Select CE

Index:

ACPE Program Number.: 0487-0000-18-001-H03-P knowledge-based activity or 0487-0000-18-001-H03-T
Contact Hour(s): 1.0 (or 0.1 C.E.U.'s)
Release Date: March 4, 2018
Expiration Date: March 4 , 2021
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

Accreditations: This CE activity is ACPE-accredited for 2.0 contact hours, or 0.20 C.E.U.'s, 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 was our Peer Reviewer. Thanks Robyn!

Disclosure of Commercialism, Unlabeled Uses, Bias, Conflicts of Interest: Prior to the delivery of the content, we will disclose any commercial support, and we do so here: No commercial support was used for developing or presenting this program. **All development, printing, mailing and internet costs, as well as ACPE accreditation fees, come solely from your program fees**. No unlabeled uses of drugs are discussed in this program. Brand names are not used, unless the Department of Justice used the brand name of the drug in its publication and hence the brand name is used here too. Faculty Patti Nussle, 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[1]

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

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

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, 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[2]

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

2 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.

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.

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.

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[3]

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 manufacturer, date of expiration and lot

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

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[4]

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

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

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

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

Question 9:

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

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

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

Safeway Pharmacies Pay $3 Million to Resolve Allegations Chain Failed to Timely Report Drug Diversion[5]

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.

5 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[6]

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

6 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[7]

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

7 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[8]

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.

8 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[9]

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

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

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.

"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.

Wellford Woman Pleads Guilty to Forging Prescriptions[10]

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

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.

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

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 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.

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.

.

Former Pharmacy Compliance Director Pleads Guilty to Introducing Adulterated Drugs into Interstate Commerce and Conspiracy to Defraud the United States[11]

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.

11 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:	
CITY, STATE and ZIP:	
EMAIL:	
NABP e-Profile #:	**Month and Day of Birth:**

ANSWERS: More DOJ Cases Against Pharmacists - 2018

Expiration Date: March 4, 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! Also, if you are a pharmacy technician, please tell us that here: