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Index:

Accreditations (Pharmacy): This continuing pharmacy education activity is ACPE-accredited for patient safety related continuing education.
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Program Title: **FDA Drug and Patient Safety Announcements**

Target Audience: All Pharmacists

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Accreditations: This CE activity is accredited by ACPE for 2.0 contact hours, or 0.20 C.E.U.'s, for pharmacists under our trade name Select CE®.

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A minimum score of 70% and also your CPE Monitor ID and month/day of birth are all required to earn a Statement of 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:

a) identify ACPE's definition of "patient safety"; and
b) describe 5 warnings published by the FDA regarding drug and patient safety issues; and
c) describe the FDA's role in preventing medication errors; and
d) list 2 examples of medication errors published by the FDA.

Introduction

In order to renew a pharmacist's license, some states have introduced a new continuing education (CE) requirement that has caught some pharmacists by surprise in recent years. Some states now require that two (2) of a pharmacist's continuing education hours must be in the ACPE topic designator "Patient Safety". But how do you know if a CE program will count toward this requirement?

The Accreditation Council for Pharmacy Education (ACPE) defines patient safety as *"The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors (An unintended healthcare outcome caused by a defect in the delivery of care to a patient.) Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting.* (definitions approved by the National Patient Safety Foundation® Board July 2003)." A CE program that addresses patient safety as defined here (and is accredited as such) will count toward the two hour requirement.[1]

The quickest and most effective way to determine whether a CE activity counts as a patient safety CE is to look at the Universal Activity Number (UAN). Each CE activity provided by an ACPE-accredited provider of continuing education has a unique UAN, and providers are required to include this number in official program announcements. The UAN is a string of numbers and letters, separated by hyphens. Each section of the UAN refers to a specific detail of the program. The last two numbers in the UAN are the topic designator. **A UAN with 05 as the topic designator is designated as a patient safety program and will count toward the two hour renewal requirement.**

Example: 0487-0000-16-002-H05-P

In this CE activity, we bring you the FDA Drug Safety Announcements recently published by the agency. These are taken from the FDA's website as cited throughout the activity. You can look at the FDA's website for additional information.

[1] http://www.papharmacists.com/page/CE_Requirements

Question 1:

ACPE defines patient safety as:

a. the prevention of healthcare errors;
b. the prevention of medication errors;
c. the elimination or mitigation of patient injury caused by healthcare errors;
d. both a and c are true.

Question 2:

Healthcare errors may be errors of:

a. judgment;
b. choice;
c. commission, omission, or execution;
d. both b and c are true.

FDA Cautions About Dosing Errors When Switching Between Different Oral Formulations of the AntiFungal Noxafil® (posaconazole)[2]

The U.S. Food and Drug Administration (FDA) is cautioning that differences in dosing regimens between the two oral formulations of the antifungal Noxafil (posaconazole) have resulted in dosing errors. To help prevent additional medication errors, the drug labels were revised to indicate that the two oral formulations cannot be directly substituted for each other but require a change in dose. Direct mg for mg substitution of the two formulations can result in drug levels that are lower or higher than needed to effectively treat certain fungal infections.

[2] http://www.fda.gov/Drugs/DrugSafety/ucm479352.htm

Prescribers should specify the dosage form, strength, and frequency on all prescriptions they write for Noxafil. **Pharmacists should** request clarification from prescribers when the dosage form, strength, or frequency is not specified. **Patients should** talk to their health care professional before they switch from one oral formulation to the other.

Noxafil is approved in two oral formulations: an oral suspension and a delayed-release tablet. It is also approved as an intravenous solution for injection. Noxafil is used to help prevent certain invasive fungal infections caused by fungi called *Aspergillus* and *Candida*. Noxafil is used in patients who have an increased chance of getting these infections due to weakened immune systems. Noxafil oral suspension is also used to treat a fungal infection called thrush caused by *Candida* in the mouth or throat area.

The FDA Adverse Event Reporting System (FAERS) database identified cases of dosing errors with Noxafil. Noxafil was approved in 2006 as an oral suspension formulation. Since the approval of Noxafil delayed-release tablets in November 2013, FDA received eleven reports of the wrong oral formulations being prescribed and/or dispensed to patients. One case resulted in death, and an additional case resulted in hospitalization. According to the reports, these outcomes were a result of

Question 3:

The antifungal Noxafil (posaconazole):

a. is available in 2 oral formulations;
b. was initially FDA-approved as an oral formulation suspension, and later FDA-approved as a delayed-release tablet;
c. has resulted in death when the wrong oral formulation has been taken;
d. all of the above are true.

health care professionals not knowing that the two oral formulations cannot be substituted for each other without adjusting the dose.

In addition to changes to the outer carton of Noxafil, its manufacturer Merck revised the prescribing information and the patient information in the drug label to alert patients and their health care professionals that the two oral formulations of Noxafil cannot be substituted for each other.

FDA Approves Brand Name Change for Antidepressant Drug Brintellix® (vortioxetine) to Avoid Confusion with Antiplatelet Drug Brilinta® (ticagrelor)[3]

The U.S. Food and Administration (FDA) approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug will be Trintellix. No other changes will be made to the label or packaging, and the medicine is exactly the same.

Because of the lag time associated with manufacturing bottles with the new brand name, health care professionals may continue to see bottles labeled with the brand name Brintellix during the transition period.

Health care professionals should check carefully to make sure they have prescribed or dispensed the correct medicine. During the transition to the new name change from Brintellix to Trintellix, prescribers can reduce the risk of name confusion by including the generic name of the medication they are ordering, in addition to the brand name and indication for use. **Patients** should make sure they have received the correct medicine. Trintellix tablets will look the same as the Brintellix tablets.

Brintellix/Trintellix (vortioxetine) is used to treat a certain type of depression called major depressive disorder in adults. It is in a class of antidepressants called serotonin reuptake inhibitors (SSRIs) that work by affecting chemicals in the brain that may become unbalanced.

In a July 2015 Drug Safety Communication, we warned that name confusion between Brintellix and Brilinta had resulted in prescribing and dispensing errors since Brintellix was approved in September 2013. Due to continued reports of name confusion between the two medicines used

[3] http://www.fda.gov/Drugs/DrugSafety/ucm456341.htm

for very different purposes, FDA worked collaboratively with Brintellix manufacturer Takeda Pharmaceuticals to change the drug's brand name.

Question 4:

Brintellix (vortioxetine):

a. is used to treat major depressive disorder;
b. has been confused with Brilinta;
c. is now known by the new brand name Trintellix;
d. all of the above are true.

Question 5:

Brintellix/Trintellix (vortioxetine) tablets:

a. are the exact same medication;
b. look different;
c. have the same NDC number;
d. all of the above are true.

Question 6:

The name Brintellix was changed by Takeda Pharmaceuticals:

a. as a result of hundreds of patient deaths;
b. because of a lawsuit by the FDA;
c. as a result of working collaboratively with the FDA;
d. all of the above are true.

Individuals responsible for ordering and stocking the medicine should be aware that Trintellix will have a new National Drug Code (NDC) number. It is important for drug information content publishers and medication-related electronic system administrators to use the new brand name Trintellix and NDC number.

FDA Warns About Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires its Strongest Warning[4]

A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, the FDA added *Boxed Warnings*, the agency's strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines.

Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.

Question 7:

If an opioid is prescribed together with a benzodiazepine:

a. it should be because alternative treatment options are inadequate;
b. patients and caregivers should be warned about the risks of slowed or difficult breathing and/or sedation;
c. patients and caregivers should be made aware of the signs and symptoms of slowed breathing and/or sedation;
d. all of the above are true.

[4] http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm

The FDA conducted and reviewed several studies showing that serious risks are associated with the combined use of opioids and benzodiazepines, other drugs that depress the CNS, or alcohol.

Two studies published in the medical literature show direct evidence of increased risk of adverse events occurring in patients dispensed both opioid analgesics and benzodiazepines. A prospective observational cohort study conducted in North Carolina found the rates of overdose death among patients co-dispensed opioid analgesics and benzodiazepines were 10 times higher (7.0 per 10,000 person-years; 95% confidence interval (CI): 6.3-7.8) than among patients dispensed opioid analgesics alone (0.7 per 10,000 person-years; 95% CI: 0.6-0.9).[5]

A case-cohort study examined the Veterans Health Administration data from 2004-2009 and found the risk of death from drug overdose increased among those with concomitant opioid analgesic and benzodiazepine prescriptions. Compared to patients taking opioid analgesics with no history of a benzodiazepine prescription, patients taking opioid analgesics with a history of a benzodiazepine prescription

Question 8:

A prospective study found the rates of overdeath death among patients co-dispensed opioids and benzodiazepines were _____ times higher than among patients dispensed opioids alone.

a. 2;
b. 5;
c. 10;
d. 20.

had an increased risk of fatal overdose (hazard ratio (HR)=2.33 (95% CI: 2.05-2.64)), and those with a current benzodiazepine prescription had a

[5] Dasgupta N, Funk MJ, Proescholdbell S, Hirsch A, Ribisl KM, Marshall S. Cohort Study of the Impact of High-dose Opioid Analgesics on Overdose Mortality. Pain Med 2016;17:85-98.

similarly increased risk (HR=3.86 (95% CI: 3.49-4.26)) for fatal overdose. In addition, the risk of drug overdose death increased as the daily benzodiazepine dose increased.[6]

Based on the trends of increased concomitant use of opioid analgesics and benzodiazepines as well as increased harms associated with concomitant use described in these four studies, we are requiring a new *Boxed Warning* to be added to the labeling of opioid analgesic and opioid cough medications and benzodiazepines.

FDA Cautions About Dose Confusion and Medication Error with Antibacterial Drug Avycaz® (ceftazidime and avibactam)[7]

The U.S. Food and Drug Administration (FDA) is warning health care professionals about the risk for dosing errors with the intravenous antibacterial drug Avycaz (ceftazidime and avibactam) due to confusion about the drug strength displayed on the vial and carton labels. Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (i.e., 2 gram/0.5 gram); however, the product is dosed based on the sum of the active ingredients (i.e., 2.5 gram). To prevent medication errors, we have revised the labels to indicate that each vial contains Avycaz 2.5 gram, equivalent to ceftazidime 2 gram and avibactam 0.5 gram (see Photos).

Avycaz is approved for intravenous administration to treat complicated infections in the urinary tract, or in combination with the antibacterial drug metronidazole to treat complicated infections in the abdomen in patients with limited or no alternative treatment options.

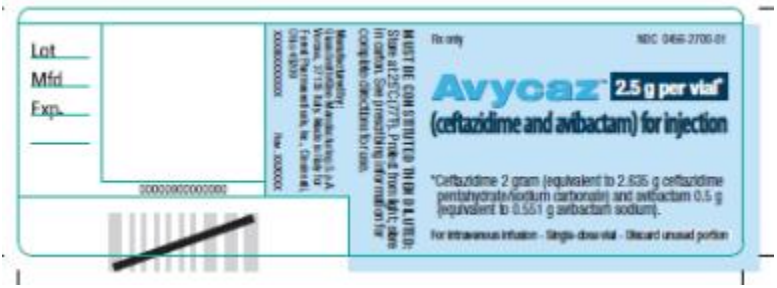
Since Avycaz's approval in February 2015, the FDA received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the

[6] Park TW, Saitz R, Ganoczy D, Ilgen MA, Bohnert AS. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. BMJ 2015;350:h2698.
[7] http://www.fda.gov/Drugs/DrugSafety/ucm463248.htm

strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase antibacterial drugs.

Before:

After:



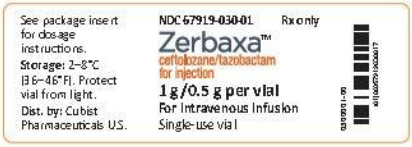
Question 9:

To prevent medication errors, the revised label of Avycaz (ceftazidine and avibactam) shows Avycaz:

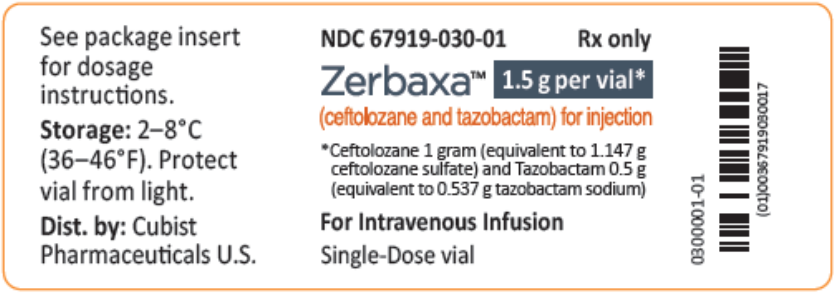
a. 2g/0.5g per vial;
b. 2.5g per vial;
c. 2g per vial;
d. 0.5g per vial.

FDA Cautions About Medication Errors for Antibacterial Drug Zerbaxa® (ceftolozane and tazobactam)[8]

Before:



After:



The U.S. Food and Drug Administration (FDA) is warning health care professionals about the risk for dosing errors with the antibacterial drug Zerbaxa (ceftolozane and tazobactam) due to confusion about the drug strength displayed on the vial and carton labeling. Zerbaxa's vial label was initially approved with a strength that reflects each individual active ingredient (e.g. 1 g/0.5 g); however, the product is dosed based on the sum of these ingredients (e.g. 1.5 g). To prevent future medication errors, the strength on the drug labeling has been revised to reflect the sum of the two active ingredients. Thus, one vial of Zerbaxa will now list the strength as 1.5 grams equivalent to ceftolozane 1 gram and tazobactam 0.5 gram (See Photos).

[8] http://www.fda.gov/Drugs/DrugSafety/ucm445919.htm

Zerbaxa is used to treat complicated infections in the urinary tract, or in combination with the antibacterial drug metronidazole to treat complicated infections in the abdomen.

We evaluated seven reported cases of medication errors that occurred during preparation of the dose in the pharmacy due to confusion with the display of the strength of individual ingredients on Zerbaxa's vial label and carton labeling. Listing the individual drug strengths led to confusion because it was different from labeling for other beta-lactam/beta-lactamase antibacterial drugs that express strength as the sum of the two active ingredients. In some cases, this led to administration of 50% more drug than was prescribed. No adverse events were reported among these seven cases.

Question 10:

To prevent medication errors, the revised FDA-approved label of Zerbaxa (ceftolozane and tazobactam) shows Zerbaxa:

a. 1g/0.5g per vial;
b. 1.5g per vial;
c. 1g per vial;
d. 0.5g per vial.

Question 11:

Of the 7 cases of Zerbaxa errors reported to the FDA, _____ led to the administration of 50% more drug than was prescribed and _____ led to adverse events.

a. 7; 1
b. 7; 5
c. some cases; no cases
d. all cases; all cases

FDA's Role in Avoiding Medication Mistakes[9]

A medication error is any preventable event that may cause or lead to inappropriate medication use or harm to a patient. Since 2000, the Food and Drug Administration (FDA) has received more than 95,000 reports of medication errors. FDA reviews reports that come to MedWatch, the agency's adverse event reporting program.

"These reports are voluntary, so the number of actual medication errors is believed to be higher," says Carol Holquist, R.Ph., Director of the Division of Medication Error Prevention and Analysis in FDA's Center for Drug Evaluation and Research.

FDA works with many partners to track medication errors, including the U.S. Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). "Every report received through the USP/ISMP Voluntary Medication Error Reporting Program (MERP) automatically gets sent to FDA's MedWatch program," says Mike Cohen, R.Ph., Sc.D., President of ISMP. "It takes a cooperative approach to monitor errors, evaluate them, and educate the public about strategies to keep errors from happening again."

Medication errors occur for a variety of reasons. For example, miscommunication of drug orders can involve poor handwriting, confusion between drugs with similar names, poor packaging design, and confusion of metric or other dosing units.

"Medication errors usually occur because of multiple, complex factors," says Holquist. "All parts of the health care system—including health professionals and patients—have a role to play in preventing medication errors."

FDA's Role

- **Drug Name Review:**
  To minimize drug name confusion, FDA reviews about 400 drug names a year that companies submit as proposed brand names. The

[9] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048644.htm

agency rejects about one-third of the names that drug companies propose.

- **Drug Labels:**
  FDA regulations require all over-the-counter (OTC) drug products (more than 100,000) to have a standardized "drug facts label." FDA has also improved prescription drug package inserts for health care professionals.

- **Drug Labeling and Packaging:**
  FDA works with drug companies to reduce the risk of errors that may result from similar-looking labeling and packaging, or from poor product design.

- **Bar Code Label Rule:**
  In accordance with an FDA rule that went into effect in 2004, bar codes are required on product labels for certain drugs and biologics such as blood. When used with bar code scanner and computerized patient information systems, bar code technology can help ensure that the right dose of the right drug is given to the right patient at the right time.

- **Error Analyses:**
  FDA reviews about 1,400 reports of medication errors per month and analyzes them to determine the cause and type of error.

Question 12:

The FDA reviews about _____ reports of medication errors each month:

a. 250;
b. 500;
c. 1,400;
d. 28,000.

Question 13:

Reports of medication errors to the FDA are:

a. mandatory from all health care providers;
b. mandatory from all consumers;
c. voluntary;
d. forwarded to the appropriate state licensing board.

Question 14:

The FDA views medication errors as occurring:

a. primarily due to the fault of the dispensing pharmacist;
b. primarily due to the fault of poor handwriting;
c. usually because of multiple, complex factors;
d. usually because of poor package design.

Examples of Medication Errors

The FDA provides some examples of medication errors to help both consumers and healthcare professionals.[10]

Misuse of Tussionex Prescription Cough Medicine

In 2008, FDA informed health care professionals about adverse events and deaths in children and adults who have taken Tussionex Pennkinetic Extended-Release Suspension (Tussionex). Tussionex is a long-acting prescription cough medicine.

Hydrocodone, the narcotic ingredient in this medicine that controls cough, can cause life-threatening breathing problems when too much medicine is given at one time or when the medicine is given more

[10] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048644.htm

frequently than recommended. Tussionex should not be used in children less than 6 years old.

Reports indicate that health care professionals have prescribed Tussionex for patients younger than the approved aged group of 6 years old and older, more frequently than the labeled dosing interval of every 12 hours

Question 15:

Tussionex:

a. should not be used in children younger than 12 years old;
b. should not be used more than once daily;
c. has been associated with fatal breathing problems;
d. has caused adverse events in children only.

("extended release"), and that patients have administered the incorrect dose due to misinterpretation of the dosing directions and the use of inappropriate measuring devices. Overdose of Tussionex in older children, adolescents, and adults has also been associated with life-threatening and fatal breathing problems.

Overdoses of Cough and Cold Products in Children

Roughly 7,000 children ages 11 and younger are treated in hospital emergency rooms each year because of overdoses of OTC cough and cold medication, according to a recent study by the Centers for Disease Control and Prevention. About two-thirds of those incidents occurred when children took medication without a parent's knowledge. Parents should keep medication out of children's reach and should never describe medication as "candy."

OTC cough and cold products can be harmful if more than the recommended amount is used, if they are given too often, or if more than one product containing the same active ingredient is used. In 2008, FDA

issued a public health advisory recommending that OTC cough and cold products not be used in infants and children under 2 years of age.[11]

Serious injuries and deaths have resulted from such errors as misunderstanding directions and failing to use the measuring devices that come with the medicine.

Question 16:

OTC cough and cold products should be:

a. used with the measuring device that comes with the medicine;
b. used in children younger than 2 years old;
c. presented to the child as candy to increase compliance;
d. used anytime a child experiences a cough or cold.

Overdoses of Acetaminophen

Taking too much of the pain reliever acetaminophen can lead to serious liver damage. The drug is sold under brand names such as Tylenol and Datril, and is also available in many cough and cold products, prescription pain relievers, and sleep aids.

To avoid accidental overdosing, patients should not take more than the recommended dose on the label. Also, acetaminophen should not be taken for more days than recommended, and should not be taken with other drug products that also contain acetaminophen without direction from a health care provider.

Parents should be cautious when giving acetaminophen to children. For example, confusion between with the more concentrated infant drops (100mg/mL) and the children's liquid (160mg/5mL) resulted in a drug manufacturers voluntary discontinuing the infant drops.

11

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm051137.htm

Question 17:

Overdoses of acetaminophen can:

a. lead to serious liver damage;
b. occur by taking it with other drug products that also contain acetaminophen;
c. occur by taking it for more days than is recommended;
d. all of the above are true.

Misuse of Fentanyl Patches

FDA has issued warnings about the fentanyl transdermal system, an adhesive patch that delivers an opioid called fentanyl through the skin.

The directions on the product label and package insert of the fentanyl transdermal system should be followed exactly in order to avoid overdose. Fentanyl patches should not be used for short-term acute pain, pain that is not constant, or for pain after an operation. The patch is only for persistent moderate-to-severe chronic pain that is expected to last for any number of weeks or longer and that cannot be managed by acetaminophen-opioid combinations, nonsteroidal analgesics, or as-needed dosing with short-acting opioids.

Fentanyl patches are mostly prescribed for patients with cancer. Recent reports to FDA describe deaths and life-threatening side effects after doctors and other health care professionals inappropriately prescribed the patch to relieve pain after surgery, for headaches, or for occasional or mild pain in patients who were not opioid tolerant.

In other cases, patients have used the patch incorrectly. The patients replaced the patch more frequently than directed in the instructions, applied more patches than prescribed, or applied heat to the patch. All of these cases resulted in dangerously high fentanyl levels in the blood.

Pharmacists should be aware the FDA-approved labeling includes:

> Following fentanyl transdermal system application, the skin under the system absorbs fentanyl, and a depot of fentanyl concentrates in the upper skin layers. Fentanyl then becomes available to the systemic circulation. Serum fentanyl concentrations increase gradually following initial fentanyl transdermal system application, generally leveling off between 12 and 24 hours and remaining relatively constant, with some fluctuation, for the remainder of the 72-hour application period. Peak serum concentrations of fentanyl generally occurred between 20 and 72 hours after initial application (see Table 6). Serum fentanyl concentrations achieved are proportional to the fentanyl transdermal system delivery rate. With continuous use, serum fentanyl concentrations continue to rise for the first two system applications. By the end of the second 72-hour application, a steady-state serum concentration is reached and is maintained during subsequent applications of a patch of the same size (see Figure 1). Patients reach and maintain a steady-state serum concentration that is determined by individual variation in skin permeability and body clearance of fentanyl.

Question 18:

The following can be seen in a patient using fentanyl patches:

a. peak serum concentration between 20 and 72 hours after initial application;
b. steady-state serum concentration reached at the end of the second 72-hour application;
c. hypoventilation throughout the therapeutic range;
d. all of the above are true.

Hypoventilation can occur throughout the therapeutic range of fentanyl serum concentrations, especially for patients who have an underlying pulmonary condition or who receive concomitant opioids. The use of fentanyl transdermal system is contraindicated in patients who are not tolerant to opioid therapy.[12]

Question 19:

Fentanyl patches should be used only for patients:

a. who are allergic to other opioids;
b. with moderate-to-severe chronic pain;
c. post-operatively;
d. all of the above are true.

Overdoses with Methadone:

FDA has issued a public health advisory cautioning practitioners to avoid overdoses when they are prescribing methadone or managing patients taking the drug.

Since the 1970s, methadone has been primarily used in treating drug abuse, but it is increasingly being used to treat pain. FDA issued the advisory because of reports of life-threatening adverse events and death in patients receiving methadone for pain control. Like other opioids, methadone causes slowed breathing, affects heart rate, and can also interact with other drugs. An overdose can occur because methadone stays in the body longer than the pain relief lasts.

[12] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2a2238e9-4b5d-c56d-8663-dd354ff9ae0c

Mix-ups Between Edetate Disodium and Edetate Calcium Disodium:

Both edetate disodium and edetate calcium disodium work by binding with heavy metals or minerals in the body, allowing them to be passed out of the body through the urine. Edetate calcium disodium was approved to treat severe lead poisoning. Edetate disodium was approved as an emergency treatment for certain patients with very high levels of calcium in the blood or certain patients with heart rhythm problems resulting from high amounts of digoxin in the blood.

But a number of uses that are not approved by FDA have emerged. These include the removal of other heavy metals from the blood and the treatment of heart disease, commonly referred to as "chelation therapies." In January 2008, FDA issued a public health advisory, warning that some children and adults have died when they were mistakenly given edetate disodium instead of edetate calcium disodium (calcium disodium versenate), or when edetate disodium was used for chelation therapies and other uses not approved by FDA.

The drugs are easily mistaken for each other because they have very similar names and are both commonly referred to only as "EDTA." One of FDA's recommendations is that the abbreviation not be used.

Question 20:

Mix-ups have occurred between edentate disodium and edentate calcium disodium because:

a. they have very similar names;
b. both work by binding heavy metals or minerals in the body;
c. non-FDA-approved uses have emerged;
d. all of the above are true.

Return this ANSWER SHEET with the $20.00 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: FDA Drug and Patient Safety Announcements

(Expiration Date: January 2, 2020)

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:

a) identify ACPE's definition of "patient safety";	Yes	No
b) describe 5 warnings published by the FDA regarding drug and patient safety issues;	Yes	No
c) describe the FDA's role in preventing medication errors;	Yes	No
d) list 2 examples of medication errors published by the FDA.	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 (e.g., 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:

_____

