



American Medical Women's Association

# 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."***



# 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.**"

<https://www.medpagetoday.com/hematologyoncology/leukemia/99981>

### FDA warns public against counterfeit anti-malarial 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



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

- 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<sup>1</sup>
- 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

<https://www.dea.gov/factsheets/counterfeit-pills>

<https://wgntv.com/news/wgn-investigates/fake-pills-flooding-the-country-targeting-teens/>



# 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

# 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](https://www.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](http://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

