

**Identifying Imposters:
Counterfeit Drugs in
the Pharmacy
Distribution Chain**

Jeannette Y. Wick, RPh, MBA, FASCP
Director, Office of Pharmacy Professional Development
University of Connecticut

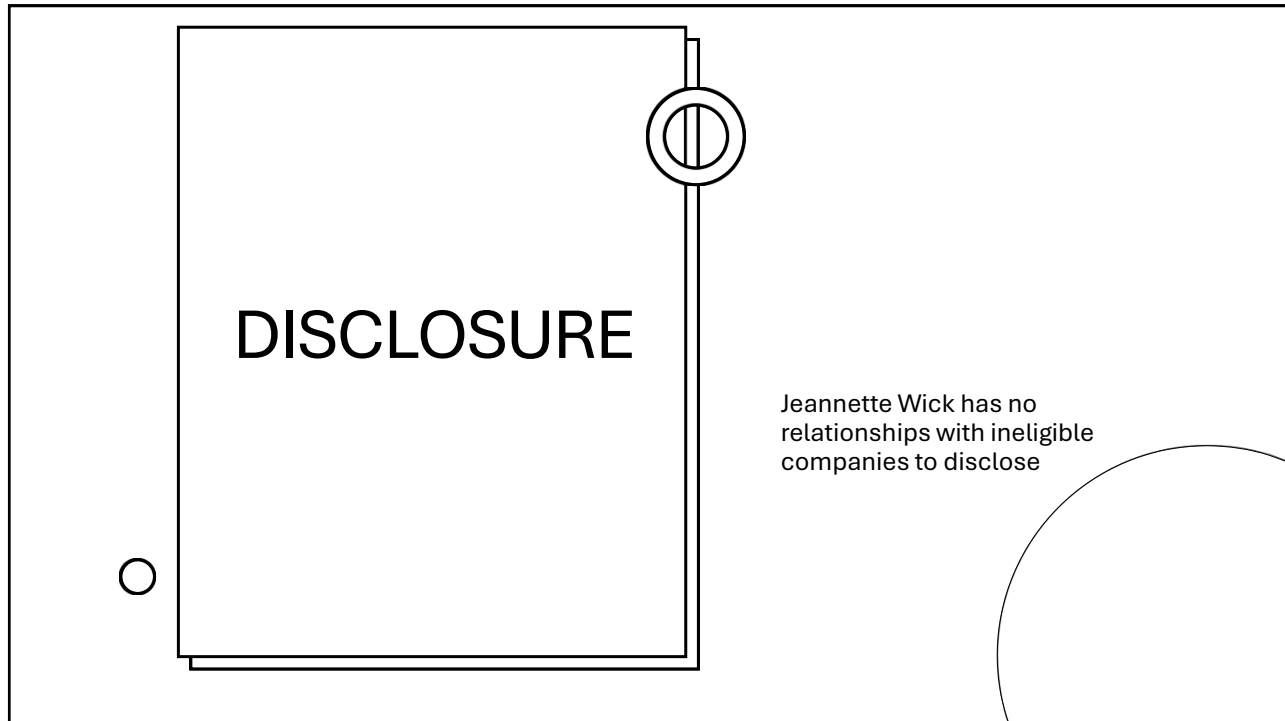
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Special Thanks

Emily Szydlo and Megan Wilcox
Students Extraordinaire

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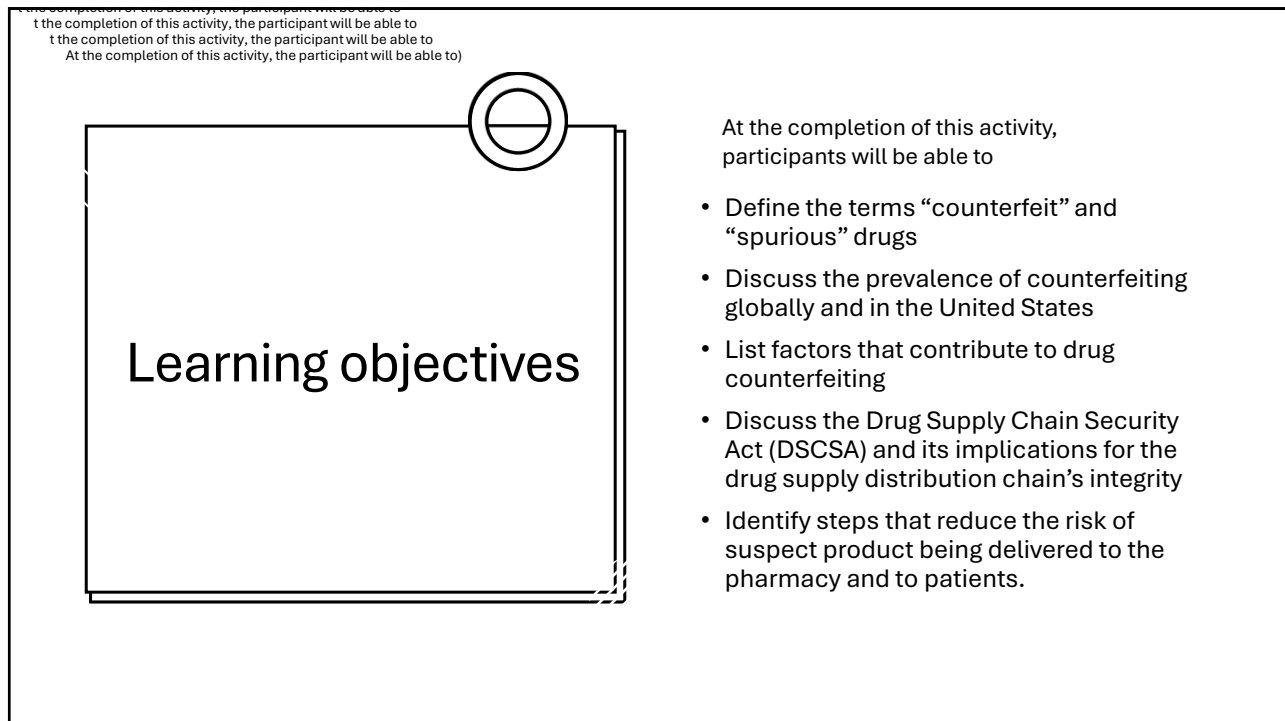


DISCLOSURE

Jeannette Wick has no relationships with ineligible companies to disclose

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Learning objectives

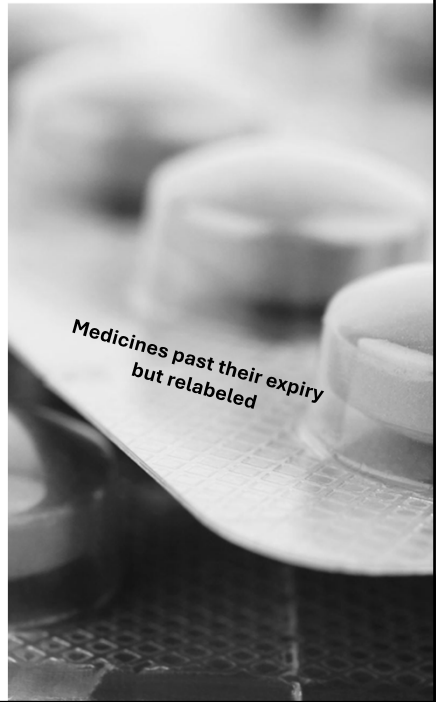
At the completion of this activity, participants will be able to

- Define the terms “counterfeit” and “spurious” drugs
- Discuss the prevalence of counterfeiting globally and in the United States
- List factors that contribute to drug counterfeiting
- Discuss the Drug Supply Chain Security Act (DSCSA) and its implications for the drug supply distribution chain’s integrity
- Identify steps that reduce the risk of suspect product being delivered to the pharmacy and to patients.

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Counterfeit and Spurious Drugs

- Products containing no active pharmaceutical ingredient (API)
 - Vials of PROCIT (epoetin) contained Miami city tap water
- Products with incorrect ingredients
 - Found counterfeit orlistat (Alli) to contain sibutramine instead
- Products with incorrect quantities of active ingredients
 - Physician supplied with more concentrated version of onabotulinumtoxinA (Botox)
- Products with correct quantities of active ingredient but fake packaging
- Copies of an original product
- Products with elevated levels of impurities and contaminants
 - Counterfeit cough syrup tainted with ethylene glycol (antifreeze)



Blackstone EA, et al. *Am Health Drug Benefits.* 2014;7(4):216-224.

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Active Learning

What's the difference between "counterfeit" and "spurious" drugs and adulterated drugs?

- A. Counterfeit or spurious drugs are usually contaminated but adulterated drugs are not.
- B. Adulterated drugs are usually contaminated but counterfeit or spurious drugs are not.
- C. Counterfeit or spurious drugs and adulterated drugs are the same thing for all practical purposes.

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Quick Comparison Table

CATEGORY	MAIN PROBLEM	FRAUD?	QUALITY ISSUE?	CONTAMINATION?	LABEL/CLAIMS ISSUE?
Spurious or counterfeit	Fake identity/ fake source	Yes	Often	Possible	Often
Substandard	Fails quality or regulatory standards	Not necessarily	Yes	Possible	Not the main issue
Adulterated	Contaminated or made in filthy conditions	Maybe	Yes	Yes	Not the main issue
Misbranded	False, incomplete, or misleading labeling	Often	Not necessarily	Not necessarily	Yes

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A Little History...

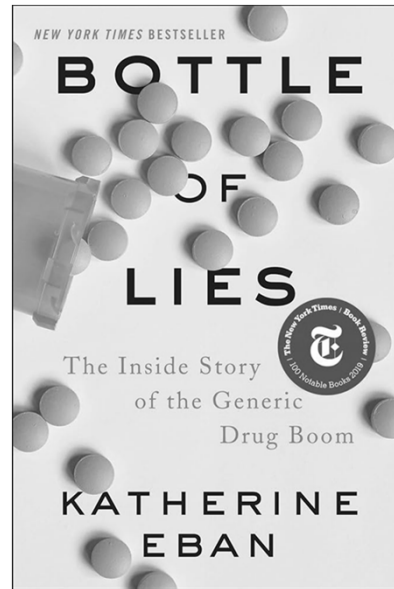
- Drug counterfeiting goes back centuries and is considered one of the oldest crimes in human history
 - Counterfeit cinchona bark in the 1600s
 - Counterfeit quinine in the 1800s
 - The WHO begins gathering information on counterfeit drugs in 1985
 - The WHO and the International Federation of Pharmaceutical Manufacturers and Associations co-host the first global conference in 1992
 - The WHO launches a project specifically on counterfeit drugs 1995
 - Drug manufacturers begin publicly reporting on discoveries of counterfeit drugs in the 1990s to 2000s
 - The U.S. experiences a nationwide epidemic of counterfeit pain pills laced with fentanyl in 2015 (> 20,000,000 annually)

Pathak R, et al. *Pharmaceut Med.* 2023;37(4):281-290; Barrett D, Dvoskin E. The Washington Post, September 27, 2021; Hirsch JA, Mandel S. NYMR FJMC. <https://newyorkmetrofjmc.org/the-hidden-risks-of-using-counterfeit-drugs/>

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Accessible Learning

- Bottle of Lies by Katherine Eban
- The global generic drug system is not nearly as safe, transparent, or trustworthy as most patients, prescribers, and regulators believe
- Offshoring + weak oversight = structural vulnerability
- Human cost = patients

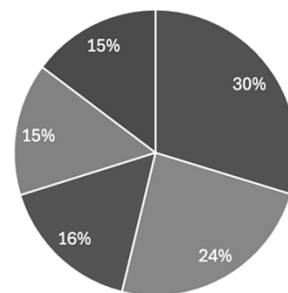


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Commonly Counterfeited Medications

- Opioid pills
- Anti-infectives
- Erectile dysfunction medications
- Cardiovascular drugs
- Expensive drugs that have with a substantial market (cancer, weight loss, etc.)

Counterfeit incidents and Therapeutic Categories



■ Genitourinary ■ Central Nervous System ■ Metabolism ■ Cytostatic ■ Dermatological

Pathak, R et al. *Pharmaceut Med*. 2023;37(4):281-290; Barrett D, Dvoskin E. *The Washington Post*, September 27, 2021; Hirsch JA, Mandel S. *NYMR FJMC*. <https://newyorkmetrofjmc.org/the-hidden-risks-of-using-counterfeit-drugs/>

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Counterfeit Drugs' Dangers

- Lack of effectiveness
- Toxicity associated with adulterants
 - Excipients include rat poison, drywall, and fentanyl
- Drug resistance
- Loss of confidence in the Pharmaceutical industry or health care system
 - ↑ need for care (treating > just underlying disease/condition)
 - ↑ out of pocket expenses and burden on healthcare providers
- Diversion of funds to organized crime

Malware attached to the seller's site is also a serious risk, as is credit card theft

Maffioli EM, et al. *BMJ Glob Health*. 2025;10(6):e017078; NABP Position Statement. NABP. <https://nabp.pharmacy/news/news-releases/fighting-fake-medicines-sold-online-requires-commitment-to-cautioning-patients/>

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Antimicrobial Resistance

Antimicrobial resistance (AMR) is a growing concern



Counterfeited antibiotics and AMR common in many regions and countries

High AMR in Africa with > 50% counterfeit antibiotics in Ghana but low counterfeited antibiotics in Sierra Leone.

> 20% AMR in Asia with counterfeit antibiotics making up < 40%

Insufficient doses of the API may increase antibiotic resistance

More evidence needed for conclusive results

Maffioli EM, et al. *BMJ Glob Health*. 2025;10(6):e017078.

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Diversion of Funds to Organized Crime

- Counterfeiting medications is \$75 billion market!
- Usually distributed by illegal online pharmacies CW2
- Roughly 30,000 to 40,000 illegal online pharmacies
- Many sell products made from research grade chemicals in laboratories owned by criminal organizations

Hirsch JA, Mandel S. NYMR FJMC. <https://newyorkmetrofjmc.org/the-hidden-risks-of-using-counterfeit-drugs/>; NABP. <https://nabp.pharmacy/news/news-releases/fighting-fake-medicines-sold-online-requires-commitment-to-cautioning-patients/>

SE1

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Which one is counterfeit?

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Slide 13

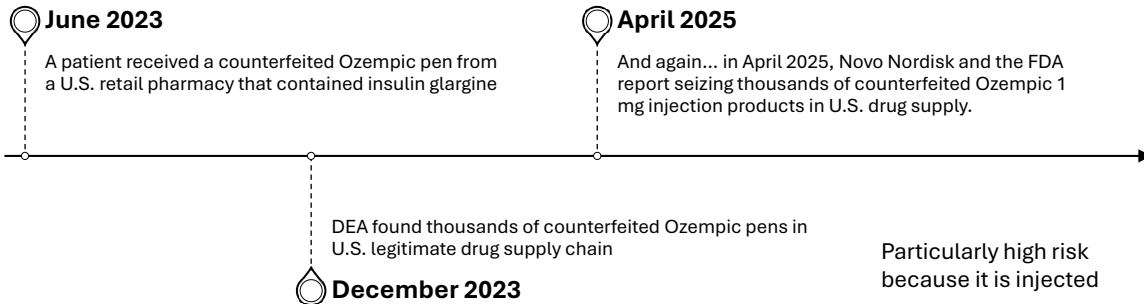
SE1 Was not sure how to cite this source in the correct format

Szydlo, Emily, 2025-11-24T19:11:43.045

CW2 Overseas a major source is integrated into the legitimate drugs supply but in the US, it is via illegal online pharmacies. The next source is unlicensed pharmacies near tourist areas in foreign countries.

White, Charles, 2025-11-29T22:09:24.957

Case #1: Counterfeit Ozempic... just from illegal online pharmacies?



Blum D. Are You Sure Your Ozempic Is Real? Fakes Are on the Rise. The New York Times. July 12, 2024; FDA. FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain>; NABP. <https://nabp.pharmacy/news/news-releases/fighting-fake-medicines-sold-online-requires-commitment-to-cautioning-patients/>

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Case #2: Counterfeit Avastin in U.S. Clinic

- Avastin is an expensive angiogenesis inhibitor used with chemotherapy in treating cancer
 - And for macular degeneration and diabetic macular edema
- U.S. health clinics (usually) unknowingly obtained counterfeit versions including product that contained no drug but other substances like cornstarch and common solvents from gray markets.
- However, some physicians knew it was counterfeit and purchased it through the gray market for the deep discounts and potential for greater profit

Mackey TK, et al. *Nat Rev Clin Oncol*. 2015;12(5):302-308.

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It's Epidemic

Been Counterfeited

Antimalarial drugs

Bevacizumab

Erythropoietin

Gemcitabine

Oxaliplatin

Pegfilgrastim

Rituximab

Zoledronic acid

Bevacizumab


- Distributer in Egypt
- → Distributer in Switzerland
- → Distributer in Denmark
- → Distributer in U.K.
- → Distributer in U.S.
- → Sent to 19 physicians

Stewart MW, et al. *Am J Ophthalmol.* 2016;170:228-231.

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The Gray Market

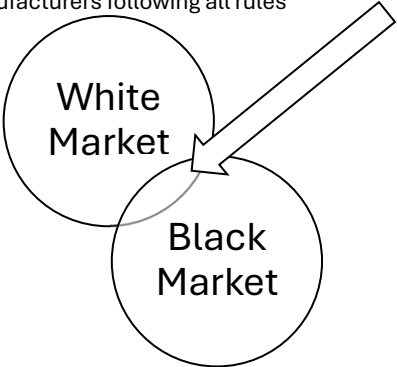
- A market outside of the primary legal pathway
- Quasi-regulated, unofficial channel for drug distribution
- This market's business practices include
 - Steep markups on (on drugs in short supply especially)
 - Aggressive marketing
 - Pumping stolen or adulterated drugs into controlled drug markets

Mackey TK, et al. *Nat Rev Clin Oncol*. 2015;12(5):302-308.

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The Gray Market

Fully legitimate, licensed wholesalers and manufacturers following all rules



White Market

Black Market

Clearly illegal sales (e.g., outright counterfeit drugs, street sales, dark web)

- Diversion and re-routing of legitimate products
- Opportunistic buying during shortages
- Mixing real, degraded, and counterfeit products
- Use of questionable intermediaries
- Creates a high-risk channel where counterfeit, stolen, or mishandled products slip in

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Prevalence of Counterfeit Medications

A Pfizer study determined that ~ 80% of Viagra ordered online was counterfeit

The DEA has seized counterfeit pills in all 50 U.S. states and D.C.

38% of Americans know someone who received a counterfeited medication or substandard medication from an online pharmacy

Facing Off Against Counterfeit Online Pharmacies: Pfizer Launches New Purchasing Website To Help Alleviate the Guesswork Around Buying Legitimate Viagra® (sildenafil citrate) Online. Pfizer. 2013 https://www.pfizer.com/news/press-release/press-release-detail/facing_off_against_counterfeit_online_pharmacies
 _pfizer_launches_new_purchasing_website_to_help_alleviate_the_guesswork_around_buying_legitimate_viagra_sildenafil_citrate_online; Counterfeit Pills Fact Sheet. DEA 2021 https://www.deadiversion.usdoj.gov/mtgs/chem_industry/documents/Counterfeit_Pills_Fact_Sheet.pdf; NABP. <https://nabp.pharmacy/news/news-releases/fighting-fake-medicines-sold-online-requires-commitment-to-cautioning-patients/>

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Active Learning

Which of the following medications is MOST LIKELY to be counterfeited and why?

- A. Erectile dysfunction medications because of the quantity restrictions imposed by drug manufacturers
- B. Any class of medication used frequently by the elderly because of the large volume sold across the country
- C. Monoclonal antibodies and designer oncology drugs because of their high cost and large eligible patient pool

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Accessible Learning

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- *Law & Order: Criminal Intent*, Season 2, Episode 6 – “**Malignant**” (2002)
 - Inspired by the Robert Courtney chemotherapy dilution case
 - The tipoff was Gemzar with Lilly’s price \$73/dose and Courtney’s price \$63/dose WITH the tubing and saline
 - Affected >4200 patients
 - 98,000 prescriptions
 - Outrage upstaged by 9-1-1



Risk = Hazard + Outrage

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Diversion and Counterfeiting Schemes: What leads to counterfeiting?

-
- Profitable drugs- those who counterfeit generate easy profits
 - Drugs in short supply
 - Novel COVID-19 vaccines and existing treatments like hydroxychloroquine (from the pandemic for instance)
 - Public health crises

Pathak R, et al. *Pharmaceut Med*. 2023;37(4):281-290.

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Public Health Crisis: COVID-19 Pandemic

- Pandemic control measures
 - Border shut-downs:
 - Transport of raw materials for drug production obstructed
- The result: drug shortages
- Desperation for products in short supply
 - Vaccines, masks, etc. led to a market ripe for counterfeiting

Pathak, R et al. *Pharmaceut Med.* 2023;37(4):281-290.

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Global and National Approaches to Stop Counterfeiting

- The World Health Organization International Medical Products Anti-Counterfeiting Task Force
- The Drug Supply Chain Safety Security ACT
- Pharmaceutical Security Institute (PSI)
 - Pharmaceutical company funded
 - Does a lot of the leg work for the FDA and EMA

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Counterfeit Drug Cases

In October 2018, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and its partners discovered > 3 million medicines and medical devices in the UK supply chain were part of a fraudulent medication business worth £9 million (\$12 million)

In a sting called Operation Shield II, Europol seized > 25 million units of medicines with a value of around £63 million (\$83.4)

In 2009, within only two months, the European Union confiscated 34 million counterfeit pills



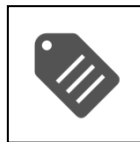
Pathak, R et al. *Pharmaceut Med.* 2023;37(4):281-290.

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Implications for Inpatient Pharmacy



Purchase from
reputable sources



Monitor for
differences in
packaging, labeling,
or general
appearance



Isolate suspect
products and initiate
an investigation to
detect the source

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Implications for Outpatient, Mail-order, and Online Pharmacies

- 95% of online retailers selling prescription medications are illegal (unsafe and unlicensed)
- 96% of online pharmacies do NOT require a prescription
- Help patients understand the characteristics of a safe online pharmacy:
 - Always requires a prescription from a prescriber
 - A licensed pharmacist is involved in the operation
 - Has a real physical address found in the U.S.
 - The website reflects licensure by the state pharmacy board
 - TRUST BUT VERIFY: Patients need to check the State Board website

@eSafeRx. FDA. <https://www.fda.gov/drugs/buying-using-medicine-safely/besafexr-your-source-online-pharmacy-information>; NABP. <https://nabp.pharmacy/news/news-releases/fighting-fake-medicines-sold-online-requires-commitment-to-cautioning-patients/>

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Implications for Outpatient, Mail-order, and Online Pharmacies



Purchase medications from reputable sources approved by regulatory drug control agencies



Keep records of delivered drug products to ensure traceability



Urge patients to report unexpected changes in their medications such as taste and appearance changes.

Pathak, R et al. *Pharmaceut Med.* 2023;37(4):281-290.

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Identifying Patients at High Risk

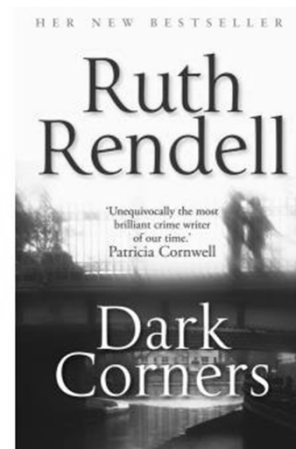
- Nations with weaker health systems and/or social protections
- Nations with disrupted supply chains
- Younger individuals
 - Social media advertising of counterfeit opioids
 - Greater trust in online pharmacies
- Those embarrassed by their medical conditions
 - Obesity
 - Erectile dysfunction

World Health Organization. WHO global surveillance and monitoring system for substandard and falsified medical products. 2017. <https://iris.who.int/handle/10665/326708>; Hirsch JA, Mandel S. NYMR FJMC. <https://newyorkmetrofmjmc.org/the-hidden-risks-of-using-counterfeit-drugs/>

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Accessible Learning

- Dark Corners by Ruth Rendell (2015)
 - Her swansong
- Carl Martin, inherits his father's cache of odd remedies, including a diet pill linked to several deaths.
- He sells the pills on the back market, a fatality ensues, and a tenant begins blackmailing him
- Prepare for a slow, claustrophobic spiral of guilt, fear, and moral compromise

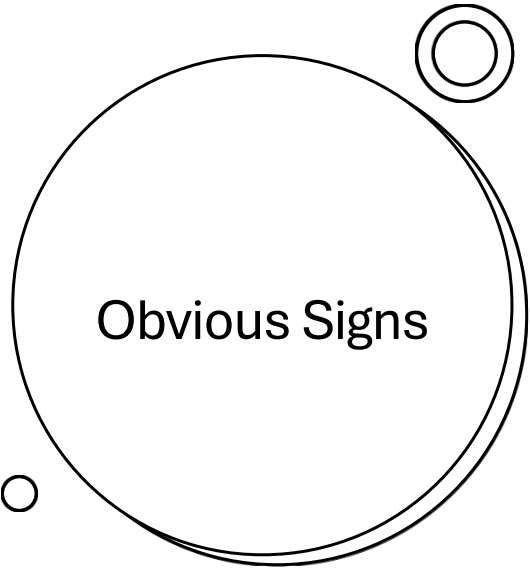


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At the Patient Level

- Novo Nordisk and Eli Lilly have online tools for patients to identify genuine products
 - https://www.novomedlink.com/semaglutide/patient-safety.html?utm_medium=vanity&utm_source=semaglutidedotcom-redirect&utm_campaign=vanity-redirect&utm_content=semaglutidedotcom-redirect
 - <https://investor.lilly.com/news-releases/news-release-details/open-letter-eli-lilly-and-company-regarding-certain-practices>
- Pharmaceutical companies keep track of complaints and accumulate data on counterfeits

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- Counterfeit medications can have subtle irregularities
 - Spelling or grammatical mistakes any place on the labeling
 - Or no label
 - Compromised packaging
 - Mold or excess powder in the vial or package
 - Flimsy labels that stick poorly to the pen or bottle

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BeSafeRx



<https://www.fda.gov/drugs/buying-using-medicine-safely/besaferr-your-source-online-pharmacy-information>



Source for Online
Pharmacy Information

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Detection Methods for Counterfeit Drugs

Color based chemical kits

Pharma code or bar codes

Serial authentication number

Radio frequency identification tags

Track and trace technologies

Overt, covert, and forensic security features

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Active Learning



A 22-year-old college student attends a weekend rave. Near the dance floor, there's a large bucket of mixed pills in different colors and shapes. Friends tell him, "Take a few—everyone does it." He's curious but also nervous. He wants to minimize risk and understand what substances might be present before taking any pills.

Which of the following is the **MOST APPROPRIATE** risk reduction step for him to take?

- A. Nibble a very small piece of one pill first and wait 15 minutes; if he feels okay, he can assume the pills are safe and take the rest.
- B. Use a reputable test kit (e.g., reagent test, fentanyl test strip) and avoid taking any pills that he hasn't checked.
- C. Choose only pills that are a familiar color and look (e.g., something he's seen online) because these are most likely to be genuine.



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Colorimetry & Color-based Chemical Kits

A chemical is used to react with the anticipated API

In the presence of the API, a color change chemical reaction occurs

Paper Analytical Device (PAD) is an example of this

Has more than one color changing agent
Drug powder is applied to the card which is placed upright in a vessel with a small amount of water
A color code for each legitimate API must be made

Bakker-'t Hart IME. et al. *J Pharm Biomed Anal.* 2021;197:113948.

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Identifying and tracking products

- Methods include
 - Barcodes (often 2D)
 - Radio frequency identification tags
 - Serialization numbers
- Used to identify products
- Often can be linked to apps

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Quickie Barcode Primer

<p>1D barcode</p> <ul style="list-style-type: none"> • Looks like a series of vertical black bars • Data is stored in one direction (left to right) • Holds a small amount of information (usually just a product number) 	<p>2D barcode</p> <ul style="list-style-type: none"> • Looks like: a square or rectangle with patterns of dots, squares, or other shapes • Data is stored in both directions (left-right <i>and</i> up-down) • Can store much more information <ul style="list-style-type: none"> • Product ID • Lot/batch number • Expiration date • Serial number • URLs or text
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(K) PO Number: 1234567891234

 (4K) PO Line: 17

 (P) DigiKey Part Number: DK-PART777A1

 (1P) Supplier Part Number: PART-XAF4444


 (Q) Quantity: 000010

 (3S) Packing Slip:


=

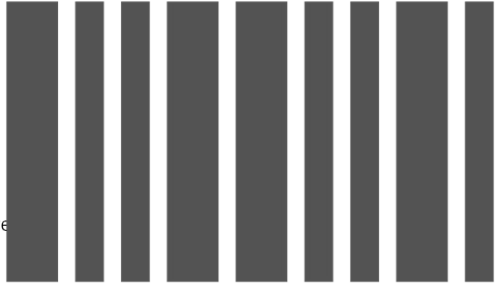


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Downsides

- Major downside is that counterfeiters sometimes replicate legitimate packaging
- RFID tags can be very pricey for pharmacies
- Serialization means more steps and check points along the production to distribution pathway
- Means manufacturers, distributors and reseller may fall behind on deadlines for regulatory agencies



Bakker-'t Hart, I.M.E. et al. *J Pharm Biomed Anal.* 2021;197:113948; Sansone, A et al. *Sex Med.* 2021;9(6):100437.

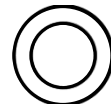
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Active Learning

During an internal audit, a technician asks, “When we receive prescription drugs from a wholesaler, what information are we required to get and keep so we can verify where each product came from if there’s a recall or a counterfeiting investigation?” Which answer best reflects the Drug Supply Chain Security Act (DSCSA) requirements?

- A. A complete pedigree including product identifier and transaction information, history, and statements from trading partners
- B. Only the manufacturer’s lot number/expiration date and the product’s NDC
- C. An invoice showing the purchase price and quantity, the lot number/expiration date, and the package insert

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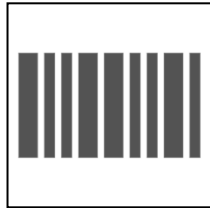
- In the US, President Obama signed the Drug Quality and Security Act (DSCSA) into law in 2013.
- Requires pharmaceutical companies to implement track-and-trace systems for prescription drugs to increase supply chain transparency from manufacturer to pharmacy.
- BONUS: Serialization technologies can help provide a better understanding of the efficiency of the production line

Track and Trace (Serialization)

Hand S. Will Pharmaceutical Serialization Solve All of Our Drug Counterfeiting Problems? Xtalks. March 17, 2017.
<https://xtalks.com/pharmaceutical-serialization-drug-counterfeiting/>

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Track and Trace



A system that gives each stock item or unit a unique identification number



Manufacturers assign the number and attach it to the product where it remains until it has been consumed.

Pathak, R et al. *Pharmaceut Med.* 2023;37(4):281-290.

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Overt, Covert, Forensic Security Features

- Overt technology
- Uses visible technology
- No need for special technology
- Often optical tools like holograms, color-shift ink, and UV sensitive ink
- Deters counterfeiters because hard to replicate




Pathak, R et al. *Pharmaceut Med.* 2023;37(4):281-290.

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Overt, Covert, Forensic Security Features

- Covert technologies
 - Cannot be seen by the human eye
 - Requires use of another technology to read
 - Examples:
 - RFID
 - Some UV sensitive inks



Pathak, R et al. *Pharmaceut Med.* 2023;37(4):281-290.

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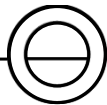


Overt, Covert, Forensic Security Features

- Medical investigations in hospitals and using autopsy
- Chemical and non-chemical drug investigations in forensic toxicology laboratories
- National and global coordinated investigations
- Digital abductive logic/reasoning

Kruger E. *Perspect Legal Forensic Sciences*. 2025;2(2):10005.

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CONCLUSION

- Purchasing counterfeit goods is illegal and transporting those goods into and throughout the U.S. may result in civil or criminal penalties.
- Criminal penalties for trafficking counterfeit goods can include fines of up to \$2 million, 10 years in prison, or both.

The Truth Behind Counterfeits. U.S. Customs and Border Patrol. <https://www.cbp.gov/trade/fakegoodsrealdangers> U.S. Customs and Border Protection

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