



INSTITUTE FOR HOMELAND SECURITY



**Sam Houston
State University**

SUPPLY CHAIN RISKS OF ILLICIT TRADE IN COUNTERFEIT PHARMACEUTICALS

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Jay P. Kennedy

Abstract

Nearly every type of product that has ever been produced has been counterfeited. While the most counterfeited goods tend to be footwear, luxury items, watches, and jewelry, in recent years there has been a dramatic increase in the prevalence of pharmaceutical counterfeits. The World Health Organization (WHO) defines counterfeit medicines as “medicines that are mislabeled deliberately and fraudulently”, yet counterfeit medicines are generally discussed alongside other forms of harmful medical products such as adulterated, expired, substandard, stolen, and falsified medicines. Each of these products moves through a mix of illegitimate and legitimate intermediaries and distribution channels before making their way into healthcare systems and ultimately to patients.

Counterfeit pharmaceuticals harm patients, the healthcare system, legitimate companies, and society. While their presence within the legitimate supply chain is increasing, the threats posed by these illicit goods can be countered through focused action and collaboration amongst industry, healthcare, and law enforcement. This paper discusses three primary risks to consumers and the healthcare infrastructure of Texas: (1) the infiltration of counterfeit drugs into the legitimate supply chain; (2) the direct threat posed by counterfeit pharmaceuticals; and (3) the risks posed by counterfeit drugs to national security and the legitimate supply chain. The paper concludes with a discussion of policy and anti-counterfeiting strategy recommendations aimed at addressing each of the identified risks and protecting Texans, Americans, and the healthcare supply chain.

Author Biography

Dr. Jay P. Kennedy completed his Ph.D. in Criminal Justice at the University of Cincinnati, where he also earned an MBA with a focus on organizational behavior. After completing his doctoral studies, Jay joined the faculty of the School of Criminal Justice at Michigan State University. As a faculty member Dr. Kennedy taught classes and executive education courses on product counterfeiting, crimes against business, white collar crime, criminological theory, and supply chain management. At Michigan State he was Assistant Director of the Center for Anti-Counterfeiting and Product Protection, the leading academic institution dedicated to issues of brand protection and anti-counterfeiting. Jay is currently the Global Lead – Brand Protection External Relations for Amazon, coordinating the company’s external engagements and messaging related to its work to fight counterfeit goods. Through his research, Dr. Kennedy has become a globally recognized expert in product counterfeiting and brand protection, regularly speaking at industry conferences and on behalf of the U.S. Department of State, Department of Justice, and the U.S. Patent and Trademark Office. Dr. Kennedy also serves as an expert advisor to the OECD’s Task Force on Illicit Trade in Counterfeits, which is currently developing a best practice guide for online anti-counterfeiting.

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1. Introduction and Overview

Counterfeit products are illegitimate copies of legitimate goods. They are manufactured through unregulated and often substandard means, then marketed and sold to consumers for the sole purpose of generating illicit profits for the counterfeiter. Nearly every type of product that is produced is counterfeited, including pharmaceuticals and medical products. Early records of trade in counterfeit goods date back over four millennia, with some records chronicling the sale of false medicines and ointments occurring in ancient Egypt. Over the past decade the most seized counterfeit goods coming into the United States have been apparel and sportswear, luxury purses and handbags, watches and jewelry, shoes, and consumer electronicsⁱ. Yet, the US Food and Drug Administration (FDA) has noted a marked rise in the prevalence of counterfeit medicines coming into the US, particularly through international mail facilitiesⁱⁱ.

1.1. Counterfeit Pharmaceuticals

The World Health Organization (WHO) defines counterfeit medicines as “medicines that are mislabeled deliberately and fraudulently”. Using this definition extends pharmaceutical counterfeiting beyond the legally defined boundaries of counterfeit goods (i.e., constrained to trademark violations). In fact, counterfeit medicines are generally discussed alongside other forms of harmful medical products and are just one aspect of illicit trade in pharmaceuticals. Adulterated, expired, substandard, stolen, and falsified medicines exist alongside counterfeits within the global illicit and legitimate supply chains. In terms of the flow of illicit pharmaceuticals through supply chains, there is not much distinction between a counterfeit, substandard, stolen, or other type of illicit good. Each of these products moves through a mix of illegitimate and legitimate intermediaries and distribution channels before making their way into healthcare systems and ultimately to patients.

1.1.1 Size of the counterfeit goods market

Due to the illicit nature of the activities surrounding the manufacturing and distribution of counterfeit goods it is difficult to obtain accurate estimates of the size of the counterfeit market. Typically, law enforcement seizure data is used to generate approximations, yet these tend to be highly speculative. For example, in 2019 the Organization for Economic Cooperation and Development (OECD) estimated that counterfeit products made up roughly 3.3% of all global tradeⁱⁱⁱ. A report by the Guardian newspaper put the figure at 10% of global trade, with a value of \$600 billion USD per year^{iv}. Estimates of the size of the global pharmaceutical counterfeiting market are just as obscure as those for the overall product counterfeiting problem. For example, the WHO, citing the FDA, has stated that up to 10% of all the medicines in the world are counterfeit^v. Scholars monitoring pharmaceutical counterfeiting estimate that global trade in fake medicines can be valued at between \$200 to \$400 billion USD^{vi vii viii}. Yet, the President of the Pharmaceutical Security Institute argues that these estimates are well off-base, noting that risks are not equally distributed and that the total percentage of counterfeit medications globally is no more than 2% of all medications.

1.1.2 Focus of this report

Manufacturers, law enforcement, and researchers have found a wide range of counterfeit medical and pharmaceutical goods within the supply chain, including prescription and OTC medications, diabetes testing strips, surgical mesh, durable medical goods such as patient beds and components for hospital equipment, as well as instruments and surgical equipment. This report

focuses solely on counterfeit pharmaceutical products. However, many of the risks identified and strategies discussed are applicable to supply chain issues related to other counterfeit medical products, as well as fake, substandard and adulterated medicines.

This paper discusses three primary risks to consumers and the healthcare infrastructure of Texas: (1) the infiltration of counterfeit drugs into the legitimate supply chain; (2) the direct threat posed by counterfeit pharmaceuticals; and (3) the risks posed by counterfeit drugs to national security and the legitimate supply chain. The paper concludes with a discussion of policy and anti-counterfeiting strategy recommendations aimed at addressing each of the identified risks and protecting Texans, Americans, and the healthcare supply chain.

2. Key Risk #1: Counterfeit Drugs Infiltrating the Legitimate Supply Chain

Unlike other types of counterfeit items, counterfeit pharmaceuticals distributed within the United States are purely deceptive in nature as consumers have not been found to go in search of fake products. This is not the case in countries with less healthcare stability, such as many African nations where consumers at times willingly choose to buy counterfeits because they cannot afford legitimate medications^{ix}. American consumers are deceived into purchasing counterfeits, despite at times ignoring the risks of less-than-legitimate sources such as online pharmacies and unregulated internet channels^x. Whether counterfeits are purchased from unregulated and rogue internet sites or from legitimate pharmacies (as has been shown in recent months with counterfeit Ozempic found on pharmacy shelves^{xi}), the legitimate medical supply chain is regularly utilized by those who operate these criminal schemes. When counterfeit drugs infiltrate the legitimate supply chain and threaten patient safety there is great potential that victimized patients will lose trust in the legitimate healthcare system.

The pharmaceutical supply chain can be quite complex, involving a number of intermediaries and distributors. Yet, a simplified model can be used for the purposes of this paper. The first step in this model supply chain is the sourcing of base ingredients by a pharmaceutical manufacturer. Once a product has been manufactured, it moves to either product packaging or into wholesale distribution. At the wholesale distribution stage, drugs are packaged and repackaged to fit the distributors needs. Following this, the pharmaceuticals are distributed to pharmacies and healthcare systems, before being distributed to patients.

Within this supply chain there are multiple points at which counterfeits can enter the system, yet counterfeits have most often tended to enter the legitimate supply chain via one of several methods: (1) a counterfeiting organization works with legitimate medical distribution companies who are complicit in the counterfeiting scheme to co-mingle counterfeit goods with legitimate products; (2) a licensed healthcare provider/organization (individual or entity) obtains or produces counterfeits and introduces them into the supply chain or distributes them directly to patients; and (3) a healthcare entity is deceived into purchasing counterfeits from a legitimate-appearing organization, often times by relying upon forged documents that falsify the provenance of the products being sold.

2.1. Infiltration via legitimate distributors

This method of infiltration can be very difficult to detect as the legitimate distributor works hand-in-hand with counterfeiters, thereby giving legitimacy to the illegitimate products. Spot checks of

items to check for counterfeit, adulterated, or otherwise illicit goods may miss the “bad apples”, providing the counterfeiters cover for their actions. Infiltration of the legitimate medical supply chain has been found to be a global issue affecting countries with weak and very strong supply chain security regimes^{xii}. Because a legitimate company is hiding counterfeits within the supply chain, illicit goods can be very difficult to detect. However, prior investigations of legitimate companies involved in infiltrating the supply chain with counterfeits have identified inventory and financial transaction records as key indicators of illegal activity. The legitimate company must account for either inventory that has not been purchased through normal channels, or income that is not attributable to purchase orders for legitimate goods.

2.2. Occupational pharmaceutical counterfeiting

The second common method whereby counterfeits enter the legitimate supply chain is through counterfeiting by a licensed healthcare provider or other legitimate healthcare entity. This type of counterfeiting is arguably the most nefarious. In these cases, a trusted individual within the healthcare community knowingly introduces fake products into the stream of commerce, deceiving patients and putting them at risk. This method of infiltration was most recently highlighted by the activities of Houston, Texas based pharmaceutical manufacturer which conspired with criminal organizations to manufacture and distribute counterfeit cough syrup^{xiii}, as well as recent distribution of counterfeit Ozempic in spas and medical clinics^{xiv}, and the purchase and distribution of counterfeit cancer drugs by doctors in California^{xv}. This type of counterfeiting tends to be conducted by solo practitioners, or providers that operate clinics or independent pharmacies. Healthcare providers working within a large hospital system or structured medical practice with multiple layers of operational management and oversight have not been found to be complicit in these types of schemes. It seems clear that opportunities for this type of infiltration are most prevalent in situations where healthcare providers have little oversight and the ability to use counterfeits to grow profit margins.

2.3. Deception by counterfeiters

The third common method whereby counterfeits infiltrate the legitimate supply chain is when a healthcare entity is deceived, sometimes on multiple levels, into believing they have purchased legitimate products. When this type of deception occurs, spotting counterfeits can be difficult. For example, in one incident using this type of deception counterfeit pills were put into legitimately labeled bottles by licensed pharmacists who had unwittingly purchased counterfeits from a rogue supplier^{xvi}. Yet, the most prominent examples of this type of infiltration was witnessed throughout the COVID-19 pandemic as both patients and healthcare systems were targeted by counterfeiters.

Because healthcare systems were at the center of responses to the crisis, counterfeiting schemes took direct aim at these institutions. For example, less than a day after President Trump declared a national state of emergency because of the coronavirus, U.S. Customs and Border Protection seized its first shipment of counterfeit testing kits. As the pandemic continued, counterfeiting schemes involving vaccines, treatments, and PPE continually developed. Despite the sophistication of the U.S. healthcare supply chain, tens of millions of units of counterfeit PPE were purchased by hospitals and healthcare providers across the country. In one case, several hundred thousand counterfeit 3M N95 masks were purchased by a hospital system in Washington state for use by front-line healthcare providers at more than 40 hospitals^{xvii}.

These products were not purchased from a sketchy back alleyway in New York, but rather were obtained through the hospital's regular purchasing process. A vetted third-party supplier sold the counterfeit masks, which had the appropriate paperwork and passed physical inspections by the hospital system. The problem was not with the hospital system's ordering process, but with the supplier's source of supply. It is unknown to the author whether the supplier was complicit in the scheme, but what is clear is that gaps in the availability of a product and disruptions to the legitimate supply chain ran headlong into heightened demand for essential items. This created the opening for counterfeit items to flood the legitimate supply chain.

The criminal networks that distribute counterfeit pharmaceuticals and other fake medical products understand that their ability to sell their illicit goods rests upon their success in creating veils of legitimacy around their products. They understand that it can be difficult to differentiate between legitimate and counterfeit goods and even brand owners can, at times, be hard pressed to distinguish their legitimate product from illegitimate fakes.

2.4. Texas' supply chain infiltration risks

Texas sits in a unique position when it comes to the supply chain risks posed by counterfeit pharmaceuticals. In terms of potential victims, Texas' population means that it is likely to experience disproportionately large numbers of victims. With over 900 hospitals^{xviii} in the state and more than 13 million patient days each year^{xix}, Texas also has the more destinations and targets for counterfeit pharmaceuticals than any other state in the country. The vast healthcare system within Texas is supported by national and international supply chains, which sometimes overlap with the legitimate non-medical supply chain, as well as the illegitimate supply chain. In terms of the movement of goods through supply chains generally, Texas' 28 border crossings are more than any other state, with nearly 68% of all U.S. international commerce flowing across the Texas-Mexico border^{xx}. It is therefore unsurprising that Mexico is Texas' largest trading partner. In terms of international trade beyond Mexico, five Texas maritime ports are among the 20 largest ports in the U.S., when ranked by total tonnage^{xxi}.

Unsurprisingly, the flow of goods from Mexico into the United States at times includes counterfeit pharmaceuticals. A U.S. Government investigation uncovered this fact earlier this year. Homeland Security Investigations (HSI) officials announced in March that operations in Texas border cities had resulted in the seizure of more than 10,000 packages of counterfeit prescription medication being sold at grocery stores and flea markets^{xxii}. Beyond this, a 2021 report by the Drug Enforcement Administration (DEA) determined that the vast majority of the millions of counterfeit pharmaceuticals (primarily oxycodone (Oxycontin®), Percocet®), hydrocodone (Vicodin®), and alprazolam (Xanax®); or stimulants like amphetamines (Adderall®)) originate in Mexico^{xxiii}. Many of these counterfeits are mass produced by drug cartels and sent across the border for distribution in the United States^{xxiv}. While many of these pills are sold on the black market, others have found their way into the legitimate medical supply chain.

The volume of cross border trade, the influence of criminal organizations that are adept at smuggling goods across the border, and the demands of a one of the largest healthcare systems in the nation combine to create substantial opportunities for pharmaceutical counterfeiting. Additionally, Texas' role in facilitating trade across the nation and throughout North America

means that the supply chain risks that threaten the healthcare infrastructure in Texas have the potential to migrate to other states and Canada.

3. Key Risk #2: Counterfeit Pharmaceuticals Pose a Direct Threat to Society

The potential to undermine patients' trust in the healthcare system and in healthcare providers should be a major concern for healthcare systems everywhere. A lack of trust in the healthcare system may lead people to avoid preventative medical care or to seek unsafe treatments and alternative medicines. Research has found that the amount of trust patients have in their healthcare provider determines how closely they will follow a healthcare regimen, which can impact their overall quality of life. Counterfeit pharmaceuticals pose a direct threat to society and established healthcare systems by placing doubt in patients' minds, which can negatively affect their healthcare choices.

Declining trust in the legitimate healthcare system will not mean that consumers will turn away from medications and healthcare wholesale. Rather, they are likely to seek alternative routes to obtain the medications they believe they need. This creates an obvious risk as demand for legitimate products available from alternative sources increases the likelihood that consumers will find counterfeit and fake products that do not perform as intended. While this is a clear and present danger within the U.S., it is a more pressing danger for areas of the world with strained or unprepared healthcare infrastructures.

It must also be remembered that the evidence of counterfeit pharmaceutical products is often times "consumed" by the patient. This can lead healthcare providers to attribute patient harm, or death, to their underlying medical condition rather than to blame the counterfeit. This can also strain healthcare systems as consumers seeking medications through alternative, risky channels are ultimately brought back into the legitimate healthcare system due to the negative health impacts of counterfeits. For these consumers, and the healthcare providers caring for them, getting well takes priority over figuring out whether a counterfeit product is the cause of the issue.

3.1. The risks of medical tourism

Texas' proximity to Mexico also means that its land border crossings are frequently used by tourists traveling to and from the United States. The ten busiest U.S. land border crossings are all shared with Mexico, half of which are in Texas and collectively accounted for approximately 94.5 million crossings in 2022^{xxv}. Increasingly, US citizens crossing the border into Mexico are transiting for medical tourism, typically for dental or cosmetic surgeries which can save them upwards of 60% off the costs of treatments in the U.S.^{xxvi}. While many consumers and international organizations rate Mexican hospitals high, at times on par with U.S. hospitals^{xxvii}, the prevalence of counterfeit medications within Mexican pharmacies is difficult to ignore.

Medical tourism within Texas is a kind of cottage industry, with companies set up to assist people with every aspect of traveling travel abroad for medical procedures, including finding healthcare providers^{xxviii}. While Houston was boasted as being a top destination for medical tourism, bringing in an about 20,000 traveling patients per year^{xxix}, Baja California alone sees upwards of 4 million traveling patients each year^{xxx}. While quality of care in Mexican facilities

may not be a concern, what is a significant concern is the rise of counterfeit pharmaceuticals in Mexican pharmacies.

A recent study by UCLA found that northern Mexican tourist towns often sell counterfeit pharmaceuticals containing fentanyl, heroin, and methamphetamine mainly to U.S. tourists seeking prescription drugs like Oxycodone, Percocet and Adderall^{xxxvi}. While Mexico has begun cracking down on these rogue pharmacies^{xxxvii}, risks to tourists and medical tourists abound. A Los Angeles Times investigation into Mexican pharmacies found counterfeits being sold at pharmacies across the entire country, sometimes in packaging that appeared to be factory sealed^{xxxviii}. Medical tourists who travel to Mexico for treatments that require prescription medications as part of post-surgery recovery may find themselves receiving high quality care within the healthcare facility, but substandard and counterfeit drugs from the pharmacy. When these individuals travel back across the border from Mexico into Texas any negative reactions to counterfeit pharmaceuticals becomes a problem from the healthcare system in Texas.

4. Key Risk #3: Risks to National Security and the Legitimate Supply Chain

Counterfeit pharmaceuticals pose a clear and present threat to national security and the legitimate supply chain. The criminal networks that support pharmaceutical counterfeiting schemes that affect Texans utilize well-worn land border crossings to move their illicit products. They also take advantage of American patients' desires for low-cost drugs obtained from pharmacies located across our northern and southern borders. These criminal networks have also begun to leverage pre-pandemic and pandemic driven changes in global supply chains to bring goods from out of the country directly into consumers' homes. At the national level, current de minimis policies and the growth of small parcels entering U.S. mail facilities have been identified as helping counterfeiters more regularly distribute their illicit goods directly to consumers.

4.1. The source of counterfeits as a threat to national security

Counterfeit pharmaceuticals are sometimes produced within the United States, yet the vast majority of the counterfeits distributed within this country originate from China, India and increasingly from Russia. Even when counterfeit pharmaceuticals are produced outside of these prime source economies, in places like Mexico or even the U.S., the base chemicals and raw ingredients can still be traced back to places like China and India. This situation threatens our national security in several ways:

- Products are manufactured outside of regulated facilities and often do not conform to government or industry standards in terms of quality, cleanliness, or potency.
- Counterfeit goods steal the intellectual property of U.S. corporations, which threatens jobs and negatively impacts our economy. It has been estimated that, depending upon the size of the global counterfeit pharmaceutical market, between 57,000 and nearly 250,000 American jobs are negatively impacted by counterfeiting^{xxxix}.
- Money from the sale of these illicit goods flows to authoritarian regimes and criminal gangs that pose direct and indirect threats to American interests, as well as American citizens, both domestically and abroad.

Countries with healthcare supply chains that include robust and sophisticated security protocols are, overall, more protected from counterfeit pharmaceuticals. Developing world nations, particularly those in sub-Saharan Africa and South America are especially vulnerable to floods of

counterfeit vaccines and pharmaceuticals, and patient deaths tend to concentrate in these areas. However, the mercenary nature of counterfeiting and the growing role of consumers using internet commerce to purchase regulated goods, means that risks exist across the entire globe, irrespective of the sophistication of the healthcare supply chain.

4.2. Legitimate online pharmacies are threatened by rogue sites

In recent years, websites like Roman.com and Forhims.com have developed to provide consumers a safe and legitimate online pharmacy option, particularly for lifestyle pharmaceuticals like erectile dysfunction medications and hair loss treatments. Yet, for several decades rogue internet pharmacies have plagued consumers and disrupted the legitimate supply chain by using legitimate commerce and shipping channels to sell and distribute illegal products. Research has found that 95% of the more than 35,000 online pharmacies operate illegally^{xxxv}, selling counterfeit, fake, adulterated, or substandard medicines. Should sites like Roman.com and Forhims.com continue to grow, and should consumers begin to utilize these sites for more of their pharmaceutical needs, more and more people will be exposed to the risks of rogue pharmacies and counterfeit goods.

This may further expose weaknesses in the online supply chain that connects manufacturers to consumers, weaknesses that counterfeiters are able to exploit to intermingle their illicit goods with legitimate products. An important emerging weakness that must be accounted for is the swiftness with which counterfeiters use online pharmacies to respond to increasing consumer demand for certain products. The seeming ubiquity of internet-based shopping options will likely lead consumers to view e-commerce as the most efficient means of filling existing product availability gaps present in the traditional pharmacy space. Consumers will leverage Internet technologies to gain access to a wide range of regulated goods, sometimes through unregulated spaces. As may be expected, products found through unregulated channels have a high likelihood of being counterfeit, adulterated, or in some way substandard or of reduced quality. Additionally, pharmacies and retailers seeking to respond to consumer demand for highly sought-after products may look to suppliers outside of their normal supply chain as a way to be responsive to the market, at times turning to online and unverified sources to acquire hard-to-find products.

4.3. Threats to regional stability across the globe

The growth of pharmaceutical counterfeiting and the increasing presence of trans-national criminal organizations threatens national security through its impact on regional stability and security in other parts of the globe, particularly in developing world nations. Terrorist and criminal groups thrive in places that lack strong governments, established and thriving legitimate small businesses, and systems that are resistant to corruption. Counterfeit pharmaceuticals that are destined for the United States at times transit through destabilized regions, and the global networks behind these schemes often have interests within these regions. Criminal groups that are funded through the sale of counterfeits and threaten regional stability across the globe impact America's ability to ensure global safety and security. The affect national governments may be less capable of controlling the growth and spread of these organizations, which create harms for their citizens and are funded by products sold to U.S. consumers. Stopping pharmaceutical counterfeiting is essential to closing off an existing and emerging revenue stream for transnational criminal groups, thereby making it more difficult for them to directly threaten foreign governments, while indirectly threatening U.S. national security.

5. Policy Recommendations for Patients and Healthcare Systems

Most strategies and tactics to address pharmaceutical counterfeiting are reactionary in nature and tend to focus on reducing the volume of products in the market. Given what has been discussed regarding the difficulty in identifying counterfeit pharmaceuticals within the supply chain responsive solutions are to be expected. Yet, there are opportunities to be more proactive in efforts to protect consumers and the supply chain from counterfeits. Healthcare systems must be on the front lines of both care and counterfeit prevention to effectively protect consumers. These efforts can be strengthened through partnerships with industry and law enforcement agencies, and the three groups together can be more effective and more impactful than either of them can be when acting alone.

5.1. Consumer messaging and education

Industry, law enforcement, researchers, and governmental agencies all agree that consumer education is key to preventing the growth of counterfeiting. Yet, some ways are more effective in building messaging aimed at helping consumers protect themselves from counterfeit products. When it comes to informing consumers about counterfeit pharmaceuticals in ways that promote safety and discourage risky behaviors, research has found the following to be effective:

- Message framing that takes into account *what* patients are being asked to consider^{xxxvi}. Specifically, counterfeiting messages that are negatively framed will have the greatest impact on an individual's efforts to protect themselves, while messages that are positively framed will have the greatest impact on an individual's efforts to protect others.
- Social media-based messaging should include elements that teach people *how* to avoid counterfeits, *why* they should purchase from regulated and legitimate channels, and compelling reasons for why these actions are beneficial to the individual^{xxxvii}.
- It is important to find a balance between staying positive and avoiding the creation of fear, while being honest about the “ripple effects” of counterfeits for the individual and society by pointing out the realities of harms or risks in ways that empower consumers to act^{xxxviii}.
- Anti-counterfeit messaging is not a one-size-fits-all solution; it must be tailored to the particular product and situation. The most effective messages have been found to have the following characteristics^{xxxix}:
 - Strong evidence that comes from a reliable source.
 - A human element that honestly addresses the negative consequences of counterfeits including their impacts on others.
 - A relatable and actionable message to a specific audience.

Effective messaging should originate from healthcare systems that patients and consumers will recognize and identify with. While the message content can be global or developed with all of society in mind, it must come from authority figures that people recognize and respect. Industry and law enforcement partners are essential supporters of these campaigns, but to be effective they should be led by local healthcare systems and providers.

The content of these messages can vary, but they should usually contain the following elements:

- A specific statement about the problem.

- What, specifically, the individual is being asked to do. This should be kept to a maximum of three discrete acts or steps.
- Why individuals should pay attention to the message and follow the “ask” that is being made.
- Who is providing the message – the source of authority.
- How consumers can access more information or contact authorities for help or support.

5.2. Educating and training healthcare providers

In addition to educating consumers, it is also essential that healthcare providers be trained and educated on how to talk about and address counterfeit pharmaceuticals. Working with industry, academic, and law enforcement partners, healthcare systems should invest resources in developing and continually disseminating education and training in the following areas:

- How to have conversations with patients about counterfeits.
 - Providers must be empowered to be proactive in opening discussions about how to avoid counterfeits, the prevalence of counterfeits in society, and the security of the legitimate supply chain. These conversations must balance being transparent about risks, while reassuring patients about the safety and security of the legitimate healthcare system.
- Ways to educate patients about counterfeit pharmaceuticals during normal provider-patient interactions.
 - Conversations are only one part of consumer education strategies. Healthcare providers should also be educated about outside resources to which patients can be directed. Continuing education should include opportunities for healthcare providers to model best practices for educating and speaking with patients so that these interactions come across as a normal part of patient-provider interactions. Over time, they will be expected by the patient and providers will become much more comfortable having these conversations.
- How to recognize the signs that a patient may be about to make a risky decision.
 - It is just as important for a healthcare provider to recognize the signs of mental and physical distress, as it is to recognize when patients are likely to make a risky decision related to the purchase of pharmaceuticals. Patients that seem troubled by the high cost of medications, rollbacks or the complete loss of insurance coverage for current treatments, or the inability to obtain prescription pharmaceuticals may be giving initial signs that they could consider searching for pharmaceuticals through unregulated and illicit channels. Understanding and identifying these signs allows the healthcare provider to intervene, start a conversation, and protect the patient.
- Common indicators that a product is likely counterfeit.
 - Healthcare providers are on the front line. The frequency of interaction they have with pharmaceuticals and their effects on patients makes them experts. When something is wrong, they can be the first to spot it. Providing opportunities for those in healthcare systems to learn about how they can spot, and report suspected counterfeits can be crucial to stopping counterfeiting schemes early and preventing harm to patients. Working with industry partners and pharmaceutical manufacturers is essential to building healthcare providers’ knowledge and skills.

- What to do when counterfeit pharmaceuticals are identified within the supply chain, the healthcare system, or in a patient’s possession.
 - When a healthcare provider does identify counterfeits within the supply chain or the healthcare system, they must know exactly what to do. While it may seem very straightforward, it is not always clear just *how* one should report counterfeit pharmaceuticals to authorities. Arming providers with this knowledge will increase the ability of industry and law enforcement partners to protect patients and stop counterfeits within the supply chain earlier and with greater effect.

5.2.1. *Responding to technological and supply chain advances*

The growth of Internet commerce, increasing supply chain sophistication, and technological advancements will shift the nature of patient-provider relationships and alter the ways in which patients access healthcare services and pharmaceuticals. In this new environment consumers will have to continually adapt to the rapid pace of technological change. Healthcare providers can assist patients with these transitions by having open, direct and informed conversations about the risks of counterfeits and how to avoid them. These conversations should be a normal part of patient care and can help to build and sustain trust within the relationship, which can support patients’ desires to have open conversations with their healthcare providers.

5.3. The pharmaceutical industry as a partner

Partnering with the pharmaceutical industry allows healthcare systems to develop and implement more effective anti-counterfeiting strategies and tactics. The most effective proactive prevention strategies utilize existing knowledge to inform efforts to safeguard patients and the healthcare system by:

- Discussing ways to design-out risks inherent to new and developing pharmaceutical technologies and supply chain/distribution processes.
- Sharing information about existing methods and behaviors of pharmaceutical counterfeiters.
- Using evidence-based practices found to be effective in the development of responsive and proactive strategies.

As mentioned in the above section regarding recommendations for healthcare provider education, the pharmaceutical industry can be an essential partner in building protections for patients. Industry partners are ideally positioned to share expert guidance with healthcare systems regarding how to spot and report counterfeits and otherwise secure the supply chain. Industry partners should be included in healthcare provider training and education and should be regularly engaged to discuss what they are seeing regarding emerging trends and key shifts in the counterfeit pharmaceutical landscape.

Industry partners are also at the forefront of technology’s growing influence on consumers and healthcare best practices. Despite recent legislation aimed at making the pharmaceutical supply chain safer^{xl}, efforts to increase public awareness of counterfeiting risks^{xli}, and increasing patent and trademark enforcement efforts, technological advances are outpacing current anti-counterfeiting efforts which tend to respond to technological changes once risks and vulnerabilities are identified. The growth and spread of new pharmaceutical technologies, while rapid, does not happen so fast as to disallow opportunities to think proactively about how to

protect patients. For example, several years ago the development of on-demand, modular pharmaceutical manufacturing units^{xliii} should have prompted conversations about controlling opportunities for counterfeiting and adulteration within healthcare systems, yet these conversations never occurred. It is not too late to have these conversations, however as this technology is currently being commercialized and scaled^{xliii} healthcare systems must take the time to talk with the industry about how to build-in patient protections, rather than seek reactive tactics once counterfeiting or other incidents occur.

Healthcare systems should seek to take the lead in conversations that discuss ways to align advances in pharmaceutical production and distribution with co-occurring advances in policy and practice that take a proactive stance against counterfeiting risks. The development of new technologies offers opportunities to develop effective and practical healthcare system-driven collaborations that address areas of potential harm early, before risks to patients develop. These strategies must be informed by what is already known about pharmaceutical counterfeiters' methods and behaviors, which requires coordination and information sharing across industry, healthcare, and law enforcement partners. Crimes like pharmaceutical counterfeiting rely upon a routinization of tasks and processes that are both efficient and effective, and which leverage identified weaknesses within the supply chain. Understanding where weaknesses and risks are likely to emerge and using prior experiences to understand how those risk might migrate and effect the supply chain and healthcare infrastructure, provides opportunities to mitigate counterfeiting risks before they materialize.

5.3.1. Supplier vetting and purchasing due diligence

Existing standards and certifications for healthcare compliance and purchasing best practices do not directly address the vetting of suppliers for counterfeiting risk. As seen during the COVID-19 crisis, healthcare systems are incredibly vulnerable to counterfeiting schemes and are regularly targeted by counterfeiters. Healthcare systems should push standards and accreditation bodies to work with industry to develop curricula that addresses this gap and builds-in knowledge development opportunities related to bad actors. Guidance can be taken from the financial services sector and defense contractors as each has developed robust standards of practice that aim to keep counterfeiters and related criminal organizations and proceeds from infiltrating legitimate streams of commerce. In the immediate term, healthcare systems can develop their own guidance around supplier vetting and selection, working with law enforcement and healthcare peers to share data and information on confirmed counterfeiters, as well as warning signs and key trends that indicate the presence of risk.

5.4. Law enforcement as a partner

More than a decade ago the federal government outlined a coordinated plan to leverage the investigative and enforcement capabilities of multiple government agencies in the fight against counterfeit pharmaceuticals^{xliv}. Federal law enforcement's dedication to stopping counterfeits has only increased since that time, and public-private partnerships have supported law enforcement's efforts to keep counterfeits out of the legitimate supply chain. These partnerships rest as much upon the efforts of law enforcement as they do the efforts of the private sector and healthcare systems. Most importantly, law enforcement agencies need reliable and actionable data, and partners that are willing to collaborate on enforcement and bring new ideas to the table.

There are a number of ways that healthcare systems in Texas can partner with law enforcement to help secure the pharmaceutical supply chain, protect patients, and advance the state of pharmaceutical anti-counterfeiting writ large, including:

- Partnering with the federal government’s intellectual property protection coordinating body, the National Intellectual Property Rights Coordination (IPR) Center. The Department of Homeland Security’s IPR Center serves as a centralizing body that brings together public and private sector entities in the fight against counterfeits. Healthcare systems would be welcome partners to this collaboration which provides channels for relationship building, data and information sharing, and support for criminal and civil enforcement action.
- Healthcare systems should look to partner with state and national law enforcement agencies on patient and provider education and messaging, intelligence sharing and data exchange, and the development of effective supply chain security solutions. Seeking to address general risks is a fine place to start, yet more immediate returns can be found when specific asks are made of law enforcement partners and healthcare systems show a willingness to support criminal investigations and prosecutions.
- Support industry law enforcement training and partnership efforts, such as those maintained by the Partnership for Safe Medicines^{xlv}, the Pharmaceutical Security Institute^{xlvi} and the International Anti-Counterfeiting Coalition^{xlvii}. Healthcare systems should approach these partnership opportunities through the lens of innovation and ideation, thinking big and challenging partners to create the environment for novel engagement and collaboration.
- Innovate and build a state-level partnership that addresses the specific risks faced by Texas’ healthcare systems and patients. The risks posed to the healthcare supply chain by counterfeit pharmaceuticals coming across the southern border or through sea and airports will continue to grow if not addressed effectively. Healthcare systems can take a leading role in developing law enforcement and industry partnerships that address the state’s specific risks and challenges. This will support a safer and more secure supply chain within Texas, while also benefiting the rest of the nation by closing off opportunities for the transshipment of illicit goods through.

Healthcare systems should view law enforcement agencies as partners and not simply as the enforcement arm of the law. While operational and tactical capabilities will vary across agencies, there are numerous opportunities to develop task forces and partnerships that target specific and general counterfeiting risks. Law enforcement agencies are as willing and eager to learn from the healthcare system as they are to share data and information and assist with protecting patients.

6. Conclusion

Pharmaceutical counterfeiting is a crime that is driven by consumer demand for legitimate, sometimes life-saving drugs. While some consumers seek to find “deals” or avoid signs of illicit activity when searching for counterfeits, it is highly unlikely that Texas’ current healthcare system leads people to willingly go in search for counterfeits. This means that counterfeiters are incentivized to do all they can to infiltrate the legitimate pharmaceutical supply chain in order to bring their fake goods to consumers. While the security of the current supply chain helps to keep many counterfeits out, those that are able to get into the legitimate stream of commerce can remain hidden amongst legitimate goods. Vigilance by patients, healthcare providers, law

enforcement and industry partners can help to increase levels of knowledge and education and speed the transmission of information that can be effective in stopping counterfeiting infiltration early, before patients are harmed. Healthcare systems in Texas are urged to be entrepreneurial in seeking solutions to existing risks, and open-minded about emerging risks that come with changes in consumer and patient behavior, supply chain innovation, and the growing presence of organized criminal groups in pharmaceutical counterfeiting schemes.

Appendix A: References

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- ⁱ <https://www.cbp.gov/trade/priority-issues/ipr/statistics>
- ⁱⁱ <https://www.fda.gov/news-events/press-announcements/fda-conducts-major-global-operation-protect-consumers-potentially-dangerous-prescription-drugs-sold>
- ⁱⁱⁱ <https://www.oecd.org/newsroom/trade-in-fake-goods-is-now-33-of-world-trade-and-rising.htm>
- ^{iv} <https://www.theguardian.com/fashion/2022/may/10/spot-the-difference-the-invincible-business-of-counterfeit-goods>
- ^v <https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>
- ^{vi} O'Hagan A, Garlington A. Counterfeit drugs and the online pharmaceutical trade, a threat to public safety. *Forensic Res Criminol. Int. J.* 2018;6:15-158. 10.15406/frcij.2018.06.00200
- ^{vii} Gurney B, Amundson G, Boumediene SL. Ways to battle the \$431 billion fake pharmaceutical industry. *Review of Business & Finance Studies.* 2017;8:33-40
- ^{viii} Gurney B, Amundson G, Boumediene SL. Ways to battle the \$431 billion fake pharmaceutical industry. *Review of Business & Finance Studies.* 2017;8:33-40
- ^{ix} <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-022-13529-7>
- ^x <https://journals.sagepub.com/doi/abs/10.1177/0002764217734264>
- ^{xi} <https://www.safemedicines.org/2023/06/june-26-2023.html>
- ^{xii} Mackey TK, Liang BA, York P, Kubic T. Counterfeit drug penetration into global legitimate medicine supply chains: a global assessment. *Am J Trop Med Hyg.* 2015 Jun;92(6 Suppl):59-67. doi: 10.4269/ajtmh.14-0389. Epub 2015 Apr 20. PMID: 25897059; PMCID: PMC4455087.
- ^{xiii} <https://www.justice.gov/usao-edtx/pr/pharmaceutical-president-and-company-sentenced-counterfeit-drug-trafficking-conspiracy>
- ^{xiv} <https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-sues-spas-wellness-clinics-selling-counterfeit-weight-loss-drugs-2023-06-20/>
- ^{xv} <https://www.cbc.ca/news/canada/manitoba/doctors-guilty-counterfeit-cancer-drugs-wfpcbc-cbc-1.5922059>
- ^{xvi} <https://www.fiercepharma.com/pharma/fda-busting-drug-counterfeiting-rings-it-doing-enough>
- ^{xvii} <https://www.kiro7.com/news/local/thousands-n95-masks-bought-by-local-hospitals-are-counterfeit-state-hospital-association-says/EHDDWPTKGRCZRHLKXTLPLS6SA/>
- ^{xviii} <https://www.definitivehc.com/resources/healthcare-insights/hospitals-in-each-state>
- ^{xix} https://www.ahd.com/state_statistics.html
- ^{xx} <https://www.txdot.gov/projects/planning/international-trade-border-planning.html>
- ^{xxi} <https://www.txdot.gov/discover/texas-maritime-ports.html>
- ^{xxii} <https://www.ice.gov/news/releases/hsi-el-paso-seizes-10617-doses-counterfeit-prescription-drugs-imported-mexico>
- ^{xxiii} <https://www.dea.gov/press-releases/2021/09/27/dea-issues-public-safety-alert>
- ^{xxiv} <https://www.dea.gov/press-releases/2019/11/04/dea-issues-warning-over-counterfeit-prescription-pills-mexico-0>
- ^{xxv} <https://explore.dot.gov/views/BorderCrossingData/CrossingRank?%3Aembed=y&%3AisGuestRedirectFromVizportal=y>

-
- xxvi <https://www.cnn.com/2023/03/07/health/medical-tourism-mexico-trend-wellness/index.html>
- xxvii <https://www.npr.org/2023/03/08/1161888974/medical-tourism-mexico-americans>
- xxviii <https://www.medicaltourismco.com/about-us/>
- xxix <https://www.laingbuissonnews.com/imtj/news-imtj/houston-becoming-a-medical-tourism-destination/>
- xxx <https://www.travelagewest.com/Travel/Mexico/medical-procedures-in-mexico>
- xxxi <https://www.uclahealth.org/news/counterfeit-pills-sold-mexican-pharmacies-found-contain>
- xxxii <https://abcnews.go.com/Health/wireStory/mexico-shutters-23-pharmacies-caribbean-coast-resorts-after-102119648>
- xxxiii <https://www.latimes.com/world-nation/story/2023-06-14/fentanyl-tainted-pills-now-found-in-mexican-pharmacies-from-coast-to-coast>
- xxxiv <https://www.statista.com/statistics/1181279/us-jobs-lost-due-to-counterfeit-drugs-by-scenario/>
- xxxv <https://www.formularywatch.com/view/online-pharmacies-that-sell-counterfeit-drugs-grew-during-the-pandemic>
- xxxvi Dahlgren, Caroline (2011) "Countering Counterfeits: An Investigation of Message-Frame and Message-Focus Effects on Persuasion," *Fordham Business Student Research Journal*: Vol. 1 : Iss. 1 , Article 6. Available at: <https://fordham.bepress.com/bsrj/vol1/iss1/6>
- xxxvii <https://a-capp.msu.edu/article/the-sociotechnical-evolution-of-product-counterfeiting-how-social-media-social-networks-and-social-commerce-are-e-socializing-product-counterfeiting/>
- xxxviii <https://www.worldtrademarkreview.com/article/brand-associations-provide-blueprint-educating-consumers-counterfeits-and-piracy>
- xxxix https://www.google.com/url?sa=i&rct=j&q=&esrc=s&source=web&cd=&ved=0CDgQw7AJahcKEwjgvvuJmoSBAXUAAAAAHQAAAAAQAg&url=https%3A%2F%2Fassets.publishing.service.gov.uk%2Fgovernment%2Fuploads%2Fsystem%2Fuploads%2Fattachment_data%2Ffile%2F994529%2FCounterfeit-Goods-research.pdf&psig=AOvVaw01kiKUrWjPjC5KXTySluTm&ust=1693476911236377&opi=89978449
- xl <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dsca>
- xli www.safepharmaceutical.com
- xlii <https://news.mit.edu/2016/portable-pharmacy-on-demand-0331>
- xliii <https://www.prnewswire.com/news-releases/on-demand-pharmaceuticals-commissions-state-of-the-art-cgmp-medicine-manufacturing-facility-301483128.html>
- xliv <https://www.justice.gov/criminal-ccips/file/883721/download>
- xlv <https://www.safemedicines.org/law-enforcement>
- xlvi Kubic, T. Enforcement efforts and partnership with industry: A needed strategy addressing counterfeit drugs. *J Commer Biotechnol* 17, 254–259 (2011). <https://doi.org/10.1057/jcb.2011.17>
- xlvii <https://www.iacctrainings.org/>



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Kennedy, J. P. (2023) Supply Chain Risks of Illicit Trade in Counterfeit Pharmaceuticals. (Report No. IHS/CR-2023-1016). The Sam Houston State University Institute for Homeland Security. <https://doi.org/10.17605/OSF.IO/3S5AH>