Generations+/Northern Manhattan

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Harlem Pharmacy Newsletter

!!! Counterfeit Drugs: A Growing Public Health Risk !!!

In the past few years, there have been growing concerns regarding the infiltration of counterfeit medications into the U.S. drug market. The Food and Drug Administration (FDA) has issued multiple warnings pertaining to this alarming patient safety risk.

Many counterfeit drugs look very similar to the genuine product and they deceive healthcare professionals as well as patients. Counterfeit medicines may include products with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging. Both branded and generic products are subject to counterfeiting. These drugs can contain mixtures of harmful toxic substances to inactive, ineffective preparations that <u>can result in</u> <u>treatment failure (and contribute to increased resistance in the case of antimalarials that contain insufficient</u> <u>active ingredient) or even death¹</u>.

All kinds of medicines have been counterfeited from life saving cancer medications (Avastin ®), cholesterol lowering agents (Lipitor®), flu prevention and treatment medicine(s) (Tamiflu®) to prescription and over-the-counter weight loss drugs (phentermine, Alli®).

The most recent counterfeit issue was bevacizumab (Avastin®) which was found to contain no active ingredient and could lead to treatment failure. This anticancer medication is also used off label to treat macular degeneration. According to the World Health Organization (WHO) the prevalence of counterfeit drugs is estimated to be 1% dispensed in the U.S. and other developed nations. Moreover, Pharmaceutical Security Institute reports that counterfeit injectable drugs are approximated 4%.

Counterfeit drugs have previously been associated with developing countries that have lax regulations. However, as more medications and drug ingredients that are sold in the U.S. are being manufactured overseas, their quality becomes increasingly difficult to control.





Methods to determine a genuine Avastin verses Counterfeit

- 400 mg/16 ml vials affected
- All cartons and vials approved for use in the U.S. have "Genetech" or "Genetech, a member of the Roche Group" printed on the label
- The lot number on the carton and vial should be 6 digits with no letters
- The expiration date is formatted as a 3-letter month and 4-digit year (e.g. JUL 2014)
- The date of manufacture is not printed on the carton or vial
- All the text on the vial labels, cartons and package inserts is in English

Why an increase in Counterfeit Pharmaceuticals:

The counterfeit pharmaceuticals industry is estimated to be a billion-dollar industry if not more. Additionally, due to the fact some drugs are getting more expensive, so consumers may be more willing to turn to nontraditional sources. New technologies make it easier for criminals to make counterfeit drugs. And now that drugs are being sold over the Internet, without face-to-face contact between buyer and seller, it's harder for consumers to know if the seller they're dealing with is legitimate. In over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit¹.

You can avoid counterfeit medicine by

Purchasing only from U.S. state-licensed pharmacies Buy drugs only from trusted retailers and avoid nonregulated online pharmacies.

When traveling abroad, take your medications with you and avoid purchasing drugs abroad.

The best way for consumers to identify potential counterfeits is to be as familiar as possible with the drugs they regularly take. If you know the size shape, color, and taste of the medications you take, you will more easily identify possible counterfeits.

How can I report suspected counterfeit drugs?

You should report suspected counterfeit drugs to the pharmacist who sold you the medication and to your doctor if you are experiencing any medical problems. Your pharmacist will know whether there has been a legitimate change in the color, shape, taste, or packaging of the medication, and how to report your concern to the FDA. You can also report your suspicions directly to the FDA by calling the Medwatch program at 1-800-332-1088.

References: ¹http://www.who.int/mediacentre/factsheets/fs275/en/

Look A-like, Sound A-like (LASA) Medications

LOOK ALIKE, SOUND ALIKE MEDICATION

Cefepime is a fourth-generation cephalosporin antibiotic that has an extended spectrum of activity against Gram-positive and Gram-negative bacteria.

The Cefepime IV premix **1g** and **2g** comes in LASA packaging. It is vital that the correct dose is chosen to prevent from medication errors such as under-dosing (which can lead to sub-optimal treatment and/or development of drug-resistant bacteria) or overdose (that can increase risk of side effects (e.g. rash, diarrhea, nausea, increase in hepatic enzymes, etc.)



TO PREVENT LOOK ALIKE, SOUND ALIKE MEDICATION ERRORS:

- Separate locations of look alike medications.
- Use look alike sound alike (LASA) auxiliary stickers on bins containing the medication
- Train staff to recognize LASA errors
- For handwritten/oral prescriptions, do not make assumptions; call the prescriber to confirm medication.
- Check patient's profile & review medication list to prevent errors

Patient Safety Awareness Week - March 4 -10

Potentials for Drug Abuse

The misconception about prescription (Rx) drugs are that they are generally conceived to be safe because they are prescribed by health providers. However, prescription medications are only safe when taken under medical supervision based on the intended patient. Taking too much of a medication can lead to an overdose and result in unwanted side effects and even death. Certain prescription medicines if taken inappropriately can cause addiction (characterized by compulsive drug seeking and use).

Commonly abused medications include²:

Pain relievers – 5.1 million

Opioids such as Oxycodone (OxyContin[®]), hydrocodone (Vicodin[®]) prescribed for pain relief.

Tranquilizers – 2.2 million & Sedatives - 0.4 million

Sedatives and depressants prescribed for anxiety or sleep problems, include Benzodiazepines (e.g. diazepam (Valium[®]), lorazepam (Ativan[®]), alprazolam (Xanax[®]).

Stimulants - 1.1 million

Stimulants prescribed for attention-deficit hyperactivity disorder (ADHD) such as dextroamphetamine (Adderall[®], Dextrostat[®], Dexedrine[®]), sleep disorder (narcolepsy), or obesity.

Additionally, greater accessibility is another factor that increases the risk of prescription drug abuse and recently we have seen a rise in availability of prescription drugs. Between 1991 and 2010, prescriptions for stimulants increased from 5 million to nearly 45 million and for opioid analgesics from about 75.5 million to 209.5 million.



Feb 11, 2012: The legendary singer, actress and producer, Whitney Houston has died at the age of 48. The causes of the singer's death are unknown. However, her death has raised issues about combining prescription drugs with alcohol.

There are many reasons for prescription drug abuse: to get a high (known as euphoria: intense feeling of well-being); to satisfy an addiction, to deal with life's pressures and stress, to "feel accepted" by peers; to treat anxiety, pain or sleeping problems; to enhance brain cognitive function; and prescription drugs may be easier to obtain than illegal drugs. Once healthcare providers understand the reasons, we can work to find safe alternatives and prevent Rx drug abuse.

 $References: {}^{2}http://www.drugabuse.gov/publications/topics-inbrief/prescription-drug-abuse$

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Prescription Drug Abuse Prevention

More than 80% of Americans have contact with a healthcare professional every year³. With prescription medication abuse on the rise it is important for EVERYONE and not only doctors and pharmacists to play a role in monitoring commonly abused medications.

Patients should always use their medications only as directed by their physician and be aware of potential side effects and interactions with other medications or foods. *Medications should only be taken by the person they were prescribed to. Never use another person's medications.* Before starting a new medication, patients should always inform their healthcare provider about any medical problems, current medications (prescription and over-thecounter), and dietary and herbal supplements they are taking. Unused or expired medications should be properly discarded per FDA guidelines or at DEA collection sites.

Parents should know what medications are in the household and where they are kept. Monitoring quantities and controlling access to medications is a good way to make sure they are not being abused. It may help to set clear rules for children and teens about drug use, including not sharing medications and always following the medical provider's advice and dosages. Parents should also serve as good role models by following these same rules with their own medications. Getting friends and family involved in safeguarding their prescription drugs as well is a good way to decrease a child's access to medications that are not prescribed to them.

Doctors can help by identifying abuse (or nonmedical use) of prescription drugs and



Henry Le (right) and Michelle Mizo (left) Pharm.D Candidates, Touro College of Pharmacy

preventing its escalation to addiction by asking a patient about their medications, identifying if problems exist, and help to set recovery goals and treatment options. During routine medical visits doctors should take note of rapid increases in the amount of medication needed, or frequent or unscheduled refill requests. Doctors should also be aware that those addicted to prescription drugs may engage in "doctor shopping" in order to obtain multiple prescriptions for the drug(s) they abuse. Even though stimulants, CNS depressants, or opioid pain relievers are commonly abused, they should still be prescribed if necessary for treatment.

Almost 60% of 12th graders are reported get their prescription narcotics from a friend or relative--*NIDA*

Pharmacists can help patients understand the medications they are being given and how to take them. By watching for fake or altered prescriptions pharmacists can also serve as a first line of defense in recognizing prescription drug abuse. Some pharmacies have hotlines that alert other pharmacies in the region that a fake prescription was found. There are also prescription drug monitoring programs (PDMPs) which require physicians and pharmacists to log each filled prescription into a State database. This can assist medical professionals in identifying patients who are getting prescriptions from multiple sources. As of May 2011, 48 States and 1 territory have enacted legislation authorizing PDMPs, 34 of which are operational.³

Abuse of prescription and over-the-counter drugs can be very dangerous. Although they are generally safe when used as prescribed, but when abused, they can be just as dangerous as street drugs. The risks associated with abuse of medications far outweigh any potential "benefits".

 $References: \ ^3 http://theantidrug.com/drug-information/otc-prescription-drug-abuse/preventing-prescription-drug-abuse/default.aspx$