Counterfeit Drugs
A growing global industry with incalculable risks

What Physicians Need to Know
WHAT IS A COUNTERFEIT DRUG?

A counterfeit drug is a fake or imitation drug that may be made with:

- the wrong dose of medicine
- no dose of medicine
- toxic or harmful ingredients leading to adverse effects, treatment failure or resistance, or death
In the News: Feb 2023
Fentanyl Laced Pills

"Fentanyl is killing our kids. We are angry about it. We are heartbroken about it. And we are determined to do all we can about it."

"Make no mistake: Unless it comes from a licensed medical provider, that pill your child thinks is Percocet or, OxyContin, or Xanax, or Adderall, may actually be fentanyl -- and if it is fentanyl, chances are, even a small part of one pill may be deadly."

FDA warned in a statement that the counterfeit drug "does not contain any of the two active pharmaceutical ingredients stated on the label, hence can be classified as falsified."

https://www.medpagetoday.com/hematologyoncology/leukemia/99981
According to Advanced Local, a multi-agency investigation in Decatur led to the seizure of 10,000 to 12,000 controlled substance tablets including counterfeit pills that were presumed to be Xanax (Alprazolam)

IN THE NEWS: JULY 2022
IMATINIB SOLD AT ‘ROGUE’ ONLINE PHARMACIES

“Of 44 online pharmacies selling the drug to U.S. customers, 52% of which were classified as ‘rogue,’ 30% as ‘unapproved,’ and 11% as ‘unclassified’...

13 didn’t require a prescription for imatinib, and only three asked about patients' health status, reported Sachiko Ozawa, PhD, MHS, of the University of North Carolina at Chapel Hill, and colleagues.”

https://www.medpagetoday.com/hematologyoncology/leukemia/99981
“ROGUE PHARMACIES AND ABORTION PILLS”

Although abortion rights are now in the hands of the states, medication abortion may still be available for those who live in abortion-restrictive states.

“Anytime you create a fractured health care system or fractured supply chain, that confusion is going to be taken advantage of by criminals,” said John B. Hertig, an associate professor of pharmacy practice at the Butler University College of Pharmacy and Health Sciences.”
The scope of the problem

An industry worth billions

- The counterfeit drug industry is a growing global industry potentially worth hundreds of billions of US dollars

Affects patented and generic drugs

- Both patented and generic drugs may be falsified, ranging from life-saving antibiotics and chemotherapeutics to erectile dysfunction treatment

Exploits low and middle-income countries

- The World Health Organization (WHO) estimates that approximately 1 in 10 medical products in low- and middle-income countries is substandard or falsified

https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
BEWARE OF ONLINE PHARMACIES

• A 2013 analysis by the National Association of Boards of Pharmacy (NABP) demonstrated that more than 97% of online sites selling prescription medications were operating illegally.

REPORT SUSPICIOUS ACTIVITY TO THE FDA

• From 2016 to 2021, the FDA took 130 unique enforcement actions against counterfeit medication rings.
• Although estimates indicate that less than 1% of prescription medication sold in the U.S. are counterfeit, U.S. patients may purchase medicines from fraudulent online pharmacies.

• Counterfeit products may also enter the supply chain when legitimate suppliers of a high-demand, expensive medication cannot meet market demand, forcing pharmacists to seek alternative suppliers (for eg, Tamiflu during influenza season).

https://www.japha.org/article/S1544-3191(15)30456-8/fulltext
TAMIFLU AND LIPITOR - CAN YOU TELL THE DIFFERENCE?

BY THE U.S. FDA

https://www.flickr.com/photos/fdaphotos/sets/72157625426153869/
COUNTERFEIT DRUGS

MAY CONTAIN...

- *no* active ingredient,
- the *wrong* active ingredient, or
- the right ingredient in the *wrong* quantity

MAY BE EXTREMELY DANGEROUS BECAUSE THE CONSUMER IS UNAWARE OF THE POTENTIAL FOR TOXICITY—FOR EXAMPLE, THEY MAY...

- Contain heavy metals,
- Be laced with lethal amounts of fentanyl
- Carry risk of infection from fungal and bacterial infection due to unsanitary conditions,
- Lead to treatment resistance or failure, or death

https://www.dea.gov/factsheets/counterfeit-pills
CONTENTS OF CONFISCATED COUNTERFEITED VIAGRA PURCHASED ONLINE

• blue printer ink
• speed or amphetamine
• Metronidazole (Flagyl) antibiotic
• drywall or plaster
• other ingredients and dyes used for intent to mimic the authentic drug

(according to a Forbes interview with Roger Bate, American Enterprise Institute scholar and author of *Phake: The Deadly World of Falsified and Substandard Medicines*)

U.S. PHARMACIST CITES DRUGS MOST OFTEN COUNTERFEITED

Expensive medications in high demand such as:

- chemotherapeutics
- antibiotics, anti-malarials, anti-virals
- anti-anxiety drugs or other antipsychotics
- vaccines
- hormones including steroids
- erectile dysfunction treatments
- weight loss aids
- analgesics

https://www.uspharmacist.com/article/counterfeit-meds
WHAT IS BEING DONE TO MAINTAIN SAFETY OF THE U.S. DRUG SUPPLY CHAIN?

• the FDA is implementing “key provisions of the Drug Supply Chain Security Act (DSCSA),” including:
  • an “interoperable, electronic tracing of product at the package level”
  • electronic review of all imported shipments of FDA-regulated products

• the FDA has issued anti-counterfeiting guidance for “pharmaceutical manufacturers who want to use physical-chemical identifiers (PCIDs) in solid oral dosage forms

https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine
How to purchase drugs safely online

The National Association of Boards of Pharmacy (NABP)'s AwareRx.org

The NABP's "List of Not Recommended Websites"

The FDA's BeSaferX

Purchasing online will always carry inherent risks not present when purchasing from a state-licensed pharmacy.

The following sites, however, help consumers shop more safely online:

- The National Association of Boards of Pharmacy (NABP)'s AwareRx.org
- The NABP’s "List of Not Recommended Websites"
- The FDA’s BeSaferX
The FDA’s BeSafeRx checklist for safe online pharmacies:

• Is a prescription from a healthcare professional required?

• Is there a physical U.S. address and telephone number?

• Is a U.S. licensed pharmacist on staff to answer your questions?

https://www.fda.gov/drugs/besafex-your-source-online-pharmacy-information/locate-state-licensed-online-pharmacy
How do I report adverse events related to the use of suspect medicines?

Complete and submit the report online:

- www.fda.gov/MedWatch/report.htm, or

- call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178