Washington State
Board of Pharmacy

Drug Diversion, Counterfeiting,

(and other *despicable* wrongdoing)

Richard D. Morrison
Pharmacist Investigator

Presentation Overview

- Diversion: Who? What? When? Where? How? Why? (Detection & Responsibilities too!)
- View video tape of actual diversion
- Awareness and prevention
- Practitioner responsibilities
- A primer on counterfeit drugs

A “POP” Quiz?!

Who diverts drugs?

- Health care professionals
- Patient abusers
- Others

What drugs are diverted?

- Controlled substances
- Legend drugs
- OTC drugs

5

When are drugs diverted?

- When procedures are not followed
- When records are not reviewed
- When staff are too trusting or naïve
- During periods of “turmoil”
- During “slow” work shifts
- Anytime!

6

Where are drugs diverted?

Drugs are diverted from any site where they are stored, stocked, administered, prescribed, or dispensed!!

7

How are drugs diverted?

(A partial list!)

- Theft
- Record alteration
- Prescription forgery
- From “wastage”
- Some for “you”… some for “me”
- Substitution

8

Why are drugs diverted?

- Known quality and potency
- Readily obtained by prescription
- Access in the work place
- Produce desired effects
- Large market if trafficking
- They are not “street” drugs

9

So what’s the motivation?

- Greed
- Self-use (impairment)
- Sympathy
- Empathy
- Sexual gratification
- Victimization (blackmail, duped)

10

Detection

- Prescriptions filled too frequently
- Prescriptions filled concurrently
- Unjustified over-prescribing
- Self-prescribing
- Prescription alteration
- Coworker lifestyle changes

11

What else should cause concern?

- Alteration or loss of records
- Unjustified purchases
- Decline in profit margins
- Patients without pain relief
- Losses of drugs subject to abuse
- Product tampering

12

Video Tape Presentation

- Show me!
- Best evidence
- A picture is truly worth a thousand words!

13

Awareness & Prevention

- Sound policies
- Common sense
- Adherence to rules
- Appropriate security measures
- Remain informed

14

What else should I do?

- Ask questions when in doubt
- Regular record review
- Track stock
- Limit stock to levels of use
- Restrict access

15

Is there more? (You bet!)

- Promptly return/destroy outdates
- Document & return unclaimed prescriptions to stock
- Maintain close working relationships
- Investigate unusual circumstances
- Rely on a code of ethics

16

Practitioner Responsibilities

- Become knowledgeable
- Know that occasionally, trusted coworkers divert
- Proceed carefully
- Follow procedures
- Keep an open mind
- Maintain confidentiality

17

Give me more hints!

- Be an astute observer
- Recognize legal and ethical responsibilities
- Notify appropriate agencies
- Keep accurate notes
- Use restraint
- Preserve evidence

18

Anything else?? (Yep!)

- Eliminate Suspects
- Recognize records are often altered
- Resolution takes time
- Report losses
- Trust intuition

19

Counterfeit Drugs

- Old problem – new “drivers” & “twists”
- Formerly… most were limited to unwitting purchases overseas
- Now… Internet access and infiltration of drug distribution system
- Victims are patients and companies

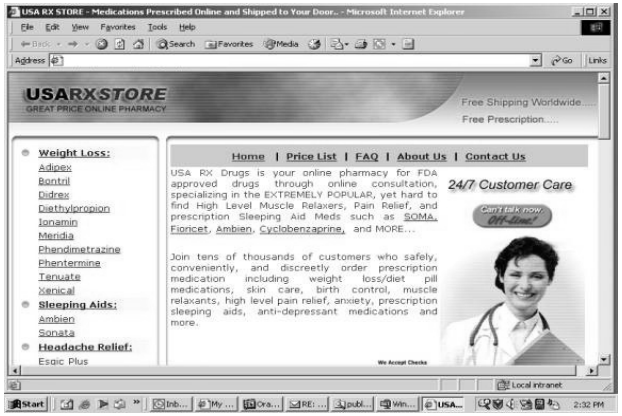
20

Give me some examples?

- Fake medications
- Diluted (to side-step red flags)
- Expired
- Bogus labels

21

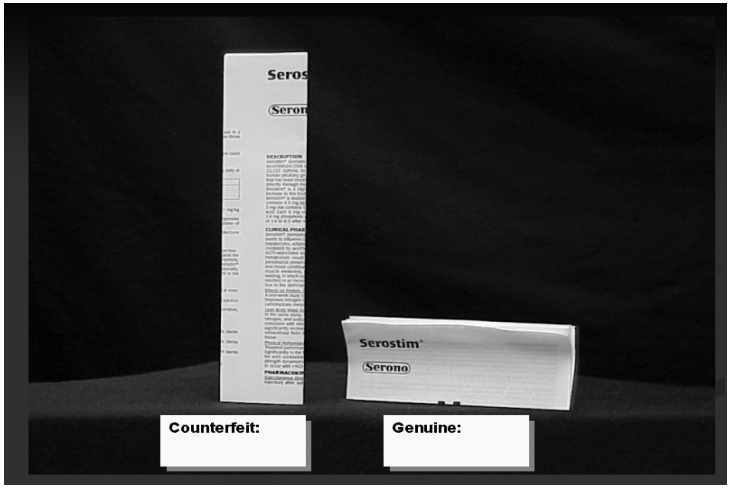
Websites may look legitimate, but often sell unapproved or counterfeit drugs from around the world



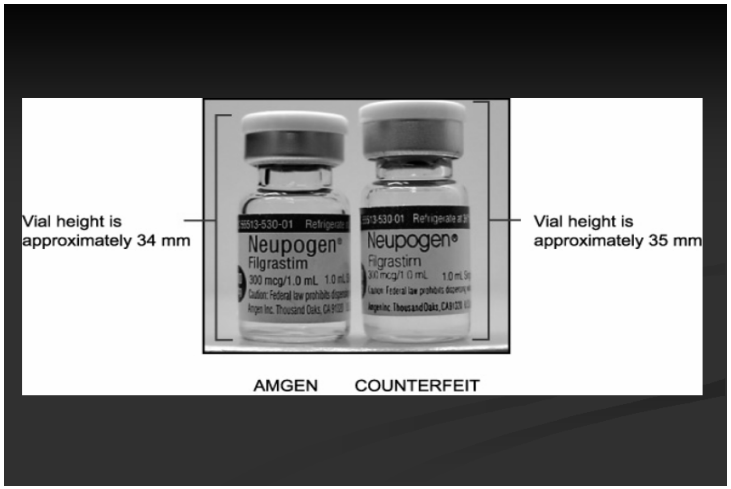
Which drugs are targeted?

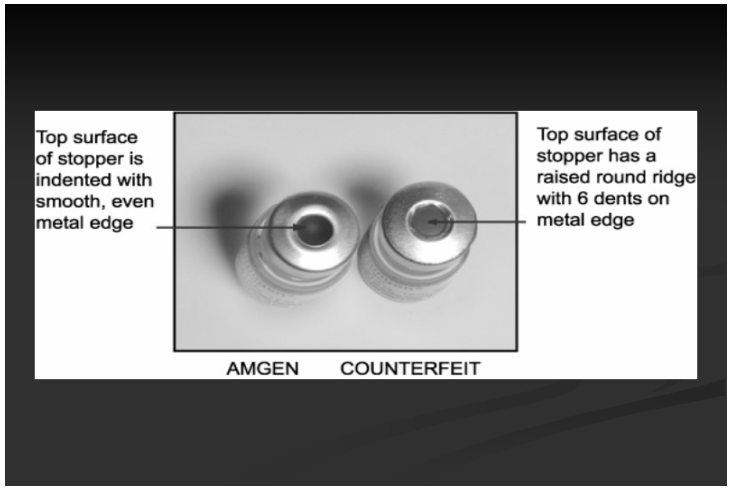
- High cost and specialty drugs (Procrit, Serostim, Nutropin, Neupogen, etc.)
- Widely prescribed medications (Celebrex, Lipitor, etc.)
- “Lifestyle” drugs, i.e., Viagra

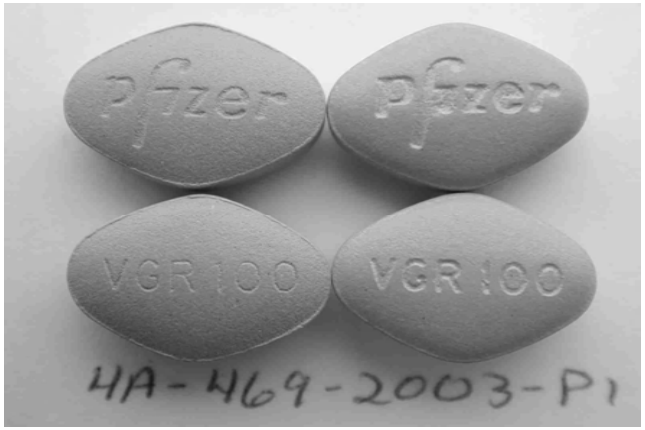
23


Counterfeit:
Genuine:


Genuine:
Counterfeit:


Vial height is approximately 34 mm
Vial height is approximately 35 mm
AMGEN
COUNTERFEIT


Top surface of stopper is indented with smooth, even metal edge
Top surface of stopper has a raised round ridge with 6 dents on metal edge
AMGEN
COUNTERFEIT



Counterfeit Authentic

Some important points:

- Petty criminals to organized crime
- Very profitable
- Sophisticated methods
- Difficult to detect and track
- Per FDA, 10% of drugs worldwide are counterfeit (some countries 50%!)

30

How does it happen?

- Manufacturer to major wholesaler (AmeriSource Bergen, McKesson & Cardinal)
- Secondary wholesalers (price driven… as bulk, overstock, etc.)
- Wholesalers sell to each other (makes tracking more difficult)
- Re-packagers (more tracking problems)
- Secondary/re-packager to major wholesaler

31

What adds to the problem?

- Rogue Internet sites
- Overwhelmed Customs workers
- Political concerns
- Lax or un-enforced regulations
- Differential pricing
- Ease in obtaining licenses

32

Strategies

- Be alert!
- Inquire about supplier anti-counterfeiting measures
- Regularly check the FDA Web site: www.fda.gov/ (MedWatch & Counterfeit pages)
- Limit or eliminate use of secondary wholesalers (unless good-standing is confirmed)

33

What's being done?

- Increased investigative efforts
- Stiffer penalties (FDA)
- High-tech tracking & packaging
- Increased border surveillance
- Greater wholesaler oversight
- Health practitioner awareness

34

Questions and Answers

35