40 hours) every two years** prior to license renewal. Every pharmacist, no matter of license number, will be on the same reporting cycle beginning with the 2019 renewal. **Please refer to the chart below for hours required to earn and report for the 2019 reporting period.**

Continuing Education Requirements by Reporting Cycle:

License Number	2019 Reporting Cycle
03-1-XXXXX	Total Hours – 60 Patient Safety/Medication Errors – 2 Law/Jurisprudence – 3 Earned between 9/16/16 and 9/15/19
03-2-XXXXX	Total Hours – 40 Patient Safety/Medication Errors – 1 Law/Jurisprudence – 2 Earned between 9/16/17 and 9/15/19
03-3-XXXXX	Total Hours – 20 Patient Safety/Medication Errors – 1 Law/Jurisprudence – 1 Earned between 9/16/18 and 9/15/19

For a full description of the changes, see the Board's announcement: https://www.pharmacy.ohio.gov/Documents/Licensing/CE/General/CE%20Reporting%20Requirements.pdf

Program Title: **FDA Drug Safety Communications - 2019**

Target Audience: All Pharmacists and Pharmacy Technicians

ACPE Program No.: 0487-0000-19-002-H05-P and 0487-0000-19-002-H05-T (knowledge-based activity)

Release Date: January 20, 2019

Expiration Date: January 20, 2022

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

Program Fee: $20.00

Estimated Time to Complete the Activity: 120 minutes

Procedures: To receive credit for completing this activity, you must supply your CPE Monitor 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 a Feedback Statement mailed to you within two 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 Feedback Statement will be sent within five 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.

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 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 FDA used the brand name of the drug in its publication and hence the brand name is used here too. Patti Nussle has no potential conflicts of interest or financial relationships to disclose.

Objectives: At the conclusion of this program, pharmacists should be able to list 7 rare but serious events, and their associated drugs, for which the FDA has issued Drug Safety Communications.

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Objectives: At the conclusion of this program, pharmacy technicians should be able to list 7 rare but serious events, and their associated drugs, for which the FDA has issued Drug Safety Communications.

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 a summary of the FDA's most recent Drug Safety Communications. These Drug Safety Communications are designed for both health care professionals as well as consumers. While we have removed some of the consumer-centered information, you may notice some lay-person terminology. This information is taken directly from the FDA's website, where you can look for additional information.[1]

FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients[2]

[12-20-2018] A U.S. Food and Drug Administration (FDA) review found that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection.

Fluoroquinolones should not be used in patients at increased risk unless there are no other treatment options available. People at increased risk include those with a history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly. We are requiring that a new warning about this risk be added to the prescribing information and patient Medication Guide for all fluoroquinolones.

Health care professionals should avoid prescribing fluoroquinolone antibiotics to patients who have an aortic aneurysm or are at risk for an aortic aneurysm, such as patients with peripheral atherosclerotic vascular diseases, hypertension, certain genetic conditions such as Marfan syndrome and Ehlers-Danlos syndrome, and elderly patients. Prescribe fluoroquinolones to these patients only when no other treatment options are available. Advise all patients to seek immediate medical treatment for any symptoms associated with aortic aneurysm. Stop fluoroquinolone

[1] https://www.fda.gov/Drugs/DrugSafety/ucm199082.htm
[2] https://www.fda.gov/Drugs/DrugSafety/ucm628753.htm

treatment immediately if a patient reports side effects suggestive of aortic aneurysm or dissection.

We reviewed cases reported to FDA* and four published observational studies [citations omitted] that showed an increased risk of aortic aneurysm or dissection associated with fluoroquinolone use. How some of the studies were designed or carried out, and the ways the data were analyzed could affect the study findings; however, taken together, the results of all four studies provide consistent evidence of an association between fluoroquinolone use and aortic aneurysm or dissection. The underlying mechanism for this risk cannot be determined from these studies, and the background risk of aortic aneurysm can vary depending on the population. The background risk has been estimated from 9 aortic aneurysm events per 100,000 people per year in the general population to 300 aortic aneurysm events per 100,000 people per year in individuals at highest risk. Because multiple studies showed higher rates of about **twice** the risk of aortic aneurysm rupture and dissection in those taking fluoroquinolones, FDA determined the warnings were warranted to alert health care professionals and patients.

We communicated safety information associated with fluoroquinolones in July 2018 (significant decreases in blood sugar and certain mental health side effects), July 2016 (disabling side effects of the tendons, muscles, joints, nerves, and central nervous system), May 2016 (restricting use for certain uncomplicated infections), August 2013 (peripheral neuropathy), and July 2008 (tendinitis and tendon rupture).

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

List of FDA-approved Systemic Fluoroquinolones

Brand Name	Active Ingredient
Avelox	moxifloxacin
Baxdela	delafloxacin
Cipro	ciprofloxacin
Cipro extended-release	ciprofloxacin extended-release
Factive	gemifloxacin
Levaquin	levofloxacin
Ofloxacin (generic brand)	ofloxacin

Question 1:

The FDA has found that use of fluoroquinolone antibiotics can increase the occurrence of rare but serious events of:

a. ruptures of the aorta;
b. ruptures of the abdomen;
c. ruptures of the nasal cavity;
d. all of the above.

Question 2:

Health care professionals should avoid prescribing fluoroquinolone antibiotics to patients who have an aortic aneurysm or are at risk for an aortic aneurysm, including patients:

a. with peripheral atherosclerotic vascular diseases;
b. with hypertension;
c. elderly patients.
d. all of the above.

Question 3:

FDA-approved systemic fluoroquinolones include:

a. ciprofloxacin;
b. levofloxacin;
c. moxifloxacin;
d. all of the above.

FDA warns that symptoms of a serious condition affecting the blood cells are not being recognized with the leukemia medicine Idhifa (enasidenib)[3]

[11-29-2018] The U.S. Food and Drug Administration (FDA) is warning that signs and symptoms of a life-threatening side effect called differentiation syndrome are not being recognized in patients receiving the acute myeloid leukemia medicine Idhifa (enasidenib). The Idhifa prescribing information and patient Medication Guide already contain a warning about differentiation syndrome. However, we have become aware of cases of differentiation syndrome not being recognized and patients not receiving the necessary treatment.

Health care professionals should describe to patients the symptoms of differentiation syndrome listed in the Medication Guide when starting Idhifa and at follow-up visits, and inform them to call their health care professional if such symptoms occur. Differentiation syndrome has occurred as early as 10 days and up to 5 months after starting the medicine. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may mimic and be difficult to distinguish from cardiogenic pulmonary edema, pneumonia, or sepsis. If patients experience unexplained respiratory distress or other symptoms, consider a diagnosis of differentiation syndrome and treat promptly with oral or intravenous corticosteroids.

Patients should contact your health care professional or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome while you are taking Idhifa:

- Fever
- Cough
- Shortness of breath
- Swelling of arms and legs
- Swelling around the neck, groin, or underarm area
- Fast weight gain of more than 10 pounds within a week
- Bone pain
- Dizziness or feeling lightheaded

[3] https://www.fda.gov/Drugs/DrugSafety/ucm626923.htm

Idhifa was approved in August 2017 to treat patients with acute myeloid leukemia (AML) with a specific genetic mutation called isocitrate dehydrogenase (IDH)-2 whose disease has come back or has not improved after treatment with other chemotherapy medicines. AML is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells. Idhifa works by blocking several enzymes that promote this abnormal blood cell growth.

In the clinical trial conducted for Idhifa's approval, at least 14 percent of patients experienced differentiation syndrome. The manufacturer's safety report, which included the period of May 1, 2018 to July 31, 2018, reported five cases of death associated with differentiation syndrome in patients taking Idhifa. Until Idhifa was approved, differentiation syndrome had been associated only with induction chemotherapy in patients with a rare form of cancer called acute promyelocytic leukemia. Health care professionals and patients may not recognize the signs and symptoms of differentiation syndrome associated with Idhifa. Another recently approved drug for AML with a specific genetic mutation called isocitrate dehydrogenase (IDH)-1, Tibsovo (ivosidenib), also carries a risk of differentiation syndrome. Health care professionals should also be vigilant in monitoring for differentiation syndrome when prescribing Tibsovo and patients should alert their health care professional of any symptoms.

Question 4:

Differentiation syndrome has occurred as early as 10 days and up to 5 months after starting Idhifa (enasidenib).

a. True;
b. False.

Question 5:

Differentiation syndrome can be difficult to distinguish from cardiogenic pulmonary edema, pneumonia, or sepsis.

a. True;
b. False.

Question 6:

Differentiation syndrome can cause a weight gain of 10 pounds within 1 week.

a. True;
b. False.

Question 7:

In the clinical trial conducted for Idhifa's approval, at least 14 percent of patients experienced differentiation syndrome.

a. True;
b. False.

Question 8:

Health care professionals should be vigilant in monitoring for differentiation syndrome in patients taking Idhifa (enasidenib) and Tibsovo (ivosidenib).

a. True;
b. False.

FDA warns about rare but serious risks of stroke and blood vessel wall tears with multiple sclerosis drug Lemtrada (alemtuzumab)[4]

[**11-29-2018**] The U.S. Food and Drug Administration (FDA) is warning that rare but serious cases of stroke and tears in the lining of arteries in the head and neck have occurred in patients with multiple sclerosis (MS) shortly after they received Lemtrada (alemtuzumab). These problems can lead to permanent disability and even death. As a result, we have added a new warning about these risks to the prescribing information in the drug label and to the patient Medication Guide. We have also added the risk of stroke to the existing *Boxed Warning*, FDA's most prominent warning.

Alemtuzumab is also approved under the brand name Campath, which was approved in May 2001 to treat a type of cancer called B-cell chronic lymphocytic leukemia (B-CLL). The Campath drug label will also be updated to include these risks in the *Adverse Reactions* section under *Postmarketing Experience*.

Patients or their caregivers should seek emergency treatment as soon as possible if the patient experiences signs or symptoms of a stroke or tears in the lining of the head and neck arteries, called arterial dissection, which can include:

- Sudden numbness or weakness in the face, arms, or legs, especially if it occurs on only one side of the body
- Sudden confusion, trouble speaking, or difficulty understanding speech
- Sudden trouble seeing in one or both eyes
- Sudden trouble with walking, dizziness, or loss of balance or coordination
- Sudden severe headache or neck pain

Most patients taking Lemtrada who developed stroke or tears in the artery linings, developed symptoms within 1 day of receiving Lemtrada. One patient reported symptoms that occurred 3 days after treatment.

[4] https://www.fda.gov/Drugs/DrugSafety/ucm624247.htm

Health care professionals should advise patients at every Lemtrada infusion to seek immediate emergency medical attention if they experience symptoms of ischemic or hemorrhagic stroke or cervicocephalic arterial dissection. The diagnosis is often complicated because early symptoms such as headache and neck pain are not specific. Promptly evaluate patients who complain of symptoms consistent with these conditions.

In the nearly five years since FDA approved Lemtrada in 2014 to treat relapsing forms of MS, we identified 13 worldwide cases of ischemic and hemorrhagic stroke or arterial dissection that occurred shortly after the patient received Lemtrada. This number includes only reports submitted to FDA, so additional cases we are unaware of may have occurred. Twelve of these cases reported symptoms within 1 day of receiving Lemtrada. As a result, we have added a new warning about this risk in the *Warnings and Precautions* section of the prescribing information in the drug label. We have also added the risk of stroke to the existing *Boxed Warning*, FDA's most prominent warning.

Question 9:

Within 1 day, Lemtrada or Campath (alemtuzumab) can cause rare but serious:

a. myocardial infarction;
b. ischemic or hemorrhagic stroke, or arterial dissection;
c. loss of hearing;
d. loss of limbs.

FDA warns about severe worsening of multiple sclerosis after stopping the medicine Gilenya (fingolimod)[5]

[11-20-2018] The Food and Drug Administration (FDA) is warning that when the multiple sclerosis (MS) medicine Gilenya (fingolimod) is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare but can result in permanent disability. As a result, we have added a new warning about this risk to the prescribing information of the Gilenya drug label and patient Medication Guide.

Gilenya is one of several medicines approved to treat a form of MS called relapsing MS, which are periods of time when MS symptoms get worse. The medicine was approved in the United States in 2010.

Health care professionals should inform patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya. When Gilenya is stopped, patients should be carefully observed for evidence of an exacerbation of their MS and treated appropriately. Patients should be advised to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped.

In the 8 years since Gilenya was approved in September 2010, we identified 35 cases of severely increased disability accompanied by the presence of multiple new lesions on magnetic resonance imaging (MRI) that occurred 2 to 24 weeks after Gilenya was stopped. Most patients experienced this worsening in the first 12 weeks after stopping. Our analyses include only reports submitted to FDA and those found in the medical literature, so there may be additional cases about which we are unaware. The severe increase in disability in these patients was more severe than typical MS relapses, and in cases where baseline disability was known, appeared unrelated to the patients' prior disease state. Several patients who were able to walk without assistance prior to discontinuing Gilenya progressed to needing wheelchairs or becoming totally bedbound. In patients experiencing worsening of disability after stopping Gilenya, recovery varied. Seventeen patients had partial recovery, 8 experienced

[5] https://www.fda.gov/Drugs/DrugSafety/ucm626095.htm

permanent disability or no recovery, and 6 eventually returned to the level of disability they had before or during Gilenya treatment.

We previously communicated safety information about Gilenya in August 2015 and August 2013 (rare brain infection), May 2012 (revised cardiovascular monitoring recommendations), and December 2011 (safety review of reported death).

Question 10:

Gilenya (fingolimod) is one of several medicines approved to treat a form of MS called relapsing MS, which are periods of time when MS symptoms get worse.

a. True;
b. False.

Question 11:

Health care professionals should inform patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya.

a. True;
b. False.

Question 12:

In patients experiencing worsening of disability after stopping Gilenya, 17 of 35 patients had partial recovery.

a. True;
b. False.

FDA warns about rare occurrences of a serious infection of the genital area with SGLT2 inhibitors for diabetes[6]

[8-29-2018] The U.S. Food and Drug Administration (FDA) is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. We are requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

SGLT2 inhibitors are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

Patients should **seek medical attention immediately** if you experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.

Health care professionals should assess patients for Fournier's gangrene if they present with the symptoms described above. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary. Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

Fournier's gangrene is an extremely rare but life-threatening bacterial infection of the tissue under the skin that surrounds muscles, nerves, fat, and blood vessels of the perineum. The bacteria usually get into the body through a cut or break in the skin, where they quickly spread and destroy the tissue they infect. Having diabetes is a risk factor for developing Fournier's gangrene; however, this condition is still rare among diabetic patients. Overall published literature about the occurrence of Fournier's gangrene for men and women is very limited. Publications report that

[6] https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm

Fournier's gangrene occurs in 1.6 out of 100,000 males annually in the U.S., and most frequently occurs in males 50-79 years (3.3 out of 100,000).[1-3] In our case series, however, we observed events in both women and men.

In the five years from March 2013 to May 2018, we identified 12 cases of Fournier's gangrene in patients taking an SGLT2 inhibitor. This number includes only reports submitted to FDA and found in the medical literature [citations omitted], so there may be additional cases about which we are unaware. In 2017, an estimated 1.7 million patients received a dispensed prescription for an SGLT2 inhibitor from U.S. outpatient retail pharmacies. [citation omitted] Although most cases of Fournier's gangrene have previously been reported in men, our 12 cases included 7 men and 5 women. Fournier's gangrene developed within several months of the patients starting an SGLT2 inhibitor and the drug was stopped in most cases. All 12 patients were hospitalized and required surgery. Some patients required multiple disfiguring surgeries, some developed complications, and one patient died. In comparison, only six cases of Fournier's gangrene (all in men) were identified in review of other antidiabetic drug classes over a period of more than 30 years.

FDA-Approved SGLT2 Inhibitors

Brand Name	Active Ingredient(s)
Invokana	canagliflozin
Invokamet	canagliflozin and metformin
Invokamet XR	canagliflozin and metformin extended-release
Farxiga	dapagliflozin
Xigduo XR	dapagliflozin and metformin extended-release
Qtern	dapagliflozin and saxagliptin
Jardiance	empagliflozin
Glyxambi	empagliflozin and linagliptin
Synjardy	empagliflozin and metformin
Synjardy XR	empagliflozin and metformin extended-release
Steglatro	ertugliflozin
Segluromet	ertugliflozin and metformin
Steglujan	ertugliflozin and sitagliptin

Question 13:

The FDA warns that with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors, cases of a rare but serious infection have been reported known as:

a. necrotizing fasciitis of the perineum;
b. Fournier's gangrene;
c. both of the above.

Question 14:

Patients on SGLT2 inhibitors should seek medical attention immediately if they experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell.

a. True;
b. False.

Question 15:

The FDA identified 12 cases of Fournier's gangrene in patients taking an SGLT2 inhibitor, and of these 12 patients:

a. all were men;
b. none required surgery;
c. all survived the gangrene;
d. none of the above are true.

FDA warns about increased risk of cancer relapse with long-term use of azithromycin (Zithromax, Zmax) antibiotic after donor stem cell transplant[7]

[08-03-2018] The U.S. Food and Drug Administration (FDA) is warning that the antibiotic azithromycin (Zithromax, Zmax) should not be given long-term to prevent a certain inflammatory lung condition in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant. Results of a clinical trial [citation omitted] found an increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients. We are reviewing additional data and will communicate our conclusions and recommendations when our review is complete.

The serious lung condition for which long-term azithromycin was being studied called bronchiolitis obliterans syndrome is caused by inflammation and scarring in the airways of the lungs, resulting in severe shortness of breath and dry cough. Cancer who undergo stem cell transplants from donors are at risk for bronchiolitis obliterans syndrome. The manufacturer of brand name azithromycin is providing a Dear Healthcare Provider letter on this safety issue to health care professionals who care for patients undergoing donor stem cell transplants.

Azithromycin is not approved for preventing bronchiolitis obliterans syndrome. It is an FDA-approved antibiotic used to treat many types of infections affecting the lungs, sinuses, skin, and other parts of the body. The drug has been used for more than 26 years. It is sold under the brand names Zithromax and Zmax and as generics by many different drug companies.

There are no known effective antibiotic treatments for prophylaxis of bronchiolitis obliterans syndrome. **Health care professionals** should not prescribe long-term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for cancer relapse and death.

[7] https://www.fda.gov/Drugs/DrugSafety/ucm614085.htm

Researchers in France identified this increased risk of cancer relapse and death while conducting a clinical trial investigating the effectiveness of long-term azithromycin to prevent bronchiolitis obliterans syndrome in patients who undergo donor, or allogenic, stem cell transplants for cancers of the blood and lymph nodes. The researchers concluded that the risks of long-term azithromycin exposure after donor stem cell transplantation may exceed the benefits. The trial could not determine why the rates of cancer relapse and death were higher with azithromycin.

The researchers stopped the ALLOZITHRO[1] trial approximately 13 months after the study completed enrollment of 480 patients because an unexpected increase in the rate of both cancer relapses and death was observed in patients taking azithromycin. Cancer relapse was observed in 77 patients (32.9%) with azithromycin treatment compared to 48 patients (20.8%) with placebo, which is an inactive treatment. A total of 95 patients died in the azithromycin treatment group versus 66 patients in the placebo group; thus, the 2-year survival rate was 56.6% in azithromycin-treated patients compared to 70.1% in those receiving a placebo.

Question 16:

Health care professionals should not prescribe long-term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for:

a. life-threatening allergic reactions;
b. cancer relapse and death;
c. dehydration;
d. all of the above.

FDA to evaluate potential risk of neural tube birth defects with HIV medicine dolutegravir (Juluca, Tivicay, Triumeq)[8]

[9/2018 Update]: The information described below has been addressed in product labeling. Health care professionals and patients can access the latest prescribing information by searching for dolutegravir at: Drugs@FDA

Safety Announcement

The U.S. Food and Drug Administration (FDA) is alerting the public that serious cases of neural tube birth defects involving the brain, spine, and spinal cord have been reported in babies born to women treated with dolutegravir used to treat human immunodeficiency virus (HIV). Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.

Neural tube defects are birth defects that can occur early in pregnancy when the spinal cord, brain, and related structures do not form properly. To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. We are investigating this new safety issue and will update the public when we have more information.

Dolutegravir is an FDA-approved antiretroviral medicine used in combination with other antiretroviral medicines to treat HIV, the virus that can cause acquired immunodeficiency syndrome (AIDS). Dolutegravir works by blocking integrase, an HIV enzyme, to prevent the virus from multiplying and can reduce the amount of HIV in the body. Approved in 2013, dolutegravir has been on the market for 5 years, and is available as a single ingredient product under the brand name Tivicay and as a fixed dose combination tablet with other HIV medicines under the brand names Juluca and Triumeq.

Health care professionals should inform women of childbearing age about the potential risk of neural tube defects when a dolutegravir-

[8] https://www.fda.gov/Drugs/DrugSafety/ucm608112.htm

containing regimen is used at the time of conception and early in pregnancy. In addition:

- Health care professionals should weigh the benefits and the risks of dolutegravir when prescribing antiretroviral medicines to women of childbearing age. Alternative antiretroviral medicines should be considered. Discuss the relative risks and benefits of appropriate alternative antiretroviral therapies.
- If the decision is made to use dolutegravir in women of childbearing age, health care professionals should reinforce the consistent use of effective birth control.
- Perform pregnancy testing before initiating a dolutegravir-containing regimen in women of childbearing age to exclude pregnancy.

Question 17:

Women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for:

a. serious cases of neural tube birth defects in their babies;
b. serious cases of neuropathies;
c. both of the above.

Question 18:

If the decision is made to use dolutegravir in women of childbearing age, health care professionals should reinforce the consistent use of:

a. Proper diet and exercise;
b. Effective birth control

FDA warns of serious immune system reaction with seizure and mental health medicine lamotrigine (Lamictal)[9]

[**04-25-2018**] The Food and Drug Administration (FDA) is warning that the medicine lamotrigine (Lamictal) for seizures and bipolar disorder can cause a rare but very serious reaction that excessively activates the body's infection-fighting immune system. This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. As a result, we are requiring a new warning about this risk be added to the prescribing information in the lamotrigine drug labels.

The immune system reaction, called hemophagocytic lymphohistiocytosis (HLH), causes an uncontrolled response by the immune system. HLH typically presents as a persistent fever, usually greater than 101°F, and it can lead to severe problems with blood cells and organs throughout the body such as the liver, kidneys, and lungs.

Lamotrigine is used alone or with other medicines to treat seizures in patients two years and older. It may also be used as maintenance treatment in patients with bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania. Lamotrigine has been approved and on the market for 24 years, and is available under the brand name Lamictal and as generics.

Health care professionals should be aware that prompt recognition and early treatment is important for improving HLH outcomes and decreasing mortality. Diagnosis is often complicated because early signs and symptoms such as fever and rash are not specific. HLH may also be confused with other serious immune-related adverse reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Evaluate patients who develop fever or rash promptly, and discontinue lamotrigine if HLH or another serious immune-related adverse reaction is suspected and an alternative etiology for the signs and symptoms cannot be established. Advise patients to seek immediate medical attention if they experience symptoms of HLH during lamotrigine treatment. A diagnosis

[9] https://www.fda.gov/Drugs/DrugSafety/ucm605470.htm

of HLH can be established if a patient has at least five of the following eight signs or symptoms:

- Fever and rash
- Enlarged spleen
- Cytopenias
- Elevated levels of triglycerides or low blood levels of fibrinogen
- High levels of blood ferritin
- Hemophagocytosis identified through bone marrow, spleen, or lymph node biopsy
- Decreased or absent Natural Killer (NK) Cell activity
- Elevated blood levels of CD25 showing prolonged immune cell activation

In the 24 years since lamotrigine's 1994 approval, FDA identified eight cases worldwide of confirmed or suspected HLH associated with the medicine in children and adults. This number includes only reports submitted to FDA and found in the medical literature, so there are likely additional cases about which we are unaware. We determined there was reasonable evidence that lamotrigine was the cause of HLH in these eight cases based on the timing of events and the order in which they occurred. The patients in these cases required hospitalization and received drug and other medical treatments, with one dying.

We previously communicated safety information associated with lamotrigine in September 2006 (possible association between Lamictal exposure during pregnancy and oral clefts in newborns) and August 2010 (aseptic meningitis warning). Lamotrigine was also covered as part of a May 2009 safety alert concerning suicidal thoughts and behavior with the entire class of anti-seizure medicines.

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Question 19:

The FDA has identified 8 cases of the immune system reaction called hemophagocytic lymphohistiocytosis (HLH) associated with:

a. ciprofloxacin;
b. empagliflozin;
c. lamotrigine.

Question 20:

HLH can be established if a patient has at least 5 of the 8 signs or symptoms, including:

a. fever and rash;
b. enlarged spleen;
c. decreased or absent Natural Killer (NK) Cell activity;
d. all of the above are signs or symptoms of HLH.

FDA review finds additional data supports the potential for increased long-term risks with antibiotic clarithromycin (Biaxin) in patients with heart disease[10]

The U.S. Food and Drug Administration (FDA) is advising caution before prescribing the antibiotic clarithromycin (Biaxin) to patients with heart disease because of a potential increased risk of heart problems or death that can occur years later. Our recommendation is based on our review of the results of a 10-year follow-up study of patients with coronary heart

[10] https://www.fda.gov/Drugs/DrugSafety/ucm597289.htm

disease from a large clinical trial that first observed this safety issue [citations omitted].

As a result, we have added a new warning about this increased risk of death in patients with heart disease, and advised prescribers to consider using other antibiotics in such patients.

Health care professionals should be aware of these significant risks and weigh the benefits and risks of clarithromycin before prescribing it to any patient, particularly in patients with heart disease and even for short periods, and consider using other available antibiotics. Advise patients with heart disease of the signs and symptoms of cardiovascular problems, regardless of the medical condition for which you are treating them with clarithromycin.

Patients should tell your health care professionals if you have heart disease, especially when you are being prescribed an antibiotic to treat an infection. Seek medical attention immediately if you experience symptoms of a heart attack or stroke, such as chest pain, shortness of breath or trouble breathing, pain or weakness in one part or side of your body, or slurred speech.

The large clinical trial, called the CLARICOR trial, observed an unexpected increase in deaths among patients with coronary heart disease who received a two-week course of clarithromycin that became apparent after patients had been followed for one year or longer. There is no clear explanation for how clarithromycin would lead to more deaths than placebo. Some observational studies also found an increase in deaths or other serious heart-related problems, while others did not. All the studies had limitations in how they were designed. Of the six observational studies published to date in patients with or without coronary artery disease, two found evidence of long-term risks from clarithromycin, and four did not [citations omitted]. Overall, results from the prospective, placebo-controlled CLARICOR trial provide the strongest evidence of the increase in risk compared to the observational study results. Based on these studies, we were unable to determine why the risk of death is greater for patients with heart disease.

Furthermore, there are no prospective, randomized, and controlled trials with prespecified long-term safety outcome measures following

clarithromycin treatment in patients who do not have heart disease. Because we currently do not have study information in these patients, and observational studies have shown different results, we cannot determine whether results of the CLARICOR trial can be applied to patients who do not have heart disease.

We previously communicated about this safety issue in December 2005, before the 10-year follow-up results were available for CLARICOR.

Question 21:

The FDA is advising caution before prescribing the antibiotic clarithromycin (Biaxin) to patients with heart disease because of a potential increased risk of heart problems or death that can occur _____ later.

a. days;
b. weeks;
c. months;
d. years.

Question 22:

The FDA advises health care professionals to advise patients with heart disease about the signs and symptoms of cardiovascular problems, regardless of the reason for which you are treating them with clarithromycin.

a. True;
b. False.

Return this <u>ANSWER SHEET</u> with the <u>$20.00 Program Fee</u> payable to:

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

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

<u>ANSWERS: FDA Drug Safety Communications – 2019</u>

(#0487-0000-19-002-H05; Expires January 20, 2022)

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

1.	a	b	c	d	12.	a	b		
2.	a	b	c	d	13.	a	b	c	
3.	a	b	c	d	14.	a	b		
4.	a	b			15	a	b	c	d
5.	a	b			16.	a	b	c	d
6.	a	b			17.	a	b	c	
7.	a	b			18.	a	b		
8.	a	b			19.	a	b	c	
9.	a	b	c	d	20	a	b	c	d
10.	a	b			21.	a	b	c	d
11.	a	b			22.	a	b		

23. After completing this program, I am able to list 7 rare but serious events, and their associated drugs, for which the FDA has issued Drug Safety Communications: Yes No

24. This CE activity <u>met my educational needs</u>: Yes No

25. The author was <u>organized</u> in the written materials: Yes No

26. The learning material was <u>useful</u>: Yes No

27. The teaching and learning methods (case format, questions embedded in the program) <u>fostered active learning</u> and were effective: Yes No

28. The <u>learning assessment</u> (the post-test) was appropriate: Yes No

29. The test questions were <u>relevant to the goals of the CE activity</u>: Yes No

30. The test questions were at an <u>appropriate level of difficulty</u>: Yes No

31. The CE activity was presented in a <u>fair and unbiased</u> manner: Yes No

32. If you perceived any <u>bias or commercialism</u>, please describe:

_____

33. Thank You! Other comments are welcome: _____

Select CE.

Our goal is to offer pharmacy CE activities in the areas of pharmacy law (ACPE topic designator "03") and patient safety (ACPE topic designator "05").

Index:

28 FDA MedWatch Alerts - 2018

ACPE Program Number: 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
Contact Hour(s): 2.0
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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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i) mail the Answer Sheet and the program fee to us. You will receive a Feedback Statement mailed to you within two 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 Feedback Statement will be sent within five 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.

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 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 FDA used the brand name of the drug in its publication and hence the brand name is used here too. Patti Nussle and Robyn Satterfield have no potential conflicts of interest or financial relationships to disclose.

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*".[11] 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.

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

Ocaliva (obeticholic acid): Drug Safety Communication - Boxed Warning Added To Highlight Correct Dosing[12]

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[13]

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 loperamide

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

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[14]

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[15] 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 related

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

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

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[16]

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.

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

Kayexalate (sodium polystyrene sulfonate): Drug Safety Communication - FDA Recommends Separating Dosing[17]

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.

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

Gadolinium-based Contrast Agents (GBCAs): Drug Safety Communication - Retained in Body; New Class Warnings[18]

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.

18 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)[19]. 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.

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

Keytruda (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement - Two Clinical Trials on Hold[20]

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)[21]. 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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20 https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574347.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

21 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 tells 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[22]

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[23].

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.[24] 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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[22] https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm546771.htm

[23] https://www.fda.gov/Drugs/DrugSafety/ucm546154.htm

[24] *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[25]

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.[26]

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

26 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 show:

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[27]

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

27 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.

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NABP e-Profile #:	**Month and Day of Birth:**

ANSWERS: FDA MedWatch Alerts - 2018

(#0487-0000-18-002-H05; Expires 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
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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:

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31. Thank You! Other comments are welcome: _____

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Target Audience: All Pharmacists and Pharmacy Technicians

Release Date: January 15, 2019

Expiration Date: January 15, 2022

ACPE Program No.: 0487-0000-19-001-H03-P or 0487-0000-19-001-H03-T (knowledge-based activity)

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A minimum score of 70% on the post-test is 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.

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

Objective: At the conclusion of this program, pharmacy technicians should be able to describe at least 5 failures 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 5 cases 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.

Compounding Pharmacies and Their Owners Indicted for Billion-Dollar Telemedicine Fraud Conspiracy; Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes[28]

On October 12, 2018, the District Court for the Eastern District of Tennessee unsealed a 32-count indictment charging four individuals and seven companies in a $1 billion health care fraud scheme. The court also unsealed an additional two plea agreements and information charging another individual and his company for their role in the scheme.

AA, 33, PB, 41, and MP, 44, all of Florida, were indicted along with their compounding pharmacies, Synergy Pharmacy Services and Precision Pharmacy Management. Co-conspirator LS, 48, also of Florida and also a pharmacy compounder, and his companies Tanith Enterprises, ULD Wholesale Group, Alpha-Omega Pharmacy, all located in Clearwater, Germaine Pharmacy located in Tampa, Florida, and Zoetic Pharmacy located in Houston, Texas, were all also named as defendants. All the defendants were charged with conspiracy to commit health care fraud, mail fraud, and introducing misbranded drugs into interstate commerce.

On September 26, 2018, HealthRight LLC, a telemedicine company with locations in Pennsylvania and Florida, and SR, 52, of Seminole, Florida, and the CEO of HealthRight, pleaded guilty to felony conspiracy for their roles in the telemedicine health care fraud scheme.

The indictment alleges that these individuals and companies, together with other persons and companies known to the grand jury, conspired to deceive tens of thousands of patients and more than 100 doctors located in the Eastern District of Tennessee and across the country for the purpose of defrauding private health care benefit programs such as Blue Cross Blue

[28] https://www.justice.gov/opa/pr/four-men-and-seven-companies-indicted-billion-dollar-telemedicine-fraud-conspiracy

Shield of Tennessee out of approximately $174,000,000. The indictment further alleges that the defendants submitted not less than $931,000,000 in fraudulent claims for payment.

According to the indictment, the defendants set up an elaborate telemedicine scheme in which HealthRight fraudulently solicited insurance coverage information and prescriptions from consumers across the country for prescription pain creams and other similar products. The indictment states that doctors approved the prescriptions without knowing that the defendants were massively marking up the prices of the invalidly prescribed drugs, which the defendants then billed to private insurance carriers.

If convicted, those charged face a term of up to 20 years in prison as to each mail fraud charge, up to 10 years in prison for the conspiracy, and up to 3 years in prison for introducing misbranded drugs into interstate commerce. Additionally, they face fines of up to $250,000 and up to three years of supervised release for each count. The companies face fines of up to twice the gross loss sustained as a result of the conspiracy. The indictment also seeks forfeiture of approximately $154,000,000.

Question 1:

The compounding pharmacies involved in this case allegedly deceived:
a. tens of thousands of patients;
b. more than a hundred doctors;
c. both a and b.

Question 2:

Arranging with others to fraudulently solicit insurance coverage information and prescriptions for pain creams through the U.S. mail can result in:

a. 20 years in prison for mail fraud;
b. 10 years in prison for conspiracy;
c. both of the above.

In addition to their roles in the health care fraud conspiracy, the Information filed against SR and HealthRight charged each of them with conspiring to commit wire fraud as part of a scheme to use HealthRight's telemarketing facilities to fraudulently sell millions of dollars' worth of products such as weight loss pills, skin creams, and testosterone supplements through concocted claims of efficacy and intentionally deficient customer service designed to stall consumer complaints.

For use of their telemarketing facilities with deficient customer service, SR and HealthRight pleaded guilty, and SR faces a statutory maximum sentence of 5 years of imprisonment for each conspiracy. The Court set sentencing for February 13, 2019.

Harvesting Vial Overfill Leads to $625 Million Settlement[29]

The Department of Justice announced that AmerisourceBergen Corporation and its subsidiaries AmerisourceBergen Specialty Group (ABSG), AmerisourceBergen Drug Corporation (ABDC), Oncology Supply Company (OSC), and Medical Initiatives Inc. (MII) (collectively, "ABC") have agreed to pay $625 million to resolve allegations arising from its operation of a facility that improperly repackaged oncology-

[29] https://www.justice.gov/opa/pr/amerisourcebergen-corporation-agrees-pay-625-million-resolve-allegations-it-illegally

supportive injectable drugs into pre-filled syringes and improperly distributed those syringes to physicians treating vulnerable cancer patients. ABC is one of the nation's largest wholesale drug companies and ranked number 11 on the Fortune 500 list. The drugs involved in ABC's scheme were Procrit®, Aloxi®, Kytril® and its generic form granisetron, Anzemet® and Neupogen®.

Last year AmerisourceBergen Specialty Group, a wholly-owned subsidiary of AmerisourceBergen Corporation, pled guilty to illegally distributing misbranded drugs and agreed to pay $260 million to resolve criminal liability for its distribution of these drugs from a facility that was not registered with the Food and Drug Administration (FDA). The settlement announced in this case also resolves ABC's civil liability to the United States under the False Claims Act for causing false claims for the drugs it repackaged to be submitted to federal health care programs.

"ABC placed corporate profits over patients' needs, endangering the health of vulnerable cancer patients," stated United States Attorney Donoghue. "This settlement, and the substantial penalty ABC has agreed to pay, reflect this Office's firm commitment to protecting those in need of healthcare and holding to account those who put the health and safety of patients at risk."

The United States contends that ABC sought to profit from the excess drug product or "overfill" contained within the original FDA-approved sterile vials for these cancer supportive injectable drugs by establishing a pre-filled syringe program through a subsidiary that it claimed was a pharmacy. The United States alleged that the "pharmacy" was in reality a repackaging operation that created and shipped millions of pre-filled syringes to oncology practices for administration to cancer-stricken patients. As part of this operation, ABC purchased original vials from their respective manufacturers, broke their sterility, pooled the contents, and repackaged the drugs into pre-filled syringes.

The United States alleged that ABC never submitted any safety, stability, or sterility data to the FDA to show that its operation ensured the safety and efficacy of the repackaged drug products. It further alleged that, at times, these pre-filled syringes were prepared in non-sterile conditions, contaminated with bacteria and other unknown particles, and lacked the required quality and purity.

In addition, by harvesting the overfill, ABC was able to create more doses than it bought from the original vial manufacturers. The United States alleged that ABC's scheme enabled it to bill multiple health care providers for the same exact same vial of drug, causing some of those providers to bill the Federal Health Care Programs for the same vial more than once. The scheme also allegedly enabled ABC to increase its market share by offering various product discounts, which it leveraged to obtain new customers and to keep existing customers buying its entire portfolio of oncology drugs.

The settlement also resolves allegations that ABC gave kickbacks to physicians to induce them to purchase Procrit through the pre-filled syringe program. The alleged kickbacks were in the form of general pharmacy credits provided to customers, but which were not identifiable as specific to Procrit on the invoice.

Through these actions, the United States contended that ABC caused false claims to be submitted to the Centers for Medicare and Medicaid Services ("CMS"), the Department of Defense's Defense Health Agency, which administers TRICARE, the Office of Personnel Management, which administers the Federal Employees Health Benefit Program, and the United States Department of Veterans Affairs (collectively, the "Federal Healthcare Payors"). Under the terms of today's settlement, ABC will pay $581,809,006 plus accrued interest to the federal government and $43,190,994 plus accrued interest to state Medicaid programs.

The settlement resolves allegations contained in three separate actions filed against ABC under the qui tam, or whistleblower, provisions of the False Claims Act. Under the act, private parties may sue on behalf of the government for false claims for government funds and to receive a share of any recovery. The private party share of the federal portion of the civil settlement will be $93,089,441.

Question 3:

The U.S. government claimed that ABC created more doses of Procrit than it bought from the Procrit manufacturer by:

a. diluting the vials of original drug;
b. pooling the contents of original drug, and then repackaging into pre-filled syringes;
c. acquiring generic drug, and then pooling with the contents of the brand name drug.

Question 4:

The U.S. government claimed that ABC created more doses of Procrit than it bought from the Procrit manufacturer:

a. in an FDA-approved repackaging facility;
b. without submitting any safety, stability, or sterility data to the FDA;
c. without submitting any efficacy data to the FDA.

Question 5:

The problem with creating more doses of Procrit from vials than it bought from the manufacturer is that it enabled ABC to bill:

a. multiple health care providers, instead of just one;
b. multiple health care providers for the same exact same vial of drug, causing some of those providers to bill the Federal Health Care Programs for the same vial more than once;
c. for the brand-name drug, when the generic drug was used.

Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Co-Pay Kickbacks[30]

Pharmaceutical company Pfizer, Inc. (Pfizer) has agreed to pay $23.85 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking three Pfizer 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). Congress included copay requirements in the Medicare program, 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 drug company is prohibited from offering, directly or indirectly, any remuneration—which includes paying patients' copay obligations—to induce Medicare patients to purchase the company's drugs.

The government alleged that Pfizer used a foundation as a conduit to pay the copay obligations of Medicare patients taking three Pfizer drugs: Sutent and Inlyta, which both treat renal cell carcinoma, and Tikosyn, which treats arrhythmia in patients with atrial fibrillation or atrial flutter. The government alleged that, in order to generate revenue, and instead of giving Sutent and Inlyta to Medicare patients who met the financial qualifications of Pfizer's existing free drug program, Pfizer used a third-party specialty pharmacy to transition certain patients to the foundation, which covered the patients' Medicare copays. Pfizer allegedly made donations to the foundation to enable it to cover the copays of these patients and received confirmation from the foundation, via the specialty pharmacy, that the foundation funded the copays.

With respect to Tikosyn, Pfizer raised the wholesale acquisition cost of a package of forty .125mg capsules of the drug by over 40% in the last three months of 2015. Pfizer allegedly knew that the price increase would also increase Medicare beneficiaries' copay obligations for Tikosyn, and potentially prevent some patients from being able to afford the

[30] https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks

drug. Pfizer allegedly worked with the foundation to create and finance a fund for Medicare patients suffering from the condition treated by Tikosyn, coordinated the opening of the fund with the implementation of its price increase for the drug, and referred patients to the fund. For the next nine months, Tikosyn patients accounted for virtually all of the beneficiaries whose copayments were paid by the fund.

Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division said: "As today's settlement makes clear, the Department will hold accountable drug companies that pay illegal kickbacks—whether directly or indirectly—to undermine taxpayer funded healthcare programs, including Medicare."

"Pfizer used a third party to saddle Medicare with extra costs," said United States Attorney Andrew E. Lelling. "According to the allegations in today's settlement agreement, Pfizer knew that the third-party foundation was using Pfizer's money to cover the co-pays of patients taking Pfizer drugs, thus generating more revenue for Pfizer and masking the effect of Pfizer's price increases. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these. At the same time, we commend Pfizer for stepping forward to resolve these issues in a responsible manner."

"Today's settlement demonstrates the FBI's commitment to making sure patients receive, and the government pays for, health care that is not compromised by kickbacks," said Harold H. Shaw, Special Agent in Charge, FBI Boston Division. "What Pfizer is accused of doing in this case—masking charitable contributions to increase company profits—violates the basic trust patients extend to the healthcare system and threatens the financial integrity of the Medicare program."

Pfizer 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 Pfizer 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 implementation of a risk assessment and mitigation process.

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

Question 6:

The U.S. government claimed that Pfizer:

a. used a foundation as a conduit to pay the copays of Medicare patients taking 3 Pfizer drugs, in violation of the False Claims Act;
b. gave free drug to Medicare patients taking 3 Pfizer drugs;
c. gave adulterated drug to Medicare patients taking 3 Pfizer drugs.

Question 7:

The U.S. government claimed that Pfizer:

a. used a third party to raise prices on its 3 drugs;
b. used a third party to saddle Medicare with extra costs, because Pfizer knew that the third-party foundation was using Pfizer's money to cover the co-pays of patients taking Pfizer drugs, thus generating more revenue for Pfizer and masking the effect of Pfizer's price increases;
c. gave away free drug to Medicare beneficiaries.

Question 8:

The problem with a drug company using a third party to pay Medicare patients' copays is that:

a. it helps Medicare patients make cost-effective healthcare purchasing decisions;
b. it helps Medicare patients get out of the hospital sooner;
c. it induces Medicare patients to purchase the company's drugs.

Pharmacy Owner Sentenced to Prison For $5 Million Employment Tax Fraud[31]

A Virginia pharmacist was sentenced to 41 months in prison for failing to account for and pay employment taxes, announced the Justice Department's Tax Division and U.S. Attorney's Office.

According to court documents, JR, Jr., 61, owned and operated Family Discount Pharmacy Inc. (FDP) with multiple pharmacy locations in 4 Virginia cities. As owner of FDP, JR was responsible for collecting and paying FDP's employment taxes.

FDP accrued employment tax liabilities of more than $5 million. JR withheld these taxes from FDP employees' wages but did not pay the taxes to the Internal Revenue Service (IRS). In over 15 years, Harper only filed one quarterly employment tax return with the IRS.

JR admitted that instead of paying the employment taxes to the IRS, he caused FDP to pay his personal expenses, including the purchase of a Jeep Grand Cherokee and a jet ski. Harper wired over $1 million to his personal bank account, made over $500,000 in stock market investments, spent over $100,000 on his son's pharmacy school tuition, and purchased over $370,000 of real property.

Question 9:

The pharmacy owner in this case was sentenced to 41 months in prison because he:

a. never withheld employment taxes from his employees' wages;
b. withheld employment taxes from his employees' wages, but it was the wrong amount;
c. withheld employment taxes from his employees' wages, but did not pay those amounts to the IRS.

[31] https://www.justice.gov/opa/pr/virginia-pharmacy-owner-sentenced-prison-5-million-employment-tax-fraud

In addition to the term of imprisonment, the U.S. District Court Judge ordered JR to serve 2 years of supervised release and to pay restitution in the amount of $5,069,555.73 and a fine of $25,000.00.

Money Laundering Conspiracy and Tax Crimes Convictions for Selling Second-hand Drugs with False Pedigrees[32]

A Texas man was convicted by a federal jury in the U.S. District Court for the Southern District of Texas of two conspiracies and tax crimes, announced the Justice Department's Tax Division.

In total, KC, 51, was convicted of nine counts, including conspiracy to commit money laundering, conspiracy to structure currency transactions, corporate tax evasion, filing false tax returns with the IRS and failing to file a tax return with the Internal Revenue Service (IRS).

CK's co-conspirator has already pleaded guilty to conspiracy to commit money laundering and was sentenced in June 2018 to 58 months in prison. He testified at trial.

The evidence at trial established that KC participated in a scheme to facilitate the fraudulent sale of second-hand prescription medications to Utah-based Green Valley Medical Distributors, LLC (Green Valley). KC, owner of Acacia Pharma Distributors, Inc. (Acacia) and Four Corner Suppliers, Inc. (Four Corner), purchased bottles of prescription medications from illegitimate sources and then sold the medications to Green Valley, which then sold the medications to pharmacies as new.

Federal regulation requires wholesale distributors of prescription medications to provide to a buyer a pedigree – a written statement identifying each prior sale, purchase or trade of the drugs being sold that includes the business name and information of all parties to the prior transactions, starting with the manufacturer. KC created false pedigrees and provided the false documents to Green Valley. Evidence at trial

[32] https://www.justice.gov/opa/pr/texas-man-convicted-money-laundering-conspiracy-and-tax-crimes-0

showed that Green Valley would withhold payment to KC until it received these false pedigrees.

KC and his co-conspirator deposited proceeds from the fraudulent sale of these second-hand prescription drugs into Acacia's and Four Corner's business bank accounts and used the funds to pay the suppliers of the illicit pharmaceuticals. At trial, the government proved that people acting at KC's direction laundered more than $36 million of illicit funds, including over $2 million in more than 230 cash withdrawals made in amounts less than $10,000 in order to evade bank-reporting requirements.

The evidence at trial also established that KC evaded assessment and payment of Acacia's and Four Corner's income tax liabilities, and that he failed to file an individual tax return for one tax year, and filed false individual income tax returns for tax years 2012 and 2013 with the IRS.

KC now faces a maximum sentence of 20 years in prison for the money laundering conspiracy and a maximum sentence of five years for the conspiracy to structure currency transactions. KC also faces a five-year maximum sentence for each count of tax evasion and a maximum sentence of three years in prison for each count of filing a false tax return. KC also faces a term of supervised release, restitution, and monetary penalties.

Question 10:

A wholesaler's owner who creates false pedigrees for second-hand prescription medications, and exchanges money in connection with these false pedigrees, can expect to be charged with:

a. money laundering;
b. violations of the Food, Drug & Cosmetic Act;
c. violations of the Anti-Kickback Statute.

Return this <u>ANSWER SHEET</u> with the <u>$15.00 Program Fee</u> payable to:

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NAME:	Pharmacist? Yes/No
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NABP e-Profile #:	Month and Day of Birth:

<u>ANSWERS: DOJ Cases Against Pharmacists - 2019</u>

(#0487-0000-19-001-H03; Expires January 15, 2022)

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

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

11. <u>For Pharmacists</u>: After completing this program, I am able to describe at least 5 failures to comply with federal drug laws: Yes No

12. <u>For Pharmacy Technicians</u>: After completing this program, I am able to describe at least 5 failures to comply with federal drug laws: Yes No

13. This CE activity <u>met my educational needs</u>: Yes No

14. The author was <u>organized</u> in the written materials: Yes No

15. The learning material was <u>useful</u>: Yes No

16. The teaching and learning methods (case format, questions embedded in the program) <u>fostered active learning</u> and were effective: Yes No

17. The <u>learning assessment</u> (the post-test) was appropriate: Yes No

18. The test questions were <u>relevant to the goals of the CE activity</u>: Yes No

19. The test questions were at an <u>appropriate level of difficulty</u>: Yes No

20. The CE activity was presented in a <u>fair and unbiased</u> manner: Yes No

21. If you perceived any <u>bias or commercialism</u>, please describe:

_____

22. How <u>long</u> did it take you to complete this CE activity? _____

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:_____

Index:

67 **More DOJ Cases Against Pharmacists - 2018**

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

Select CE® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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.

Select CE® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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

Fee Information: $30.00

Estimated Time to Complete the Activity: 120 minutes

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

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, Peer Reviewer 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.

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[33]

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, MG,

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

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 McKesson for their cooperation throughout the investigation.

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.

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[34]

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 become "patients" of Wellness Pharmacy. The pharmacy filled numerous prescriptions for the marketer's family and received nearly $200,000 in

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

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 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 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.

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.

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.

Pharmacist Pleads Guilty in Scheme to Re-use Medications Left over from Nursing Homes[35]

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 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

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

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[36]

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 related charges

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

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

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.

Safeway Pharmacies Pay $3 Million to Resolve Allegations Chain Failed to Timely Report Drug Diversion[37]

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.

[37] 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[38]

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

[38] 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[39]

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

[39] 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 and 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 and c are true.

DaVita Rx Agrees to Pay $63.7 Million to Resolve False Claims Act Allegations[40]

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.

[40] 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[41]

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.

[41] 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[42]

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.

[42] 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[43]

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.

[43] 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

(#0487-0000-18-001-H03; Expires 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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CE Reporting Changes for All Ohio-licensed Pharmacists - All Pharmacists Must Report CE in 2019!
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Medication/Patient Safety
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