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.
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
1. Authentic Avastin FDA-Approved for Use in the United States

2. Counterfeit Product

- Avastin® Bevacizumab 400 mg/16 ml
- Each vial contains 400 mg bevacizumab, trehalose dihydrate, sodium phosphate, polycarbonate, water for injections.
- Made in Switzerland by F. Hoffmann-La Roche Ltd, Basel.
Keppra, Anti-epileptic

Arimidex, Breast cancer

Casodex, Prostate cancer

Aricept, Alzheimer’s

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

- 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
"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 NCPC.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.

Protect yourself from counterfeit products.
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