

### Counterfeit Drugs

A growing global industry with incalculable risks

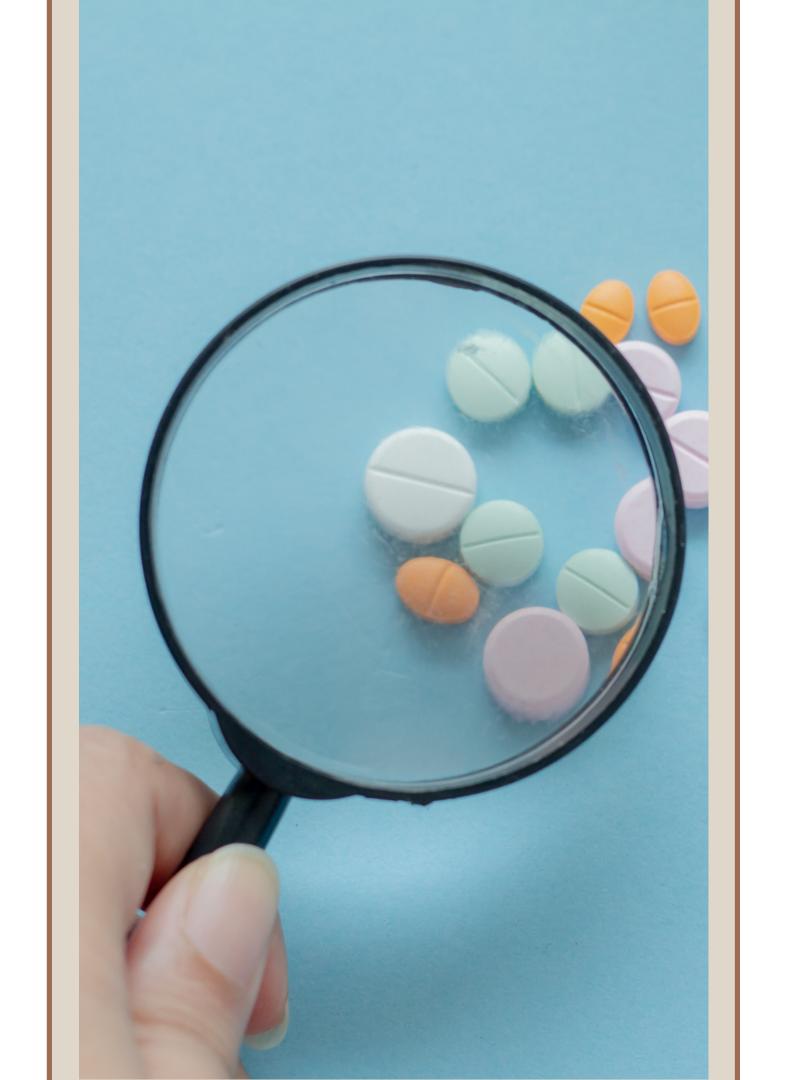
What Patients Need to Know



## 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

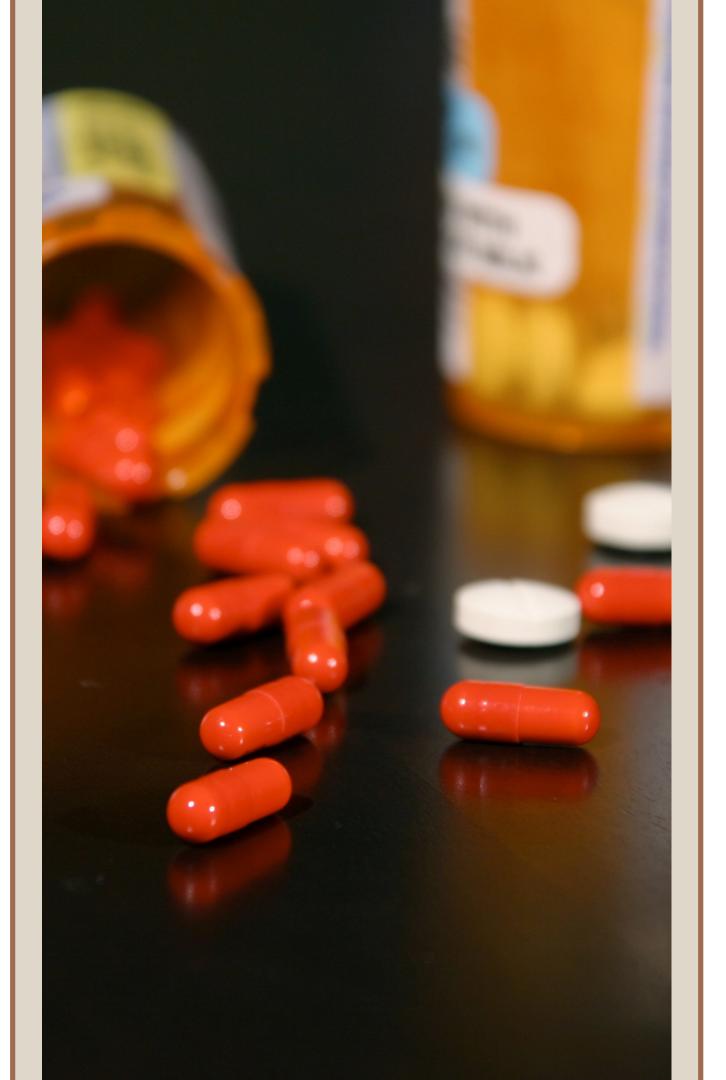
### COUNTERFEIT DRUGS

#### **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)

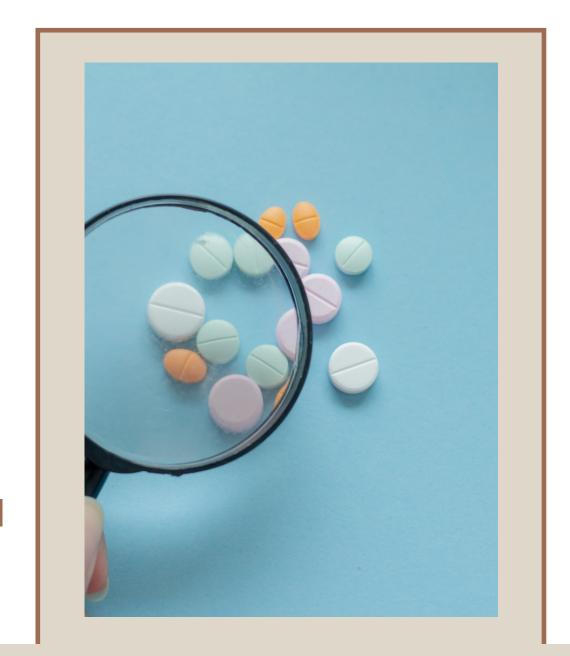
## U.S. PHARMACIST CITES DRUGS MOST OFTEN COUNTERFEITED

#### 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

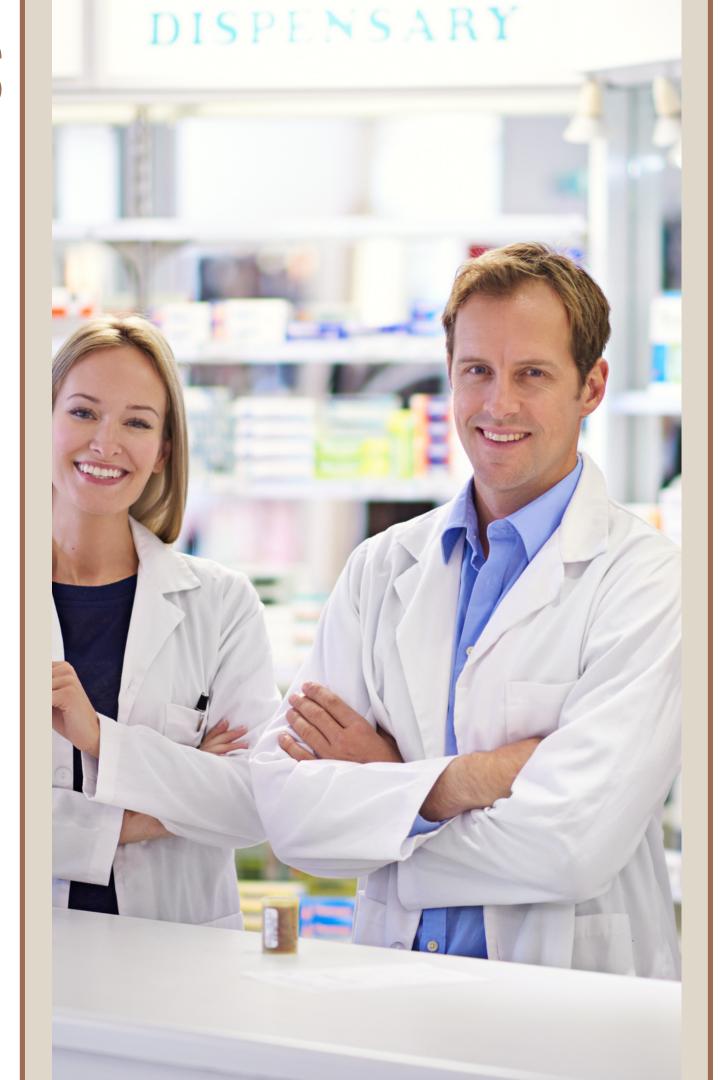


### HOW TO PURCHASE PHARMACEUTICALS SAFELY ONLINE

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
- 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, 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

