

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

ISMP urges increased action at the practice level to halt the growing danger of counterfeit drugs



PROBLEM: Counterfeit drugs, or fake drugs, made to resemble genuine pharmaceutical manufacturers' medications (**Figure 1**), have been a longstanding threat to the health and safety of patients. Alarming, this problem has grown far more ubiquitous in recent years. Most have attributed this rise to the skyrocketing profits made by criminal groups, the growth of unregulated online marketplaces posing as legitimate pharmacies, and the increasing use of social media to advertise counterfeit medications. For example, during the coronavirus disease 2019 (COVID-19) pandemic, more patients became accustomed to purchasing medications online. However, not all online pharmacies are created equal. According to the National Association of Boards of Pharmacy (NABP), about 95% of so-called online pharmacies operate illegally.¹ Lack of awareness and education about this issue results in serious risks to patients' lives.

In 2023, the Drug Enforcement Administration (DEA) seized more than 79.5 million fenta**NYL**-laced counterfeit tablets.² DEA testing shows as many as 7 out of 10 counterfeit medications contained a potentially lethal dose of fenta**NYL**. While anyone can unknowingly purchase counterfeit medications, young adults and individuals in marginalized groups are most at risk. According to the Centers for Disease Control and Prevention (CDC), fenta**NYL**-related adolescent overdose deaths tripled from 2019 to 2021. About a quarter of these deaths are linked to counterfeit medications.³



Figure 1. Examples of the medications (right side of each pair): **CYTOTEC** (mi**SOPROS**tol) (top), **SUTENT** (**SUNI**tinib) (middle), and **DIFLUCAN** (fluconazole) (bottom), along with counterfeit versions (left side of each pair).

More Than an Illicit Drug Problem

Counterfeit medications are often associated with illicit drug use, which may cause some people to believe "it can't happen to me." However, counterfeit drugs represent a serious threat to all, from young people seeking help with attention-deficit/hyperactivity disorder (ADHD) to elderly patients looking for the lowest price for their prescriptions. Examples of counterfeit drugs include chronic medications for diabetes and heart disease, cancer drugs, and antivirals for infectious diseases such as human immunodeficiency virus (HIV). Counterfeit drugs are frequently adulterated with potentially lethal ingredients including lead, mercury, toxins, or harmful chemicals. More troubling, as mentioned above, an increasing number of fake drugs are laced with fenta**NYL**, fueling the epidemic of overdose deaths plaguing the United States. Fenta**NYL** is now the leading cause of death for Americans aged 18 to 45.⁴

Even when not contaminated with dangerous or deadly material, counterfeit drugs often lack the required active ingredients to be effective. Their use can lead to treatment failures, complications, and other morbidities. They also impose significant economic burdens on patients and healthcare organizations due to the costs associated with ineffective treatments and management of prolonged illnesses.

A Global Crisis

The World Health Organization (WHO) identified counterfeit medications as "one of the urgent

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SAFETY briefs



Dialysis bags may rupture during mixing.

We received reports of NxStage PureFlow Bicarbonate Solution Bags rupturing when practitioners attempted to break the seal between compartments in the dual chamber bag. The smaller chamber contains a salt solution (pH less than 2, acidic), and the larger chamber contains a bicarbonate buffer (alkaline) solution. Practitioners must apply pressure to the bags to break the seal between the compartments to mix the components before use. In one report, when the nurse was applying pressure to break the seal, the bag ruptured splashing contents on the nurse's face. She had to be treated for eye exposure in an emergency department.

Just this week, NxStage notified customers they are voluntarily recalling 724 lots of NxStage PureFlow Bicarbonate Solution (www.ismp.org/ext/1389). Do not use impacted product (refer to Appendix A in the notification) and contact NxStage to arrange for return. Our affiliate, ECRI, has released a hazard alert (www.ismp.org/ext/1388) with

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New Website Coming Soon!

At the end of May, ISMP will be integrating www.ismp.org with the website of our affiliate organization, ECRI. Combining our websites will unify sign-ins, streamline access to our many products and services, and provide a comprehensive source for safety information.

As part of the process, there will be some changes to the way users navigate ISMP's site and access subscription-based information. Detailed information on how to navigate our new website will be available during launch, and you will continue to be able to use the www.ismp.org address.

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health challenges for the next decade.⁵ Fake drugs have become a big business globally—estimated to be worth as much as \$431 billion a year.⁶ According to WHO, counterfeit drugs account for roughly 10% of the medical products circulating in low- and middle-income countries, with an estimated one million people dying annually from taking fake or substandard medications.⁷

Counterfeit medications have entered the supply chain worldwide, including the European Union, Canada, and the United States. As the internet has become a global marketplace, it can be difficult for federal and state authorities to track and prosecute rogue sites, which sophisticated criminal networks often operate. Many illegal online pharmacies pass themselves off as Canadian pharmacies providing prescription medications at lower prices. Criminal groups may include the word “Canada” in their URL or show individuals dressed as medical professionals and a maple leaf symbol on their landing page, making it difficult to discern between a legitimate and fake site. Some online pharmacies source their drugs from other countries known to produce counterfeit medications.

Adverse Events

Whether they were aware of the scheme or not, some healthcare practitioners have been caught in the dark world of counterfeiters. For example, in 2021, two California oncologists pled guilty to purchasing more than \$1 million of unapproved and counterfeit cancer drugs from a company owned by a Winnipeg internet pharmacy. The US Food and Drug Administration (FDA) found the discounted oncology drugs contained no active ingredients. Canadian authorities prosecuted and sentenced the owner of the Winnipeg internet pharmacy.⁸

We also shared concerns about the impact of counterfeit medication in our March 7, 2024, newsletter article, *Accidental overdoses and adverse effects from compounded GLP-1 agonists* (www.ismp.org/node/126032). A hospital reported that, in less than a week, three patients required admission to the intensive care unit due to severe hypoglycemia from compounded semaglutide. The patients had received multiple pens without a prescription from people identified as “nurses” in a hotel room or a gathering akin to a “Botox party,” and the drugs were thought to be counterfeit.

SAFE PRACTICE RECOMMENDATIONS: Healthcare organizations have a crucial role in raising awareness of this threat to patients and should consider the following strategies:

Educate practitioners. Educate staff about the potential for patients to present to different healthcare settings (e.g., emergency department, physician's office) with adverse reactions after knowingly or unknowingly taking counterfeit medications. Monitor patients for unexpected outcomes (e.g., increased side effects, medication not working as it previously had) and consider if counterfeit medications could be the culprit. When reviewing a patient's medication history, include a scripted open-ended question asking where they obtain their medications.

Follow literature and media reports. Maintain an awareness of publicized incidents and the medications involved to focus on known problem drugs and pharmacological categories.

Educate patients. Prescribers, pharmacists, and nurses are among the most trusted sources of medical information and uniquely positioned to educate patients about the risk of counterfeit drugs. Proactively have professional staff share with patients the warning signs that may indicate a pharmacy could be selling counterfeit drugs. Refer patients to the ISMP consumer website (www.ismp.org/ext/1383) and FDA's BeSafeRx campaign (www.ismp.org/ext/618). Even when comparing counterfeit and real medication side-by-side, it can be difficult to tell the difference without laboratory testing. However, there are important safety tips that patients can consider when purchasing medications:

Use a verified pharmacy. Educate patients about the National Association of Boards of Pharmacy's (NABP's) searchable list of accredited online pharmacies (www.ismp.org/ext/1344) that comply

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the following recommendations. Educate nurses that the product's small chamber has been reported to leak when squeezed to mix the bag. Don personal protective equipment before mixing dialysate bags. Protective eyewear and gloves are recommended to reduce the risk of eye and skin exposure. If NxStage PureFlow Bicarbonate Solution bags with impacted product numbers must be used, place a towel over the dialysate bag before compressing the bags. After mixing, verify that the towel is dry and that the bag is not leaking. Do not use dialysate bags that have ruptured. If skin exposure occurs, rinse thoroughly with water. For eye contact, flush the eyes thoroughly for 15 minutes and consult a physician. Report problems with dialysate bags to the manufacturer, ECRI (www.ismp.org/ext/1162), and FDA.

Kentucky law prevents practitioners from being criminally charged for medical errors.

We were pleased to learn that Kentucky Governor Andy Beshear recently signed a bill (House Bill 159: www.ismp.org/ext/1363) into law that protects healthcare practitioners from being criminally charged for medical errors, making Kentucky the first state to do so. Under this bill, practitioners, including nurses, pharmacists, and physicians, “shall be immune from criminal liability for any harm or damages alleged to arise from an act or omission relating to the provision of health services” with exceptions for gross negligence and intentional misconduct.

This follows our April 7, 2022 newsletter article, *Criminalization of human error and a guilty verdict: A travesty of justice that threatens patient safety* (www.ismp.org/node/30908), when we shared how RaDonda Vaught had been convicted of criminally negligent homicide and gross neglect of an impaired adult following the 2017 tragic death of Charlene Murphey. RaDonda was found guilty of negligent homicide, lost her nursing license, and was sentenced to three years of supervised probation in Tennessee.

ISMP, along with others, feared the criminal charges and the guilty verdict against RaDonda set a dangerous precedent with

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with quality assurance criteria. You can also report suspicious online pharmacies via this website. With any online pharmacy, check to see if there is a licensed pharmacist available who can answer questions about the medication. This is not only helpful when seeking information, but also speaks to the legitimacy of the pharmacy.

Check for spelling errors. Review packages and labeling for spelling errors. Misspellings anywhere on the packaging (e.g., product name, manufacturer, main ingredients on bottle label) are one of the most noticeable mistakes on counterfeit products.

Evaluate medication appearance. Inform patients that, although manufacturers might change products or pharmacies might provide different generic products, any concerns about differences in size, color, or shape of the medication when the prescription is refilled should be addressed. For this reason, it is best to obtain a refill before the current prescription is finished. Educate patients to compare the new medication and packaging with the previously filled medication. Patients should note any differences and ensure the drug description on the new pharmacy label matches that of the drug inside the container. If they have any questions, patients should consult their prescriber or pharmacy before taking the medication.

Assess medication quality. Legitimate medications will have a factory-made appearance. If tablets are cracked, have a bubbled-up coating, are crumbly or moldy, or come in jars containing excess powders or crystals, patients should be suspicious. Medications that come in the original manufacturers' packaging should be sealed. If the package has been opened, has a broken seal, appears to have been tampered with, comes in different or no packaging, is missing the label, or just does not look right, patients should check with a healthcare practitioner before taking the medication.⁹

Report concerns. Law enforcement cannot stop the dangerous flow of counterfeit drugs without the support of public and private stakeholders. Many private sector companies have counterfeit drug operations dedicated to supporting law enforcement efforts. Some manufacturers have a team that investigates possible criminal groups creating and distributing counterfeits and have forensic laboratories with scientists who specialize in analyzing and tracking counterfeit medicines. Practitioners should also be aware of and share resources from government agencies that offer information to combat counterfeit drugs, such as:

- CDC (www.ismp.org/ext/1346)
- FDA (www.ismp.org/ext/1347)
- The National Intellectual Property Rights Coordination Center (www.ismp.org/ext/1348)

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To learn more, FDA Division of Drug Information is offering a **FREE** webinar, **FDA Drug Topics: Fraudulent Drugs: You're Using What?**, on **May 21, 2024**. To register, visit: www.ismp.org/ext/31.

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worrisome implications for safety. We were concerned the guilty verdict would prevent practitioners from reporting errors, undermine the creation of a culture of safety, accelerate the exodus of practitioners from clinical practice, exacerbate the shortage of healthcare providers, perpetuate the myth that perfect performance is achievable, and impede system improvements. We are thankful for the path Kentucky has taken with this new law. We hope similar actions will be taken by other states. We encourage practitioners to report medication errors to their organization, to ISMP, to state agencies where required, and/or to a patient safety organization (PSO), to facilitate learning about the causes and prevention of medication errors.

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Report medication and vaccine errors to ISMP: Please call 1-800-FAILSAFE, or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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