continuing education for pharmacists

Volume XL, No. 8

Overview of Counterfeit and Substandard Medicines

Shabbir J. Imber Safdar, Executive Director, Partnership for Safe Medicines

Mr. Shabbir Safdar has no relevant financial relationships with ineligible companies to disclose.

Goal. The goal of this lesson is to review the history of counterfeit and substandard drugs in global and U.S. supply chains using case studies, and what it has taught pharmacists in protecting the quality of medicines dispensed to their patients.

Objectives. At the completion of this activity, the participant will be able to:

1. identify counterfeit drug sources within U.S. supply chains;
2. differentiate misbranded, diverted and counterfeited drugs;
3. list legal consequences from purchasing non-FDA-approved medications; and
4. recognize state and federal reforms to the drug supply chain.

The Global Perspective

Criminals and counterfeiters will never stop trying to slip their drugs into legitimate drug supply chains. While there is no exact figure, the World Health Organization (WHO) estimates that $200 billion in counterfeit medicines enter the global market every year and that one in 10 medical products in low- and middle-income countries are substandard or fake.

However, counterfeit medicine is a global problem and no country is immune or impenetrable. According to the Organisation for Economic Co-operation and Development (OECD), counterfeit medicines are produced in countries scattered around the globe, and counterfeiting schemes range in size from small, less sophisticated operations, to others on an industrial scale. Fake, but accurate-looking, copies of medicine and packaging are often made in different countries and then shipped to a third location where they are assembled and distributed. OECD analysis found that between 2014 and 2016, the top three producers of counterfeit medicines in the world were India, China, and Hong Kong. During this same timeframe, Hong Kong and the United Arab Emirates were the two main transit points for counterfeit medicines shipments.

Counterfeiters have traditionally faked prescription drugs that have a higher value, but they will fake any medicine as long as it will make them money. It does not matter whether they are branded, generic or over-the-counter medicines. In 2020, data from the Pharmaceutical Security Institute showed that the top five therapeutic categories targeted by counterfeiters were (1) genitourinary, (2) central nervous system, (3) anti-infective, (4) hormones, and (5) cytostatic drugs.

Counterfeit medicines may contain no active pharmaceutical ingredients (API), the wrong API, or the wrong amount of API. In addition to compromising a patient's treatment, counterfeit medicines erode the confidence that individuals have in medicines, healthcare providers, and health systems. While relatively harmless ingredients such as corn starch, potato starch, or chalk have been found in counterfeit medicines, others have been found to contain a fatal level of toxic chemicals and incorrect API.

Counterfeits within the U.S. Drug Supply Chain

The early 20th century was a dangerous time to be an American citizen purchasing medications. The marketplace was filled with harmful and ineffective drugs, and Americans had no way of knowing with any certainty what was in any medicine that they purchased. That began to change after the 1906 Pure Food and Drugs Act enhanced the federal government's consumer protection powers by requiring that foods and drugs bear truthful labeling statements and meet certain standards for purity and strength.

The 1906 law had some major shortcomings, but it laid the cornerstone for what would become the U.S. Food and Drug Administration (FDA). In 1938, President Franklin Delano Roosevelt signed the federal Food, Drug, and Cosmetic Act (FD&C), a set of laws giving authority to FDA to oversee the safety of food, drugs, medical devices, and cosmetics. For the first time, drugs and devices were required to come with adequate instructions; all new drugs had to be proven safe for their labeled use

before they could be marketed in the country; and drugs or devices that inherently endangered health were illegal to market.

Today, American patients have some of the highest levels of confidence in the world that the medications their pharmacists dispense to them are the ones that they are prescribed. In a recent poll, over 70 percent of respondents believed that pharmacists will do the right thing for them and their families.

In 2013, Congress passed the Drug Supply Chain Security Act (DSCSA) which mapped out a 10-year plan to build systems to identify and trace prescription drugs as they are distributed in the U.S., and establish national licensing standards for wholesale distributors and third-party logistics providers. The Act is expected to be fully implemented in November 2023. The U.S.'s track-and-trace system requires that every entity that handles a medicine keeps electronic records of where it came from, tracking a prescription drug's entire life from the manufacturing floor all the way to the moment it is dispensed to a patient.

Even with the added protections in the DSCSA, everyone involved in the distribution of prescription drugs must remain vigilant about the possibility that "bad actors" will try to sneak their fakes into the drug supply. Once fully implemented, the DSCSA will create an individual electronic record at the package level as medicine makes its way through the U.S. drug supply chain. These electronic records will be more secure than the current pedigree papers system and allow for faster confirmation of a medicine's legitimacy between trading partners.

Misbranded Drugs

Criminals who sell counterfeit and substandard drugs often face charges of distributing, receiving or introducing "misbranded drugs" into interstate commerce.

The Federal Food, Drug and Cosmetic Act forbids the sale of misbranded drugs, which are defined as products with a label that "is false or misleading in any particular." Some examples include:

- the sale of products that make claims about treating disease that FDA has not substantiated or approved;
- illegally imported medicines that omit labels in the English language or omit FDA-required warnings;
- medicine in packaging with labels that misrepresent its source, expiration date, or contents.

Diverted Drugs

Drug diversion is the illegal distribution of genuine prescription drugs for illicit purposes. Typically, prescription drugs are taken from legal and medically necessary uses and diverted to uses that are illegal. Diverted medicines can come from thefts at warehouses and pharmacies. Prescription drug rings have collected medicines that were already dispensed to patients to make millions of dollars recirculating medication to other patients who did not know they were getting diverted drugs. Below are two examples of prescription drug trafficking rings that made their profits from diversion schemes.

Cumberland Distribution, Inc., 2006–2009. Between December 2006 and August 2009, three residents of Houston, Texas – including the president of licensed drug distributor Cumberland Distribution, Inc. – made more than $50 million in proceeds by purchasing secondhand HIV treatments, antipsychotics, antidepressants, blood pressure and diabetes medications from unlicensed suppliers and distributing them to independent pharmacies across the country.

How did this operation work? Cumberland's now-former president, Jerrod Nichols Smith, and his co-conspirators bought prescription medicine collected by prescription drug traffickers who paid patients in New York and Miami for medicine that had already been dispensed to them. They either shipped the drugs directly to a Cumberland-owned warehouse in Nashville, Tennessee or "laundered" the medicine through licensed pass-through distributors they had set up in Louisiana and Arkansas to give it the appearance of legitimacy before it, too, landed at the warehouse. Once the bottles of medicines arrived in Nashville, Cumberland employees sorted and checked them, removing patient labels and "cleaning" the bottles with lighter fluid. The drugs were then resold, complete with forged documentation, to deceive pharmacies that had purchased them.

Unsurprisingly, this wasn't a process that was precise or accurate. Pharmacies that bought from Cumberland reported receiving prescription drug bottles that contained the wrong medicine, the wrong dose information, or in at least one case, Tic Tac mints. Eventually, Cumberland's customers reported these problems to FDA, who raided the warehouse in 2009. For the remaining three months of the conspiracy, Smith and his co-conspirators moved to another warehouse, set up private email accounts and burner phones, and used freight forwarding companies and a private pilot to evade the authorities.

This case took nine years to wrap up, ending in a 15-year prison sentence for Smith, six years in prison for his main co-conspirator, four years of probation for the third person, and cumulative forfeitures of almost $3 million.

The Cumberland Distribution case is typical of several similar large scale diversion operations, including a wide-ranging scheme that surfaced in 2012, when the United States Attorney for the Southern District of New York charged 48 people for their roles in a diversion scheme that collected hundreds of millions of dollars worth of second-hand medicines from New York City patients, and sold them back into the drug supply chain via wholesale drug distributors in Alabama, Florida, Louisiana, Massachusetts, Nevada, New York, New Jersey, Pennsylvania, Texas, and Utah.

Follow-up charges included a pharmacist in the Bronx who received a 36-month sentence for buying secondhand drugs that were delivered to him in plastic bags and beer boxes. He dispensed them to patients, and then sought reimbursement from government health benefits programs.

Gilead Sciences v Safe Chain Solutions, LLC, et al., 2020–2021. Gilead Sciences' 2021 lawsuit against a large network of sketchy drug distributors, several of the pharmacies they supplied, and money launderers demonstrated that diversion is still a strategy used by criminals looking to insert counterfeit medicines into the U.S. drug supply chain.

How did this operation work? Court documents unsealed in January 2022 showed that Gilead Sciences had identified more than 85,000 bottles of counterfeit Gilead HIV treatments that were sold to U.S. pharmacies over a two-year period, with thousands of additional bottles confiscated during court-permitted seizures at warehouses and offices spanning 17 locations and nine states. The alleged counterfeiting ring used secondhand Gilead bottles collected from patients, resealed the bottles with the wrong medications inside to make them look new, and sold the medications to pharmacies at prices drastically below wholesale acquisition cost. The defendants allegedly forged pedigrees by listing purchases made from authorized distributors that never happened, and even registered a domain that closely resembled a real distributor's domain to be able to send emails verifying the legitimacy of their prescription drugs.

This led to patient harm that could be documented. Some of those bottles contained acetaminophen instead of the correct medicine and, in one case, a patient who thought they had taken their HIV drug, had actually taken an antipsychotic that rendered them unable to walk or speak. Some pharmacists who caught the fakes either recognized discrepancies in the packaging or called Gilead to verify the pedigree that accompanied the medicine. Unfortunately, other pharmacies continued to purchase from these defendants after being told by Gilead that they were being sold counterfeit medications and were among the defendants in Gilead Sciences' lawsuit.

Counterfeited Drugs

As stated above, counterfeit medicines are made in many countries across the globe, often in very poorly controlled and unhygienic conditions. The people making these fake medicines are generally unqualified, and the products that they create can contain impurities or be contaminated with bacteria.

Investigators have found a wide variety of ingredients in counterfeit medicines. Some pills contained inert fillers such as dextrose and lactose, or common household items, such as wall paint and floor wax. Other pills contained toxic heavy metals, such as mercury, or poisons such as arsenic, rat poison and antifreeze.

Counterfeiting prescription drugs is an attractive proposition for criminals due to the high profit margins and relatively few legal consequences when compared to illicit drugs. Counterfeiters have access to high quality printing so they can make perfect-looking packaging. They can obtain specialty packaging such as vials and vial capping machines to make fake injectables. They also have access to industrial pill presses, so making perfect-looking pills is trivial.

Several cases that involved counterfeit medications are listed below.

Pretending the Medicines Are Canadian. There is an established pattern of criminals pretending that the medicines they are selling come from Canada's drug supply. One of the pioneers of this particular scam was Andrew Strempler, a pharmacist in Canada who was first warned by FDA on October 31, 2001 to make certain that the medicines he sold to Americans on his website, RxNorth, were FDA-approved. They were not.

Quality Special Products/ Montana Health Care Solutions/ Canada Drugs, 2009 – 2012. In January 2012, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) contacted FDA about 41 packs of counterfeit Avastin® that a U.K. wholesaler, River East Supplies, Ltd., had shipped to Volunteer Distribution, a company located in Tennessee. Investigators found that Volunteer Distribution distributed foreign oncology drugs for Quality Specialty Products (QSP) and Montana Health Care Solutions (MHCS). They also uncovered a web of transactions that showed that River East Supplies, QSP, MHCS, and a fourth company in Barbados, Rockley Ventures – all CanadaDrugs.com subsidiaries – were illegally supplying U.S. medical practices with non-FDA-approved drugs.

A November 2014 grand jury indictment charged Canada Drugs, and 13 additional defendants, with selling $78 million worth of unapproved, mislabeled and counterfeit cancer drugs between 2009 and 2012 – including two of the three instances of fake bevacizumab that FDA found in 2012. The case ended in 2018 with guilty pleas. Canada Drugs, Rockley Ventures, River East Supplies and owner Kristjan Thorkelson were sentenced to five years of probation and ordered to pay fines and forfeitures totaling more than $34,250,000, less than half of the value of the illegal medicines they sold. Thorkelson and the associated companies also closed their businesses and surrendered their domain names and websites to the United States.

Genuine Avastin® has only seven authorized distributors in the U.S., and each delivers medicine directly to doctors' offices. If the medical staff who ordered treatments for their practices had checked whether the distributor was authorized, they could have been sure they were treating vulnerable patients with genuine products.

Sourcing from Anywhere

While some companies like to pretend they are Canadian to win the confidence of their customers, it doesn't really matter to any of these criminals where the medications come from, whether the medicine will help the patient, or even not hurt the patient. The only thing these criminals are looking for is the cheapest price, and patients have no recourse if they are harmed or the treatments do not work.

Medical Device King (MDK), 2009–2013. In 2003, William Scully and Shahrad Rodi Lameh founded Pharmalogical, Inc., a licensed New York wholesaler that sold pharmaceutical products to doctors, hospitals, and clinics. When Pharmalogical wasn't making a profit, Scully and Lameh registered *Medical Device King* as a trade name and turned to importing Botox and Mirena IUDs. They persevered even though FDA advised them that they were selling "unapproved new drugs," deceiving their customers by marketing their products as FDA-approved.

MDK expanded into foreign oncology drugs in late 2010 or early 2011, and continued to sell them until May 2012, when FDA agents searched Pharmalogical's offices for counterfeit Avastin®.

A year later, on May 13, 2013, FDA warned almost 800 medical offices that they might have purchased counterfeit bevacizumab disguised as Altuzan® (the Turkish version of a medicine sold in the U.S. as Avastin®) from MDK. The letter listed 33 products that MDK had advertised to medical practices, including Altuzan® that contained no active ingredient.

In April 2014, the U.S. District Court of the Eastern District of New York indicted Scully and Lameh on 73 counts of conspiracy, mail fraud, wire fraud, distribution of misbranded and counterfeit prescription drugs, trafficking in counterfeit goods, and smuggling. The investigation found that MDK had sold $17 million in misbranded prescription drugs, including unapproved IUDs made in Finland, and a fake cancer treatment that reached an oncology practice in Iowa.

In October 2014, Lameh pleaded guilty to conspiracy to commit wire fraud and conspiracy to distribute misbranded drugs, and received a sentence of three years probation and a monetary judgment of $500,000.

A jury found Scully guilty of 64 felonies in November 2015. He was sentenced to five years in prison, and $900,000 in forfeitures, but that conviction was vacated in December 2017 because the lower court had excluded evidence showing he sought legal advice about importing drugs with foreign labels. Eventually, Scully pleaded guilty to one felony count of introducing a misbranded drug into interstate commerce and was sentenced to 32 months in prison (17 months after time served) in October 2018.

It is impossible to say how much fake medicine reached patients in the years these companies were active, or how many lives were shortened as a result of active ingredient-free "medicine," but it is possible to say this supply chain break was completely avoidable.

Some of the cancer treatments oncology practices bought came from Turkey and traveled through several European Union pass-through distributors before landing with American doctors to treat late-stage cancer patients. The drugs' circuitous route obscured the fact that they were fake.

Pretending to Be a Legitimate Source

While some companies and websites simply sell fake medicines, there are some enterprising counterfeiters who take it upon themselves to do it all – they *manufacture* and *sell* counterfeit medicines. Here is a look at how one such group made and sold fake medications to patients in the U.S. and tried to break into the U.S. drug supply chain.

Case Study: *Healthy Nation. The Criminals*. In this case, two men flew 6,000 miles under the false belief that they were meeting a new business partner who would help them slip their counterfeit medications into the legitimate drug supply. Maksym Nienadov, a citizen of Ukraine, started a company called Healthy Nation in 2015. The company distributed medications in Ukraine and sold them online. Volodymyr Nikolaienko joined the company as the business grew, and in May 2018, U.S. Immigration and Customs Enforcement's Homeland Security Investigations (HSI) received a tip about Healthy Nation. Nienadov and Nikolaienko were advertising counterfeit medicines online and completing transactions using *WhatsApp*, a free, secure messaging application for smartphones.

Once a customer showed interest in one of the fake medicines, Nienadov and Nikolaienko would organize payment via money transfer using *WhatsApp*. When they received the funds, they shipped the counterfeit medicines to the customer. The fake medications Healthy Nation sold were lifesaving drugs to treat diseases such as cancer and hepatitis C. People looking for a cure received vials and bottles of "lies."

An accusation that Nienadov and Nikolaienko were selling counterfeit medicines, however, did not mean that federal agents could arrest the men. First, agents had to build a case proving that Nienadov and Nikolaienko were breaking the law. Second, there was the issue that the U.S. and Ukraine do not have a mutually recognized treaty of extradition. Even if the agents could prove their case, Ukraine would not necessarily hand its citizens over to face prosecution in the U.S. HSI's best option was to get the Ukrainians to come to the U.S.

Conning the Conmen. In June 2018, an undercover agent (UA) sent the defendants a message via *WhatsApp* asking to purchase a specific cancer medication. The UA and the counterfeiters agreed on a

price, and after receiving payment, the defendants shipped the medication to a secure location in Texas. The following month, the UA purchased more of the first cancer medication as well as a second one. The UA got an email address to communicate with Nienadov and Nikolaienko by pretending that messages sent via *WhatsApp* were getting lost. Then, the government filed a search warrant with the email service provider, which gave federal agents a window into Healthy Nation's operating history. They found communications with medical glass vial manufacturers and print shops in multiple countries; email conversations that mentioned additional drugs that Healthy Nation hoped to counterfeit; and a discussion with a company in India to purchase a machine that could cap medicine vials.

In October 2018, federal agents received the first test result that proved that the drugs sold by Nienadov and Nikolaienko were fake. More would follow in the coming months. With confirmation that a crime was being committed, the UA hatched a plan to arrest the pair. The UA convinced the original tipster to purchase some more fake medicine from Healthy Nation and to offer to introduce the men to his business partner who could help them break into the U.S. drug supply chain. The only catch was they had to come to the U.S. for the meeting.

In December 2018, the tipster even offered to help Nienadov and Nikolaienko get business visas for their trip. All they needed to do was to send him pictures of their passports. Once that information was in hand, the UA dutifully filled out the necessary paperwork and submitted it on behalf of the men to the U.S. embassy in Ukraine.

In April 2019, Nienadov and Nikolaienko flew to Houston, Texas to meet this new potential business partner. However, that new business partner was the UA, and the men never made it back to Ukraine. The pair was arrested on their way back to the airport. The U.S. Department of Justice brought 19 charges against Nienadov and Nikolaienko. In July 2020, both men entered guilty pleas, admitting to conspiracy, trafficking in counterfeit drugs, and smuggling goods into the U.S. Nienadov also admitted to introducing misbranded drugs into the country. In March 2021, Nienadov and Nikolaiendo were sentenced to 71 and 33 months in federal prison, respectively. After completing their sentences, the men will be deported.

Consequences for Providers

Procuring medicine from outside the secure U.S. drug supply chain puts more than patients at risk. The person who purchases the non-FDA-approved medications opens themselves up to legal consequences, such as loss of license, potential lawsuits, and jail sentences.

Purchasing medications from outside the U.S. supply chain is not legal. Despite the urban myth, ordering medicines from online pharmacies, even those that may be in Canada, is also illegal. People refer to it as "personal importation," but that only refers to hand-carrying a personal quantity of medicine across the border, not mail order.

Ordering medicines for patients creates legal liability for providers who can be charged with introducing misbranded medications into interstate commerce, a violation of the Food, Drug, and Cosmetic Act. The liability for actually dispensing these medications to patients can result in charges of insurance fraud, which carries fines and repayment sanctions as well.

The case studies below involve individuals who put profits before patients and what it cost them.

Case Study: *McLeod Cancer and Blood Center, 2007–2009.*
In November 2012, the U.S. District Court in the Eastern District of Tennessee charged McLeod Cancer and Blood Center (MCBC) in Johnson City, Tennessee with buying unapproved cancer treatments from a Canadian supplier and submitting fraudulent claims for them to Medicare and other government health benefits programs.

Between September 2007 and early 2008, and again from August 2009 to February 2012, McLeod Cancer and Blood Center in Johnson City, Tennessee purchased nine different unapproved cancer treatments at a discount from Quality Specialty Products (QSP), an unlicensed wholesaler also known as Montana Health Care Solutions, which Canada Drugs acquired in 2009. Over the same period, the medical practice paid $2 million dollars for the drugs, billed government health benefits programs approximately $2.5 million as if it had paid for legitimate medicines, and kept the difference.

MCBC's relationship with QSP began in September 2007, when QSP sent out a fax advertising chemotherapy treatments at lower prices than the FDA-approved ones that they had been buying. The practice's three doctors, managing partner William Ralph Kincaid, Millard Lamb and Charles Famoyin, and its business manager, Michael Dean Combs, decided to purchase QSP's products. They received medicines from Turkey, India, the European Union and elsewhere, and billed insurance and health benefits programs as if the drugs were FDA-approved.

MCBC stopped ordering from QSP in early 2008, when the center's nursing staff recognized that foreign labeling on the products they received from QSP meant that the medicines were not approved for sale in the United States and confronted practice physicians.

William Kincaid resumed ordering from the Canadian company after he and his business manager met with a QSP representative at a local restaurant in August 2009. Kincaid and Combs concealed the source of the medicine by having it shipped to Just Store It, a storage business in which Kincaid was a part owner. Later, the questionable drugs were taken to the medical practice and secretly intermingled with FDA-approved drugs from legitimate sources.

Among the medicines Kincaid imported from QSP was a foreign version of rituximab, a chemotherapy treatment that requires cold chain shipping, and cannot be frozen or shaken without losing its effectiveness. Because the rituximab MCBC purchased was made in a Swiss facility that FDA had never inspected, there was no way to ascertain that it had been shipped safely.

Ultimately, William Kincaid received a two-year prison sentence after pleading guilty to a felony count of receiving misbranded drugs with intent to defraud or mislead. He also agreed to pay $2.55 million of a $4.25 million settlement of civil claims under the False Claims Act.

Case Study: *American Inhalation Medication Specialists, Inc., 2004–2009.* Between approximately January 2004 and August 2009, a Kingsport, Tennessee pharmacist named Robert Harshbarger, Jr., doing business as American Inhalation Medication Specialists (AIMS), illegally imported iron sucrose from companies in China rather than pay for FDA-approved Venofer®. According to an indictment filed in November 2012, he sold the misbranded product to Kansas Dialysis Services (KDS) in prefilled plastic syringes that he had been told would not preserve the stability of the drug, and he actively lied to KDS, claiming that he was supplying genuine Venofer®. KDS paid AIMS over $875,000 for Venofer® and billed Medicare, the Veterans Administration and other healthcare benefit programs more than $840,000 while unknowingly administering iron sucrose of unknown quality to their patients.

Ultimately, Harshbarger pleaded guilty to felony counts of introducing misbranded drugs into interstate commerce and health care fraud in May 2013. Even without any reports of harm to patients, he received a 48-month federal prison sentence and agreed to pay almost $1.3 million in fines, forfeitures, and restitution. The Tennessee State Board of Pharmacy revoked his license in November 2013.

Changing the System for the Better

In a perfect world, we would not have to worry about counterfeit medicines getting into our secure drug supply chain. When it does happen, it is important to take stock of what went wrong and improve the system to prevent the same thing from happening again. Below is a case that helped to spur change in the state where counterfeiting took place, but also on a federal level.

Case Study: *Uplabeling Counterfeit Epogen Victim.* In 2002, a 16-year-old liver transplant patient in Deer Park, New York, was prescribed 40,000 units per milliliter Epogen® to treat his postoperative anemia. His pharmacy filled his prescription and the label looked right, but the medicine he actually received was twenty times weaker than it should have been. For eight weeks, the teenager endured injections that left him screaming and doubled over in pain. His doctor was mystified. As law enforcement unraveled the scheme, FDA issued a counterfeit warning, and then the young man's pharmacist called to explain.

The Crime. A few months earlier, a small pharmacy in Miami bought 110,000 vials of low-dose Epogen® from two licensed and reputable wholesalers at a cost of $25 per vial. However, the pharmacy did not dispense any of this medicine to even one patient. The pharmacy sold the vials to a counterfeiter named Jose Grillo.

Grillo transported the temperature-sensitive vials in paint cans to a trailer. After soaking the vials overnight, the counterfeiters rubbed off the low-dose labels and replaced them with fake high-dose labels. This is referred to as *uplabeling*. Suddenly, those 110,000 vials were a higher dose product worth $470 each.

Criminal wholesalers sold and resold the vials until the uplabeled Epogen® landed at a small wholesaler in Arizona that sold them back to one of the original wholesalers in Florida. That original wholesaler thought the vials were genuine and placed them with the rest of the high-dose Epogen® stock. A national pharmacy chain bought them, and that is how a 16-year-old transplant patient in Deer Park, New York ended up with them. Everything about the vials looked correct except for two small degree symbols.

Reforms to the Drug Supply Chain

State Level. After the Epogen® case, the state of Florida convened a statewide grand jury to examine the practices of pharmaceutical wholesalers. In March 2003, a 47-page report detailed the scope of the problem within the state and made recommendations to improve safety. The report noted that an "alarming percentage of prescription drugs flowing through the wholesale market have been illegally acquired" through theft, patient drug buy-back rings, and illegal importation. Medicine sold by the over 1,300 wholesalers licensed in the state was "likely to become tainted due to improper handling or storage." The grand jury could not determine how much of Florida's drug supply was stolen, mishandled, tainted, or uplabeled, but it concluded that any amount of adulterated pharmaceuticals was too much.

Florida's Bureau of Statewide Pharmacy Services (BSPS) and Department of Health (DOH) were already improving drug security by cracking down on the enforcement of paper pedigrees that recorded who had manufactured and handled prescription medications when the grand jury was convened. The grand jury, however, added recommendations, including strengthening permit requirements and direct agency oversight of wholesalers; hiking penalties for pharmaceutical crimes so that they were substantial felonies; allowing relevant state agencies to immediately seize and destroy offending pharmaceuticals or close establishments

warehousing drugs in an unsafe manner; and requiring wholesalers to consistently use and verify pedigree records.

A 2012 analysis of Florida's pharmaceutical distribution regulations showed that the bulk of these recommendations were implemented.

Federal Level. With advances in technology, examining physical papers and making phone calls to ensure prescription drugs are legitimate quickly became a thing of the past. As mentioned earlier, Congress passed the Drug Supply Chain Security Act in 2013 which mapped out a 10-year plan to build systems to track and trace prescription drugs as they are distributed in the U.S., and established national licensing standards for wholesale distributors and third-party logistics providers. No other country in the world has a system like it, and it is the best way to keep counterfeit and substandard medicine from reaching American patients.

What Lessons Do These Cases Teach Pharmacists?

Pharmacists are generally the last line of defense in keeping patients safe from these counterfeits. If something seems too good to be true, it probably is. This applies to the acquisition of pharmaceuticals. Pharmacists should be skeptical about any medicines offered at prices drastically below wholesale acquisition cost. With specialty drugs, manufacturers only distribute through a limited number of authorized wholesalers. Many of these lists are easily verifiable on the manufacturers' websites. Pharmacists can call or check the manufacturer's website to verify the distributor is genuine. If a distributor reaches out with cut-rate prices and they are not on the list, that should be a red flag. In the Gilead case, some of the criminals allegedly put names that closely resembled authorized distributors on the pedigree papers so that at casual glance, nothing would seem suspicious. "The devil can be in the details," and frequently it is those details on the packaging and pedigrees that trip up counterfeit prescription drug rings.

Inspect the product. Court papers in the lawsuit that Gilead filed against the drug counterfeiting ring state that members of the conspiracy resealed used bottles with fake foils, and that close inspection of the bottles revealed remnants of the original foils. The Cumberland Distribution and counterfeit Epogen® cases also involved irregularities in packaging. Small discrepancies in the labeling may reveal it is a counterfeit and expose a pharmacist to liability, or a pharmacist may notice the packaging is different from the product purchased previously.

New features of drug traceability can protect pharmacists and their patients. In the Gilead case, a pharmacist checked the transaction sale log and found irregularities when they compared the sales logs with the actual selling wholesalers listed. The ability to do this down to a unit level is part of the DSCSA rollout.

Beware of the consequences of trading safety for price. In the case of the fake Avastin®, hundreds of doctors across the country were warned by FDA, many paid enormous fines, and some were taken to court. Several even lost their licenses. While the business of pharmacy is financially difficult, cutting corners on safety is a mistake that will be difficult to recover from, even if it is not discovered until a year or more later.

Educate patients. As pharmacy benefit managers (PBMs) and insurance companies tweak their formularies to maximize their revenue at the expense of patients, patients are forced to look for dangerous, foreign sources of medication. If a patient is concerned about being able to afford their medication, they need to be warned about the dangers of purchasing medicines online. In a recent poll, forty-five percent of Americans think that all websites offering healthcare services or prescription drugs have been approved by FDA or state regulators. If a patient wants to purchase their medicines online, they should be encouraged to only purchase them from pharmacies that have a pharmacy license from the state's board of pharmacy or, if they must go online, have a "dot pharmacy" (*.pharmacy*) domain name.

Be prepared to report suspicious products. Pharmacists should be prepared to report suspicious products. They are the last line of defense between a patient receiving a counterfeit or substandard medication. Medicines should be carefully examined when they arrive at the pharmacy. Pharmacists need to know the quickest and best way to resolve any concerns they may have. This might include keeping a list of phone numbers for various brand protection units at different pharmaceutical companies that medicines are purchased from. If a pharmacist suspects they have received a shipment of counterfeit medicines, it should be immediately quarantined, and the manufacturer and FDA Office of Criminal Investigations contacted.

• • • • • • • • • • • • • • • • • •

The author, the Ohio Pharmacists Foundation and the Ohio Pharmacists Association disclaim any liability to you or your patients resulting from reliance solely upon the information contained herein. Bibliography for additional reading and inquiry is available upon request.

This lesson is a knowledge-based CPE activity and is targeted to pharmacists in all practice settings. Disclosure: Individuals responsible for planning OPF continuing pharmacy education activities have no relevant financial relationships with ineligible companies to disclose.

Correspondence Course Quiz on page 31.

Program 0129-0000-22-008-H99-P
Release date: 8-15-22
Expiration date: 8-15-25
CPE Hours: 1.5 (0.15 CEU)

The Ohio Pharmacists Foundation Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

continuing education quiz

Overview of Counterfeit and Substandard Medicines

1. Between 2014 and 2016, all of the following were top producers of counterfeit medicines EXCEPT:
   a. Ukraine.
   b. China.
   c. India.
   d. Hong Kong.

2. Counterfeiters have traditionally faked all of the following medications EXCEPT:
   a. branded.
   b. generic.
   c. herbal.
   d. OTCs.

3. According to the Pharmaceutical Security Institute, which of the following was a top five therapeutic category targeted by counterfeiters?
   a. Endocrine
   b. Gastrointestinal
   c. Anticoagulation
   d. Central nervous system

4. Which of the following Acts required that foods and drugs bear truthful labeling statements and meet standards for purity and strength?
   a. Pure Food and Drugs Act
   b. Food, Drug and Cosmetic Act

5. Selling a product stating claims about treating a disease that FDA has not approved is an example of a:
   a. diverted drug.
   b. misbranded drug.
   c. counterfeit drug.

6. Which of the following terms refers to the illegal distribution of genuine prescription drugs for illicit purposes?
   a. Adulteration
   b. Drug Diversion
   c. Misbranded
   d. Counterfeit

7. In the Gilead Sciences v Safe Chain Solutions, LLC, *et al.* case, the defendants allegedly forged pedigrees by listing purchases made from authorized distributors that never happened.
   a. True
   b. False

8. Counterfeiting prescription drugs is attractive to criminals for all of the following reasons EXCEPT:
   a. high profit margins.
   b. few legal consequences.
   c. ease of getting licensed.

9. All of the following tactics were used by counterfeiters who were ultimately caught EXCEPT:
   a. using multiple subsidiaries to supply non-FDA-approved drugs.
   b. marketing products as FDA-approved.
   c. supplying fake medicines in lieu of life-saving drugs.
   d. using the U.S. track-and-trace system.

10. *Personal importation* refers to medicines received through mail order.
   a. True
   b. False

Please print.

Program 0129-0000-22-008-H99-P
0.15 CEU

Name_____

Address_____

City, State, Zip_____

NABP e-Profile ID_____Birthdate_____ (MMDD)

Return quiz sheet to Correspondence Course, OPA,
2674 Federated Blvd., Columbus, OH 43235-4990
or fax to 614.389.4582

11. Purchasing non-FDA-approved medications can result in all of the following legal consequences EXCEPT:
   a. loss of license.
   b. jail sentences.
   c. potential lawsuits.
   d. charges of insurance fraud.

12. *Uplabeling* refers to replacing low-dose labels with fake high-dose labels.
   a. True
   b. False

13. What is the best resource for a pharmacist to determine if a distributor of a specialty drug is genuine?
   a. DSCSA
   b. Product labeling
   c. Manufacturer's website
   d. Distributor's sales log

14. What is the best web domain to recommend to a patient wanting to purchase medicines online?
   a. Canadian website
   b. FDA website
   c. "dot pharmacy" domain
   d. DEA website

15. If a pharmacist suspects they have received a counterfeit medicine, they should do all the following EXCEPT:
   a. quarantine it.
   b. immediately return it.
   c. contact the manufacturer.
   d. contact FDA Office of Criminal Investigations.

Completely fill in the lettered box corresponding to your answer.

1. [a] [b] [c] [d]	6. [a] [b] [c] [d]	11. [a] [b] [c] [d]
2. [a] [b] [c] [d]	7. [a] [b]	12. [a] [b]
3. [a] [b] [c] [d]	8. [a] [b] [c]	13. [a] [b] [c] [d]
4. [a] [b]	9. [a] [b] [c] [d]	14. [a] [b] [c] [d]
5. [a] [b] [c]	10. [a] [b]	15. [a] [b] [c] [d]

I am enclosing payment for (*please check one box*):
- ❑ **$3** for this month's quiz.
- ❑ **$30** for 2022 Monthly CPE only.
- ❑ **$40** for 2022 Monthly CPE + Law CPE
- ❑ **$40** for 2022 Monthly CPE + Patient Safety CPE
- ❑ **$50** for 2022 Monthly CPE + Law + Patient Safety CPE
- ❑ I have already remitted payment for 2022 quizzes

Make all checks payable to *Ohio Pharmacists Association*.

1. Rate this lesson: (Excellent) 5 4 3 2 1 (Poor)
2. Did it meet each of its objectives (p. 7)? ❑ yes ❑ no
   If no, list any unmet_____
3. Was the content balanced and without commercial bias?
   ❑ yes ❑ no If no, why?_____
4. Did the program meet your educational/practice needs?
   ❑ yes ❑ no
5. How long did it take you to read this lesson and complete the quiz? _____
6. Comments/future topics welcome.

To receive CPE credit, your quiz must be received no later than August 15, 2025. A passing grade of 80% must be attained. CPE credit for successfully completed quizzes will be uploaded to the CPE Monitor. CPE statements of credit can be printed from the CPE Monitor website. Only current OPA members may receive CPE credit for this lesson.