

A RISKY PROPOSITION

HOW OPENING THE U.S. TO FOREIGN MEDICINES WILL PUT
AMERICAN CHILDREN AT HEIGHTENED RISK



THE PARTNERSHIP FOR
SAFEMEDICINES.org

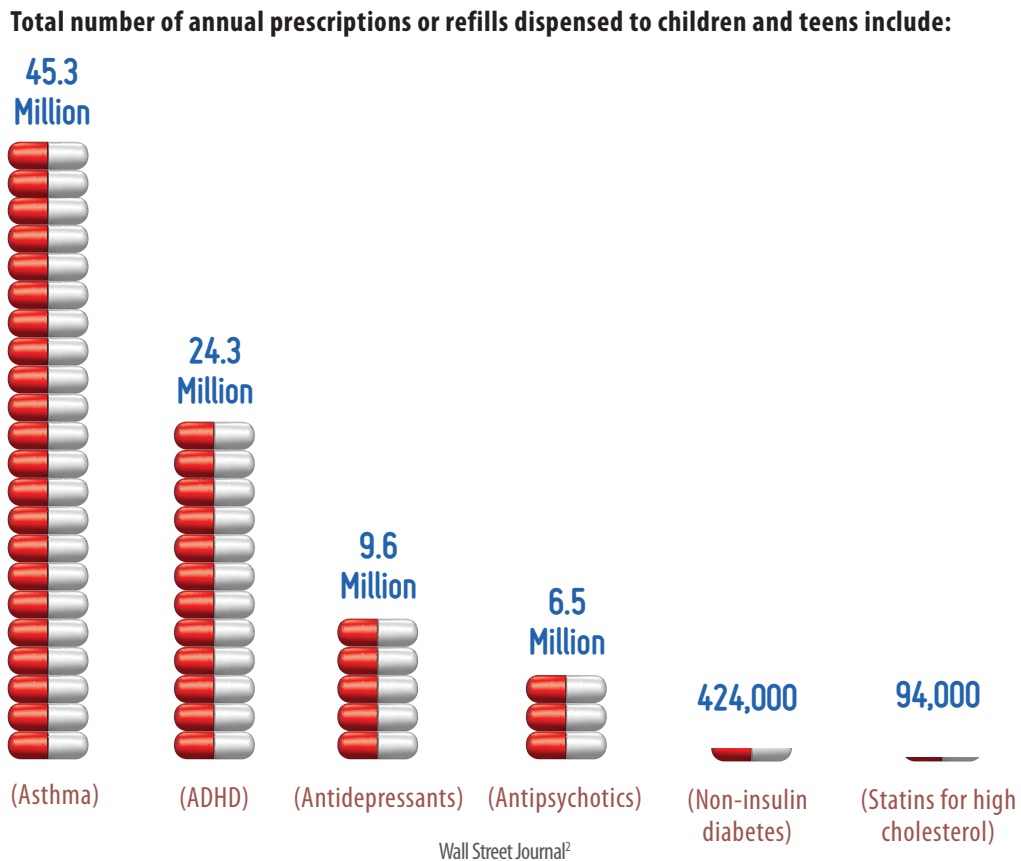
A RISKY PROPOSITION

Table of Contents

- 4** Fake Drugs and Impact on Children
- 5** Children and Medicine
- 7** A Closed and Secured U.S. System
- 8** Online Drug Sellers
- 11** Open and Unsafe:
The Consequences of Parallel Trade
- 13** Proposed Policy: Unintended
Consequences
- 15** Negligible Savings
- 16** Lessons from the Past



More than one-quarter of all U.S. children and teens take medication on a regular basis. In fact, in 2009, nearly 7 percent of those children and teens were taking two or more medications.¹



Given the vast number of children who rely on prescription medications for life and health, parents should be aware of a growing epidemic: counterfeit, fake and tainted medicines. Fortunately, today, this health threat exists predominantly outside the U.S., and has been recognized by the Food and Drug Administration (FDA).³ However, some Washington policymakers are considering opening the U.S. market to importation. This policy is driven by perceived (but unsubstantiated) cost reductions that many experts dispute.⁴ Apart from this economic debate, however, importation would open the U.S. market to counterfeit and tainted medicines, creating a public health risk for vulnerable patient populations like children that depend heavily on medicines for their well-being.

¹ Mathews, Anna W., "So Young and So Many Pills," *Wall Street Journal*, December 28, 2010.

² Ibid.

³ <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf>

⁴ Danzon PM, Johnson SJ, Long G, Furakawa MF. Commercial Importation of Prescription Drugs in the United States: Short-Run Implications. *J Health Poly Pol Law*. 2011; 36(2): 295-316; Vernon JA, Golec JH, Hughen WK. The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate. *Am J Law Med*. 2006;32:175-192.

Fake Drugs and Impact on Children

In the past year alone, according to data collected by the Pharmaceutical Security Institute (PSI), law enforcement and health oversight agencies reported 2,054 worldwide incidents of counterfeiting⁵, illegal diversion, and theft of medicines, covering 593 distinct products in virtually every therapeutic category.⁶ These criminal operations not only peddle “lifestyle” drugs, such as diet pills or erectile dysfunction medicines, but also medicines that are used to treat children, such as fake asthma inhalers, medicine to treat pediatric cystic fibrosis patients, as well as patients with cancer, other chronic diseases and more.⁷ Raids on counterfeit drug operations around the globe often turn up the very medicines that are prescribed to children. Some examples:

- 1 Citizens in the Netherlands and the United Kingdom were exposed to counterfeit flu medicine in 2006, while British officials impounded 5,000 packets of the fake drug the same year.⁸
- 2 On June 13, 2011, London resident Premal Gandesha plead guilty to importing forged asthma inhalers through his company, Blueridge UK Ltd., from outside the European Economic Area without having the proper licenses.⁹
- 3 Tragedy struck Nigeria in 2009 when 84 children between two months and seven-years-old died after taking a teething medicine that had its sweetening agent replaced by counterfeiters with a cheaper but deadly chemical commonly found in antifreeze and brake fluid.¹⁰

The New York Times

84 Children Are Killed by Medicine in Nigeria

- 4 In Lahore, Pakistan in 2006, three children died as a result of counterfeit injected medicine just two months after local authorities seized over \$100,000 worth of fake drugs from two wholesale dealers. The mother of one of the deceased children said she bought it from the city’s best pharmacy, and the injections were administered at a hospital and private clinic.¹¹
- 5 In 2009, Interpol confiscated 12 million fake medicines – including drugs posing as antibiotics, anti-tetanus medication, and aspirin – in raids carried out in Cambodia, China, Indonesia, Laos, Myanmar, Singapore, Thailand and Vietnam. Authorities arrested 30 criminals and shut down more than 100 pharmacies.¹²
- 6 In 1995, paracetamol cough syrup that included a toxic chemical used in antifreeze as part of its composition killed 89 children. The same deadly concoction struck again three years later in India, adding another 30 infants to the death toll.¹³

⁵ <http://www.psi-inc.org/incidentTrends.cfm>

⁶ <http://www.psi-inc.org/therapeuticCategories.cfm>

⁷ Liang BA. Fade to Black: Importation and Counterfeit Drugs. *Am J Law Med.* 2006;32:279-323.

⁸ http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html

⁹ <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON120428>

¹⁰ <http://www.nytimes.com/2009/02/07/world/africa/07nigeria.html>

¹¹ http://www.dailytimes.com.pk/default.asp?page=2006\03\19\story_19-3-2006_pg7_17

¹² <http://www.google.com/hostednews/afp/article/ALeqM5gjqBW2erdaxk4We44wy7P-g80W9A>

¹³ http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html

Fortunately, the United States' closed, safeguarded drug distribution system tightly regulates the supply chain and distribution of medicine, minimizing the problem of fake and counterfeit drugs to about 1 percent of the market. This stands in stark contrast to other countries where upwards of 40 percent of medicines are fake.¹⁴ However, many experts are concerned that the growing number of fake internet pharmacies provides a global distribution channel for fake or tainted medicines, making it much easier for criminal drug rings to sell their ineffective and harmful products to American consumers.¹⁵

The following is an overview of the emerging problem of fake medicine and fake pharmacies, the threat posed by drug importation, and a discussion of why parents must be vigilant in order to protect the health of our children.



Children and Medicine

While counterfeit medicines present dangers to consumers of any age, it is an especially important issue for children. First, children do not make their own healthcare decisions for the most part, and must rely on parents and other adults to provide effective medication treatment. As a result, unlike informed adults, children cannot be their own last barrier to harm. They are therefore highly vulnerable to risks posed by any failed drug supply safety protections.

Second, medically speaking, the safe medication dose for a child is sometimes higher, or, far lower than for an adult because of the way children's bodies metabolize medicine.¹⁶ There is a science to prescribing and dispensing medicines to children that doctors and pharmacists carefully use. For instance, the World Health Organization reports:

“Children’s bodies differ from adults and metabolize medicines differently. Therefore, they need different dosage forms. Similar differences exist between children of different ages, weights, and physical conditions.”¹⁷”

¹⁴ <http://www.who.int/mediacentre/factsheets/fs275/en/>

¹⁵ Mackey T, Liang BA. The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks. *J. Pharm. Sci.* Jun 22. doi: 10.1002/jps.22679. [Epub ahead of print]

¹⁶ <http://www.who.int/mediacentre/factsheets/fs341/en/index.html>

¹⁷ <http://www.who.int/childmedicines/questions/en/index.html>

Of course, counterfeiters do not take the patient's age, weight, or development into consideration when selling fake or sub-standard forms. Moreover, they are not interested in whether the child is taking other medications or if the combination of them will result in an adverse reaction. Nor are these sellers concerned that the products sold to treat children for important diseases aren't effective. They simply do not care that what they are selling is known to harm, not heal, because making money – not real medicines – is their business.



Thus, the health risks to children from counterfeit, fake or adulterated products include potentially greater health risks than the same medicine taken by an adult. Further, these drugs may not contain the active ingredient included in prescribed medicines. As a result, children taking counterfeit medicines for serious conditions, such as a bacterial or viral infection, are at risk for rapid decline in their health due to the untreated, underlying condition and their weaker immune systems and lower weight. Finally, for the same reasons, these products can be especially harmful to children because of toxic or deadly ingredients used in their creation, such as floor wax, boric acid, toxic road paint, and other materials unsuited for drugs.

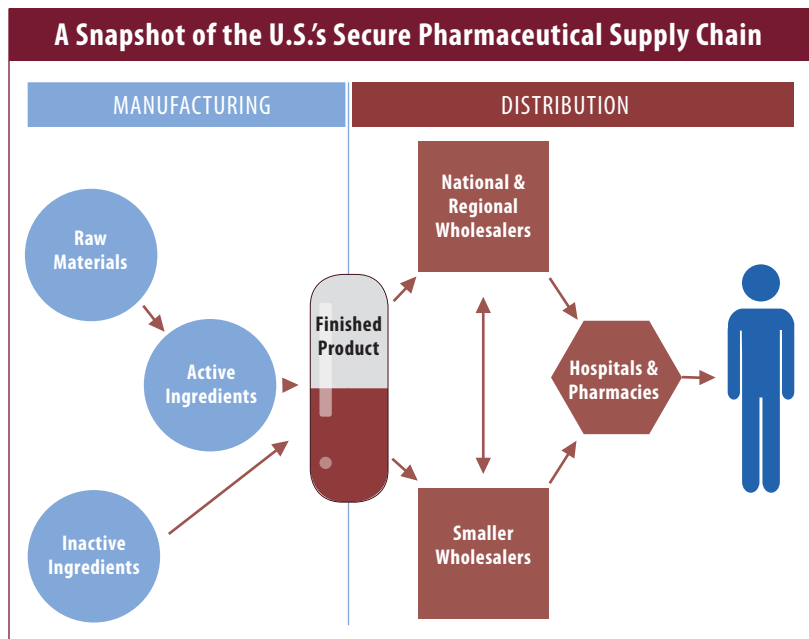
A Closed and Secured U.S. System

When parents go to a pharmacy and pick up medicines for their children, they can be confident that what they are getting is effective, safe, and precisely what the doctor prescribed. That's because the FDA-approved and regulated medicine has been through an extensive regulatory and oversight process before entering the market, including steps to ensure secure transit from factory to wholesaler, then to the pharmacy, and ultimately into our homes.

America's closed and secure system covering the supply chain and sale of medications is much stronger than those in many other countries. State and federal agencies closely regulate the flow of source material for medicine, its manufacturer, distribution and sale, and ultimately its dispensation at licensed pharmacies. These agencies include:

- Food and Drug Administration (FDA);
- Drug Enforcement Agency (DEA) Office of Diversion Control;
- Immigration and Customs Enforcement (ICE);
- Department of Homeland Security;
- State Boards of Pharmacy.

U.S. regulators and law enforcement agencies constantly work to prevent criminals from profiting off fake drug sales at the expense of Americans. The scope of operations range from targeting elaborate criminal enterprises, such as Latin American drug cartels, to two-man shops in North Korean back alleys. This combination of a closed and secure system, along with aggressive law enforcement efforts explains why there are fewer incidents of counterfeit drugs in the U.S. medicine supply than in many other countries.



Source: Pew Prescription Project

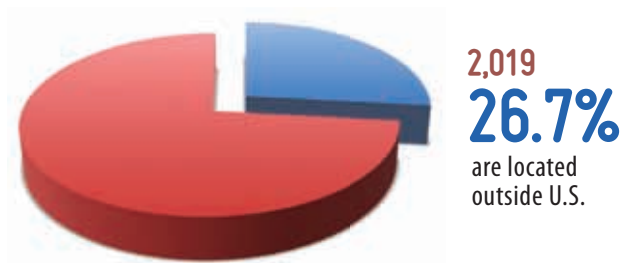
U.S. regulators and law enforcement agencies constantly work to prevent criminals from profiting off fake drug sales at the expense of Americans.

Online Drug Sellers

Despite government efforts, American families are not entirely free from risk. Some Americans are circumventing the protected closed system by buying medicines from fake “online pharmacies” that they may not know are scams. Buying online from entities that are not legal, accredited pharmacies is a high-risk activity for loved ones. A recent study by the National Association of Boards of Pharmacy (NABP) shows:



Of the 7,541 purported online pharmacy sites examined, 7,234 (95.9 percent) were found to be operating outside state and federal laws and failed to meet the standards set by the NABP Verified Internet Pharmacy Practice Sites (VIPPS) program¹⁸



2,019 (26.7 percent) purported online pharmacies have a physical address located outside of the U.S.¹⁹



3,310 (43.9 percent) purported online pharmacies offer medicine not approved by the FDA and therefore unlawful to sell in the U.S.²⁰



Another study by the World Health Organization confirmed that as much as 50 percent of illegal Internet sales worldwide are counterfeit.²¹

¹⁸ <http://www.nabp.net/news/assets/IDOIReportApril11.pdf>

¹⁹ <http://www.nabp.net/news/assets/IDOIReportApril11.pdf>

²⁰ <http://www.nabp.net/news/assets/IDOIReportApril11.pdf>

²¹ <http://www.who.int/mediacentre/news/releases/2006/pr69/en/>

An estimated 90 percent of counterfeit drugs are sold online, with sales approaching \$75 billion this year.²² Unfortunately, online drug selling is a low-risk/high-profit activity. This entices criminals to enter the counterfeit drug market. This is compounded by weak and sometimes nonexistent penalties (especially when compared to penalties for illegal drug sales) and law enforcement, potential shortages in the U.S. drug supply, as well as under-staffed, under-funded and weak anti-counterfeiting laws and regulatory agencies outside the U.S. This has created tremendous risks and challenges for families trying to obtain real medicines online, and many drug regulatory agencies globally warn against purchasing medicines online.²³

One of the difficulties these fake online pharmacies pose for U.S. regulators and law enforcement is that they are located offshore, beyond the physical reach of authorities. In his report for the journal *Clinical Therapeutics: Policy Implications of Drug Importation*, Francis Palumbo, PhD, executive director of the Center on Drugs and Public Policy at the University of Maryland writes:

“When consumers buy from [purported Internet pharmacies], it is definitely buyer beware. They are often not licensed anywhere we are aware of.”

As the number or volume of counterfeit drugs has grown, the number of fake online pharmacies has appeared to spike as well. And, given trends in the former, there may well be



90%

of counterfeit drugs are sold online...



... with sales approaching

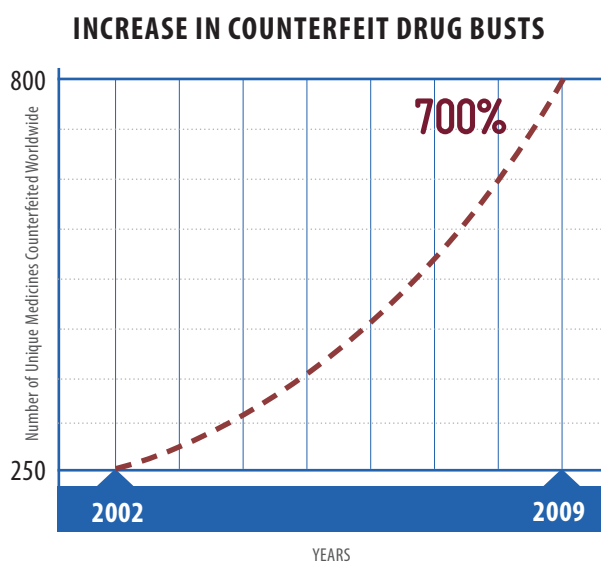
\$75 billion

this year.

²² <http://blogs.reuters.com/small-business/2010/03/23/mobile-drug-authentication-app-needs-work/>

²³ Liang BA, Mackey T. Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales. *Am J Law Med.* 2009;35(1): 125-184.

more and more fake online pharmacies trying to sell their counterfeit medicines in the U.S. and elsewhere. As Tom Kubic, head of PSI and former FBI Deputy Assistant Director reported, there has been a 700 percent increase in drug counterfeiting from 2002 to 2009 and more than 800 unique medicines counterfeited worldwide in 2009 alone. In 2002, there were only 250.²⁵



Further, these illicit online drug sellers have been nimble, and moved into other areas online, such as social media. Facebook, Twitter, YouTube, and other interactive social media have been reported to now be infiltrated with these illegal drug purveyors.

Parents should be aware of these risks, since counterfeiters have already employed these so-called online pharmacies as a lucrative channel for the distribution and sale of fake medicine.²⁶

“When consumers buy from [purported Internet pharmacies], it is definitely buyer beware. They are often not licensed anywhere we are aware of.”²⁴

Francis Palumbo, PhD, executive director of the Center on Drugs and Public Policy at the University of Maryland, Baltimore



²⁴ <http://www.sciencedaily.com/releases/2008/07/080717221157.htm>

²⁵ <http://garwarner.blogspot.com/2010/12/36-million-americans-buy-drugs-online.html>

²⁶ Mackey T, Liang BA. The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks. J. Pharm. Sci. Jun 22. doi: 10.1002/jps.22679. [Epub ahead of print]

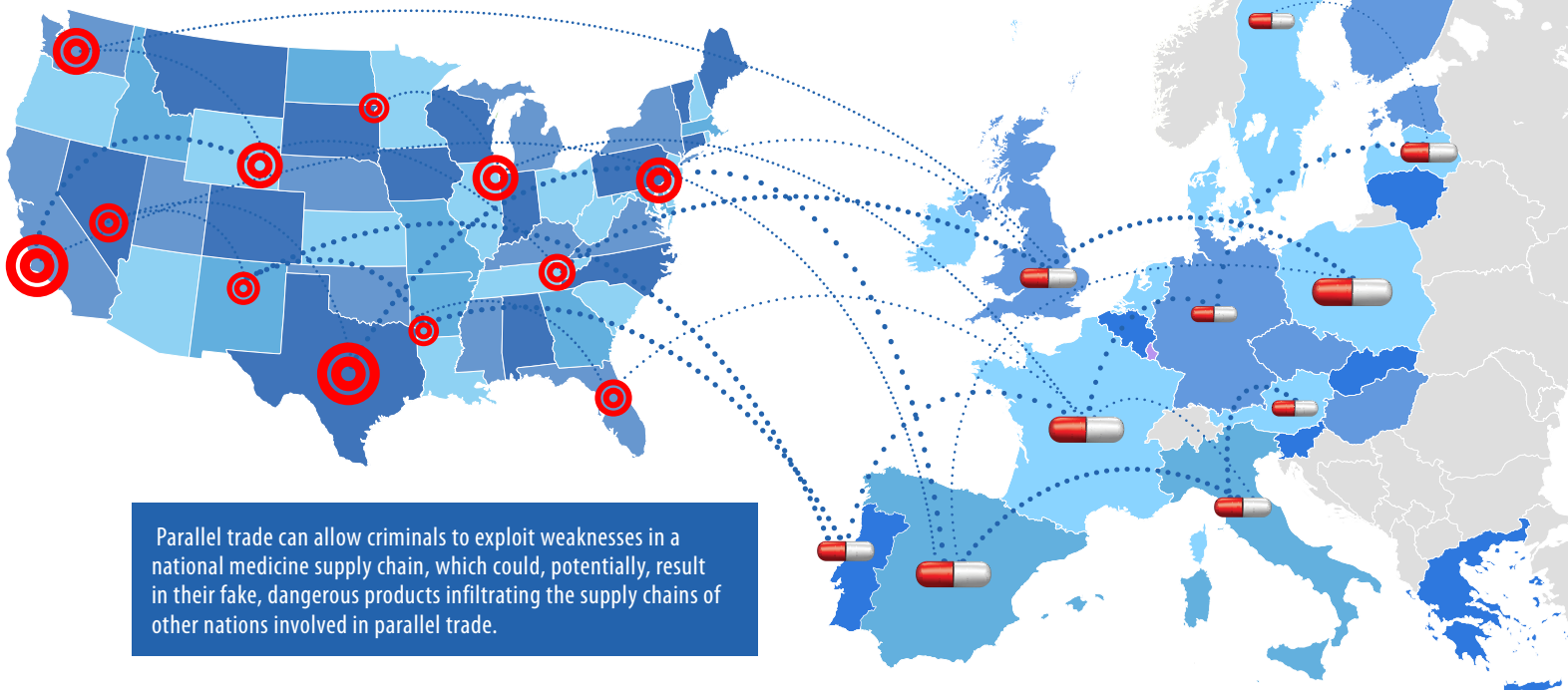
Open and Unsafe: The Consequences of Parallel Trade

Many developed nations, such as those belonging to the European Union, are quite vulnerable to counterfeit medicines despite their strong systems for approving and overseeing prescription drugs. One of the main reasons is international or “parallel” trade – a policy that has been exploited by counterfeiters, scammers and drug traffickers.

Parallel trade is open trade between countries that must be facilitated under EU law, effectively allowing products such as medicines to cross borders in order to promote commerce. The problem is that parallel trade comes with limited regulatory barriers; thus, medicines may pass through many countries as they make their way throughout Europe, including some that have weak oversight or more lax enforcement of their

medicine supply and distribution chains. In combination with parallel trade and the fact that repackaging drugs is legal in the EU (as it is in the U.S.), these conditions have attracted criminal enterprises that see opportunity in the arbitraging of medicines from country to country. Some medicines are repackaged and relabeled, while others are completely counterfeit. All present safety risks.

Parallel trade is one of the ways by which criminal enterprises exploit weak oversight systems in developing countries in order to introduce their fake products into the supply chain of far more developed countries. To understand how dangerous a more open system that enables



Parallel trade can allow criminals to exploit weaknesses in a national medicine supply chain, which could, potentially, result in their fake, dangerous products infiltrating the supply chains of other nations involved in parallel trade.

importation could be for the U.S., one need not look any further than across the pond to Europe. In 2007, the Medicines and Health Regulatory Agency (MHRA) in conjunction with the European Medicines Agency (EMA) announced the recall of batches of three medications, including a drug to treat schizophrenia and bipolar disease, a blood-thinning drug and a prostate cancer drug, following the discovery of counterfeit tablets in the legitimate supply chain.²⁷ According to the European Commission, counterfeit medicine seizures rose 118 percent in 2008 in the European Union, and 8.9 million counterfeit pharmaceuticals were seized by EU custom officials.²⁸

Indeed, as Dr. Bryan Liang, Executive Director at the Institute of Health Law Studies at the California Western School of Law and Director of the San Diego Center for Patient Safety at UC San Diego School of Medicine, reports, open trade is an invitation for criminals to exploit the demand for life-saving medicine, imperiling the safety of the drug supply and the health of millions of patients who rely on them:

“Other European countries have also faced the problem of counterfeits. Wholesalers in Europe have been duped into introducing counterfeits into the legitimate supply chain ... In Italy, a licensed medicines dealer was found to be distributing counterfeit gastrointestinal drugs. In France, customs agents seized 542,000 fake drugs in 2003. In Spain, authorities raided six laboratories producing counterfeit steroids, hormones, and cancer drugs. The operation was capable of producing 20,000 fake doses per hour, 30 million doses and 10 tons of high quality tablets were found, with vials, capsules, tablets, and injectables all represented. These fake products were confirmed to have been sold through parallel trade in Italy, France, and Portugal, and more broadly through the Internet.”²⁹

The latest estimates by the WHO, the Organization for Economic Co-operation and Development and the Pharmaceutical Security Institute show that more than 30 percent of medicines in some areas of Latin America, South East Asia and Africa are counterfeit. In many of the former Soviet Republics, counterfeits also may comprise a dangerous market share approaching 20 percent. This parallel trade driven threat is complicated by the accession of EU member states that are significantly poorer than their counterparts. With a free flow of commerce, including medicines, it is inevitable that the high volumes of counterfeits in some of these countries will eventually spread to others within the EU.³⁰

²⁷ MHRA, “£250,000 fake drug stash seized in undercover operation.” March 4, 2009. <<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON041227>>

²⁸ European Commission, “Report on EU Customs Enforcement of Intellectual Property Rights: Results at the European Border-2008.”¹⁰ European Commission, “Report on Community Customs Activities on Counterfeit and Piracy: Results at the European Border-2007.”

²⁹ Liang BA. Fade to Black: Importation and Counterfeit Drugs. *Am J Law Med.* 2006;32:279-323.

³⁰ <http://www.psi-inc.org/geographicDistributions.cfm>

Proposed Policy: Unintended Consequences

Congress is once again considering proposals that would permit Americans to purchase medicines from pharmacies outside the U.S., legislation known as “drug importation.” As already noted, this policy is premised on savings that have not been documented and likely do not exist. Moreover, importation greatly increases the risks that the global counterfeit drug trade may be imported into our homes, placing vulnerable patients such as our children and other loved ones at risk.

Importantly, we cannot rely on other countries’ safety laws for our own protection. Canadian regulators, for instance, often waive inspections for drugs that only “pass through” Canada, a process known as “trans-shipping.” Drugs that are postmarked in Canada but meant for U.S. consumers are not regulated or checked, and are just as susceptible to counterfeiters as European countries that allow parallel trade. Thus, under the pending U.S. legislation, Americans who order medication from a “Canadian” pharmacy may not even get pills approved for sale in Canada. In fact, the medicine could come from anywhere in the world, and may not even be the medicine that it purports to be. Indeed, one of the largest online Canadian drug sellers was found to be selling counterfeit drugs to U.S. customers.³¹

Further, beyond not selling approved, regulated Canadian drugs, data suggest that most online drug sellers are not



S. 319

Pharmaceutical Market Access and Drug Safety Act of 2011

even Canadian, despite what consumers believe. More than 4,000 of these purported online pharmacies do not even provide a physical address.³² A fake “online pharmacy” selling counterfeit medicines can make its site appear to be a legitimate Canadian pharmacy without any fear of sanctions because these criminal operations may open and close rapidly, and often are out of the reach of Canadian law enforcement efforts.

³¹ Liang BA. Fade to Black: Importation and Counterfeit Drugs. *Am J Law Med.* 2006;32:279-323.

³² <http://www.nabp.net/news/assets/IDOIReportApril11.pdf>



Indeed, FDA says it cannot protect the supply of imported medicine. FDA Commissioner Margaret Hamburg sent a letter to Congress saying it would be “logistically challenging” to guarantee the safety of imported medicines, citing four main reasons:

- 1 The drug may not be safe and effective because it was not subject to a rigorous regulatory review prior to approval;
- 2 The drug may not be a consistently made, high-quality product because it was not manufactured in a facility that complies with appropriate good manufacturing practices;
- 3 The drug may not be substitutable with the FDA-approved product because of differences in composition or manufacturing;
- 4 The drug may not be what it purports to be, because it has been contaminated or is a counterfeit due to inadequate safeguards in the supply chain.³³

³³ <http://talkingpointsmemo.com/documents/2009/12/letter-from-fdas-hamburg-on-safety-issues-in-drug-import-amendment.php?page=1>

Hence, the anonymity of the Internet means anyone can claim anything about themselves online including sham businesses. This means that **“Canada” Doesn’t Always Mean “Canadian”** and labels or postmarks from “trusted” countries do not mean the contents are from these countries. Drugs from Canada, UK, and other western countries are viewed as safe, inexpensive and, particularly with the increased popularity of the Internet, easily accessible -- all reasons why proponents of importation reference Canadian and European drugs so often. Unfortunately, many Americans – as well as Members of Congress – are unaware of the actual personal and public health dangers. But these dangers are more and more prevalent as a result of fake medicines and pharmacies, and the open and largely unregulated trade policies that make it possible to infiltrate the global drug supply.



Negligible Savings

Finally, as some policymakers continue to push for open importation from Canada and other countries, citing cost as their driving force, they ignore the fact that savings driven by importation would actually be negligible.³⁴ Beyond economic analysis noted above, IMS Health reported:

“... 0.6 percent of total drug spending, would be saved by payers; sensitivity analyses range from 0.2 to 2.5 percent under plausible assumptions and up to 17.4 percent under unrealistic assumptions about unlimited foreign supply, costless trade, and zero profits for intermediaries.”³⁵



0.6%
of total drug
spending
would be saved
by payers

And even if a savings of less than 1 percent is enough to lure Americans, it is unlikely that other countries can effectively supply America. For example, a recent study by Dr. Marv Shepherd, Director of the Center for Pharmacoeconomic Studies and Chairman of the Pharmacy Administration Division at the University of Texas at Austin’s College of Pharmacy shows that all of Canada’s drug supply would be depleted in 224 days if a mere 10 percent of Americans went north for their medicine.³⁶

³⁴ Danzon PM, Johnson SJ, Long G, Furakawa MF. Commercial Importation of Prescription Drugs in the United States: Short-Run Implications. *J Health Pol Law.* 2011; 36(2): 295-316; Vernon JA, Golec JH, Huguen WK. The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate. *Am J Law Med.* 2006;32:175-192.

³⁵ <http://jhpl.dukejournals.org/cgi/content/abstract/36/2/295>

³⁶ <http://www.cpjournal.ca/doi/pdf/10.3821/1913-701X-143.5.226>

Lessons from the Past

These safety concerns are not new. Back in 1987, Congress passed the Prescription Drug Marketing Act in response to high-profile cases of unsafe and ineffective counterfeit cefaclor, a widely used antibiotic that, at the time, found its way into the U.S. drug supply from a foreign source.

Neither are concerns about practices by so-called online pharmacies. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 passed after high school student Ryan Haight's tragic death in 2001, an event that awakened the nation to the dangers of fake, online pharmacies dispensing medicines that are controlled substances without additional oversight.

These human tragedies and policy experiences from abroad should be learned and understood. The U.S. should take further steps to crack down on fake online pharmacies by banning any online drug sellers from transacting business in this country unless accredited by NABP VIPPS.

Fortunately, for parents across the United States, only a tiny fraction of the global supply of counterfeit drugs ever makes it into our own drug supply.³⁷ All that could change rather quickly, however, if federal policymakers open up the closed system that has protected our medicines uniquely well for decades, and allow importation from foreign-based pharmacies. That is why parents should understand the very real public health risks – and risks to their own families – that a change in importation policy would pose.

Parents with ill children should only have to focus on getting the right healthcare at the right time for their loved ones. Families should never have to grapple with determining whether the medicines they are giving their children are safe. Policymakers should do their part by putting safety first, and resisting calls to sacrifice proven protections that safeguard our medicine supply especially at a time when the threat of fake medicine and fake online pharmacies is so large and growing.

“You know, we don't really know the full dimensions of the problem. But we do know that in certain countries, somewhere between 30 – 50 percent of really important drugs for health are in fact counterfeit.”

Margaret Hamburg, Commissioner, FDA

³⁷ <http://www.cbsnews.com/stories/2011/03/10/60minutes/main20040693.shtml>



THE PARTNERSHIP FOR

SAFEMEDICINES.org

WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS.