

Helping Your Patients Avoid COUNTERFEIT COUNTERFEIT MEDICINES MEDICINES?

FOUR SIMPLE STEPS WILL HELP SAFEGUARD PATIENTS

FROM THIS GROWING THREAT TO THEIR POCKETBOOKS AND THEIR HEALTH.

Viagra, Lipitor, Tamiflu, Ambien, Diflucan – popular and expensive drugs you probably prescribed in the last week – are under a growing threat. Increasingly sophisticated counterfeit copies of these and other medicines are entering the U.S. pharmaceutical market, tainting the image of trusted brand name drugs and calling into question the security of existing drug supply chains. Often using the Internet as their storefront, counterfeiters are exploiting the global medication market to the tune of more than \$39 billion annually.¹ Though the scope of the problem is intentionally obscured by its perpetrators, the Food and Drug Administration (FDA) has seen a quadrupling of its yearly counterfeit drug investigations since the late 1990s,² and U.S. Customs and Border Protection has more than quadrupled its interceptions of illegal prescription drug parcels to nearly 10,000 per year.³ These efforts have not stanchd the flow of dubious pharmaceuticals, as the Government Accountability Office estimates that 40,000 parcels containing pharmaceutical products pass through just one U.S. international airport every day.⁴ The problem is expected to worsen as the convenience of Internet pharmacies attracts more consumers, even those with drug coverage.

Drug imposters have been deceiving patients as long as there has been demand for effective medications. Beyond duping purchasers out of their earnings, coun-

terfeit medications pose significant health risks. Active ingredients or excipients (substances that bind active ingredients) may be absent, diluted to sub-potency or poisonous. The consequences of using bogus medicines include therapeutic failure, drug resistance and direct toxicity. Recent examples in the United States include fake contraceptive patches and watered-down Epogen and Procrit, while developing nations have suffered thousands of deaths from the substitution of antifreeze for children's paracetamol syrup. In the United States and nations where chronic diseases account for the majority of prescriptions, patients who use counterfeit medications lose the opportunity to moderate the progression of their illnesses and avoid life-threatening sequelae. The four Ontario, Canada, residents who died of heart attacks and strokes after their pharmacist dispensed Norvasc copycats made from pressed talc are testament to how fake drugs rob people of their money, health and lives.⁵

Counterfeiters seek large profits while limiting their risks of detection, so they favor higher-priced drugs for conditions patients may be reluctant to reveal to their doctors. Viagra, Cialis and Propecia – so called “embarrassment drugs” – are prime counterfeit targets. Expensive medications with large markets are also fertile ground for fakes. Hence, cholesterol-lowering medications are widely reproduced. A list of pharmaceutical products susceptible to adulteration, counterfeiting or diversion

WHEN AN UNANTICIPATED SIDE EFFECT OCCURS, BE ALERT TO THE POSSIBILITY THAT A PATIENT MAY BE USING COUNTERFEIT MEDICATIONS.

is maintained by the National Association of Boards of Pharmacy (see the list on page 35). Many states are now mandating that drugs from the list have proven pedigrees (records of pharmaceutical product transport and storage from manufacture to point of distribution or sale) before they may be dispensed to patients.

What physicians can do

You can help your patients avoid purchasing counterfeit medications by urging them to adopt the following safeguards. (See also the patient handout on page 36.)

Use VIPPS-approved Internet pharmacies.

The FDA's Counterfeit Alert Network (<http://www.fda.gov/oc/initiatives/counterfeit/network.html>) warns consumers who purchase medications via the Internet to order only from sites that display an approved membership seal called the Verified Internet Pharmacy Practice Sites (VIPPS) seal, shown on page 36. The seal should be linked to the National Association of Boards of Pharmacy Web site (<http://www.nabp.net>), where consumers can view information about the pharmacy or search for another VIPPS Internet pharmacy. Consumers can also contact their state board of pharmacy for assistance.

Patients should be alert to the fact that sites without the VIPPS seal may be selling counterfeit products. This includes sites that purport to be Canadian pharmacies. Many such sites are fronts for rogue distributors in developing nations. The FDA has warned that intercepted samples of Diovan, Nexium,

Crestor, Celebrex and others from clearing-houses for Web sites with names like Canadiandrugstore.com and Canadian-safe.com have contained counterfeit products.⁶

Avoid cross-border purchasing. Although U.S. Customs and Border Protection states, "in virtually all instances, individual citizens are prohibited from importing prescription drugs into the United States,"⁷ uneven enforcement of existing laws has enticed thousands of patients to take advantage of cheaper prescription drugs available in neighboring countries. The FDA is awaiting final approval to begin enforcing long dormant sections of the Prescription Drug Marketing Act (PDMA) that would markedly decrease cross-border importation. The act was signed into law in 1988 to prevent the entry of counterfeit, adulterated, misbranded, subpotent or expired drugs into the United States, but it has not been enforced, largely because of a lack of "track and trace" technologies such as radio frequency identification tags. These technologies have since come of age and are already being used by manufacturers of commonly counterfeited or diverted drugs, including Lipitor and Oxycontin. Full implementation of the PDMA will substantially change the way medications are transported across borders, alter state and county drug purchasing programs, and curtail Internet pharmaceutical sales. Whether enforcement will reach individual drug purchasers is unclear. In the meantime, patients who fill their prescriptions by traveling to Mexico – where counterfeit drugs account for 25 percent of medications – risk becoming unwitting accessories in today's "War on Drugs."⁸

Examine pill appearance and packaging.

Because counterfeit drugs infiltrate the national drug supply through a variety of clandestine channels, simply avoiding Internet and cross-border purchases will not sufficiently protect patients. You can help your patients avoid using copycat drugs by counseling them to recognize the details of pills and packaging. Any alteration from a previous prescription

■ Counterfeit medications are a \$39 billion per year industry that robs patients of their money and well-being.

■ Counterfeiters favor high-priced embarrassment drugs and drugs that are widely used.

■ When purchasing medications via the Internet, patients should use sites with the "VIPPS" seal.

About the Author

Dr. Teichman is medical director of the Victoria Healthcare My My International Clinic in Ho Chi Minh City, Vietnam. He was previously an assistant professor in the Department of Family Medicine at West Virginia University, Harpers Ferry Rural Family Practice Residency. Author disclosure: nothing to disclose.

should be brought to the attention of the dispensing pharmacist. Packages contain overt and covert systems to reveal tampering or substitution. These include bar codes, holograms, frangibles (tamper evident materials including patterned tapes and seals) and taggants (substances that appear when drugs are exposed to climates dissimilar to their destination climate or when placed under ultraviolet light). Though counterfeiters continually close the gap between manufacturers' packages and their copies, many fake drugs are found in packages with hazy lettering, flat printing rather than imprinting or embossing, and a lack of expiration dates or lot numbers.

You can also help patients identify variances by comparing medicines they received from an Internet pharmacy to drug samples you received from the manufacturer. Many counterfeits are detected by patients who notice a change in tablet size, shape, color, texture, smell or hardness. These organoleptic qualities of drugs are tell-tales of drug stability and quality, and patient reports of unusual pill taste or odor should be investigated rather than dismissed. In addition, when an unanticipated side effect occurs or the patient's condition worsens

inexplicably, you should be alert to the possibility that a patient may be using counterfeit medications.

Report suspicious medications. If you or your patients think they have received a counterfeit medication, advise them not to use it. File a report with the FDA's Medwatch system (<http://www.fda.gov/medwatch/>). Return the drug to the pharmacy where it was dispensed, or contact the manufacturer.

Despite manufacturers' and the government's best efforts to identify counterfeit medications and disrupt their distribution, the prescription medication market is too lucrative for leagues of rogue profiteers to ignore. It will take layers of intervention and prevention to stop fake drugs from reaching patients. Informed and attentive physicians and patients are two of the most critical layers in maintaining a safe and dependable drug supply. **FPM**

Send comments to fpmedit@aafp.org.

1. World Health Organization. Counterfeit medicines: Fact sheet No. 275. Available at: <http://www.who.int/mediacentre/factsheets/fs275/en>. Accessed Jan. 15, 2007.

2. U.S. Food and Drug Administration. *Combating Counterfeit Drugs: A Report of the Food and Drug Administration*. February 2004. Available at: http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html. Accessed Jan. 15, 2007.

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4. Senate Committee on Homeland Security and Governmental Affairs. *Buyer Beware: The Danger of Purchasing Pharmaceuticals Over the Internet* (hearing report). June 17, 2004.

5. Government of Ontario Ministry of Community Safety and Correctional Services. Chief Coroner makes recommendations resulting from investigation into 11 Hamilton deaths (news release). Available at: <http://ogov.newswire.ca/ontario/GPOE/2006/01/09/c0820.html>. Accessed Jan. 15, 2007.

6. U.S. Food and Drug Administration. FDA warns consumers not to buy or use prescription drugs from various Canadian Web sites that apparently sell counterfeit products (news release). Aug. 30, 2006. Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01441.html>. Accessed Jan. 15, 2007.

7. United States Customs and Border Protection. Medication/drugs. Available at: http://www.cbp.gov/xp/cgov/travel/clearing_goods/restricted/medication_drugs.xml. Accessed Jan. 15, 2007.

8. U.S. Department of State. Consular Information Sheet: Mexico. Available at: http://travel.state.gov/travel/cis_pa_tw/cis/cis_970.html. Accessed Jan. 15, 2006.

■ Patients should avoid purchasing drugs outside the U.S. border; in Mexico, an estimated 25 percent of drugs are counterfeit.

■ If a medication has unusual packaging or appearance, advise your patient not to use it.

■ You can report suspicious medications to the FDA's Medwatch system or notify the pharmacy or manufacturer.

THE TOP 14 COUNTERFEITS

The National Association of Boards of Pharmacy has created the "National Specified List of Susceptible Products," available at <http://www.nabp.net/ftpfiles/NABP01/List.pdf>, which identifies 32 drugs that are most susceptible to adulteration, counterfeiting or diversion and that pose the greatest risk to public health. Shown here are the 14 drugs that top the list.

1. Combivir (lamivudine/zidovudine)
2. Diflucan (fluconazole)
3. Eпивir (lamivudine)
4. Epogen (epoetin alfa)
5. Lamisil (terbinafine)
6. Lipitor (atorvastatin)
7. Norvasc (amlodipine besylate)
8. Procrit (epoetin alfa)
9. Serostim (somatropin, mammalian derived)
10. Sustiva (efavirenz)
11. Trizivir (abacavir/lamivudine/zidovudine)
12. Viagra (sildenafil)
13. Zerit (stavudine)
14. Zyprexa (olanzapine)

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