

#### The Issue:

In the US patients get their medication through a closed, secure, drug supply chain. Every entity in the supply chain is regulated either at the Federal or state level within the US. However, in other countries and throughout Europe, the regulations aren't as robust, causing counterfeit medications to be accessible to patients including those in the US. Many online retailers and motivated criminals have brought the counterfeits over to the US over the last ten years.

These medications are not only unsafe; many have been proven to be lethal.

The United States is experiencing a wave of counterfeit drugs. In settings such as cancer treatment clinics, kidney dialysis centers, and in the home where consumers buy medication over the Internet, multiple significant counterfeit incidents have been recorded in the last 12 months.

We must take action now to protect American patients. Counterfeit drugs silently injure and kill their victims because the evidence is so hard to prove after the fact.

#### What is a counterfeit drug?

A counterfeit drug is a medication that isn't made to the exacting potency and purity standards in factories licensed, inspected, and approved by the US Food and Drug Administration. The FDA reviews and approves both research and generic medications, both for prescription and over-the-counter access. An example of a dangerous counterfeit is a drug that contains no active ingredients.

The underlying disease that should be entirely treatable is left to run unchallenged through the patient's system. The image below shows how much a counterfeit drug can look authentic.



Images of authentic and fake Lipitor: Even pharmacists with years of experience cannot identify a fake drug by sight. Even basic lab tests are often fooled by criminals who use enough genuine ingredient to show up on a chemical screening test.

If you have high cholesterol, taking a pill made up of just chalk instead of your real medication is like a death sentence.

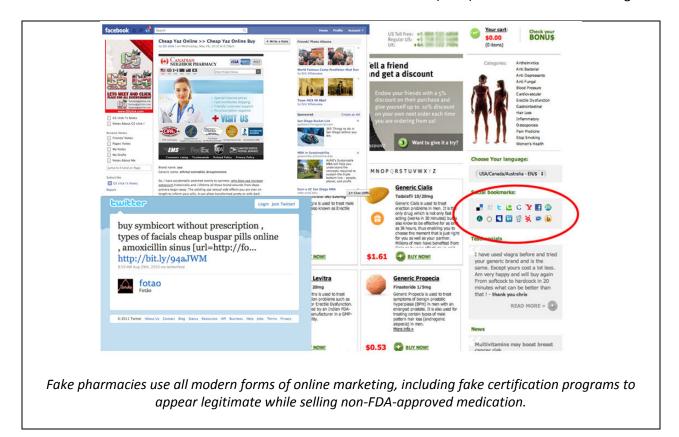
#### How consumers fall victim to crooks

For a variety of reasons patients break the secure supply chain: embarrassment, cost, threat of prosecution, and pride are all factors. They go online and seek "foreign licensed pharmacies" which are usually not pharmacies at all. Many patients have no idea the risk they are taking with their safety in the absence of licensure and regulatory oversight. They often believe that a website with a maple leaf is actually a Canadian pharmacy.

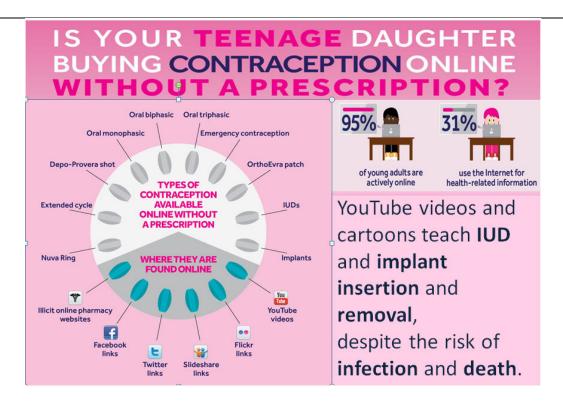
The truth is that these websites are rarely Canadian and they are rarely actual pharmacies. They are usually just one portal in a network of thousands run by globally-organized criminal cyber gangs operating out of the reach of US law enforcement.



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Criminals also take advantage of some consumers need to hide their purchases. PSM researchers have documented criminals specifically targeting young American women online for sale of contraceptive medication and contraceptive devices. Such medication requires oversight by a medical professional, and in the case of a contraceptive device, should not be inserted or implanted by a patient themselves.



Contraceptive medication and devices are sold online to Internet-savvy young women, with deadly instructions for self-implantation and administration.

Worse are drugs that are made in facilities without sufficient manufacturing cleanliness standards, or who make their fakes from toxic ingredients because it's a cheap filler that creates a similar taste or texture to the real product.





These photos were taken by Pfizer security agents during raids on counterfeit manufacturing labs in Pakistan and Columbia.

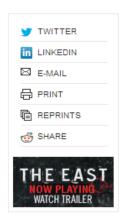


#### 84 Children Are Killed by Medicine in Nigeria

By LYDIA POLGREEN Published: February 6, 2009

DAKAR, Senegal — A toxic chemical mixed into a teething medicine for babies has killed at least 84 children in <u>Nigeria</u>, health officials there said Friday, more than tripling the toll in a wave of infant deaths that began in late November.

The children died after taking a medicine called My Pikin Baby Teething Mixture, a syrup for teething pain, according to Nigeria's Health Ministry. Health officials said that a batch of the medicine that went on sale in November contained diethylene glycol, an industrial solvent and an ingredient in antifreeze and brake fluid.



The New York Times has reported multiple times about medication throughout the world that has been adulterated with diethylene glycol. 365 people died in Panama in 2006 from a similar incident. Heavy metals such as lead, mercury, and aluminum, along with active ingredients that cause unwanted health effects are all well documented.

All of these cases have happened, and not just once, but over and over again throughout the world.

And with the rise of porous borders created by the intersection of the Internet, global shipping, and the inability of border agents to keep up with the volume of shipping, the problem has entered the United States.

### It's not just patients: even healthcare professionals fail at this, often endangering patients

Healthcare professionals are also fooled by these scam artists, and sometimes they collaborate with them out of greed. Just recently in the UK a trained EMT died after self-prescribing a medication she ordered over the Internet from an online pharmacy.



### Patient story: Lorna Lambden

#### Even getting real medication can be deadly

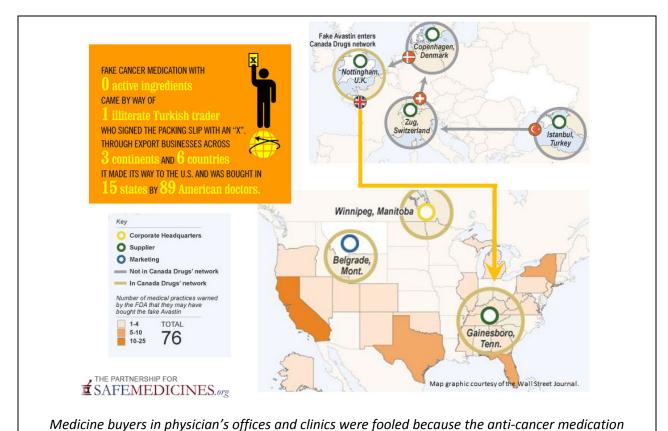
She bought medication online without a prescription and without a pharmacist to inform her.

Said her family: "Lorna died after taking a small amount of medication which she had purchased on the internet to help with tiredness and sleeping. This medication turned out to be exceptionally dangerous. The Coroner thought Lorna's death was a tragic accident. Please can this be a warning to anyone purchasing prescription drugs on the internet!"



Lorna Lambden, 27, ordered from an online pharmacy ended up receiving a very powerful sleeping aid without any safety instructions.

And over the last two years, the FDA has discovered that hundreds of doctors offices and clinics have been doing business with unlicensed distributors peddling non-FDA-approved medications from foreign sources. In some cases the clinics were looking to trade off a little safety for a discount, a practice also known as fraud. To date the FDA has made several arrests of doctors and clinic administrators for such behavior.



appeared to come from a distributor in England. By buying and re-selling the medicine repeatedly, its

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true origin of Turkey was obscured. They did this because the medicine was entirely fake.

#### What you can do - educate patients and healthcare professionals!

An educated patient or healthcare professional is much safer from counterfeits! You can educate your patient community by sharing materials customized by The Partnership for Safe Medicines. Our materials can be customized to newsletters, websites, social media sites and email communications. Our kits contain:

- Multi-page training materials on safe drug sourcing for physicians, nurses, and pharmacists.
- Consumer tri-fold brochures and one-page handouts on saving money safely and spotting warning signs of medication that might be counterfeit.
- Illustrated brochures and comic books that tell the story of heinous counterfeit criminals brought to justice in the United States.
- Bite-sized consumer and physician safety tip materials that can be embedded in email or print newsletters, Twitter or Facebook feeds, or a website.

For more information about partnership opportunities, contact:

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