

Counterfeit Drugs

A growing global industry with incalculable risks

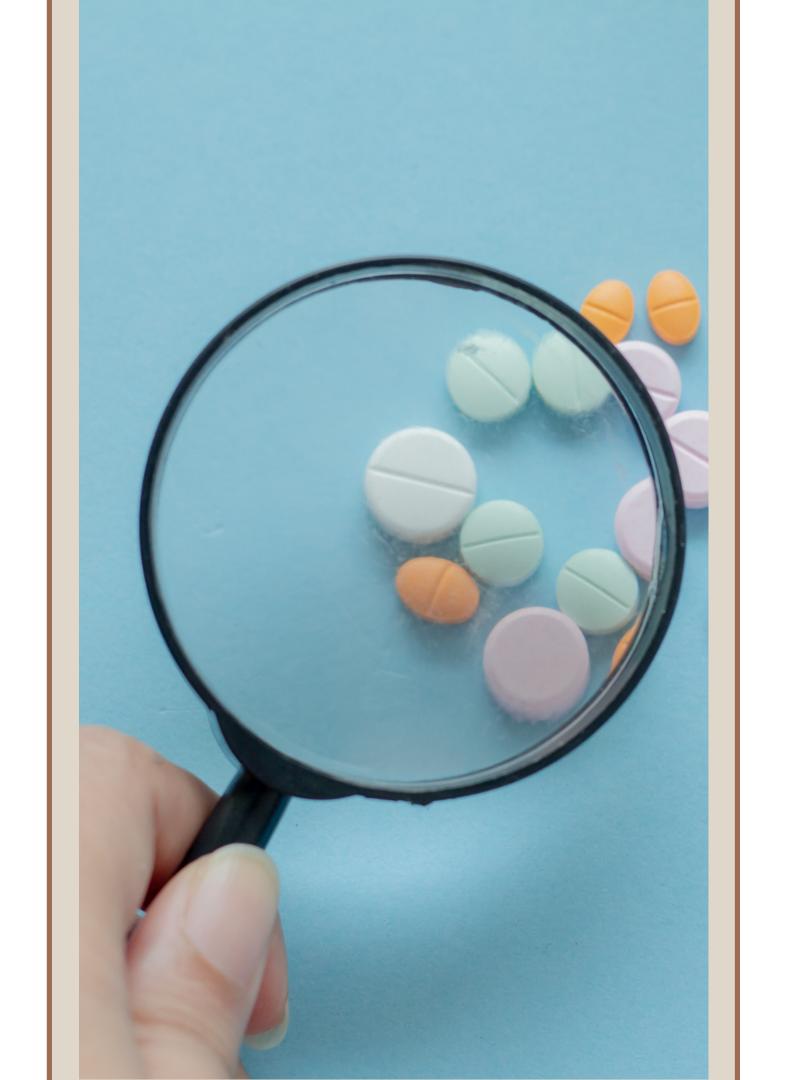
What Physicians Need to Know



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 beartbroken 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."

IN THE NEWS: FEB 2023 FDA WARNS AGAINST COUNTERFEIT ANTI-MALARIAL DRUG COMBIART TABLETS

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."

FDA warns public against counterfeit antimalarial drug COMBIART Tablets



Food and Drugs Authority (FDA) has cautioned the general public against patronising a counterfeit antimalarial drug, COMBIART Tablets (Artemether/Lumefantrine 20/120) on the market.

FDA warned that the counterfeit drug doesn't contain any of the two active pharmaceutical ingredients it claims to have.

IN THE NEWS: JULY 2022 COUNTERFEIT XANAX IN NORTH ALABAMA

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."

"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

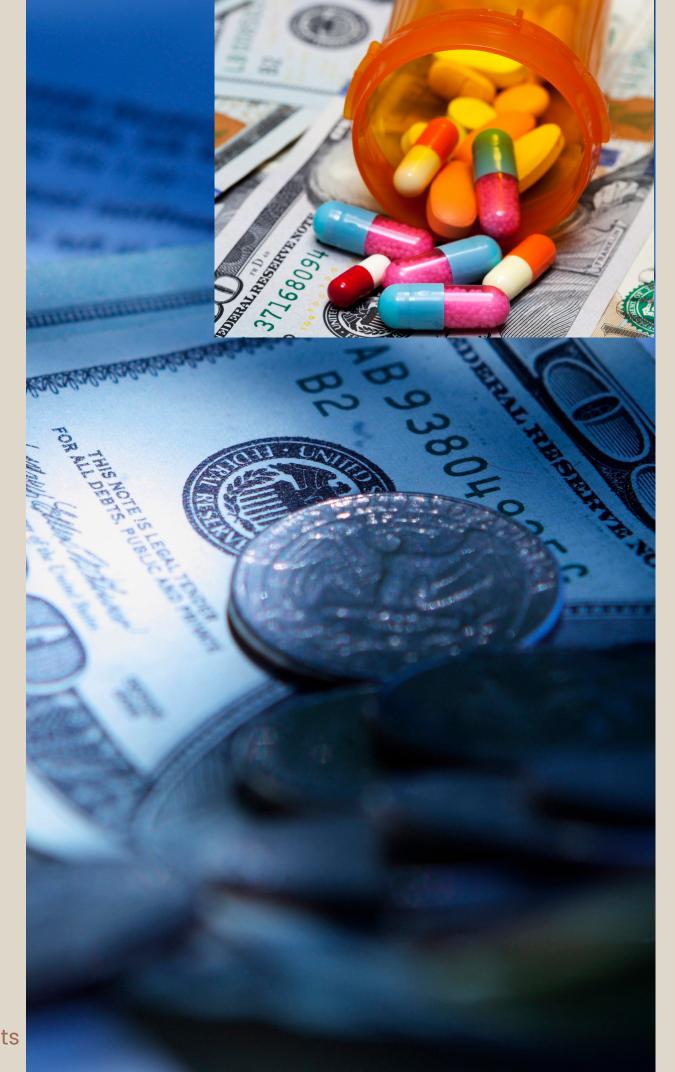
•The counterfeit drug industry is a growing global industry potentially worth hundreds of billions of US dollars

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

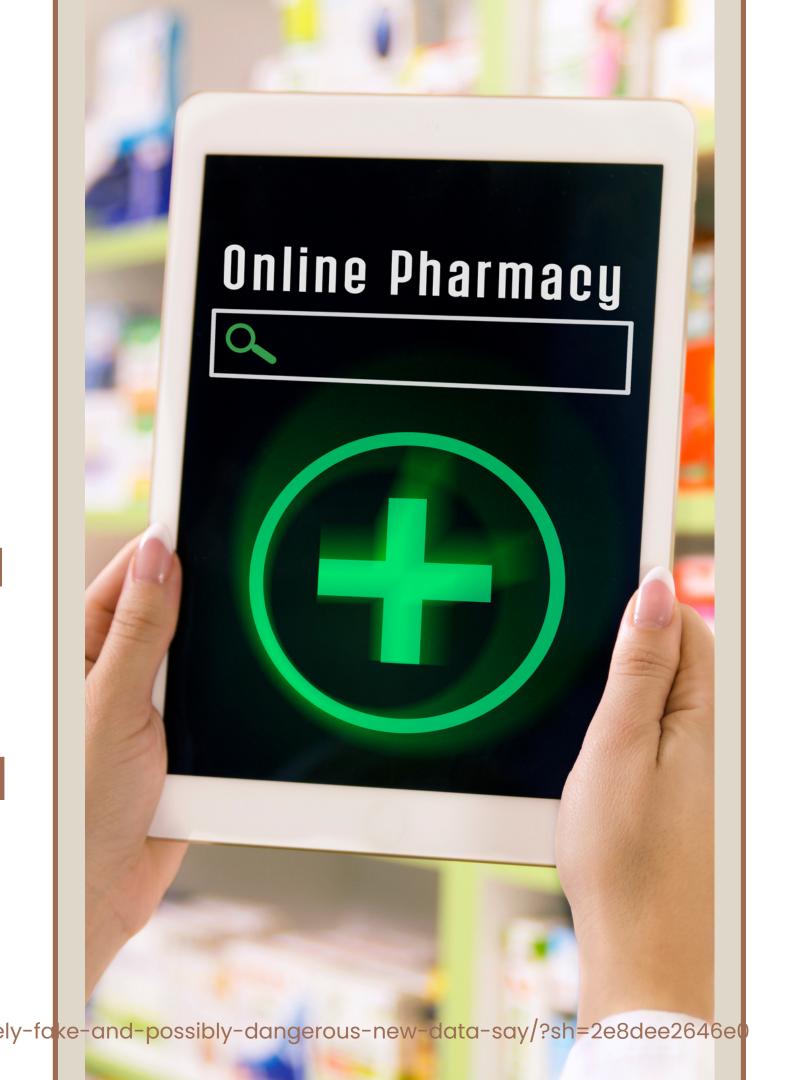


BEWARE OF ONLINE PHARMACIES

•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



https://www.forbes.com/sites/melaniehaiken/2013/09/12/buying-viagra-online-its-very-likely-fake-and-possibly-dangerous-new-data-say/?sh=2e8dee2646e0https://journals.sagepub.com/doi/10.1177/10600280221092482

ARE COUNTERFEIT DRUGS A PROBLEM IN THE U.S.?

- •Although estimates indicate that <u>less than 1%</u> of prescription medication sold in the U.S. are counterfeit, U.S. patients may purchase medicines from fraudulent online pharmacies1
- •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)

TAMIFLU AND LIPITOR CAN YOU TELL THE DIFFERENCE?

BY THE U.S. FDA





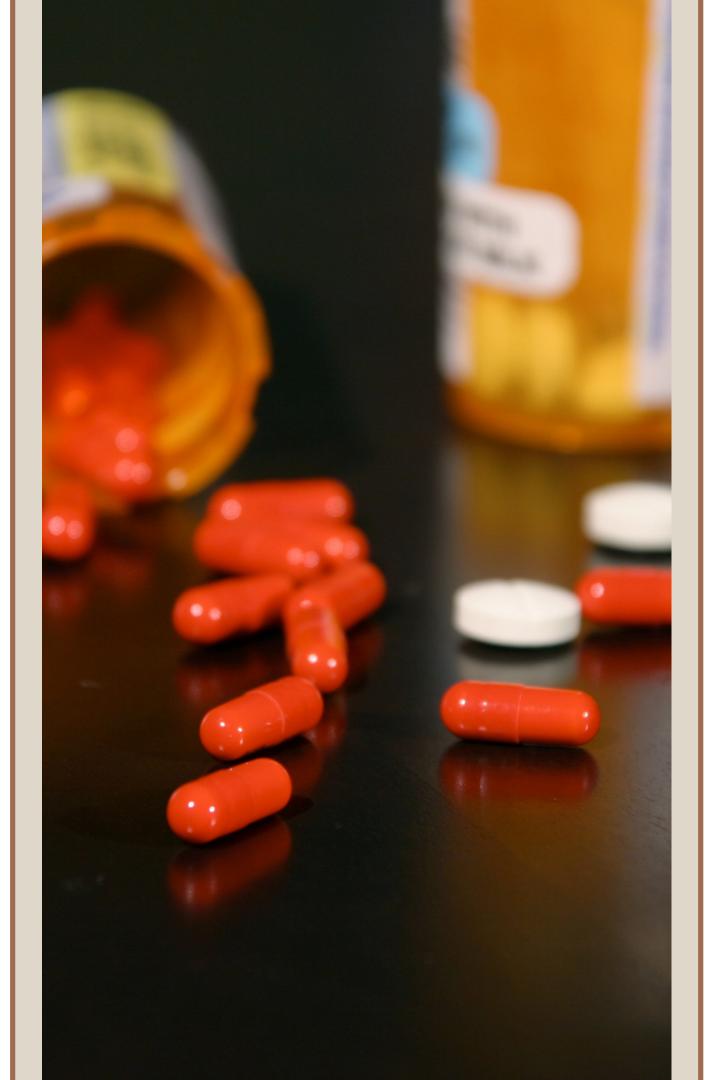
COUNTERFEIT DRUGS

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



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 Institue scholar and author of *Phake*: *The Deadly World of Falsified and Substandard Medicines*)

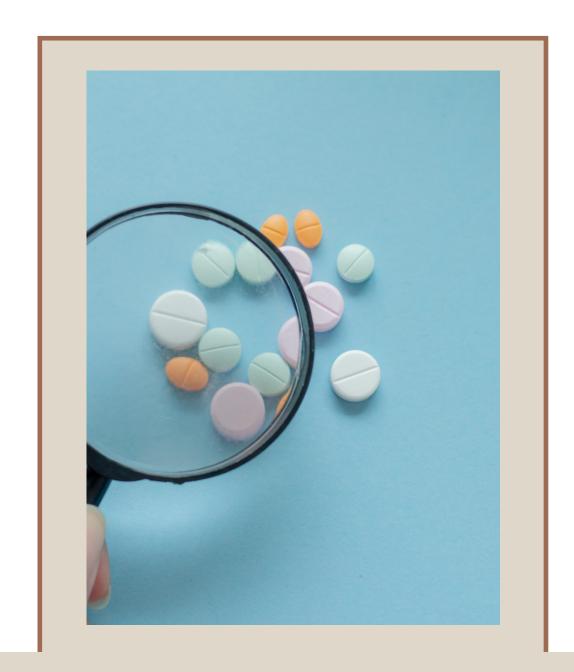
U.S. PHARMACIST CITES DRUGS MOST OFTEN COUNTERFEITED

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

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

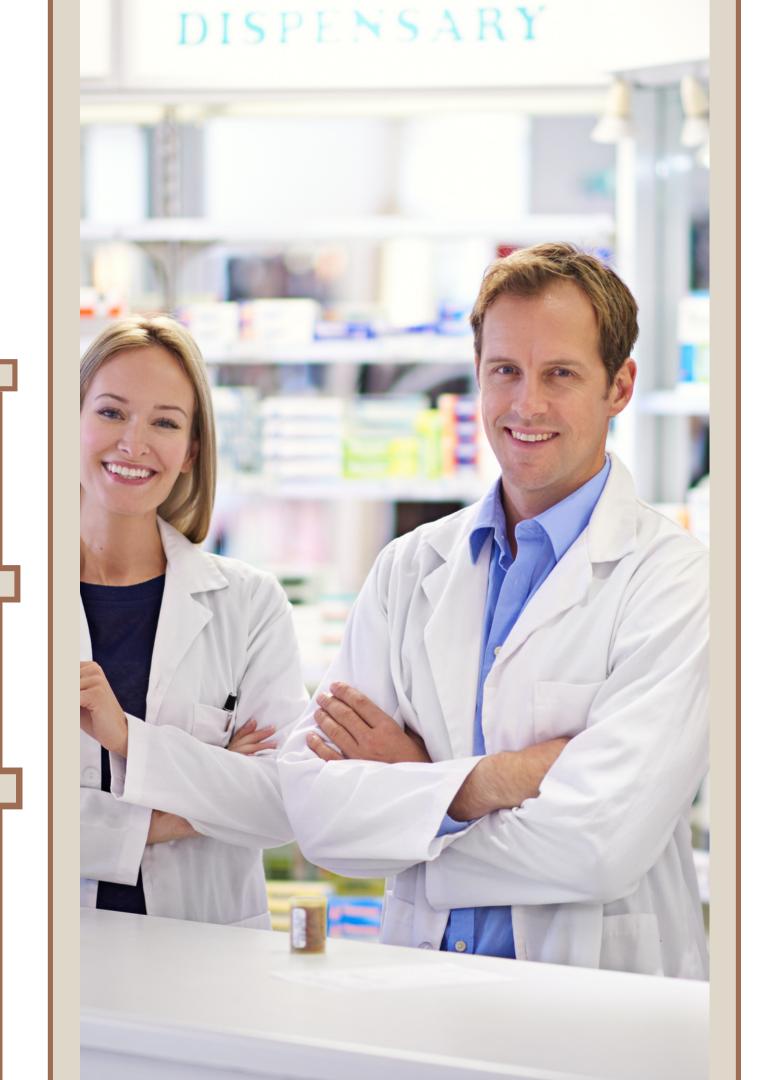


HOW TO PURCHASE DRUGS SAFELY ONLINE

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?



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

