

Challenges Investigating and Prosecuting Pharmaceutical Crime

UNODC TECHNICAL CONFERENCE ON TRAFFICKING IN FRAUDULENT MEDICINES

February 14-15, 2013

Vienna, Austria

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- Views offered in this presentation are my own views, and not necessarily views of the Department of Justice.

DOJ/CONSUMER PROTECTION BRANCH AUTHORITY

- CPB “is responsible for criminal and civil litigation and related matters arising under the Federal Food, Drug, and Cosmetic Act (FDCA) and other federal statutes that protect public health and safety.”

http://www.justice.gov/civil/cpb/cpb_home.html

THE PROBLEM

- Large quantities of prescription drugs coming in from “Canada” and other countries create challenges for Customs and Border Protection & FDA.
- “Prescription drug abuse is the Nation’s fastest-growing drug problem.” (United States Office of National Drug Control Policy, 2011)



THE PROBLEM

- Trade/B2B sites: anyone with a computer can now become a drug wholesaler



THE PROBLEM

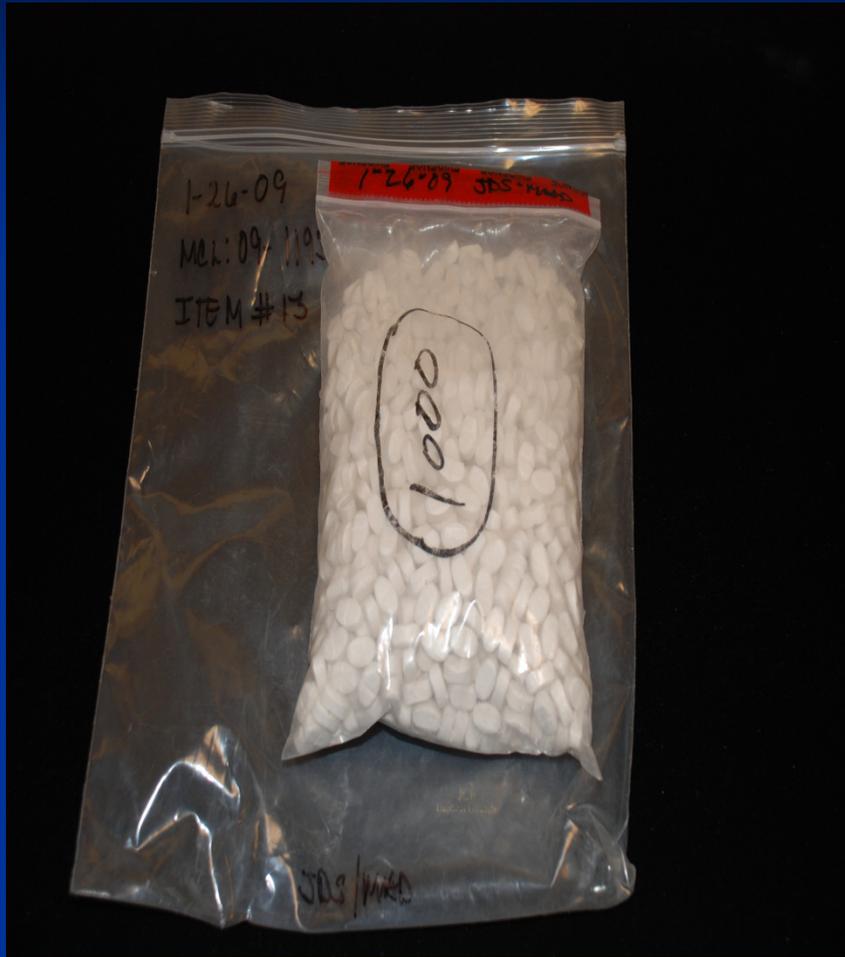
- Physicians are ordering directly from unlicensed brokers/wholesalers
 - Receiving drugs not approved for U.S. market
 - Receiving drugs not properly stored and shipped
 - Receiving counterfeits

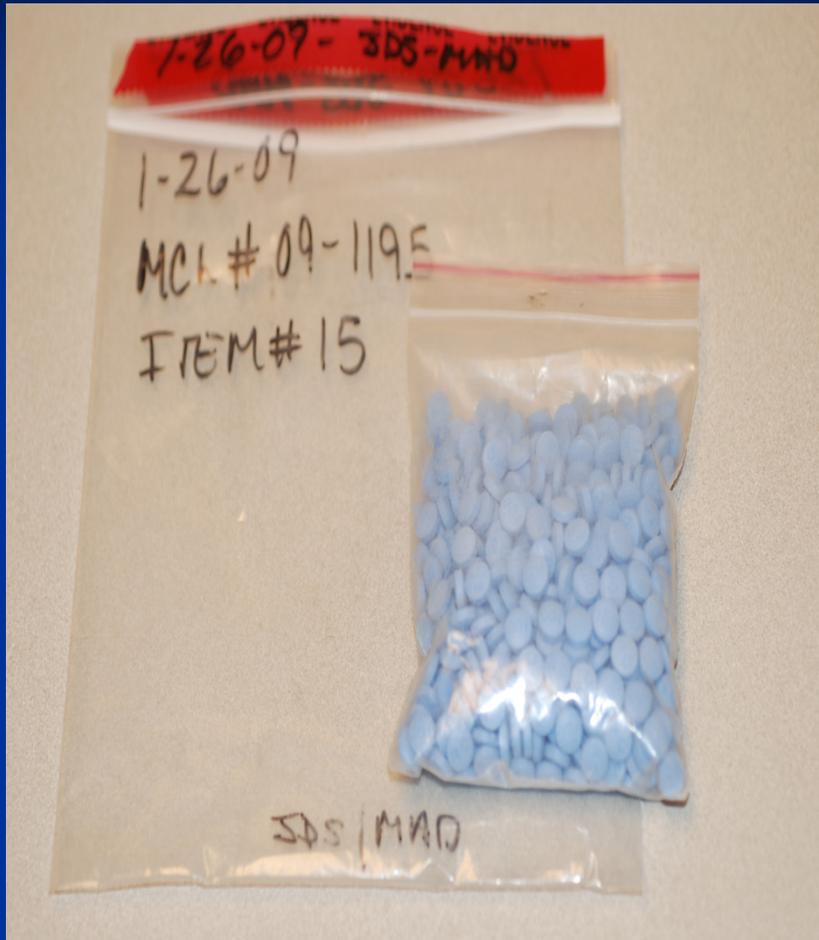
Unapproved/Counterfeit Drugs

- Drugs can be counterfeit, unapproved, misbranded:
 - Contains API – too much/too little
 - Different API (sildenafil vs. tadalafil)
 - No API
 - Harmful/toxic ingredients

Direct Customer Orders

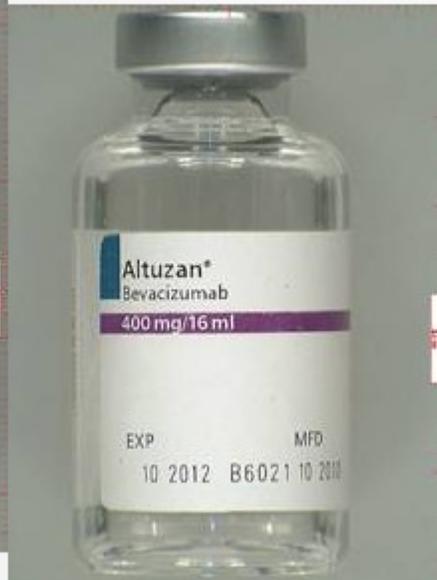




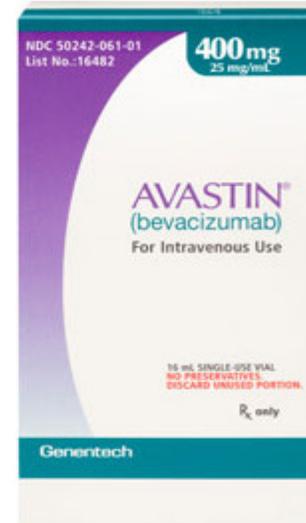


Physicians looking for cheaper suppliers

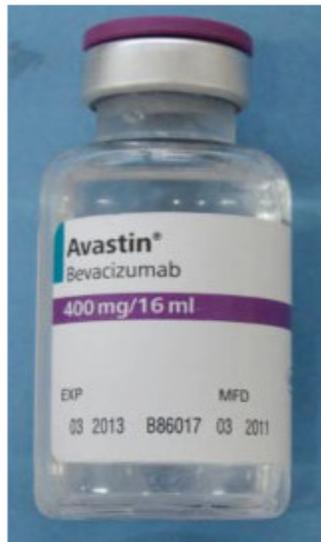
UNAPPROVED & COUNTERFEIT



Authentic Avastin FDA-Approved for Use in the United States



Counterfeit Product







Keppra, Anti-epileptic



Arimidex, Breast cancer



Casodex, Prostate cancer



Aricept, Alzheimer's

U.S. Criminal Prosecutions

- Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq.
- Counterfeit drug provisions:
 - Selling, dispensing, or holding for sale counterfeit drug
 - Making, selling, controlling things used to print/imprint drug, container, or labeling
 - Mimicking a drug mark, stamp, tag or label

U.S. Criminal Prosecutions

- Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq.
- Misbranded/adulterated drug provisions
 - **Misbranded** - includes false or misleading labeling
 - **Adulterated** - includes differing in strength, quality, or purity from the standards set forth in an official compendium

U.S. Criminal Prosecutions

- FDCA – FDASIA Amendments
 - July 2012: new 20 year maximum term of imprisonment/\$1 million USD fine for knowingly & intentionally adulterating a drug
 - Key element: “reasonable probability of serious adverse health consequences or death”

U.S. Criminal Prosecutions

- Trademark infringement, 18 U.S.C. § 2320
 - July 2012: new 20 year maximum term of imprisonment /\$5 million USD fine for trafficking counterfeit drugs
- Mail fraud, wire fraud
- Conspiracy to commit other offenses
- Money laundering – international monetary transactions

Global Challenges

- Tracing **money**
 - Phony or shell names
 - Intermediaries
 - Bank and wire transfer details

Global Challenges

- Tracing **packages**
 - Phony names/addresses
 - False customs declarations
 - Drop shippers/re-packagers
 - Multi-jurisdictional businesses

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"On the Internet, nobody knows you're a dog."

Global Challenges

- Identification of key players
- VOIP telephones
- New websites

Global Challenges

- FORMAL REQUESTS
 - Mutual Legal Assistance Treaties/Letters Rogatory
 - Requests made for bank records, corporate records, e-mail/server records, phone records, identifications, interviews
 - Can take many months, or years

Global Challenges

- Will foreign country notify account holder?
- Will foreign country open own investigation?

Global Challenges

- OTHER MEANS TO GATHER EVIDENCE:
 - Tracker warrants – ok with foreign country? Assistance with surveillance?
 - Are there informal ways to receive information?
 - Industry assistance: purchasing product, testing product, identifying subjects, introducing agents to subjects; international resources

Charging Decisions

- Can we extradite from defendant's country ?
- From another country where defendant is found?
 - Do we have extradition treaty?
 - Does foreign country have similar laws?
- Can we seize assets?

**DO YOU KNOW
WHERE YOUR
LAST PILL
CAME FROM?**



**McGRUFF SAYS COUNTERFEIT DRUGS
CAN PUT YOUR LIFE AT RISK.**

Nobody would buy dangerous medicines on purpose. But when you buy prescription or even over-the-counter drugs online from unknown sources, you could be risking your health and well-being. Counterfeit medicines made by criminals often contain dangerous elements such as antifreeze, floor wax and even lighter fluid – instead of the proper active ingredients.

Be sure to buy from legitimate sources and to avoid websites that may pretend to look legitimate but are not. Don't buy fake. Get real. And help me "Take A Bite Out Of Crime®."

**Counterfeits Hurt.
You Have the Power to Stop Them.**

Avoid counterfeit products.
Visit NCP.C.ORG/GETREAL



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**COUNTERFEIT DRUGS CAN
PUT YOUR LIFE AT RISK.**



When you buy prescription or even over-the-counter drugs online from unknown sources, you could be paying a steep price – your health. Counterfeit medication not made by medical scientists can injure or even kill you. Know where your medication is coming from by purchasing from legitimate sources. Don't buy fake. Buy safe.

Counterfeits Hurt. You Have the Power to Stop Them.

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