GLOBAL HEALTH COMMENTARY

The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks

TIM K. MACKEY,[1,2] BRYAN A. LIANG[1,3,4]

[1]Institute of Health Law Studies, California Western School of Law, San Diego, California

[2]Joint Doctoral Program on Global Health, University of California, San Diego State University, San Diego, California

[3]San Diego Center for Patient Safety, University of California, San Diego School of Medicine, San Diego, California

[4]Department of Anesthesiology, University of California San Diego School of Medicine, San Diego, California

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ABSTRACT: Counterfeit drugs are a global problem with significant and well-documented consequences for global health and patient safety, including drug resistance and patient deaths. This multibillion-dollar industry does not respect geopolitical borders, and threatens public health in both rich and resource-poor nations alike. The epidemiology of counterfeits is also wide in breadth and scope, including thousands of counterfeit incidents per year, encompassing all types of therapeutic classes, and employing a complex global supply chain network enabling this illegal activity. In addition, information technologies available through the Internet and sales via online pharmacies have allowed the criminal element to thrive in an unregulated environment of anonymity, deception, and lack of adequate enforcement. Though recent global enforcement efforts have led to arrests of online counterfeit sellers, such actions have not stemmed supplies from illegal online sellers or kept up with their creativity in illegally selling their products. To address this issue, we propose a global policy framework utilizing public–private partnership models with centralized surveillance reporting that would enable cooperation and coordination to combat this global health crisis. © 2011 Wiley-Liss, Inc. and the American Pharmacists Association J Pharm Sci 100:4571–4579, 2011

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INTRODUCTION

At the end of 2010, a global effort to combat the distribution and sale of counterfeit and illegal medicines online culminated in "Operation Pangea III," resulting in the seizure of approximately one million illicit and counterfeit pills valued at approximately $2.6 million.[1] Represented by a number of international organizations, approximately 45 countries, and other private and public actors in a multipronged effort, this operation is the largest enforcement action in size and scope against criminal internet-based activities involving illegal sales of dangerous counterfeit medicines.[1]

Yet the pervasive public health and patient safety risks associated with counterfeit medicines are well established and continue to represent a global health problem.[2] Even the definition of what constitutes a "counterfeit" medicine is unclear and has been the subject of ongoing global debate. In the United States, counterfeit drugs are defined by the US Food and Drug Administration (FDA) as drugs falsely labeled or misrepresenting itself as being manufactured or distributed by a legitimate drug manufacturer, processor, packer, or distributor.[3] At the global level, the World Health Organization (WHO) defines counterfeits medicines as those that are "deliberately and fraudulently mislabeled with respect to identity and source."[4] WHO recognizes the challenges in achieving a standardized definition due to divergent interests of state actors that often trigger intellectual property considerations versus those of public health. In response, WHO has requested its member states to

Correspondence to: Bryan A. Liang (Telephone: +619-515-1568; Fax: +619-515-1599; E-mail: baliang@alum.mit.edu)

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provide their terminology for "counterfeit" as used in national drug legislation in order to better assess this issue.[5]

Debate on the counterfeit definition includes unilateral action in countries such as Kenya that have enacted their own anticounterfeit laws that are more inclusive than global definitions and may impact trade in legitimate and unauthorized generic drugs.[6] Countries such as India, which engage in the manufacturing of generic exports of medicines, have fought to repeal or amend these anticounterfeit laws emerging in African countries, aimed in part at combating local counterfeit drug production and distribution.[6] Such disputes have resulted in trade disputes, such as petitions filed by India and Brazil with the World Trade Organization regarding export seizures by Dutch customs authorities for generic medicines that have been deemed "counterfeit."[7] These disputes further complicate global harmonization and local regulation of counterfeits and point to the need for an internationally accepted definition of what constitutes a "counterfeit" medicine.

Yet these standardized definitions may not capture the wide range of fake and dangerous drug products including those that are expired, inactive or improperly stored/transported, have the wrong concentrations or dosage, have no active ingredient, or contain harmful or toxic contents.[2] Adulterated drugs may not be sufficiently recognized as a class of counterfeit drug products, given that they are poisonous and insanitary, are contaminated or otherwise have unsafe ingredients, and lack adequate controls of manufacture (such as Good Manufacturing Practices). Victims and healthcare providers are likely unaware that a counterfeit product or adulterated product can be the source of patient injury or death.[2] Differentiating genuine medicines from their counterfeit versions is exceptionally difficult as well, often requiring laboratory tests to verify authenticity.[8] In this paper, we primarily utilize the WHO definition of counterfeit medicines to address this global health policy issue, but note that adulterated and diverted products may also constitute subtypes of counterfeit products.

These counterfeit medicines have a disastrous effect on global health and on individual patient safety, including patient injury, nontreatment, and death. Importantly, contamination of the global drug supply chain can also lead to antimicrobial resistance for diseases with a high global disease burden and mortality, such as malaria, HIV, and tuberculosis (TB).[9–10] In fact, counterfeit medicines have been implicated in over 700,000 deaths from malaria and TB alone.[11]

Below, we review some of the key issues with the global scourge of counterfeit drugs. We first describe the epidemiology of the fake drugs sold, and then the global challenges associated with this criminal activity. We then examine the broad scope of this global health problem as well as the underground economy and technology that enables this illicit activity. Finally, we discuss the limitations of current international regulation and enforcement efforts and propose a global policy framework leveraging the advantages of public–private partnerships (PPPs) under a centralized system.

EPIDEMIOLOGY OF FAKES

Counterfeit medicines are not confined to specific drug classes, and instead span a broad spectrum ranging from lifestyle to life-saving medicines, as well as generic drug forms.[9] This includes counterfeits in therapeutic classes that extend to antimalarials, antibiotics, birth control, cancer, diabetes, erectile dysfunction, heart disease, schizophrenia, and transplant drugs.[9] Surveillance by the Pharmaceutical Security Institute, a nonprofit organization dedicated to the development of anticounterfeiting resources, have shown that close to 1000 counterfeit incidents occurred in 2005 involving some 100 countries, with 687 different pharmaceutical products in a wide array of therapeutic and organ system categories.[12]

Regardless of the product or category, the danger remains. Patient harm and death has been demonstrated with tainted erectile dysfunction drugs, diethylene glycol (antifreeze) introduced into a variety of counterfeit medicines (including cough syrup and fever medication), fake inhalers with infected water directly inhaled by cystic fibrosis patients, and deaths and allergic reactions resulting from adulterated heparin.[2,9,13,14]

GLOBALIZED CRIME

Global recognition of the serious multiple challenges and threats posed by counterfeit medicines is reflected in the efforts by WHO to raise awareness and coordinate international law-enforcement efforts against this global health threat.[4] However, efforts to stem this global crime have been uneven at best.

Although most of the manufacturing and trade in counterfeit medicines occurs in Asia, counterfeit medicines are pervasive worldwide.[9] This hazard was evidenced by the Interpol counterfeit seizures in 2009, including 20 million pills in China and Southeast Asia, 34 million pills in Europe, and hundreds of millions of dollars in counterfeit drug seizures in Egypt.[9] However, experts fear that this is only a small representation of the grandiose scale of the global counterfeit medicine market, estimated at some $75 billion in worldwide sales in 2010, with counterfeit incidents occurring all around the world and involving multiple international actors.[9,15]

Once faked, globalization of counterfeit drug trade and pharmaceutical markets provide opportunities for criminals to engage in this highly profitable and

relatively low risk business.[2] These include sophisticated criminal networks involving multiple routes of import and export across borders and free trade zones around the world in order to introduce products into both legitimate and illicit global drug supply chains and disguise their actual source.[16] Participants in this "shadow" industry include organized crime syndicates such as the Russian mafiya, Mexican gangs, Chinese Triads, and Colombian drug cartels. In a disturbing economic decision, these criminal entities have shifted operations over to counterfeit drugs in response to increased enforcement efforts against the cocaine and heroin illicit drug trade.[16] However, these criminal operations can also be versatile; they may engage in the sale and trade of both counterfeit medicines and illicit drugs simultaneously.[8] These funds not only implicate an expansion of organized crime, but they also contribute to potential terrorist threats.[17]

GLOBAL SCOPE

Counterfeit purveyors are also equal opportunists, and do not discriminate between the developed world and countries that are resource-poor.[9] Because of the broad range of products these criminals offer, price elasticity they enjoy through substandard materials, and lack or vulnerability of safety/regulatory controls, they can address the demand and price sensitivities of consumers with different socioeconomic status (SES) effectively.

Hence, counterfeit producers can penetrate multiple global markets, including selling counterfeits for expensive chronic diseases in developed countries and counterfeits for cheaper, more essential medicines in resource-poor countries. In fact, prevalence of counterfeit medicines may vary based on geographical regions or even locally within country, segmented between urban and rural areas.[4] These differences highlight the particular vulnerability of patient populations who lack access to medicines and may be more susceptible to counterfeit drug purchase and use.

DEVELOPED COUNTRIES

The European Union (EU) is particularly threatened by an influx of counterfeit medicines, especially those sold on the Internet. With estimates depicting annual increases of counterfeit sales of 15% per annum and one in five Europeans admitting they have purchased a prescription drug without a prescription, counterfeits have become a serious public health problem in this region.[18] This increase was also further evidenced by the seizure of 11.4 million counterfeit drugs at EU borders in 2009, representing a 422% increase since 2006.[19]

In addition, high-profile discoveries of counterfeiting operations within the EU, such as a counterfeiting operation in the United Kingdom that was producing 500,000 counterfeit pills daily, continue to highlight the risk of both counterfeit production and consumption in middle to high income countries in Europe.[2] Similar instances involving counterfeit production and distribution have been discovered in countries such as The Netherlands, Italy, Spain, and France, sold both through EU parallel trade and on the Internet.[2,20,21]

RESOURCE-POOR COUNTRIES AND EMERGING MARKETS

Of particular concern is also the rapid spread of counterfeit medicines in resource-poor countries of the developing world, which have low levels of gross national product per capita. These countries are especially vulnerable because they lack sufficient infrastructure and technical expertise to regulate and police criminal activity.[22] Counterfeits are also a significant problem in emerging markets that are transitioning from developing to developed standing, such as the "BRIC" countries of Brazil, Russia, India, and China.[23] In these countries, a growing consumer base for prescription drugs, close proximity to counterfeit manufacturers, and the need to access drugs at lower prices have meant that counterfeit drugs are common in these markets.[23,24]

In low-resource countries, counterfeit medicines are commonly sold to treat life-threatening illnesses.[25] These areas includes regions such as Africa, where organized counterfeit crime rings are rampant due to failure of local regulatory systems and challenges in surveillance and enforcement.[8] These low SES populations are disproportionately impacted, given their need for essential drugs to fight infectious diseases such as malaria, TB, and HIV/AIDS—the very diseases that attract fakes and that are counterfeited there.[22]

Indeed, the literature on counterfeits in resource-poor countries is deeply concerning. Surveys and studies have shown that an estimated 30% of drugs sold in Kenya are counterfeit, that between 38% and 53% of vital antimalarial drugs in mainland Southeast Asia are counterfeit, and that in several other cases, patients have been left untreated and died as a result of counterfeit vaccines that comprised only water or saline.[16,22]

DISPROPORTIONATE IMPACT IN RESOURCE-POOR SETTINGS

The impact of counterfeits in essential drug stocks has a profound and disproportionate impact in resource-poor countries. These include increased morbidity and

mortality, adverse effects, therapeutic failure, inaccurate reports of drug resistance due to substandard medicines, and rise of drug-resistant pathogens.[22] Counterfeits also compound healthcare problems common to resource-poor countries, such as a poor public health infrastructure for outreach, and may add to additional loss and waste of economic- and health-related resources whose populations already suffer from significant access limitations.[8]

In an effort to combat the prevalence of counterfeits in developing countries, the US Agency for International Development (USAID) and the US Pharmacopeia Convention have joined the Promoting the Quality of Medicines Program to promote quality, safe, and efficacious medicines that are used in USAID's priority health programs.[26] These efforts are crucial, given that counterfeits have been discovered in a number of low-resource countries within its scope, including Uganda, Senegal, Niger, Philippines, Ghana, Ivory Coast, Democratic Republic of Congo, Laos, Burma, Vietnam, and Cambodia, as well as others.[16,27]

IMPACT ON USA

USA, although more insulated from the dangers of counterfeit medicines introduced into the domestic drug supply chain, has also reported patient safety issues and deaths related to counterfeit medicines.[2] As the world's largest market for pharmaceutical sales, it is natural that counterfeit manufacturers and sellers have targeted USA as its most lucrative market.[2] This includes counterfeits for blockbuster drugs including Lipitor (which was subject to recall due to discovery of counterfeit lots), Viagra, Zyprexa, and Epogen.[2,28] More recently, the FDA had discovered counterfeit "Generic Tamiflu" (Tamiflu has never been approved as a generic product by the FDA) and counterfeit Alli (a popular weight-loss drug) being sold over the Internet.[29,30]

Unfortunately, these incidents of counterfeit are not limited to suspect sales. These counterfeit medicines have been discovered in USA hospitals, clinics, and pharmacies, and may be sourced through the "gray market," a secondary market where counterfeit medicines may slip between cracks in the distribution supply chain.[2,21] In addition, counterfeits may use stolen drugs that are then diverted to criminal parties for illegal sale. Recently, FDA commissioner Margaret Hamburg announced that addressing counterfeit medicines was crucial for the FDA in fulfilling its public health mandate to protect patients and the nation's drug market.[31]

ILLICIT E-COMMERCE

Facilitating the globalization of counterfeit medicines and their illegal sale are advances in information technology, particularly the internet.[8] This illicit e-commerce is extensive: WHO estimates that over 50% of medicines purchased from sites that do not list their physical address are counterfeit.[4] Other studies have found even greater concerns, including that only approximately 4% of online drug sellers are fulfilling legal mandates for selling prescription drugs.[32] Indeed, accessibility to Internet technology that can actively market, mislead, and act as an anonymous and virtual outlet for sale of counterfeit medicines may account for the estimated 90% increase in worldwide counterfeit sales from 2005–2010.[9] These advantages and other Internet-supported suspect activities[33] create the perfect storm for illicit sales of counterfeit medicines and hamper enforcement efforts.

With increasing numbers of people using the Internet to search for health information, it is not surprising that consumers end up purchasing drugs from online pharmacies, including vulnerable groups such as seniors and low-income patients.[34,35] Unfortunately, many, if not most, online pharmacies are involved in illegal activity, including selling medicines without a prescription, selling medicines using a medical questionnaire in lieu of a prescription, presenting misleading, false and inaccurate claims and advertising about their products and services, and selling and exporting drugs without appropriate authorization.[35] This has led to documented patient deaths for online pharmacy sales globally, including USA, New Zealand, and Canada.[35] These online pharmacies have also been linked to organized crime such as Russian cybercriminals who operated "Canadian Pharmacy" and Julio Cruz and Domingo Gonzales, former cocaine drug dealers with South American connections who hatched their counterfeit drug plan in prison.[2,36]

ONLINE DRUG SELLER REGULATION AND ENFORCEMENT

Challenges of regulation and enforcement of these illegally acting, illicit online drug sellers are magnified due to the vagaries of the digital marketplace. This includes the ability for sites to open and close with high frequency, use of mirror sites and data aggregators to conceal presence, and increasing use of forms of e-marketing.[35,37] Further complicating the issue is a litany of service providers, both illegal and legal, which enable sales online, including Internet service providers, online payment processors, logistic providers, and search engines/search engine marketing companies.[35,37]

Emerging counterfeit issues also center on the Internet. For example, one key observation is that illicit online pharmacies are on the cutting edge of marketing their dangerous products. This includes the use of direct-to-consumer-advertising for drugs in social media and other interactive forms of Internet media

including Facebook, Twitter, and Friendster.[37] These social media platforms involve high traffic and have the potential to be "pushed" to consumers in a very cost-effective manner. However, they are not adequately regulated in USA or globally.[37] In addition, illicit online pharmacies have also engaged mobile technology platforms as a way to enhance their online presence and mislead consumers about the safety of their medicines.[38]

LIMITED POLICY EFFORTS

In an attempt to combat some of these challenges, the United States passed legislation in 2008 prohibiting the sale and distribution of controlled substances over the Internet.[39] However, this law only relates to controlled substances and does not address regulation of overseas online pharmacies, the primary suppliers of counterfeit medicines.[35] Voluntary efforts include the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation program through the National Association of Boards of Pharmacy. VIPPS is designed to accredit online pharmacies on the basis of robust compliance and licensure requirements.[35] However, as of June 2011, only 28 pharmacies were listed in its database.[40]

The EU has recognized the need to address counterfeits in the context of Internet, where some member states allow for the sale of medicines online.[41] In approving legislation to combat the sale of counterfeit medicines, the EU requires stamping and serialization of pharmaceutical products shipped in the EU, safety seals and holograms to make falsifying packaging more difficult, and harsher criminal penalties for illegal acts involving counterfeit drugs.[18] The EU will also require online pharmacies to have authorization to sell to the public, be linked to a central website of authorized Internet pharmacies, and comply with certain regulatory requirements before they are issued an EU logo to indicate they are in compliance.[18,42]

The EU requirements for online pharmacies appear to go one step further than the USA efforts of voluntary compliance under VIPPS accreditation. However, text of the proposed law approved by Member European Parliament officials must also be approved by the EU Council of Ministers in order to become law, after which national legislation to implement it by Member States must be accomplished within 18 months.[42] These potential legislative and timing hurdles add to the challenges of establishing globally-harmonized regulation of online pharmacies and counterfeit drugs.

TECHNOLOGY AS SOLUTION

Detecting counterfeits is also a significant challenge that has not yet been adequately addressed through emerging technologies and end-to-end authentication and track and trace systems.[43] The most promising and potentially efficient tracking and authentication technology that has presented itself is radiofrequency identification (RFID) tags.

Both authentication and track and trace systems use RFID tags affixed to packaging or medicine packs in accordance with certain standardized formats required by the FDA that would track drug shipments in a networked database.[43] End-to-end authentication and e-pedigree would integrate manufacturers, wholesalers, and pharmacies within the drug supply chain of custody.[43] However, though promising, these systems are difficult to implement, requiring interoperability between different actors, an ability for systems to communicate using standard protocols, and the added costs and logistical challenges of changing internal processes of shipping and handling.[43,44] In addition, challenges regarding the unfunded cost of implementation of FDA e-pedigree mandates in the USA, which have been estimated to range from $84,000 for individual pharmacies to $1.3 billion for large-chain pharmacies, may present significant barriers to RFID adoption.[45] Further, counterfeit drugs purchased from illicit online pharmacies may negate the cost-effectiveness of RFID technology by legal actors, given that counterfeits will continue to have a pathway to consumers.[45] Though states such as California have enacted laws requiring implementation of e-pedigree systems, the ability of the industry to actually deploy these technologies remains uncertain, and implementation of the law has repeatedly been delayed.[43,46]

GLOBAL COOPERATION: A POLICY PROPOSAL

The emerging counterfeits drug problem globally, particularly concerning illicit online sales, has increased the attention to addressing this issue across geopolitical borders. International cooperation in Operation Pangea III has been hailed as widely successful. However, its effects may be temporary, given that previous operations have also led to large seizures, yet the illicit counterfeit trade continues unabated. Further, unresolved political concerns regarding enforcement actions against generic producers such as India, and claims of counterfeit definitions as a surreptitious method of making all non-brand-name drugs illegal have stymied efforts to ramp up this global anticounterfeit initiative.[27] However, the WHO's International Medical Products Anti-Counterfeiting Taskforce provides an excellent model for collaboration and coordination among private and public sector actors, which is needed to address this problem.

PUBLIC–PRIVATE PARTNERSHIPS

In order to maximize the opportunities presented by this framework for globally harmonized regulation

and enforcement, a sustained, unified, and active effort to address this dynamic problem is needed. This approach should include an emphasis on the formation of PPPs to leverage the respective strengths and technical capabilities of various partners.

Effective surveillance of illicit online pharmacy actors can only be accomplished through active and real-time surveillance involving both the public sector and private industry. This includes utilizing the technical expertise of Internet service companies that provide the technology and services that drives e-commerce and consequentially online counterfeit sales (e.g., Internet service providers, domain registrars, etc.), drug company intelligence on suspected counterfeits, and corporate supply chain management knowledge combined with law enforcement and drug regulatory expertise. Through the development of a public–private network of trained professionals focused on counterfeit drug sales, who utilize technology such as web search analytics, traffic information, search engine marketing, and domain/registry information, detection of illegally operating websites could be active, dynamic, and ultimately more effective than current *ad hoc* efforts.

In addition, these partnerships can result in the development of innovative technologies that would enable automated surveillance and reporting using algorithms, logic models, crawling bots/spiders, and key term searches. With these tools, PPPs could actively survey the web for illicit online pharmacies selling suspected counterfeits under certain fixed parameters. Such systems can be disseminated to both developed and resource-poor countries for their use at low or no cost. After this information has been processed, regulators and enforcement agencies could then verify information and data regarding suspected counterfeit products reported through the surveillance system, seek verification of status with manufacturers, and then assess appropriate action. Efforts should include reactively notifying the public and acting against illicit sellers to protect patient safety and public health, and proactively learning policy lessons to further block future counterfeit sales.

CENTRALIZED AND ACTIVE SURVEILLANCE SYSTEM

Crucial to this kind of dynamic surveillance system is the responsible generation and sharing of information regarding illicit online pharmacies and suspected counterfeit products across multiple stakeholders globally. In order to accomplish needed information collation and timely reporting of surveillance data, the formation of a centralized and standardized reporting system accessible to these actors for the purposes of collective reporting should be engaged. Through this system, registered healthcare providers, regulators, government agencies, international organizations, non-governmental organizations (NGOs), pharmaceutical manufacturers, and public health agencies would have the ability to access, report, share, and collaborate on data involving public health risks of suspected counterfeit drugs, including online providers as well as in-person sites for purchase. These reports could be anonymous or permit the reporter to identify himself/herself for additional information and feedback as has been successfully performed in other patient safety settings.[47,48] This would create a network of accessible surveillance data that could be followed up, investigated, and studied by a central drug regulatory authority as well as other interested parties (e.g., academics, policy researchers, NGOs, etc.), and could be implemented as an extension of existing global surveillance infrastructures such as WHO's Rapid Alert System website, which provides multisector detection and reporting of counterfeit drugs from the Western Pacific Region.[49] The results of this event reporting could then be communicated back to all members of the system, including pharmaceutical manufacturers, for verification, and possibly to the public as a form of adverse event reporting similar to FDA's Medwatch system or the Partnership for Safe Medicines SafeMeds email alert system,[50] in order to inform patients about risks regarding certain websites or drugs. Such a system could also be a repository for anonymous and consumer-based reporting of illicit websites and counterfeit products, such as is currently available on the FDA's website.

INDUSTRY INITIATED PREVENTION AND ENFORCEMENT EFFORTS

The development of PPPs that engage public and private sector actors in conjunction with a centralized global active surveillance system is a crucial and fundamental step in identifying illicit online pharmacies and effectively shutting them down before they can harm patients. However, a comprehensive solution to stem the current ongoing supply of counterfeit products that enter the Internet distribution market also requires more active participation and collaboration between pharmaceutical manufacturers and private sector technology and service providers to develop innovative solutions of securing the global drug supply chain.

Some of these private efforts show promise, addressing at least some of the weaknesses of past efforts.[44] This includes potential use of enhanced labeling, packaging security measures, and supply chain security systems through industry collaboration. These efforts utilize technology and software

solutions such as mass serialization at individual product level and drug pedigree management, new unique coding and identification solutions, and use of physical–chemical identifiers to combat counterfeits.[51–53] Other innovative technologies, such as the development of mobile product authentication solutions and mobile or "mPedigree" enabling consumers to verify and report if a drug is counterfeit using mobile technology have been employed in resource-poor countries and may show promise in the future.[54,55]

Collectively, these industry-driven high-technology solutions may have the potential to stem the supply of counterfeit products that fuel illicit online sales.

POTENTIAL BENEFITS

The ultimate output of any active surveillance system is the production of timely and reliable information that regulators and law enforcement can use to ensure patient safety and protect public health. The proposed system would provide this level of information in an organized fashion within a standardized and central location. Importantly, both developed and resource-poor countries could participate in such a system after the relevant information technology infrastructure is provided. Further, public health communications can take advantage of the extensive mobile phone presence in resource-poor areas such as Africa and Southeast Asia.[56] Indeed, by housing it within a collaborative system with knowledgeable teams, regulators as well as law enforcement, healthcare providers, and industry can collaborate to ensure that potentially harmful products are removed and websites made inaccessible.

Such a dynamic feedback system could result in additional seizure of counterfeit drugs by law enforcement, the removal of suspected counterfeit drugs from the drug supply chain by healthcare providers, the takedown of websites illegally selling such drugs, and interdiction using cooperative law enforcement systems and public health actions. Hence, both the physical and technical infrastructure for counterfeit sale and profit would be disabled with such efforts aided by some industry-led initiatives such as those explored above.

The potential for creating such a program is significant. The FDA has indicated that it will provide up to $3.5 million to invest in the development of a rapid global surveillance and monitoring system for counterfeit drugs with WHO.[57] A task force of global public health, law enforcement, drug regulatory authority, academic researcher, and private sector stakeholders should be convened to begin the process of creating such a cooperative global governance system.

CONCLUSION

The scourge of counterfeit drugs worldwide threatens patient safety and public health. The scope and incidence is rapidly increasing, and all organ systems and countries are affected. The growing use of the internet has fueled the counterfeit drug trade. To address this issue, global health stakeholders from the public and private sectors must cooperate and together work to understand, detect, warn, and address the criminal element threatening the drug supply and patients. The world must move forward to address this major concern. Otherwise, the next victim of counterfeit drugs may be our own friends, families, and loved ones. And in that case, no enforcement, policy, action, or rhetoric will ever bring back the time lost because of that system failure. The time to act to address counterfeit drugs is now.

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