

House Energy and Commerce Committee
Subcommittee on Oversight and Investigations
Hearing on “Counterfeit Drugs: Fighting Illegal Supply Chains”
February 27, 2014

One Page Summary - Testimony of Bruce Longbottom, Eli Lilly and Company

- Lilly has seen our own brand medicines counterfeited around the world, and we have seen counterfeiters target a range of therapies, from our medicines for mental illness to our medicines for cancer. Counterfeit medicines are a growing problem that is not limited to innovative products or any particular categories of medicine.
- The most common way that counterfeit medicines enter the United States and reach U.S. patients is through the Internet (illegitimate online “pharmacies” or B2C and B2B sellers that facilitate sales/shipments).
- There are approximately 40,000 to 50,000 active online drug sellers operating globally. The vast majority – nearly 97% according to the National Association of Boards of Pharmacy – is operating illegally by failing to comply with pharmacy and patient safety laws and standards. There are tens of thousands of fake online pharmacies that put patients at risk.
- According to FDA, 23% of adult Internet consumers surveyed bought medicine online in 2012.¹ And an estimated 36 million Americans have frighteningly done so without a doctor’s prescription. The Internet has become a more significant part of our everyday lives and shopping habits; it is critical that our public policy and laws evolve along with our technology.
- **Combating counterfeit drugs in the United States and internationally requires a robust strategy to combat their sales on the Internet.** The strategy – which includes Governmental Accountability Office findings (GAO) dating back to 2005²– will require: 1) better public education; 2) stronger laws; 3) improved enforcement of our existing laws; and 4) voluntary cooperation and adoption of best practices by Internet commerce companies.
- Many will argue that policies and laws should not change to deal with the problem online, but as with serialization, it is possible and must be done to protect the sanctity of the pharmacy and the quality and integrity of the U.S. drug supply.

¹ FDA BeSafeRx:

<http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/UCM318643.pdf>

² GAO: <http://www.gao.gov/products/GAO-05-372>

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Good morning, Mr. Chairman and members of the subcommittee. I am Bruce Longbottom, Assistant General Counsel for Trademarks for Eli Lilly and Company, which is a global pharmaceutical company. Lilly invests heavily to research, develop and manufacture safe and effective pharmaceutical medicines, which treat many diseases and save lives.

First let me thank the Chairman, Ranking Member, and members of the subcommittee for their focus on this important issue and for inviting Eli Lilly to - testify about "Fighting Counterfeit Drugs and Illegal Supply Chains." We appreciate the attention you are devoting to investigate the problem of counterfeit medicines, which pose an ongoing risk to patient health and safety. The threat of counterfeit medicines is an issue that is near and dear to Lilly and, most importantly, to the patients that depend on the integrity of the Lilly brand.

Lilly has seen our own brand medicines counterfeited around the world, and we have seen counterfeiters target a range of therapies, from our medicines for mental illness to our medicines for cancer. One of the world's most commonly

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counterfeited products is medicine for erectile dysfunction or ED. Lilly has seen enormous quantities of counterfeit ED medicine circulating the world, and it is telling of the expansive criminal network of pharmaceutical counterfeiters. Some product will contain dangerously high levels of Active Pharmaceutical Ingredients (API), some might contain the wrong APIs, or none. Some counterfeit drugs contain dangerous toxic ingredients. Lilly is not alone in this experience. Counterfeit medicines are a growing problem that is not limited to innovative products or particular categories of medicine. Authorities around the world can attest that there are counterfeit versions of branded, generic, and even over-the-counter medicine. Criminals can profit readily from trade in counterfeit medicines, as it offers lower risks and higher rewards than other criminal activity. In countries plagued with disease, public reports indicate there may be huge quantities of counterfeit vaccines and antibiotics. As such, Lilly has come to view this issue as a global health threat, and one that we must diligently work to combat in partnership with others.

In that spirit, Lilly would like to thank and applaud the Energy and Commerce Committee for its hard work last year to pass the Drug Quality Security Act of 2013

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(DQSA). That new law’s establishment of a national pharmaceutical track-and-trace system is a critical and necessary step for ensuring the integrity of the U.S. drug supply, and it helps to establish a model internationally. That system will serve to close gaps in the supply chain for prescription medicines in the traditional distribution model – those traveling from legitimate manufacturers to wholesale distributors to pharmacies to patients. But while DQSA establishes important requirements for the good guys, the focus of today’s hearing is on the bad guys: the illegal supply chain. As such, I will focus my remarks today on the most common way that counterfeit medicines enter the United States and reach our patients: through the Internet.

As most of us obtain our medicines at a local brick-and-mortar pharmacy, the new DQSA is great added protection for us. However, there is also a newer, less traditional distribution model that also delivers prescription medicines to patients – it is called the Internet. More and more of us are becoming very comfortable with using the Internet not just for accessing information, but also for purchasing all sorts of products. Indeed, ecommerce is projected to grow 10% year over year³. It is very

³ CPC Strategies: <http://www.cpcstrategy.com/blog/2013/08/ecommerce-infographic/>

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easy to shop online. This is also true in the area of healthcare and medicine.

According to FDA, 23% of adult Internet consumers surveyed bought medicine online in 2012.⁴ And an estimated 36 million Americans have frighteningly done so without a doctor’s prescription. The latter statistic is from study by The Partnership at Drugfree.org in 2010, so that number is likely much higher now.

As more and more Americans look online for their medicines, whether those medicines have been prescribed by doctors or have been self-prescribed (which of course invites other significant problems, including drug abuse), what do they find? Today, according to LegitScript, there are approximately 40,000 to 50,000 active online drug sellers operating globally. But the vast majority – nearly 97% according to the National Association of Boards of Pharmacy -- is operating illegally by failing to comply with pharmacy and patient safety laws and standards – such as requiring only FDA-approved medicines and state-licensed pharmacists. This means there are tens of thousands of fake online pharmacies that put patients at risk!

⁴ FDA BeSafeRx:

<http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/UCM318643.pdf>

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Is this OK? Of course not. Whether we walk up to a counter and present our prescription to a pharmacist, or we find a website, select a medicine, submit a prescription, and click our mouse to trigger shipment of a life-saving drug – in either case the pharmacy must follow the laws put in place to protect patients. In short, just like the brick-and-mortar supply chain will be made secure under DQSA, the Internet supply chain should be secure. How secure?

A pharmacy is, in a sense, set apart from other locations where products or services are being offered to the public. In particular, when we interact with a pharmacy, we should expect two things:

1. Prescription drugs that have been approved by the FDA, and
2. Those drugs being dispensed by a pharmacist who has been licensed by the state board of pharmacy; often representing the ‘last stop’ for warnings to patients about contraindications – or the medically-harmful combination of therapies.

In other words, the prescription medicines have been issued a “gold seal of approval” by the FDA and the person dispensing the medicine has been issued a “gold seal of approval” by the state licensing authority. That is the maximum potential of the FDA-approved pharmacy. That is what we should all expect from

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every pharmacy, whether online or real world. And so, as you examine this problem and how to fight it, we must think about how to protect the integrity of accredited pharmacies as they exist in the online world.

There is of course no silver bullet, no one solution to the problem found when the Internet and prescription medicines intersect, especially given the global nature of the Internet. But there are several elements to the solution, and as the Internet becomes an even more prominent part of our everyday lives, it is critical that our public policies adapt and evolve with it.

- Part of the solution is patient education. The average person needs to understand the risk they take by purchasing drugs from an unknown source on the Internet. Initiatives like FDA's BeSafeRx campaign launched in 2012, the online public service announcements run by the Center for Safe Internet Pharmacies (CSIP) and the Alliance for Safe Online Pharmacies (ASOP) in 2013, and the potential new dot-pharmacy top-level domain applied for by the National Association of Boards of Pharmacy (NABP) are just three examples of critical work being done by stakeholders to educate consumers. I am happy to share more information about

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any of these initiatives in subsequent interaction with the subcommittee staff. Still, education can only go so far, and more must be done.

- Another part of the solution is to have stronger laws. As passed by this Committee, the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) expanded existing penalties for drug counterfeiting by increasing the maximum penalties from a possible \$2,000,000 fine and 10 years imprisonment to maximum penalties of \$5,000,000 and 20 years imprisonment. The Act also added a criminal offense for knowingly and intentionally adulterating a drug with a reasonable probability of causing serious adverse health consequences or death. This too is a good start, but all too often the laws don’t keep up with criminals’ practices – especially on the Internet – so we thank Congress for remaining vigilant in looking for new ways to close legal loopholes.

- Another part of the solution is more aggressive enforcement of existing laws. Although the July 2013 GAO report on Internet pharmacies outlined a variety of law enforcement challenges - including that most illegal sites operate abroad and operate through complex global organizations which disguise their identities – nevertheless law enforcement actions can be effective and are a necessary deterrent to criminal activity online. I want to take the opportunity to recognize and

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express Lilly's appreciation for the good work that has been done by U.S. government agencies, including by FDA/OCI, CBP, and HSI. Their hard work and attention to this issue has a meaningful impact, and it must continue. For example, in June 2013 the US Government collaborated with nearly 100 countries on Operation Pangea VI. According to the FDA, this Operation resulted in the elimination of 1,677 websites selling illegal prescription drugs, and dangerous drugs valued at \$41 million were seized. Without CBP's excellent work and international cooperation, there would be even more illegal product in circulation today, finding its way to people in need of treatment. Coordinated international enforcements like this are critical. Ideally, they would be done throughout the year. They can serve as a more effective deterrent if they are systematic and ongoing campaigns.

- Last, but definitely not least, part of the solution is voluntary cooperation by Internet-based companies. According to LegitScript, the number of advertisements for illegal drugs and pharmacies found on major search engines like Google and Bing [Microsoft] has declined by more than 99.9% percent since 2010. The Center for Safe Internet Pharmacies (CSIP), of which Google and Microsoft are members along with 11 other Internet commerce and payment companies,⁵ provides a way for

⁵ CSIP: <http://www.safemedsonline.org/who-we-are/members/>

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these ecommerce stakeholders to be part of the solution too by developing voluntary best practices, collaborating with law enforcement, and - as mentioned earlier - helping to educate consumers about the threat of illegal online drug sellers. These companies can help to transform the Internet landscape when it comes to online pharmacies by adopting model voluntary practices and holding them up as an example for the rest of the world. And our government, along with other governments, can help to encourage their adoption internationally.

I am sure you are well aware that there is one primary tool in the Drug Quality Security Act used to tighten defenses against counterfeit and illegal drugs reaching patients in brick-and-mortar pharmacies: that tool is serialization. Likewise, there is also one primary tool that could be used to tighten defenses against counterfeit and illegal drugs reaching patients from online pharmacies - that tool is delisting. That tool could be used to exclude "bad" online pharmacies (those that fail to comply with the standards mentioned above to which we hold an actual physical pharmacy) from natural search results found using search engines. In other words, if a website selling medicines did **not** sell only FDA-approved drugs or did **not** provide those services using a state-licensed pharmacist, after delisting you would **not** find that

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website in the search results. The online pharmacy would still be available on the Internet, no doubt hosted in another country, but it would not be found by the patient in the U.S. who is doing an Internet search for his or her medication. If natural search results were cleaned up in this way, that would be the Internet equivalent of what DQSA is doing to tighten the traditional supply chain. The supply chain for counterfeit drugs is long, complex and stretches far around the globe. De-listing "bad" online pharmacies from natural search results would effectively serve to break that chain before it reaches U.S. patients.

Finally, whenever increased oversight of the Internet is discussed, objections are raised such as (1) it's censorship, (2) it'll hurt innovation, or (3) it's futile because the Internet is just too big. In the case of pharmaceuticals, these objections are not correct and they do a disservice to public health and safety. Our existing laws and regulations were put in place as a safety net to protect patients, and now the Internet has ripped a large hole in that safety net which needs to be patched. I have brought with me today a document summarizing media reports of patients harmed by illegal online drug sales, which I request to have submitted for the record along

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with my testimony. It demonstrates how very real this issue is, how it has impacted real lives. And these are the cases that have been reported. Some are never known. The Internet is here to stay. The number of fake online "pharmacies" is growing. The question is: what are we going to do about it? We have to do something. This is an area where the pharmaceutical industry and major Internet commerce companies agree, as told by the public commitments and statements of the Center for Safe Internet Pharmacies (CSIP), which includes Google, Microsoft, GoDaddy, Visa and PayPal as its members: the growth of illegitimate online drugs sellers is a big problem and we have to work together to protect people and do something about it. Lilly stands committed to this goal of patient safety in both brick-and-mortar and Internet-based pharmacies, and we appreciate the opportunity to testify before the Subcommittee today to advance that goal.

I look forward to your questions. If I can't answer them now, I will talk with others at Lilly and get right back to you.

Thank you.