



# Counterfeit Drugs

A growing global industry with incalculable risks

**What Patients 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



# 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
- 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



# THE SCOPE OF THE PROBLEM



- The counterfeit drug industry is a *growing* global industry potentially worth hundreds of billions of US dollars
- 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
- 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=2e8dee2646e0>

<https://journals.sagepub.com/doi/10.1177/10600280221092482>



# 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 PHARMACEUTICALS 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) [AWARERX.ORG](http://AWARERX.ORG)
- THE NABP “LIST OF NOT RECOMMENDED WEBSITES”
- THE FDA **BESAFERX** RESOURCE



# 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

