COUNTERFEIT DRUGS
AND NATIONAL SECURITY

BRIAN D. FINLAY

STIMSON

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The deadly implications of counterfeit drugs are well understood to be a central challenge to the integrity of public health systems around the globe, as well as a direct threat to our individual health and welfare. What is less understood is that the profits from this sinister crime are increasingly being co-opted by an array of organized criminal groups and terrorist entities as a means by which to fund their nefarious operations around the world. As such, counterfeit pharmaceuticals pose a direct threat to national and international security.

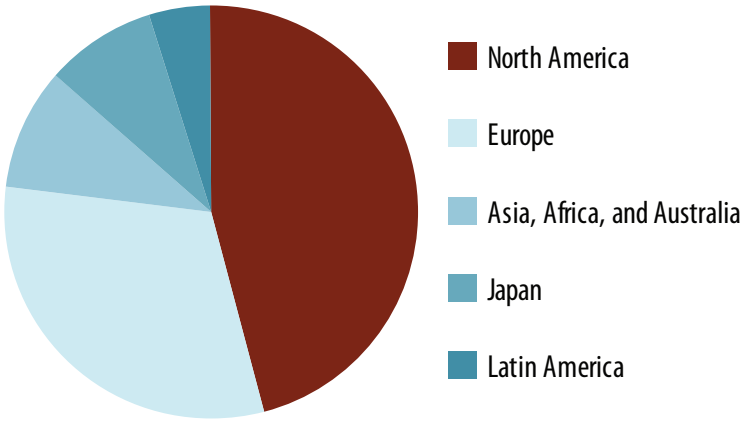
According to the World Health Organization (WHO), counterfeit drugs could make up as much as half of the global pharmaceutical market, with the largest share of fake products circulating in the developing world where regulation and enforcement capacity is comparatively weak.[1] Though the basis of this estimate is unclear, the figure is especially alarming given the narrow definition of "counterfeit" used by the agency.[2] However, it is clear that counterfeit pharmaceuticals remain one of the world's fastest growing industries. Recent trends suggest a massive increase in counterfeit drug sales to over $70 billion globally in 2010. This is an increase of more than 90 percent from 2005.[3] Although the counterfeiting of, and trafficking in, all manner of products is on the rise globally—including currency, documents, software, and electronics—no other bogus product has the capacity to harm or even kill its consumer as do illicit pharmaceuticals. Additionally, most other counterfeits are not quite as lucrative. According to a recent report on counterfeit drugs by the global pharmaceutical firm Pfizer, profits from counterfeiting today surpass gains made from heroin and cocaine.[4]

These alarming rates of growth are, in part, a result of the growing size and sophistication of drug counterfeiting rings, and the widening involvement of organized transnational criminals and even international terrorist groups looking to fund their illegal and unrelated activities worldwide. Indeed, not only have groups such as the Russian mafia, Colombian drug cartels, Chinese triads, and Mexican drug gangs all become heavily involved in producing and trafficking counterfeit drugs over the past decade, but mounting evidence also points to the direct involvement of Hezbollah and al Qaeda.[5] With increased opportunity to make gains from the pharmaceutical counterfeit industry, nefarious actors are likely to pay even more attention to it in the future. As such, the problem is not only a public health hazard of highest magnitude; it is also a national and international security threat.

Figure 1:

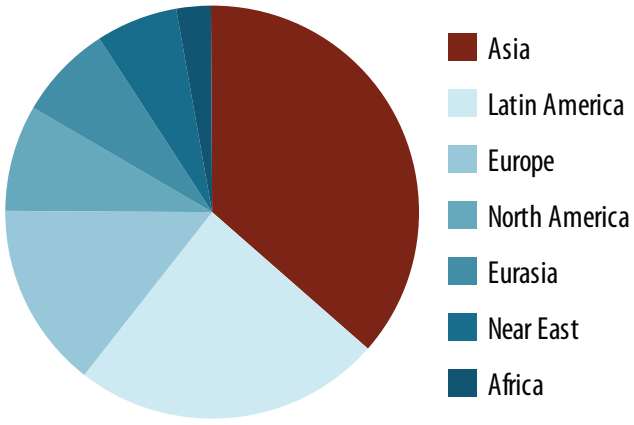
Geographic Distribution of Global Pharmaceutical Sales, 2007

US dollars (billions)



Source: UN Office on Drugs and Crime: Globalization of Crime: A Transnational Organized Crime Threat Assessment, Vienna: 2010, p.185.

Geographic Distribution of Counterfeit Incidents, 2009

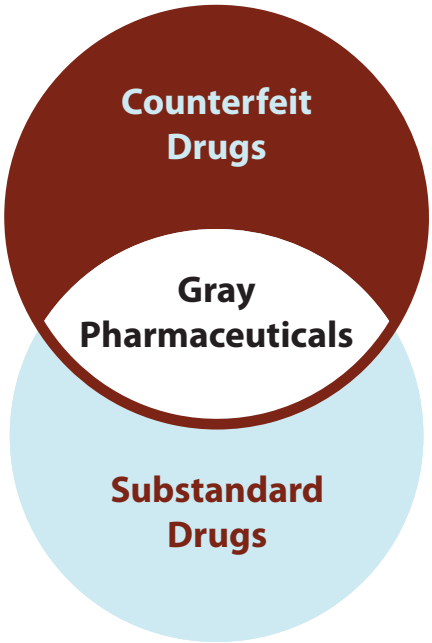


Source: Pharmaceutical Security Institute, accessed online at: http://www.psi-inc.org/geographicDistributions.cfm

Defining the Scope of the Problem: Counterfeit vs. Substandard vs. Gray

Counterfeiting affects all medical products, from medicines and pharmaceutical ingredients to medical devices and diagnostics. The terms "counterfeit drugs" and "substandard drugs" are often confused. For public health purposes, the WHO defines a counterfeit drug as one that is "deliberately and fraudulently mislabeled with respect to identity and/or source," and substandard drugs as, "genuine drug products which do not meet quality specifications set for them."[6] If substandard drugs are knowingly produced to make an unlawful product, they too are considered counterfeit. Furthermore, an additional "gray pharmaceutical" space is emerging where illicit profiteers are ostensibly marketing competitive brands without regulatory approval. These products are seldom "counterfeit" *per se*, but are very often substandard. Nonetheless, they threaten virtually all of the negative consequences of a *bona fide* WHO-defined counterfeit: circumvention of health regulations, undercutting public confidence, and potentially providing a comparatively easy source of income to criminal elements.

Because this is an opportunistic crime, the United Nations Office for Drugs and Crime (UNODC) finds that this type of counterfeiting is more likely to emerge where regulatory capacity is low. Surveys of anti-infective medications in Asia and Africa, for instance, have found as much as 60 percent of local drug supplies with active ingredients outside of medicinal limits. In West Africa, anti-malarial medicine, antibiotics, anti-tuberculosis drugs, and anti-retrovirals have all been targeted by counterfeiters resident in South and East Asia.[7]



As indicated by the data presented above, it is important to note that counterfeit drugs—including overt forgeries, pharmaceutically-sound close imitations, substandard generic medications, gray pharmaceuticals, and repackaged expired drugs—are not only a problem of the developing world. A growing volume of interdictions in the industrialized world shows that counterfeits are also pursuing Western markets (See Box 1). In many countries, including many across the developed world, weak or insufficient enforcement has contributed to these steadily rising trends. Drug regulatory systems in most countries, including in North America, expend far more time and effort on pre-marketing approvals than on post-market monitoring. No matter how thoroughly premarketing assessment is conducted, it is only one of the functions necessary for ensuring the efficacy and safety of drugs. Indeed, a recent WHO study found that less than 20 percent of the organization's member states are thought to have a well-developed drug regulation system.[8]

Box 1:
Examples of Counterfeit Medicines

Counterfeit medicine	Country/Year	Report
Alprazolam (anti-anxiety drug)	Canada/2007	Pills found with high levels of aluminum, titanium, arsenic, and other metals (led to Canada's first casualty on fake drugs)
Xenical (obesity medication)	United States/2007	Contained no active ingredient and sold via Internet sites operated outside of the United States
Cavinton (cardiovascular conditions and cerebral insufficiency)	Russia/2006	Medication included foreign substances. About 600 boxes of false Cavinton discovered in warehouse.
Zyprexa (biopolar disorder and schizophrenia)	United Kingdom/2006	Detected in the legal supply chain; lacked sufficient active ingredient
Nandrolone (treats osteoperosis and aplastic anaemias)	Spain/2004	Drugs had inadequate amounts of active ingredients. Discovery led to the largest counterfeit drug bust in Spain's history.
Cialis (erectile dysfunction)	Singapore/2004	Pills included active ingredients, but also consisted of varying amounts of other medication (sildenafil) to compensate potency.

Source: WHO, Counterfeit medicines: Fact Sheet No. 275, January 2010; National Review of Medicine, "BC woman killed by fake drugs bought online," July 2007; The Partnership for Safe Medicines, Counterfeit Drugs in Europe: Fact Sheet, July 2004; Graham Satchwell, A Sick Business: Counterfeit Medicines and Organized Crime, The Stockholm Network, 2004; The Lancet, "Russia cracks down on counterfeit drugs," October 2006.

The lack of strict monitoring and regulatory mechanisms allows for easy access to legitimate channels of distribution, making counterfeiting an appealing source of illicit revenue. Since national counter-trafficking initiatives primarily target narcotics, fake drugs encounter fewer obstacles to infiltrating the pharmaceutical supply chain. Since the legal implications are routinely much lower in comparison to, for instance, illicit drug trafficking—even though profits and consequences can be equally high—counterfeit pharmaceuticals are becoming the contraband of choice for both international and national criminal elements.

In the face of existing legislative and enforcement weaknesses, parallel trade, and elongated supply chains, it is clear that even Western countries have to do more to prevent counterfeiting.[9] Because of the overwhelming volume of global trade witnessed over the past decade, weak public health protections and enforcement in one country generate border enforcement challenges for even the most well-regulated public health system.

Of course, importation of counterfeits across national boundaries is only one part of this increasingly complex problem. More and more, criminals are perpetrating this form of health fraud from within countries of the developed world—including the United States

and Canada—in order to shorten supply chains, reduce costs, and lower the likelihood of detection. This is especially true of gray market pharmaceutical producers who rely upon legal gaps, governments' inability or unwillingness to enforce existing laws, and on their own flexibility of operations. Criminals and terrorist organizations are known to seek out the weakest link among local jurisdictions. As capacity increases in one region, illicit syndicates and terrorists move on to expose the loopholes in the next. Often, when one illicit facility is shut down, criminal producers are able to quickly reconstitute operations in other jurisdictions within days.[10]

In short, with easily penetrable borders, lacking or minimal oversight, and opportunities to expand through internet-based sales, the counterfeiting of pharmaceutical products has become an attractive means through which to fund criminal activities. Due to the complex and global nature of this threat, effective responses will require a wider array of inter-agency involvement from within government and enhanced cooperation between governments, as well as improved partnerships with legitimate private pharmaceutical and supply chain industry actors.

The Growing Challenge to Biologicals

> *Counterfeit medical products have been detected in most of WHO's Member States and in all its regions. Cases have involved widely-used medicines such as atorvastatin and paracetamol, limited-use medicines such as growth hormone, paclitaxel, and filgrastim, erectile dysfunction medicines, and medical devices such as contact lenses, condoms, surgical mesh, and diagnostic test strips used by diabetic patients to monitor their blood glucose concentrations. Both expensive products and cheap ones, generic and branded products are being counterfeited with the result that they appear in community pharmacies and hospitals, as well as other less-regulated settings.*[11]

According to UNODC, the latest criminal trend is the importation, repackaging, and sale of difficult to counterfeit drugs, including biological formulations. In 2006, a Pharmaceutical Security Institute report recorded 26 incidents of counterfeit biologics worldwide, which is 1.23 percent of the overall total of counterfeit cases documented that year. Less than 1.5 percent is not a negligible amount; severe injury or death could be magnified by false biologics since they are likely to offer no therapeutic value. Moreover, those with low levels of active ingredients are particularly worrisome as they can contribute to the development of drug-resistant strains of disease that can, in turn, spread globally. Counterfeit biologics are also difficult to detect since they are usually administered through injections and cannot be discerned by taste. This, along with the more sizeable cost differentials of these products makes counterfeiting biologics an ever more attractive and disconcerting illegal enterprise.[12]

The November 2009 seizure of illegally imported human immunoglobulin vials from a company in Mumbai is one case in point. Since the product contained immunoglobulin, it appeared that the vials were imported from a lesser producer in China and repackaged under a leading brand name. The counterfeits were being offered at 25 percent less than the market price. In 2006, Brazilian authorities found counterfeit Fluarix, an influenza vaccine, circulating throughout the country. Boxes of false doses were discovered right before an anti-influenza campaign in Brazil commenced, which aimed to inoculate 18 million Brazilians that year.[13] Similarly, about 250 counterfeit biological products—from meningitis vaccines to anti-cholera medication—were seized by a Nigerian federal task force in 2000. Reports indicate that these illegal biologics were being set aside without proper cold-chain storage requirements and were administered to unsuspecting citizens.[14] Another case in Kochi, India, involved the seizure of counterfeit brand name immunosuppressants—drugs designed to support organ transplantation worth some US$11 million. Further evidence that counterfeit pharmaceutical products are being imported illegally from China emerged with three separate seizures at the port of Chennai in May 2009 alone.[15]

Domestic production and the sale of counterfeit (as well as gray market) pharmaceuticals also pose a growing threat. For instance, on May 21, 2003, the US Attorney's Office for the Southern District of Florida filed charges against three individuals for unlawful sale and wholesale distribution of counterfeit versions of Amgen, Inc.'s prescription drug Procrit—a medication indicated mainly to help cancer, anemia and HIV patients increase their red blood cell count. The vials being distributed by all three men labeled as 'Procrit' did not contain any active ingredients, but instead contained only bacteria-tainted water.[16]

Health Fraud as a National Security Threat

Box 2

After his first in-center dialysis in January 2008, Randy Hubley of Toledo, Ohio suffered severe abdominal pain, diarrhea, and shortness of breath. Two days later, Randy collapsed and did not regain consciousness. Investigations attributed his death to heparin, an anticoagulant that treats blood clotting during kidney dialysis. According to reports, the heparin used before his treatment was counterfeit—the drug was contaminated with oversulfated chrondroitin sulfate, a compound that is structurally similar to heparin, rendering detection of the false substance extremely difficult. Counterfeit heparin induces severe allergic reactions; in 2008, the FDA documented 81 deaths and about 600 allergic reactions linked to the tainted drug. Its origin was traced back to a production plant in Changzhou, China, which also exports pharmaceuticals to Germany, Canada, France, Italy, and other countries.

The growing danger of counterfeit pharmaceuticals is well understood to pose a serious challenge to the health of North Americans (see Box 2), yet public health is not the only consequence of this sinister crime. Counterfeiters also work to evade legitimate taxation and quality controls. They threaten to destroy corporate brands and undermine public confidence in health infrastructures. Perhaps most distressingly, growing evidence suggests that these crimes are increasingly linked to criminal syndicates whose activities range from petty crimes to global terrorism. In short, the lucrative nature of counterfeiting threatens to feed larger and even more insidious criminal and terrorist activities in the United States and around the world.

These concerns go beyond the specious claims that terrorists may use the US drug supply to introduce poisons or biological agents to the homeland. Rather, these criminal entities are using the funds derived from counterfeiting indirectly to support their extremist and often violent activities around the globe. This trend is in keeping with a growing sophistication of terrorists and criminal networks that exploit the forces of globalization, such as a well-developed supply chain, in an effort to support their local, national, and even international operations. Examples in the sphere of proliferation of arms—both weapons of mass destruction and small arms—include individuals such as Viktor Bout and A.Q. Khan, who managed illicit international proliferation networks and shipping arms or materials to build them to the highest bidder worldwide. The increased focus on the counterfeit drugs industry by non-state actors is also a result, in part, of successful international efforts to cut off traditional sources of revenue to terrorist organizations.

As noted, the sale of counterfeit pharmaceuticals is often perceived as a problem endemic to developing countries where consumers are likely to seek inexpensive medications. However, given the fact that industrialized countries invest more in health programs for their citizens, criminals are beginning to target legitimate (and lucrative) supply distribution chains in

developed nations as well, including in North America and Europe. Counterfeit operations by European criminal organizations have been recently uncovered. For instance, Italian authorities discovered a clandestine facility for the production of counterfeit medication owned by Camorra, an organized criminal group based in Naples. A connection between Camorra and several Islamic terrorist groups has also been identified.[20] Such linkages between organized crime groups and terrorist organizations are especially disconcerting since both parties may be involved in remittance exchanges.

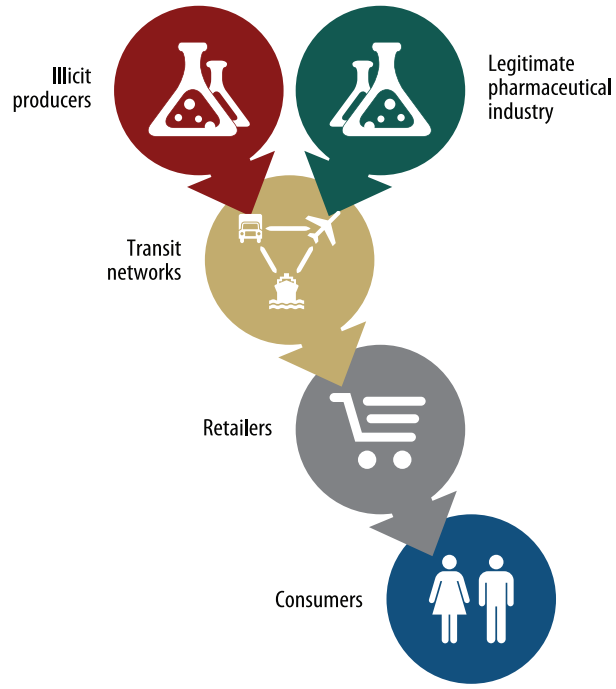
According to the American Council on Science and Health, there is documented evidence of groups including the Irish Republican Army, the Basque separatist group ETA, Chechen rebels and North African guerillas using drug counterfeiting as a source of funding.[21] An Interpol report in 2004 also identified terrorist financing through counterfeiting pharmaceuticals by loyalist and Union terrorists in Northern Ireland, and local ethnic-Albanian extremists in Kosovo.[22] In addition, the US Justice Department recently discovered a multi-national counterfeiting ring that smuggled counterfeit drugs into the United States and funneled its profits to the terrorist group Hezbollah. Finally, recent cases have linked al Qaeda to counterfeiting activities as well.[23] According to documents seized from al Qaeda camps, Abu Sayyaf and Jemmah Islamiyah—terrorist groups closely affiliated with al Qaeda—have turned to counterfeiting operations as a means to replace revenues lost as a result of counterterrorism efforts instituted after September 11, 2001.[24]

How is Trafficking/Counterfeiting Conducted?

According to the incident database of the Pharmaceutical Security Institute, countries in Asia report the largest share of counterfeits detected globally (See Figure 1). This is likely not only due to lax enforcement, but also to the scale of production of counterfeits emanating from China and countries of South and Southeast Asia. Other major producers include Nigeria, Russia, Mexico, Brazil and Latin America. Gray and substandard pharmaceutical product manufactures in the United States also pose a serious challenge to both public health and national security.

Depending upon their point of origin, these products can pass through multiple links on the illicit supply chain prior to acquisition by the consumer (See Figure 2). While the lion's share of WHO-defined counterfeits appears to be produced overseas, a growing share of counterfeits, substandards, and gray pharmaceuticals are being packaged from within Western markets—including the United States and Canada. In turn, their profits can support all manner of illegal activity, from illicit drug and human trafficking to weapons proliferation to terrorism.

Figure 2:
The Counterfeit Pharmaceutical Supply Chain



Many counterfeit and substandard drugs are produced overseas, often in Southeast Asia, China, India, Nigeria, Russia, Mexico, Brazil, and Latin America. Growing anecdotal evidence suggests that many substandard and "gray" pharmaceuticals are being produced in Western industrialized countries.

Both licit and illicit products are funneled into the legitimate supply chain through freight forwarders, shipping companies, importers, diverters, tertiary and secondary wholesalers, and individual and online purchasers.

Products may end up on the shelves of local pharmacies and legitimate online retailers, or may be marketed directly to consumers via phony internet pharmacies or through personal black markets.

Patients may either unknowingly purchase a counterfeit from a legitimate retailer, or knowingly purchase illicit product at cut rate prices through the black market.

Conclusion

Counterfeit, gray, and substandard drugs pose an unequivocal threat to the public health of North Americans. The US Food and Drug Administration (FDA) reports the number of counterfeit drug investigations have grown almost ten-fold in the last five years. Although the Agency estimates that less that 1 percent of drugs on the US market fall into one of these illicit categories, this could still mean that there is as much as a 1-in-100 chance of obtaining an illicit product. This also means that of the 4 billion prescriptions filled in the United States each year, as many as 40 million may be filled with counterfeits.[25] This astonishing figure does not account for the growing number of incidents involving gray area pharmaceuticals originating in North America itself, which can cause similarly damaging effects to human health and security.

Beyond the widening public health challenge posed by this growing and increasingly lucrative crime, evidence suggests that counterfeit, gray, and substandard drugs are also providing material support to criminals and terrorist organizations working to undermine national security. By providing illicit income to organized crime and other criminal gangs, and corollary profiteering to global traffickers in illegal drugs, weapons, and humans, the unchecked flow of these pharmaceuticals into and within Western markets helps support burgeoning crime syndicates in the United States and around the world. Moreover, growing evidence points to the direct correlation between the profits derived from these products and international terrorist activity. Shutting down these counterfeit and gray market producers, traffickers, and illicit salesmen in this country and around the globe must be a top public health *and* national security priority for our nation's law enforcement, national security, and public health agencies. In addition, the private sector must bear its share of the responsibility for prevention.

According to the WHO, many factors contribute to creating an environment in which the manufacture of, and trade in, counterfeit medical products can thrive:

- Governments' unwillingness to recognize the existence or gravity of the problem;
- Inadequate legal framework and penalties;
- Weak administration and coordination, with measures not focused on fighting counterfeiting;
- Ineffective control of manufacturing, import and distribution of medical products;
- Ineffective collaboration among bodies and institutions, such as health authorities, police, customs and the judiciary, involved in regulation, control, investigation, and prosecution;
- Ineffective collaboration and exchange of information between public and private sector;
- Insufficient international collaboration and exchange of information.[26]

Recommendations

Due to the complexity of the global drug production and distribution system, there is no single tactic that can eliminate the public health and national security threats posed by counterfeit pharmaceuticals. As such, a layered strategy is necessary, involving a wider array of inter-agency actors from within the government, enhanced cooperation between governments internationally, and improved partnerships with legitimate private pharmaceutical and supply chain industry actors. Immediate actions should include:

1. Raising Awareness: Governments typically view and thus manage the counterfeit drug issue as a public health and criminal enforcement challenge, yet indisputable and growing links between this industry and organized crime and terrorist organizations indicate that the national security community must play a larger role in preventing counterfeit drugs. Governments must encourage a more widespread recognition of the multidimensional nature of this growing threat and institute appropriate collaborative mechanisms. Legitimate private industry must also recognize their role in prevention and work more transparently with the government.

2. Mandate action by the national security community: The growth of trafficking networks around the globe has helped bring about a convergence of threats: counterfeit pharmaceuticals, narcotics, human trafficking, dual-use nuclear black markets, small arms and conflict resources including diamonds and timber. Together, these challenges have become so widespread that they threaten to overwhelm the capabilities of even well-intentioned governments to mitigate their destructive effects. The national security community must be given an explicit mandate to address these challenges in order to ensure the adequate and coordinated resources necessary to ameliorate the threat. In short, like the prevention of drug and human trafficking, counterfeit pharmaceuticals must become a mandate of government security apparatuses.

3. Enhanced security over international purchasing and distribution: At present, the lion's share of concern over the counterfeit pharmaceutical threat remains the developing world. As a large percentage of pharmaceutical products are distributed by international relief agencies and through government assistance programs, it is incumbent upon these actors to ensure that the products they are distributing are safe. At times, these agencies' pursuit of low-cost drugs has led them to deal with unapproved suppliers. This irresponsible practice should stop as it provides a direct conduit for organized crime and terrorist organizations to capitalize upon well-meaning development assistance for nefarious purposes.

4. Development of a transparent and verifiable chain of custody from point of production to point of sale: Efforts to establish a so-called "e-pedigree" system to track and trace pharmaceuticals have lagged because of the costly and complex infrastructure necessary to institute such a system, lack of agreed-upon industry standards, and questions regarding patient privacy raised by some civil liberties organizations. New

pressure should be brought to bear by the national security community to ensure that the public and private sectors collaborate in the design and implementation of a nationwide drug serialization system with a track-and-trace capacity. Governments should work collaboratively with industry to identify common e-pedigree standards and, where necessary, incent compliance with those criteria.[27]

5. Legal gap analysis: All governments should be encouraged to ensure that they have relevant, up-to-date laws, as well as rigorous penalties consistent with the trafficking in illicit narcotics to ensure that traffickers can be prosecuted and/or sufficiently deterred.

6. Enhanced early "authentication" procedures: Governments should be more proactive in exercising early validation of manufacturing sites and formal registration/validation of all importers both from a public health perspective, as well as from a national security standpoint. This should include not only more rigorous enforcement of importers and at national borders, but also with domestic manufacturers whose standards and custody practices may not be consistent with either public health standards or national security interests.

7. Enhanced enforcement: Although public health agencies—even in the developed world—recognize the challenges presented by counterfeits, substandard drugs, and gray pharmaceuticals, their ability to enforce compliance with existing laws is ineffectual due to limited resources. Recognizing that the challenges these products pose are not only a threat to public health but also a direct threat to international security, additional resources should be directed toward enforcement agencies at all levels, in all countries, to inhibit the growth of this scurrilous industry.

Endnotes

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2 The WHO defines a counterfeit drug as one that has been "deliberately and fraudulently mislabeled with respect to identity and/or source… Counterfeit products may include products with the correct ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging." See World Health Organization, "General Information on counterfeit medicines," 2006.

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27 See also: Roger Bate, *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade*, Washington DC, 2008, p. 67.

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"The deadly implications of counterfeit drugs are well recognized to be a growing threat to public health. Less well understood are the links between this sinister crime and organized criminal groups and terrorist organizations. This report examines the growing nexus between public health and national security through the prism of counterfeit pharmaceuticals."

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The Stimson Center
1111 19th Street, NW, 12th Floor
Washington, DC 20036
Phone: 202-223-5956 | Fax: 202.238.9604
www.stimson.org