

Cyberspace Chat

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When finasteride suddenly stops working— is it counterfeit?

For many years, I have been prescribing generic finasteride for the cost savings it has provided patients. I always assumed patients would be more willing to bear the expense of a “cosmetic” medication that yields delayed results, if the cost was easy to budget. I also prescribe the 5mg dose and allow them to section it and take every other day because this is cheaper than the 1mg pill. For years, I had also been telling patients I knew of no difference between generic 5mg finasteride and the brand name Proscar. However, I then had the experience of a physician patient who moved out of state and refilled his generic with a different generic brand and reported to me that within weeks he noticed accelerated shedding. He then called the pharmacy in Tucson to ask what generic brand they were using and asked me to specify that brand of generic to the new pharmacy. After the change, the shedding stopped. Following this experience, I have switched a couple of patients who had been stable on finasteride but then complained of a sudden increase in shedding back to the brand name. I assumed perhaps they had received counterfeit medications being distributed among the generic brands as I had seen a story about this in the news some months ago. The following cyberchat discussion caught my eye as it confirmed other hair restoration doctors had noted similar experiences, too.

The thread began with Brad Wolf’s comments: “I recently had a patient complain of increased shedding 2-3 months after switching from brand name to generic finasteride. He counts every hair he sheds every day and went from 20-30 to 70-100 shed hairs a day. He really knew something was going on when his (unreported) decreased libido started improving. He started right back on the Propecia®.”

In response, Jim Harris had this to share: “I’ve never had anyone switch from the name brand to the 5mg generic notice a change but have had several that bought foreign ‘generics’ that noticed a difference. I never know what to tell patients when they inquire about buying foreign.”

A response by Bob Haber supports the premise that some patients may have been exposed to counterfeit medications: “I think we have all experienced patients who had unexplained flares of their condition that resolved with restarting a branded drug. I think that while the vast majority of the time there is no difference between branded and generic, there are exceptions. I’ve switched a few hundred patients to the generic 1mg. Two patients told me they experienced shedding within a few weeks of the switch. That seems too quick to make sense, but I tell my patients that if they experience shedding to go back to the branded product. I always assume anything bought online may be counterfeit.”

Discussion

Sudden loss of finasteride effectiveness, even though discussed as an issue of generic versus brand name, is more likely

to be caused by the growing problem of counterfeit medication distribution. Even supposing a generic brand had “less” active ingredients, based on most of our experiences, a lower dose is unlikely to result in sudden shedding—but absence of medication or counterfeits are a different issue. A review of recent publications supported by government investigations confirms Dr. Haber’s assumption that a high percentage of online medication purchases, especially those that are offshore and don’t require a prescription, are counterfeit. The issue of counterfeit medications has made headlines in the United States and abroad. A conservative estimate of the Center for Medicine in the Public Interest predicts the sales of counterfeit medication, using the internet as a global distribution channel, will grow twice as fast as sales of legitimate pharmaceuticals. Counterfeit medication seizures by customs officials in the European Union reportedly increased by 384% between 2005-2006, and global sales of such drugs were expected to reach \$75 billion in 2010. In addition to their ineffectiveness, some counterfeit drugs have been tainted and toxic and linked to patient fatalities. In one case, the U.S. FDA identified a patient who had purchased medication from an Eastern European website and died from dangerously high levels of metals in her liver, including aluminum, strontium, and arsenic. Needless to say, illegal counterfeit medications are not produced with any regulatory oversight to prevent contamination or use of unlicensed analogues of the drugs they are counterfeiting.^{1,2}

While legitimate internet pharmacies that prescribe in accordance with local laws and regulations do exist, the World Health Organization (WHO) estimates that medications purchased from online pharmacies that conceal their physical address are counterfeit over 50% of the time. The European Alliance for Access to Safe Medicines (EAASM) found that 62% of medicines ordered via the internet and without a prescription were substandard and/or counterfeit. In another survey of internet pharmacies, the FDA identified 85% of drugs purported to be from Canadian pharmacies actually came from 27 different countries and were often counterfeit. While data regarding internet sales of Propecia® were not found, overall data from internet sites that sell drugs without a doctor’s prescription were revealed to be frequently fraudulent and illegal in their endeavor to make money without providing any patient benefit. It should be no surprise, for example, that when the bird flu scare was in full swing, internet sites offered Tamiflu to eager consumers. The FDA tested five samples from different online sites and none contained the anti-viral ingredient, oseltamivir. In another sting operation dealing with 2,383 seizures worldwide of suspected counterfeit Viagra, over 80% were found to be counterfeit. Cheaper costs and convenience were the most common reasons for patients to buy online.^{1,2}

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The WHO estimates that up to 60% of drugs in some developing countries and up to 20% in some developed countries are counterfeit. It is estimated that 10-15% of drugs sold worldwide are counterfeit. Through importation and re-importation, counterfeit drugs enter into a country's drug supplies and wind up in drug stores. In 2003, there were 200,000 bottles of Lipitor that were recalled when they were determined to be counterfeit. The medications were a mixture of a counterfeit drug from Central America blended with the actual drug in South America and were subsequently illegally imported and sold in the U.S. In 2005, there were 100,000 instances of counterfeit drugs reported in New York state alone.³

One way this occurs is that large wholesalers buy back drugs from secondary wholesalers to cover short-term shortages. Excess supplies with impending expirations are sold among large and small wholesalers. It is believed that during these transactions the opportunity exists for counterfeits to be brought into the drug supply.³ Efforts to control the supply of counterfeit medications in the United States, Europe, and worldwide have been in the works with legislation and strategies to protect consumers underway. Some strategies include barcodes within the medication to identify their authenticity, but this type of security measure adds to the expense of medications, which fuels the quest for cheaper alternatives.

Lifestyle drugs are common targets for counterfeiters. For instance, Viagra has been a known and investigated target. It seems reasonable to assume finasteride would be an attractive target, too. Recommendations to health care providers are to raise awareness with consumers to discourage them from using online websites that offer cheap medication without a prescription. Not only are the patients likely to be wasting their money, they could receive a dangerous counterfeit. Currently, patients in Tucson pay about \$10/month for generic finasteride therapy, which is probably less than the postage for an online counterfeit. Doctors who suspect a patient may have received a counterfeit drug should contact the pharmacy that provided it and ensure the pharmacist is aware of the problem so they can alert their supplier.¹

References

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