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Emergent Trends in the Chinese Counterfeit Pharmaceutical Supply Chain and Opportunities for Public-Private Reform

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EMERGENT TRENDS IN THE CHINESE COUNTERFEIT PHARMACEUTICAL SUPPLY
CHAIN AND OPPORTUNITIES FOR PUBLIC-PRIVATE REFORM

By

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EXECUTIVE SUMMARY

This research seeks to identify and analyze emerging trends in the Chinese counterfeit pharmaceutical trade, extending from the supply chain's point of origin to domestic and overseas retail dispensary. To aid readability, Chapter 1 of this thesis opens with key conclusions and policy recommendations for various Chinese and U.S. stakeholders based on the shortcomings identified in Chapter 5. Chapter 2 begins with a review of international roadblocks to diagnosing the issue, such as lack of consensus on working definitions and cross-border discrepancies in pharmaceutical oversight regulation. This section also provides a general overview of existing factors driving demand for counterfeit medicine worldwide. Chapter 3 continues the literature review by answering the question “Why China?”—it provides context into China's counterfeiting history and reactive risk management approach to demonstrate that the country's counterfeit drug production constitutes a national security and global public health threat. This chapter analyzes China's regulatory weaknesses and healthcare landscape to explain why it is uniquely positioned to meet global demand for inexpensive, alternative medicine. Chapter 4 takes on the critical research question of how China's counterfeit drug trade has evolved with the current wave of globalization. This section utilizes systematic review and thematic analysis frameworks to identify three overarching globalization trends that are underrepresented in current research—specifically, how China's geopolitical influence, use of Internet platforms, and the COVID-19 pandemic have enhanced China's ability to proliferate counterfeit pharmaceuticals. The purpose of this chapter, therefore, is to bridge disparate observations in existing research and to demonstrate that China's current counterfeit drug landscape stems from a larger, non-state driven globalization. Chapter 5 concludes with a discussion of current U.S. and Chinese anticounterfeiting projects and their potential weaknesses in light of the new threats identified in Chapter 4.

GLOSSARY

ADR: adverse drug reaction

API: active pharmaceutical ingredient

ASOP: Alliance for Safe Online Pharmacies

BRI: Belt Road Initiative

CPIWG: Counterfeit Pharmaceutical Inter-Agency Working Group

CSIP: Center for Safe Internet Pharmacies

DSCSA: Drug Supply Chain Security Act

GMP: good manufacturing practices

NABP: National Association of Boards of Pharmacy

NDA: new drug application

NMPA: National Medical Products Administration

SCDHEC: South Carolina Department of Health and Environmental Control

SSFFC: substandard/spurious/falsey-labelled/falsified/counterfeit

CHAPTER 1

KEY RECOMMENDATIONS

Below are the conclusions and recommendations for Chinese and U.S. stakeholders based on the new threats and regulatory shortcomings identified in Chapters 4 and 5.

CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

- a. Increase NMPA inspection capacity. Presently, the NMPA inspects only a fraction of all factories annually. Increasing staffing would free up more resources to pursue anticounterfeiting investigations.
- b. Pursue more long-term public-private partnerships to fight fake medicine. Online pharmacies are complex, hopping between multiple platforms. It is necessary to leverage the expertise of firms—especially technology companies.

OTHER CHINESE GOVERNMENT AGENCIES

- a. Continue to encourage and provide incentives for mergers and acquisitions among Chinese drug manufacturers. Increasing market concentration of legitimate drug manufacturers will lessen the burden on strained Chinese regulatory authorities by reducing factory inspections, thus freeing more staff and time to pursue investigation of non-licensed counterfeit drug manufacturers. Reducing market fragmentation will support U.S. regulatory counterparts by facilitating customs inspections.
- b. Restore Chinese citizens' faith in village clinics and township health centers. Increasing utilization of village medical facilities will lessen the burden on urban top-tier hospitals, ensuring that more citizens receive quality care and will not seek out nefarious alternatives. Doing so will also reduce stress on the elderly population reliant on these hospitals for chronic treatment, since these populations are doubly vulnerable to counterfeit scams.
- c. Expand clinical pharmacy and problem-based learning discipline in University pharmacology curriculums. Given the shortage of pharmacists in China, it is critical that they are properly trained to educate patients on counterfeit drug risks and to connect them with affordable alternatives.
- d. Ensure that all countries wishing to join the Belt and Road Initiative have clear IP regulations and IP dispute settlement processes.
- e. Adapt anticounterfeiting legislation to respond to the growth of social media and messaging apps in counterfeit drug transactions.

U.S. DEPARTMENT OF JUSTICE

- a. Prioritize prosecution of rogue internet pharmacy operators. This will require strengthening ties with countries historically unable or unwilling to aid the U.S. in prosecuting and investigating counterfeiters.

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

- a. Seek out Chinese collaboration in international aid packages. This would destigmatize the concept of “Western aid” and strengthen existing multilateral international aid efforts. Ensuring that aid packages are administered within existing regulatory protocols will ensure that these funds are not spent on substandard medical clinics and counterfeits.

FDA

- a. Host a database of all FDA-approved API manufacturers that a drug manufacturer can source for its generic drugs. This recommendation is originally cited in a recent report from Johns Hopkins (Choe et al., Johns Hopkins, p. 6) and this paper concurs with those findings. This would alleviate pressures caused by the pandemic-era drug shortage while ensuring that sourced APIs are legitimate and not affiliated with counterfeiters capitalizing from the drug shortage.
- b. Unit-level drug traceability is critical given the globalized state of the drug supply chain. Standardize IT and documentation discrepancies between the FDA’s DSCSA Pilot Program members so that drug data can be easily understood and matched across supply chain levels.
 - i. Use blockchain technology to connect disparate systems. KMPG is already piloting the project under the DSCSA (Borden & Trefcer, 2020), but this should be pursued with federal grants beyond Pilot Program member funding. The FDA should highlight blockchain’s potential as a breakthrough anticounterfeiting tech.

DHEC

- a. Secure reliable access to Pfizer, Moderna, and Johnson&Johnson COVID-19 vaccines and other coronavirus treatments. Although the Biden Administration has taken steps to expand rollout on a national scale, state-level distribution should be streamlined. People are more likely to seek out counterfeit vaccines if their appointments are delayed or cancelled.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (NABP)

- a. Improve consumer education programs about rogue online pharmacies. This can include research as to whether the .pharmacy domain is influential in helping consumers discern legitimate online pharmacies from fake ones.

U.S. CLINICIANS, HEALTHCARE PROVIDERS, AND PHARMACISTS

- a. Increase awareness about affordability limitations that fuel patients’ counterfeit purchases. Providers should prescribe by a drug’s international nonproprietary or generic name when possible. This is especially important because many rogue online pharmacies do not require a prescription and will easily entice patients. This could also mean actively rejecting the “free pharma lunch,” a practice in which drug companies sponsor meals with physicians to influence prescribing practices and pitch name brands over generics.

- b. Pharmacists should take greater responsibility in relaying accurate information and treatment options. Since pharmacies have been deemed essential to remain open amid COVID-19 pandemic lockdowns, pharmacists have a unique role to play as the customer's first point of reference for drug knowledge within many communities. Pharmacists should be particularly alert to an uptick in inappropriately prescribed medications for COVID-19 treatment such as chloroquine and hydroxychloroquine.

ONLINE / E-COMMERCE COMPANIES AND NONPROFITS

- a. Amazon's proprietary machine learning technology can play a greater role in exposing B2B and B2C counterfeit merchants. Although the private sector has taken some promising steps toward public sector collaboration, there is still untapped potential in terms of its vetting technology. Many aforementioned counterfeit treatments, especially those associated with fraudulent COVID-19 treatments and vaccines, are shipped from China through e-commerce websites like Amazon. Amazon has acknowledged its propensity to attract counterfeit medicine: in February 2019 the company launched Project Zero, a combination of machine learning, self-service counterfeit removal tool, and product serialization to detect suspect listings and empower legitimate merchants to protect their intellectual property. However, the project is still limited in that brands must be invited to the program, brands without trademarks cannot register, and the onus remains on individual firms to self-report incidents in addition to balancing other financial and regulatory responsibilities. E-commerce moguls such as Amazon should work to prevent counterfeiters from having access to its potent platform in the first place (Perez, 2020).

Amazon has taken the lead in upping its seller screening process, beginning an in-person verification process in early 2020 that would require prospective merchants to meet with Amazon representatives to obtain access. However, with growing COVID-19 social distancing protocols, the company has once again had to settle for verification via video conferencing and machine learning risk assessments of individual sellers, such as their possibly links to previously removed accounts.

Amazon should expand its proprietary machine learning detection capability as a product line under Amazon Web Services. Although AWS currently offers an Amazon Fraud Detector for its customers, it is mainly suited to businesses "especially prone to attacks from bad actors who often exploit different tactics such as creating fake accounts and making payments with stolen credit cards" (Amazon, 2020). Amazon Fraud Detector currently only offers protection for fraudulent credit card activity in direct B2C transactions but seems to lack sufficient protection for larger-scale B2B platforms or advertisement hosts. Prominent AWS customers such as Facebook and Chinese search engine company Baidu could benefit greatly from expanded proprietary detection technology customized to respond to their counterfeit advertisement liability risk exposures. In fact, Baidu has dealt with previous episodes of websites selling counterfeit drugs by finding "loopholes" that enabled them to buy search engine keywords and generate web traffic (Lee & Oreskovic, 2010). Amazon has demonstrated the industry know-how to be a first mover but should shift more attention to stopping fraud before the checkout process.

- b. Provide moderate tax incentives for private sector firms participating in anticounterfeiting nonprofits. Currently, the nonprofit CSIP (Center for Safe Internet Pharmacies) is funded solely by its founding members such as Google, GoDaddy, PayPal, American Express, and Yahoo. The nonprofit has made great strides, but funding should be bolstered by involving small and medium-sized industry stakeholders. This could be achieved in the form of tax incentives to solicit companies' participation in the nonprofit. CSIP is classified as a public charity; as such, it is exempt from Federal income tax under section 501(c)(3) of the Internal Revenue Code. However, providing tax credits to the individual corporations as an incentive to join and fund the nonprofit would increase the scope of its mission. Provision of these tax incentives could be contingent on certain performance metrics such as collective actions taken or outcomes of investigations.
- c. The two registers for safe online pharmacies, run by LegitScript and the NABP respectively, should be reassessed to include overseas online pharmacies that have genuine drugs. Currently, the NABP considers *any* genuine overseas online pharmacy unauthorized regardless of its international safety certifications, placing it in the same grouping as rogue online pharmacies selling counterfeits. U.S. consumers plagued with high domestic drug prices will seek out cheaper alternatives regardless. Therefore, this would widen the safe options available to those seeking cheaper non-controlled substances, making it less likely that they end up taking counterfeit drugs. Importing from genuine overseas pharmacies would also address the conflict-of-interest claims raised against the CSIP and NABP eliminating competition against Big Pharma.
 - a. To facilitate this, the FDA should permit importation from genuine overseas online pharmacies under the Personal Importation Policy.
- d. Social media, e-commerce, and messaging platforms should increase policing of suspicious product listings and users believed to be connected with counterfeit drug transactions. They should exercise reasonable due diligence in monitoring web traffic and ambiguous content, especially posts requesting users to redirect payment to a separate platform or private message. These technology companies could also work in tandem with international consumer protection agencies in their respective regions such as the Iberoamerican Forum of Consumer Protection Agencies (FIAGC), ASEAN Coordinating Committee on Consumer Protection (ACCCP), and Consumers International.

THE GENERAL PUBLIC AND INTERNATIONAL COMMUNITY

- a. Expand the definition of “counterfeit.” In light of developing trends identified in this paper, this should also include drugs with legitimate APIs which have been utilized improperly to treat an illness other than that for which they were made. This applies to chloroquine, hydroxychloroquine, or other improper drug use for COVID-19 infection. Global cooperation must effectively tackle emergent counterfeiting trends relating to Chinese governance, online platforms, and the pandemic of opportunism—but this will require more consensus on what really constitutes a “counterfeit” drug.

CHAPTER 2

BACKGROUND AND USER DEMAND INCENTIVES

One chronic problem hindering international progress has been a lack of consensus on what constitutes “counterfeit.” To date, the WHO definition remains most universal, defining a counterfeit medicine as:

A product that is deliberately and fraudulently mislabeled with respect to source and/or identity. Counterfeiting can apply to both generic and branded products. Counterfeits may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with incorrect quantities of active ingredients or with fake packaging. (Kopp, n.d.).

Over time, the WHO has pivoted to using the term “substandard/spurious/false-labelled/falsified/counterfeit (SSFFC)” to refer to this medical products group. This lengthy title has understandably led to confusion, with countries citing that the definition is either too broad or too narrow to fit their unique regional challenges. Governments also sought clarity on how these terms relate to intellectual property rights. For instance, there has been repeated confusion about counterfeit versus substandard classifications, with the latter emphasizing quality issues over legality of production. Substandard or “out of specification” drugs are produced by known manufacturers but fail to meet international quality standards due to issues such as over or under-concentration of the API (active pharmaceutical ingredient), contamination, mislabeling, or packing problems arising out of either inadvertent or deliberate negligence from the manufacturer (Christian et al., 2012, p. 2). Because these manufacturers are known, it is relatively easier to trace and correct these supply chain irregularities. Counterfeits, on the other hand, are spurious in

nature—they are significantly harder to regulate because the manufacturer is unlicensed and/or unknown. Put differently, while all counterfeit medicines are substandard, not all substandard medicines are counterfeit.

Given this confusion, the Seventieth World Health Assembly agreed in May 2017 to adopt the term “substandard and falsified (SF) medical products” to comprehensively refer to these substances. According to the WHO, the new terminology should allow more accurate comparison of cross-border data, but specifically does not cover protection of intellectual property rights (World Health Organization, 2017). Nevertheless, while a consensus has been created on paper, definitions and laws of individual countries vary widely in practice. Without a practical definition, it remains difficult to track drug movement, quantify their sales, and create interagency and cross-border partnerships aimed to improve detection and law enforcement.

Therefore, the crisis can be understood to involve both substandard and falsified medicine. For the purpose of this discussion, however, “counterfeit” will refer primarily to those substances produced by an *unlicensed* manufacturer that contain insufficient or no active ingredient or an otherwise toxic substance. It is these entities that expand most quickly and pose the greatest threat to public health and national security because they fall outside of traditional legal frameworks for detection and regulation.

Explaining this growing prevalence of unlicensed drug manufacturers first requires a brief understanding of individual user “incentives” that drive their demand. It should be noted that, while this discussion will attempt to explain the counterfeit drug market perpetuated within one region, there are patterns of human behavior worldwide that have created the need for this alternative.

Perhaps one of the most obvious reasons for counterfeit drug consumption is the user's insufficient information about the product's origin. Because medicine is a post-experience or credence product, consumers cannot ascertain the drug's utility immediately after consumption, especially in the case of counterfeits with insufficient or no API. It is nearly impossible to accurately evaluate the counterfeit drug's quality because consumers often do not have the knowledge or expertise to detect its fraudulence and stop taking it (in other words, they "don't know what they don't know"). The counterfeit creates a service gap and information asymmetry whereby the unlicensed manufacturer knows more about the product than the user—indicating that users cannot adjust their consumption behavior until long after the damage is done (Christian et al., 2012, p. 6). The ease of use and greater accessibility of fraudulent online pharmacies has only increased the number of victims as they believe they are patronizing legitimate pharmacies.

This misalignment of incentives is compounded by government failure in policymaking. This creates a catch-22: governments are not economically incentivized to effectively regulate against information asymmetry unless they are pressured by their citizens, and citizens will not pressure their governments if they are unaware of the counterfeit drug they consume (Christian et al., 2012, p. 7). With this, it is clear how individuals and governments can become unwitting participants in the exploitation of their own supply chains.

Another common incentive that is especially poignant in the United States is the exorbitant cost of many essential medicines. The United States' unique regulatory structure centered around patent protection and FDA marketing exclusivity has created a monopoly for many pharmaceutical companies to set their own prices that are prohibitive to many Americans. High U.S. drug prices also cascade to places like China (albeit to a lesser extent), where the push toward Traditional

Chinese Medicine and over-the-counter treatments has left a gap for those still seeking Western prescription medications (Wong, 2004, p. 173).

Third, large-scale outbreaks and epidemics often drive demand for treatments out of necessity. Africa is no exception—the Northern and Southern shores of Lake Victoria within Uganda and Tanzania host some of the highest malaria death rates in the world. In a region already suffering from poor drug regulation and dispensary, the influx of counterfeit drugs adds insult to injury. There is a growing body of evidence suggesting that China is to blame for this massive upswing, especially given the growing investment and trade into Uganda from the Chinese government and its state-owned companies within the last decade (McLaughlin, 2013). With so many people in dire need of artemisinin combination therapy, the primary malaria treatment, counterfeiters are remorseless and adept at exploiting a helpless situation. As experts explain, “counterfeit medications follow demand. In the United States, customers find fake Viagra. When patients hear of a new cure or treatment, demand skyrockets. In East Africa, patients need malaria medication.” (McLaughlin, 2013). The surge in counterfeit drugs as a response to disease outbreak has only worsened thanks to the COVID-19 pandemic. As many in the United States and around the world have been directly impacted by hospital overutilization and slow government testing and vaccine distribution plans, fake treatments and counterfeit vaccines have been touted and accepted as legitimate treatments for the virus. However, because the public health and political effects of COVID-19 have been amplified by globalization (more so than malaria, which is now largely treatable and localized), the pandemic’s effects on the counterfeit pharmaceutical supply chain warrant separate discussion.

The public and private sectors also see counterfeit drugs slip through the cracks because medical supply chains are highly globalized. Control methods, scope of regulatory agencies, and

enforcement mechanisms vary greatly between countries, indicating that regulatory weaknesses in a single country can create cascading failures that corrupt the entire supply chain. One drawback to detecting weak links at different stages of the supply chain is the lack of evidence-based research done to quantify and investigate the regulatory disparities within and across countries. However, one recent study (Pezzola & Sweet, 2016) created the first cross-national indices of pharmaceutical regulation. This study used data from the World Health Organization (WHO) Country Pharmaceutical Situation 2011 survey of 78 small and developing countries. State regulatory infrastructure, public quality control, and monitoring of the private market with regular or annual inspections were used as the main dimensions in calculating the indices, where item discrimination scores were also calculated to determine an item's correlation with a better regulatory structure. For instance, whether a government publishes its good manufacturing practices tells us more about its regulatory structure than does the presence of semi-autonomous MRA; thus, the former would have a higher discrimination score than the latter (Pezzola & Sweet, 2016, p. 7). The study concluded that while there is growing global harmonization in legal systems regarding patent ownership, global pharmaceutical standards are still fractured:

[A] universal norm for pharmaceutical legislation is yet to emerge . . . when there are changes to systems, they appear to occur in starts and fits. There is no smoothness across public and private markets. Some countries have private markets at a more advanced regulatory state and others lead their market reform and oversight from their public sectors. (Pezzola & Sweet, 2016, p. 16)

Private, governmental, and public health stakeholders should remember not only that the supply chain is as strong as its weakest link, but that these weak links will only become more commonplace as more countries are added to the value chain.

In addition to creating regulatory disparities, supply chain interdependencies also obfuscate drug trails and hinder accurate tracking of medicine during manufacture or transport. Counterfeiters are able to exploit a product's fluidity by ensuring that channels move through several other countries prior to being imported to the target country. To the surprise of intelligence agencies, counterfeit drugs coming from China often travel west through the Middle East and Europe to disguise their origin. According to intelligence reports cited in the Canadian Medical Association Journal, fake medicine changes hands upwards of 30 times before being dispensed to the ultimate consumer (Lewis, 2009). To provide one illustrative case, in 2012 two legitimate Canadian businessmen unknowingly aided in distribution of counterfeit Avastin, a drug used for cancer treatment, to U.S. doctors. Like many other counterfeits, the Avastin's journey was nothing short of chaotic: investigators theorized a "zigzagging route that may have taken the product through Turkey and Egypt before it was sold to Swiss and Danish wholesalers" through EU regulated channels (Weaver et al., 2012). From there, the counterfeits traveled to a U.K.-based wholesaler before being distributed to U.S. doctors. Despite being a developed country, the United States is far from immune to counterfeit infiltration even within supposedly regulated channels.

CHAPTER 3

CHINA: CHALLENGING THE INTEGRITY OF THE GLOBAL PHARMA SUPPLY CHAIN

This chapter explores the *current* factors, such as China’s regulatory weaknesses and healthcare infrastructure, that have positioned China to become one of the world’s prominent counterfeit medicine suppliers.

While counterfeit drugs are manufactured within dozens of countries around the world, this paper discusses contributing factors and implications specifically related to China, given that it is one of the world’s largest manufacturing and distribution hubs. According to a report published by U.S. Customs and Border Protection, 6% of all 27,599 IPR seizures in 2019 were of pharmaceuticals and personal care products. Most notably, however, 48% of all seizures—ranging from watches and jewelry to pharmaceuticals to consumer electronics—were from China (U.S. Customs and Border Protection, 2019). China has a notorious history as the origin point of dozens of counterfeit product types, making it a strategic interest in the United States’ discussion on the integrity of the pharmaceutical supply chain.

Despite the Chinese government’s claims of more stringent anticounterfeiting measures, its attitudes toward the issue are generally lax and continue to shift responsibility on importing countries, resulting in a risk management approach that is more reactive than proactive. Dr. Marvin Shepherd, a professor emeritus from the College of Pharmacy at the University of Texas, summarizes this attitude well: “As one China government official told me at a Beijing conference two years ago, ‘drug exports are not our problem, they are your [U.S.] problem’” (Shepherd, 2010). Not all blame should be reserved for the government’s perceived lack of concern, however; there are patterns inherent in China’s demographics, healthcare delivery models, and even cultural

attitudes toward intellectual property that make it more susceptible than other regions as a counterfeiting hub.

WHAT IS DRIVING DEMAND FOR COUNTERFEIT PHARMACEUTICALS IN CHINA?

There are a number of regulatory weaknesses that compromise China's quality of drug production. Good manufacturing practices (hereinafter "GMP") are the internationally acknowledged practices to ensure that medicinal products are produced and controlled according to quality standards. Given the sharp uptick in pharmaceutical manufacturers in China within the last 20 years, the NMPA (formerly the CFDA), the Chinese administration charged with regulating drugs and medical devices, has created strict requirements for obtaining a GMP license. Despite this, there is still great variability in how GMP is applied in China (Mossialos et al., 2016, p. 92). Most Chinese pharmaceutical firms are accustomed to serving the domestic market, and those who do distribute internationally export traditional Chinese medicine to other Asian regions rather than to their Western counterparts. In effect, Chinese pharmaceutical companies are not well-aligned with international GMP standards and instead adhere to haphazard, un-delineated local GMP regulations (Mossialos et al., 2016, p. 93).

The NMPA's staff numbers are also inadequate given the size of its regulatory responsibility. As fewer NMPA staff are available to carry out inspections, their oversight quality and scope are severely compromised. The NMPA and its affiliates therefore inspect only a fraction of all factories annually, making it more likely that substandard or counterfeit drugs will fall through the cracks (Mossialos et al., 2016, p. 93). There is a dire need to increase NMPA staffing not only to detect substandard production by licensed manufacturers, but also to free up more time and human resources toward investigations and seizures of unlicensed, counterfeit production.

Although China's growing elderly population bears a clear connection with growing demand in long-term care and pharmaceuticals supply, the marginalization of this demographic in healthcare is still widely overlooked in existing literature (Xiang et al., 2020, p. 1). Age structure diagrams show a shift in median age from 24 in 1950 to 35 in 2010, with projections that one in four Chinese citizens will be 65 or older by 2050 (United Nations, 2011). The country furthermore faces a shrinking population of younger caregivers as it reaps the seeds of its one-child policy implemented in the late 1970s. The resulting "4-2-1" family structure—four grandparents, two parents, and one child—has become the standard as adult caregivers abandon Confucian traditions of filial piety and entrust their elderly parents to institutional care alternatives instead (Zhan et al., 2008).

Part of the issue stems from generational differences on the perceived "worthiness" of elderly patients and quality of rural facilities in general. A 2016 case study on Qincun Hospital, a rural primary hospital located in Guangdong Province, China, found that although more people were willing to receive gerontological services due to the facility's high reimbursement rates, they remained skeptical about doctors' motivations and competency. A daughter-in-law bringing her mother for treatment suggested that doctors knew little but settled for treatment because her mother-in-law was "too old to be healed." As with many other cases of elderly patients in China, low expectations on medicine and treatment efficacy stemmed from the fact that the mother-in-law's symptoms were chronic and incurable (Xiang et al., 2020, p. 7).

The incentives for the elderly to unknowingly acquire counterfeits become even clearer when one considers the coverage issues tied to Chinese insurance schemes. China has recently invested enough into its public health insurance program to cover 95% of the population. However, given that the size of China's aging population is disproportionate to that of other developing

countries, there is a trade-off between access and quality. In essence, while there is widespread coverage, there is a low benefit level for each elderly citizen (Yates, 2014). The public health insurance program is funded by paid contributions from the employed workforce; however, since the labor force has declined as the result of three decades of the one-child policy, “the current system is likely to meet great challenges as incoming funding from salaried contributions falls short of outgoing healthcare expenditures” (Yates, 2014). A 2020 Credit Suisse report corroborated this trend, indicating that 39% of China’s 245 million baby boomers expect that existing social security plans will not meet their needs (Tan, 2020). In light of these factors, an unlicensed third party’s offering of a much-needed medication not covered by social security look enticing.

Several research initiatives agree that an upward trend in chronic disease, paired with negative attitudes toward the need to treat them, constitutes a potential crisis to the legitimacy of the long-term care system. Realizing their perceived unworthiness and burden in a hospital setting, China’s elderly population has shrinking options. Furthermore, unsustainable demand for name brand, chronic medications has driven up prices worldwide, making it more likely that the elderly—both in China and abroad—seek out counterfeits with unlicensed online pharmacies (see Chapter 4). This forgotten demographic furthermore poses a security risk as it relates to the elderly’s susceptibility to scams involving counterfeits. Chen Shiqu, Deputy Director at China’s Criminal Investigation Bureau, has noted that illicit healthcare product scams targeting senior citizens have become more frequent. One 2018 investigation in Nanjing, Jiansu Province seized more than 3 million yuan (\$464,000 USD) and 2,000 counterfeit cardiovascular products from an operation targeting individuals over 65. Shockingly, these products contained mostly vegetable oil (Zhang, 2018).

This aging population and its chronic illness burden are closely linked to and exacerbated by a complex, fragmented healthcare system dating back to the 1980s. Following China's economic liberalization in 1978, the country shifted toward a market-oriented approach that welcomed increased private healthcare spending. Perhaps one of the most perverse consequences of this shift was a 15% mark-up in drug sales, which allowed providers to reap unprecedented profits from prescription drugs (Mossialos et al., 2016 p. 7). It is likely that increased opportunity for pharmaceutical profiteering, a subsequent overdependency on drug profits, and the rapid decrease in government healthcare spending during this time laid the groundwork for overprescribing and affordability issues that exist in China's healthcare system today.

In 2009, China announced a massive reform of its healthcare system that aimed to provide equitable access to all citizens by 2020, departing from this aforementioned market-oriented approach (Yip & Hsiao, 2014, pp. 805-807). Public expenditures were set to increase from ¥481.6 billion to ¥836.6 billion between 2009 and 2012 (Yip & Hsiao, 2014, p. 806). Among many other things, this reform provided for the creation of a national system of essential medicines that would be covered by the medical insurance system. Such large-scale investments aimed to catalyze safe and accessible care while eliminating the need for informal or counterfeit market alternatives.

Nevertheless, these reforms pivoted once more in 2013, when the Third Plenum of the 18th Central Committee of the Communist Party announced its goal to boost privatization of hospitals to 20% market share by 2015. Yip and Hsiao further note that, while China's motive was not explicitly shared, it can be perceived "partly as a strategic move to use private sector competition to stimulate changes in the otherwise stymied public hospital reform" (p. 807). Specific arguments for and against the privatization of China's healthcare system are beyond the scope of this analysis, but they are illustrated briefly to provide context for the complexity of China's health policy goals

and the amount of effort still required to achieve cohesive delivery. Given how recently these economic reforms were implemented, it is no surprise that fragmentation within the Chinese healthcare system remains high.

Fragmentation can entail lack of coordination between lower-level village clinics (VCs) or township health centers (THCs) and their higher institution counterparts, often manifesting as service duplication or a level of care inconsistent with the authority of the institution administering it (Montenegro et al., 2011, pp. 5-16). For instance, the widespread yet unfounded societal belief that village clinics and township health centers administer substandard care has left these facilities underutilized, while top-tier hospitals are strained to service nearly 20% of annual outpatient consultations—many of which are only for minor health issues (Skrybus, 2019). Sharing parallels with duplicative fee-for-service models notorious within the U.S. healthcare system, fragmentation of China’s healthcare system has created myriad issues ranging from poor service quality, higher costs, low patient satisfaction, and insufficient care for its aging population (World Health Organization, 2008).

This fragmentation has spread even beyond the patient-provider setting, allowing for a decentralized network of small drug manufacturers that profit from overprescribing. According to figures from the National Bureau of Statistics of China, China has approximately 3,500 domestic drug producers, the top five of which capture only 13.2% of market share—a fraction of that held by their more dominant counterparts in other developed countries (Mossialos et al., 2016, p. 95).

The link between fragmentation and counterfeiting is twofold: first, an oversaturated and low-barrier market seeking thousands of new drug applications (NDAs) for nearly identical molecules has put significant stress on the NMPA, leading to insufficient quality inspections (Mossialos et al., 2016, pp. 95, 172). Consolidating Chinese pharmaceuticals manufacturing into

fewer, larger players would improve the scope and accuracy of NMPA and FDA foreign export inspections, for example, but much work is still needed before federal inspections can be deemed a trustworthy method for detecting counterfeits. Secondly, market saturation often results in delayed NDA approvals, meaning that patients must wait much longer to receive life-saving medication through traditional channels. Although the Chinese government has broached the issue by encouraging mergers and acquisitions, protectionism of these firms continues to deprive Chinese patients of breakthrough medications and generic derivatives. China's growing pool of chronically ill patients will turn to nefarious drugs to meet excess demand unmet within legal frameworks. As interconnected issues of facility underutilization, overprescribing, delayed approvals, and insufficient inspections cascade into one another, counterfeit drugs will continue to maneuver their way into an already stifled system.

One must also consider the shortcomings of providers themselves. Literature notes that, while a shortage of trained pharmacy professionals in developing Asian countries does not actively promote spread of falsified medicines, it is an additional challenge to quelling them. Those few specialists with the necessary minimum training to spot dangerous trends often work in the corporate industry as opposed to community pharmacies and are therefore not equipped to oversee the community pharmacy groups most affected (Buckley & Gostin, 2013, p. 11). The shortage is especially acute in China: as of 2010, there were only 185,692 licensed pharmacists or one pharmacist for every 7,380 people, which is much lower than in other developed countries (Fang et al., 2013, p. 523). A shortage of experienced professionals at the customer touchpoint is especially dangerous because medicine retail, as the last step in the pharmaceutical supply chain, is the most susceptible to manipulation.

Perhaps this shortage is due not only to a decrease in individuals entering the practice, but also a shift in the roles demanded of them. The 2009 healthcare reforms have demanded more from pharmacists beyond simple selling and dispensing of medication, but the educational programs churning them out are slow to modernize. While an explicit link between pharmacology education and demand for counterfeits has not yet been established, there are correlations suggesting that the gaps in pharmacology and holistic training certainly do not help.

One review (Fang et. al, 2013) suggests that the answer to creating a more skilled workforce lies with clinical pharmacy education. Beyond being experts on drugs, clinical pharmacists provide pharmacotherapy support during inpatient medical ward rounds in order to optimize drug selection and dose. They obtain extensive medication history, check medication and administrative errors, identify drug interactions, monitor adverse drug reactions (ADR), and offer supplemental patient counseling (Tahniyath, 2017, p. 60). Therefore, a shortage of Chinese clinical pharmacists presents several missed opportunities for intercepting counterfeits toward the latter end of the supply chain.

A clinical pharmacist's close work with detecting ADRs provides a potential avenue for detecting counterfeit reactions, especially in the case of patients who have acquired them unknowingly through online pharmacies. Special training allowing clinical pharmacists to apply theory to unique patient interactions could also alleviate fragmentation by ensuring that the facility is offering a level of care consistent with its resources. Most importantly, however, clinical pharmacists are vital for transparency and patient awareness. Learning of all available treatment and affordability options at the time of diagnosis would make it less likely that patients seek out counterfeit alternatives. Despite this, there is still no standardized curriculum for clinical pharmacology and the majority of programs in Chinese institutions emphasize the product over

the patient (Fang et al., 2013, p. 523). Existing discussions rarely link clinical pharmacy and counterfeit drugs with concrete figures, so additional research is needed to study this group's role in detection or interception.

The last and perhaps most cited threat permitting the spread of counterfeit drugs is China's notorious reputation for subverting intellectual property laws. In its 2020 Special 301 Report, the Office of the United States Trade Representative emphasized China's continued status on its Priority Watch List, a standing it has held since 2006. This designates China as a trading partner that does not "adequately or effectively protect and enforce intellectual property (IP) rights or otherwise denies market access to U.S. innovators and creators that rely on protection of their IP rights" (Office of the U.S. Trade Representative, 2020). While lack of IP enforcement undoubtedly poses a threat in many developing countries, the scope and inconspicuous nature of China's subversion tactics constitute a unique risk to the global market. Much research has been done on the extensive collection of "regulatory gambits" that China has imposed on its trading partners, especially those U.S. companies wishing to operate in China. According to a 2018 report from the White House Office of Trade and Manufacturing Policy, these tactics include but are not limited to: forced joint ventures and partnerships, discriminatory patent restrictions, intense security vetting, indigenous technology standards inconsistent with international norms, and localization of research and development (White House Office of Trade and Manufacturing Policy, 2018, p. 6)

A coerced partnership between multinational corporations and Chinese companies results in the involuntary and inorganic transfer of intellectual property during the manufacturing process, typically as a condition for accessing the Chinese market. In extreme cases, the Chinese company can be a majority shareholder in the MNC's operations—stripping the latter entity of the effective control essential for any foreign direct investment (OTMP, 2018, p. 6). China is also known for its

extensive, discriminatory patent approval process. China enforces a limited term on its foreign joint venture partners, typically 10 years, during which the foreign patent holder has exclusive control over the patent while in partnership with a domestic entity. China claims the right to use that foreign technology or IP in perpetuity even after the licensing or use term has expired (OTMP, 2018, p. 7).

In other cases, there is significant delay between the foreign company's intellectual property transfer to the domestic entity and its patent award, leaving a window for counterfeiters to exploit proprietary information accessible to the public. One such case was illustrated with Pfizer's launch of its drug Viagra into the Chinese market in 2000. Pfizer had not yet been granted a patent for sildenafil citrate (the active ingredient in Viagra) at the time of its announcement, allowing counterfeiters to obtain swaths of information on its plans from the State Intellectual Property Office's public disclosures (Bronshtein, 2008, p. 444). The counterfeiting group illegally manufactured the chemical and sought its own patent ahead of Viagra's release. Consequently, 90% of Viagra pills in circulation were already counterfeit within six months of its introduction into the market (Bronshtein, 2008, p. 444).

To worsen matters, these practices continue despite repeated promises of change from the Chinese government. Within the last decade, foreign criticism has not deterred these practices; it has simply pressured the Chinese government to become more allusive in its approach. China's unwillingness to set aside discriminatory gambits is partially bolstered by its position within international organizations. Since its entry into the WTO in the early 2000s, China has maintained strong latitude in convincing the organization to permit its protectionist barriers despite promises to gradually remove them (Bradsher & Mozur, 2007). Because China's global position and bargaining power within these forums continues to evolve, its implications for the changing

counterfeit drug supply chain warrant further discussion in later sections. These later sections will also address the steps China has taken to overcome these aforementioned regulatory and healthcare weaknesses while examining room for further improvement both within China and internationally.

CHAPTER 4

SUPPLY CHAIN GLOBALIZATION AND CHINA'S ROLE IN EMERGING COUNTERFEIT PHARMACEUTICAL TRENDS

This chapter explores *new* trends in the counterfeit pharmaceutical supply chain that have emerged within the last two decades as a result of Globalization 3.0, or non-state driven globalization. This section considers how these unprecedented factors and technologies have enabled actors within China to enhance their production, distribution channels, and legitimacy while evading law enforcement detection.

The systematic literature review has introduced well-corroborated research regarding the existing counterfeit pharmaceutical landscape. These findings, whether case-based or theoretical, have been synthesized through years of private and public sector projects, coalitions, and security assessments in an attempt to quantify the nature of the epidemic. Despite decades of investment and intelligence sharing, however, the catalysts and/or mechanisms bolstering the counterfeit pharmaceutical supply chain are more complex, elusive, and intertwined with global financial and governance systems than previously believed.

The last 20 years have brought on unprecedented methods for value and information exchange, many of which are facilitated by avant-garde technologies and software that had yet to be conceptualized prior to the turn of the millennium. American foreign affairs commentator Thomas Friedman famously articulated this post-2000 movement as “Globalization 3.0”—a phase characterized by the power of individuals, rather than states or companies alone, to leverage new platforms and compete globally (Friedman, p. 10). These platforms, such as the Internet, supply-chaining, informing, and wireless connectivity, are deemed “flatteners” because of their ability to

converge and connect billions of people throughout the world (Thomas Friedman, *The World is Flat*, p. 203).

This movement toward empowerment of the individual has immediate ramifications for the pharmaceutical supply chain because non-state actors and counterfeiters are increasingly adept at exploiting these same platforms and technologies for nefarious purposes. The dual-use dilemma, as this has been coined, presents lawmakers, pharmaceutical companies, and healthcare providers with an array of policy options ranging from risk retention (i.e. simply accepting the loss to public health, intellectual property, and eroded market share) to strengthening litigation capabilities and enforcement mechanisms in international coalitions. The challenge, therefore, lies in establishing a balance between complete market liberalization and isolationism. Considering the newly globalized landscape, how can governments, pharmaceutical companies, and healthcare providers secure their supply chains without compromising the benefits of globalization?

To answer this, one must first analyze how modern globalization has transformed the counterfeit drug landscape. Recent research has broached emerging trends, but some key conclusions and recommendations have been slow to implement or fail to fully consider all players that influence supply chain dynamics. To understand the implications of this evolution, one must look further into the relative influence that these new players exert and the constantly evolving mechanisms they use to do so. The principal goal of this analysis, therefore, is to fill the gap in disparate observations by evaluating them as stemming from a larger theme of non-state, non-Western driven globalization.

Trends discussed within this section are analyzed with particular attention to specific coalitions, tools, and communication mediums that have proliferated counterfeit drugs within the last 10 to 15 years. Although this list is far from exhaustive, three overarching issues are

underrepresented in pharmaceutical research and are crucial for national and public health security:

1) China's changing position within the global governance system; 2) the Internet and digital supply chains; and 3) The COVID-19 pandemic.

1. CHINA'S RISE TO GLOBAL PREEMINENCE

Since the start of the 21st century, academics and governments have debated the durability of the United States' ascendancy into international politics. Unipolar optimists insist that the U.S. has a unique set of advantages that make it untouchable by other global players, such as a wide military and economic gap, its benevolence and sensitivity to others' interests in multilateral forums, and the attractiveness of its ideology and culture (Layne, 2012, p. 204).

On the contrary, the United States' unipolarity is retreating. Globalization has disproportionately accelerated development worldwide. In other words, the rising tide of economic globalization may lift some boats higher than others. This new wave of globalization has undermined the United States' very status as the preeminent global superpower. The center of economic power has shifted away from the Euro-Atlantic region toward Asia—with China as its leader. However, the U.S. is partly responsible for China's surge; the Trump Administration's retreat from multilateral organizations like the WHO has left a power vacuum in global governance systems that China is more than equipped to fill (Youde et al., 2020, p. 2). Nevertheless, China's upward trend coincides with erosion of the United States' power. (Layne, 2012, p. 204).

Upon entering the WTO in 1999, China was given more latitude on protectionist measures with the understanding that these measures would gradually decrease as its economy developed. On the contrary, President Xi Jinping has been more resolute than his predecessors in resisting challenges to China's core nationalist interests. Although China showed willingness to abide by international norms at the beginning of the 21st century, the growth of Beijing's economy has seen

China adapt a much more ambiguous relationship with global governance institutions, either denying or showing indifference toward international norms and values.

This shift is particularly important for public health and the pharmaceutical industry. Notably, China has contributed much to global health governance over the last several years; for example, it has led the effort in treating malaria in Eastern Africa and has invested over \$123 million to the Ebola humanitarian response in Western Africa (Council on Foreign Relations, n.d.). In doing so, however, China has devised its own set of health governance standards and protocols that complicate existing multilateral attempts at public health cooperation. The Council on Foreign Relations notes that China administers aid opaquely and unilaterally and asks countries to approach it for support rather than publishing formal requests for aid proposals (Council on Foreign Relations, n.d.).

Also consider China's increasing investment in Uganda since 2010. China moved into Africa "in its own way, with the government, state-owned companies, and private businesses all doing deals on their own terms, avoiding involvement with international organizations that work on health, education, and poverty reduction" (McLaughlin, 2013). Without independent oversight, Chinese clinics and treatment centers may do more harm than good by cutting corners, introducing counterfeit artemisinin combination therapy not yet approved by the WHO, or otherwise introducing counterfeits into countries receiving Chinese aid. For Ugandans, China's alternative to Western aid has mostly harbored resentment—they attribute the deluge of fake drugs in Kampala and lack of quality care at malaria clinics to a greater Chinese presence in the region. There is significant potential to influence drug regulations with bilateral aid packages that operate outside of global governance and institutional frameworks; therefore, the U.S. should acknowledge these tools and reprioritize this knowledge through the lens of counterfeit drugs.

The second argument supporting China's increasing involvement in counterfeit distribution is its position as a primary exporter for pharmaceuticals, and one upon whom the U.S. is heavily dependent for its drug supply. Chinese economist Li Daokui recently noted that China understands its strategic influence in the sector: "We are at the mercy of others when it comes to computer chips, but we are the world's largest exporter of raw materials for vitamins and antibiotics. Should we reduce the exports [in the trade war], the medical systems of some western countries will not run well" (Ferry, 2020). To further illustrate the United States' growing reliance on China, also consider that China supplies nearly 80% of all APIs used in U.S. drugs and that the tariffs proposed in 2019 would have excluded pharmaceuticals and their inputs, underlying U.S. reluctance to curtail drug imports from China (Huang, 2019). As the supply of all drugs coming from China increases, it follows that the proportion of those that are counterfeit or substandard will increase proportionately.

Lastly, a discussion on Chinese global influence would not be complete without considering the country's recent massive infrastructure investments and their impact on world trade. During visits to Kazakhstan and Indonesia in 2013, president Xi Jinping announced his Belt and Road Initiative (BRI), an ambitious collection of railways, pipelines, border crossings, and highways throughout Central and Southeast Asia that would increase regional economic integration and widespread use of the Chinese renminbi currency. Its scope is massive, proposing an overland Silk Road Economic Belt extending to Eurasia (reminiscent of the ancient Silk Road), a Maritime Silk Road extending throughout South and Southeast Asia, and various economic zones with China as their hub. To some, it has been seen as a symbol of China's growing soft power—the United States and other Asian countries are equally concerned that the initiative could be a "Trojan horse" for Chinese military expansion (Chatzky & McBride, 2020).

What does this mean in terms of counterfeit drug movement? It is difficult to fully grasp the immediate implications on transnational organized crime because the project has no publicly stated KPIs, does not conform to western ideas of institutionalization, and has ambiguous timelines and membership protocols (Shepard, 2020). While the BRI's exact impact on counterfeit pharmaceuticals is underrepresented in current research, the large-scale cross-border movement that it facilitates nearly guarantees an uptick in transnational organized crime. The extensive railway system proposed under the BRI would undoubtedly give counterfeiters an easier and cheaper way to transport falsified medicine. Furthermore, there is a mistaken belief that because the majority of regional trade still occurs through the South China sea corridor, brands should not be concerned with the growth of counterfeit supply chains through land routes created through the BRI. On the contrary, one case study from Italy shows that China and Hong Kong are the main sources of counterfeits coming into Italy. More counterfeits trickled into Italy not long after the BRI launched—pharmaceutical products were seized on 30 separate occasions in Italy during 2014-2016 alone. These patterns suggest that more counterfeit goods will be supplied from China through the Belt and Road Initiative in the future (Bandini, n.d., p. 6).

China's Belt Road Initiative also threatens to foster counterfeit pharmaceutical trade insofar that it establishes strategic partnership with the Greater Mekong Subregion (GMS). This region, made up of Cambodia, Laos, Myanmar, Thailand, Vietnam, and China's Yunnan and Guangxi autonomous regions, is a documented hotspot for multiple types of transnational organized crime, with trafficking of falsified medicines totaling between US\$520 million and \$2.6 billion (United Nations Office on Drugs and Crime, 2019). The BRI will provide many benefits for regional economic integration but will also "present significant non-traditional security challenges to this region because the countries lack adequate safeguards to prevent cross-border

criminal activities” (Luong, 2020, p. 25). There is little doubt that added infrastructure under the BRI will enable the counterfeit drug and transnational crime epidemic to expand its borders beyond the GMS, so more research should be done on the relationship between Belt Road-Mekong interconnectivity and counterfeit drugs.

2. THE INTERNET AND ONLINE PHARMACIES

With more than 4 billion active users worldwide, the internet has become a common medium for individuals to communicate, exchange information, and participate in e-commerce to purchase everyday goods and services. With this newfound freedom and ease of use, however, come tens of thousands of additional routes and web domains through which counterfeit drugs can travel into the homes of unsuspecting users. This most recent wave of globalization has made it quite evident that for every groundbreaking and simplifying technology, there are twice as many complexities whose risks must be closely considered. The same facilitating tools that allow the majority of the population to “plug and play” are the same ones that can be criminally exploited—often leaving public health and safety hanging in the balance.

Citizens and public officials in developed countries should not consider themselves immune to the growing prevalence of counterfeit drugs via the web. On the contrary, it is a ubiquitous issue that the largest interagency coalitions—even INTERPOL’s world-renowned Operation Pangea—have yet to fully quantify or contain. Due to its relatively strong regulatory authorities and border patrol, the U.S. is far less likely than developing countries to see counterfeit drugs transported in bulk and sold in underground street markets. However, this means that U.S. consumers are relatively more vulnerable to online channels, perhaps because they are more trusting of professional-looking websites and are less adept at identifying suspicious medications. Indeed, the fact that counterfeit pharmaceuticals are credence goods with sophisticated masking

technology has made it difficult for the FDA and other overseas regulatory agencies to properly teach consumers how to spot them early on. A survey from the National Association of Boards of Pharmacy confirms that the U.S. is not immune: from 10,000 online pharmacies surveyed, over 97% did not meet the NABP's patient safety and pharmacy practice standards or otherwise violated U.S. state and federal laws (U.S. Government Accountability Office, 2014, p. 38).

China is one of the most dangerous perpetrators with respect to unlicensed internet pharmacies. A 2019 study with LegitScript and the Association of Safe Online Pharmacies evaluated Chinese search engine data and found that of all internet pharmacies originating in China, 57% were operating outside the scope of Chinese law and regulation (LegitScript, 2019, p. 37). According to John Clark, a global security expert and former Pfizer Chief Security Officer, illegitimate online pharmacies out of China are a growing threat capable of circumventing the U.S.'s closed drug supply system (PhRMA, 2011).

Despite the FDA's programs to raise public awareness of the issue, illegitimate online pharmacy operations persist due to extremely well-crafted marketing methods that make it difficult to differentiate them from legitimate websites (U.S. Government Accountability Office, 2014, p. 38). Though not exclusive to China, rogue pharmacies furthermore feign legitimacy by purporting to be Canadian, a country known for cheaper legitimate prescription drugs (Chaudhry, 2009, p. 53). Many entice customers with their convenience and ease of use, as they often do not solicit a prescription and require only a credit card (Shepherd, 2010, p. 1) or a quick online questionnaire. The same LegitScript project also found that rogue internet pharmacies in China post fake NMPA certificates, making it seem as though they are compliant with Chinese pharmaceutical regulations ("China's policies on Internet pharmacies," 2013).

Rogue Chinese internet pharmacies are especially dangerous because they often feed into other criminal offenses, such as fraud and money laundering. Prior cases involving secondary use of money laundering to wash funds suggests that these pharmacies could be at the heart of malignant transnational organized crime networks, generating more revenue and claiming more victims than current government intelligence would suggest. The link between online pharmacies and TOC is not totally understood but is substantial; the regulatory gaps that exist against the former have attracted the latter, threatening state sovereignty, global security, and cybersecurity (Mackey & Liang, 2013, p. 3). Thus, the emergent issue of counterfeits through online pharmacies appears much larger than law enforcement ever imagined possible.

China's use of internet and technology platforms to facilitate counterfeit drug trade is also unique from other countries in that perpetrators operate far beyond their traditional website domains, using third-party platforms to actually contact customers and process transactions. Furthermore, marketing, product listings, and payment processing are often split up between social media, e-commerce, and messaging platforms respectively, making evidence collection difficult for law enforcement investigations. This tactic of marketing pharmaceuticals directly to the end consumer rather than health professionals, coined DTCA (direct-to-consumer advertising), is formally outlawed in China but has become increasingly difficult to control with the explosion of the internet. A recent study examining popular Medicine 2.0 technologies found that "illicit 'no prescription' eDTCA promotion by a fictional online pharmacy was easily accessible and reached a number of global users in diverse countries, including developed countries, low-and-middle income countries (LMICs), as well as certain emerging "BRIC" countries (i.e., Russia and China)" (Mackey & Liang, 2013, p. 3). Popular among these platforms is WeChat, a messaging app launched in 2011 by international technology conglomerate Tencent. Hosting over one billion

users, the messaging app has supplemented rogue internet pharmacy operators by providing them with anonymity and an outlet to process payments, making it difficult to trace funds back to the original drug listing. Overall, WeChat is used as a primary contact method via its messaging feature, for promoting the business via its social media feature, and for processing payments via the integrated Tenpay option (LegitScript, 2019, p. 21). Real but unregulated medicines have also been transacted within WeChat, but in multiple cases pharmaceuticals were found to contain insufficient active pharmaceutical ingredients (LegitScript, 2019, p. 16).

3. THE COVID-19 PANDEMIC

The COVID-19 pandemic has underscored major weaknesses across all major industries and national governments. It has pushed global supply chains to their limits and introduced unprecedented uncertainty into the world's financial markets, businesses, workplaces, schools, and homes. The pharmaceutical industry is no exception to this dilemma and has in many ways been one of the hardest hit with regard to the resource hardships and externalities related to public health misinformation. We are seeing the start of what the WHO has termed an “infodemic”—the risks associated with an excessive volume of information regarding COVID-19, including “false prevention measures or cures that pose concerns for the public to distinguish fact from fiction, and for government agencies to conduct evidence-based policymaking” (Erku et al., 2020, p. 1955). This misinformation instills unfounded fears in the general population and undermines people's receptiveness to legitimate public health advice and precautionary measures. The net result is that there has been a surge in counterfeit medicine sales, stemming from both demand-side misconceptions about COVID-19 itself and a supply-side surge from those eager to exploit the general population's fears.

First, COVID-19 has altered the counterfeit drug dynamic in the sense that it has broadened what constitutes a “counterfeit”—instead of drugs containing insufficient or no API, some substances touted as COVID-19 treatments have legitimate APIs but are designed for use with other medical conditions and therefore have no documented efficacy in treating COVID-19 infection. These drugs, while technically sourced from licensed manufacturers, are counterfeit in that they are deliberately misrepresented with respect to their identity and treatment purpose. They are only successful when used in conjunction with the conditions they were designed to treat, so their abuse in COVID-19 treatment could cause worsening symptoms or harmful side effects. One notable trend is stockpiling of hydroxychloroquine, which U.S. President Donald Trump promoted as “very powerful” and a “game-changer” despite no significant scientific proof that it would benefit COVID-19 patients.

The FDA revoked emergency use authorization of the drug in June 2020, but not before companies had widespread misbelief about its use and donated nearly 63 million doses to the Strategic National Stockpile. This stockpiling has created shortages of the drug for conditions where it has been proven effective, such as malaria, lupus erythematosus, and rheumatoid arthritis. This misinformation pattern could jeopardize public health of African countries, for example, given that a strong majority of global malaria cases and deaths occur in the region. Furthermore, the drug is being redirected for treatment where its benefits are little understood and supported by only a few clinical trials. A randomized, controlled trial from February 2020 published by Chen Z. et al. (as cited in Erku et al., 2020) compared the efficacy of standard COVID-19 treatments with a combination of standard treatments and hydroxychloroquine and found that the latter “significantly shortened” clinical recovery time and body temperature recovery time ($p = 0.0476$). However, the study had a small number of cases ($n = 68$) and data further warns that long-term

application of hydroxychloroquine could pose detrimental side effects to be taken seriously such as retinopathy, cardiac arrhythmias, severe hypoglycemia, agranulocytosis, and thrombocytopenia (Erku et al., 2020, p. 1958). This highlights the public health sphere's battle with anchoring and confirmation bias among the public—while the majority of clinical trials have deemed it unsafe for COVID-19 treatment, it continues to be justified by desperation for a quick cure. Although the drug might not be considered “counterfeit” under current WHO standards, it should be seen as equally deceptive and cannot be separated from the larger counterfeit crisis. The WHO has stated that clinical trials confirm “hydroxychloroquine does not prevent illness or death from COVID-19” (World Health Organization, 2021), but the infodemic has politicized healthcare and diminished the influence of legitimate public health guidance in ways never before seen with counterfeit drugs.

China in particular has been quick to take advantage of the demand surge around hydroxychloroquine. India, the largest producer of hydroxychloroquine, sources its raw materials from China. In an interview with the Financial Times, the managing director of pharmaceutical company Zydus Cadila, Sharvil Patel, hinted that China has price gouged in light of demand for the drug: “They just say they don't have material, and when you pay them five times more, 10 times more, then they get material” (Findlay & Yu, 2020). Chinese suppliers later confirmed that they increased ingredient prices 375% and adjusted contracts with Indian buyers because its government contracts for hydroxychloroquine were of higher priority (Findlay & Yu, 2020). To a certain extent, China has worsened the misinformation crisis by knowingly enabling its distribution despite evidence of its dangers, all the while exacerbating financial hardships for countries seeking a cure.

The COVID-19 pandemic has also made the supply chain less secure by causing a shortage of essential medications. The sudden demand spike for certain pharmaceuticals in the wake of the pandemic has been of such great magnitude that it has exceeded manufacturers' capabilities for maintaining an adequate supply level (Choe et al., 2021, p. 1). Furthermore, many of the common drugs used in COVID-19 treatment such as vasopressors, sedatives, and injectable solutions were already at risk of shortage even before the pandemic (Choe et al., 2021, p. 1), making them especially susceptible to supply chain insecurity. It does not help that the healthcare sector has steadily offshored its manufacturing within the last decade. The projection that Asian countries will dominate the global economy within the next decade has incentivized pharmaceutical firms to relocate factories to the region. Even though offshoring provides opportunities for greater efficiencies, its net effect during the pandemic has been to create more fragmented supply chains that could have disastrous ramifications in a healthcare context (Kajjumba et al., 2020, p. 3). This "bullwhip" effect cascading through the entire supply chain has led to calls for drug companies to onshore operations in order to guarantee reliable supplies. Nevertheless, overseas workforce shortages and shipping delays caused by the global lockdown will continue to impede efficient medication supply in the immediate future.

Because of this, it has been significantly easier for bad actors to capitalize on this shortage by filling the gap and disguising counterfeits as readily sought essential medications. According to John Leonard, Executive Director of Trade Policy and Programs at U.S. Customs and Border Protection, the "pandemic and resulting supply shortages have incentivized counterfeiters to create products that could endanger your health rather than protect it" (KSDK News, 2020). While the CBP has seized everything from falsified N95 masks to cleaning products, even more concerning are seizures of falsified coronavirus drugs such as an unauthorized Chinese L24 pill used in

influenza treatment. From statistics on 2020 CBP seizures, Leonard further concluded that most of it is made in Asia but particularly in China (KSDK News, 2020).

Counterfeiting has persisted even with a vaccine in sight. Despite the expansion of the vaccine rollout scheme under the Biden administration, shortages persist largely because the Trump Administration's decision to limit federal involvement has left each state to devise its own distribution plan. Tension, miscommunication, and mistrust have mounted among health experts and government authorities as they combat the mountain of logistical challenges associated with quickly designing and fine-tuning such a complex program (Hennigan et al., 2021). For the average American, this materializes as ongoing frustration over appointment unavailability and lack of clarity regarding phase eligibility. In early February, representatives from Prisma Health and the Medical University of South Carolina had only received a fraction of their weekly vaccine allotment, leading to appointments being rescheduled or canceled altogether without warning (Wakeman, 2020). The shortages are not limited to the U.S., however—the European Union has been struck hard with what the New York Times deems a “full-blown crisis,” with Spain becoming the first country to suspend immunizations in early March due insufficient doses. Furthermore, “many countries, particularly poorer ones, are struggling to secure any vaccine at all” (“E.U. Vaccine Shortages Snowball Into a Crisis,” 2020).

As with other aforementioned COVID-19 treatments, counterfeiters have been swift to respond. In mid-February 2021, details were released regarding the arrest of a Chinese man who profited more than 2.78 million dollars by passing off syringes of saline solution and mineral water as a coronavirus vaccine. More than 600 were shipped to Hong Kong for overseas smuggling to undetermined destinations, sold under the guise that the vaccines were sourced internally from real manufacturers. Counterfeit vaccines have also been distributed at exorbitant prices in Chinese

hospitals and have even been administered in distant rural areas by criminals posing as village doctors. The Chinese government has confirmed these are not isolated incidents, with this man being one of 70 in China recently arrested for this type of infraction (“China arrests leader of fake vaccine scam,” 2021). It should be noted that there is a small possibility that the real vaccine is distributed through unauthorized channels; however, given the stringent storage requirements for many vaccine types, it is highly unlikely that it could be transported by a third party without its quality in some way being compromised. To make matters worse, the influx of misinformation, phony treatments, and shortages of safe treatments coincide with a drop in regulatory oversight. Travel restrictions due to the pandemic have entirely precluded FDA inspection of manufacturing plants in China, making it more likely that inferior coronavirus treatments will enter the U.S. (Choe et al., 2020, p. 2).

CHAPTER 5

HAVE EXISTING INITIATIVES ADDRESSED NEW CHALLENGES?

This section highlights key measures from the U.S. and China that have already been taken to address the counterfeit drug epidemic. However, in light of the new information presented in Chapter 4, these projects should be redesigned or reconsidered to better respond to these unique threats. Although this is not an exhaustive list of measures undertaken, these projects best fell within the scope of this research.

CHINA’S NOTABLE ANTI-COUNTERFEITING INITIATIVES AND SHORTCOMINGS

One of China’s largest and most recent anticounterfeiting overhauls came in August 2019, with the amendment of its Drug Administration Law first introduced in 1984. This legislation comprehensively governs all things related to drug manufacturing and usage in China, such as citizens’ right to health, standardization of online drug sales, defining fake drugs, and punishment and liability for criminal infractions therein. TraceLink, a pharma digital supply and tracking software, has summarized the following as improvements under the amendment:

- The establishment of a drug traceability system based on NMPA drug traceability standards and specifications and designed to ensure that all information generated in drug research, manufacturing, distribution, and usage is true, accurate, and traceable
- Ensuring the country’s drug supply through a monitoring system
- Establishing a pharmacovigilance system for drugs distributed in China
- Enhancing the existing drug registration system
- Increasing specific penalties for non-compliance. (“Must-Know China Track and Trace Compliance Terms,” 2020)

Critically, the amendment also changes the definitional scope of “counterfeit drug.” Genuine drugs are no longer considered counterfeit simply because they have not been approved within China, although their importation and manufacture still require a drug registration approval certificate. Those dealing genuine but unregistered drugs within China will still be in violation of applicable laws but will not be charged with manufacturing and importing counterfeit drugs, a crime which often carries much steeper penalties. This reprioritization is significant because it will perhaps free up necessary resources and staff to crack down on actual falsified and substandard medicines, which is especially crucial given the NMPA’s existing staff shortages and inspection delays.

The 2019 DAL also makes provisions for the creation of a drug traceability system that will further monitor quality of drug production, facilitate risk controls and recalls, and intercept counterfeit and inferior drugs (“Must-Know China Track and Trace Compliance Terms,” 2020). There is clear evidence that China is taking measurable steps to improve policing of counterfeit drugs, but it should be noted that implementation dates for these additions are either loosely held or have not yet been provided. A Track and Trace system had been discussed as early as 2015, but complications over the recall of expired vaccines from producer Changchun Changsheng Life Sciences Ltd. a few years later proved that there is still much work to be done on China’s path toward establishing a traceability system. Increasing specific penalties for non-compliance might not be entirely effective given the limited success of prior fines. For counterfeiters, whose profits go into the millions, existing penalties for counterfeit pharmaceutical production “are considered a mere cost of doing business in China, rather than a deterrent from engaging in counterfeiting” (Bronshtein, 2008, p. 438) Assuming the economic rationality of counterfeiting criminals, China should also work to increase the certainty and celerity of punishment rather than its severity.

The last 10 years have also seen more Chinese public-private partnerships to leverage shared anticounterfeiting intelligence. Back in 2013, the leading Chinese search engine company Baidu received access to the SFDA's (now the NMPA) databases on certified drugs, OTC drug instruction manuals, and registries of certified online drug stores. When Chinese web users search for online drug stores, Baidu's software will automatically display a "certified" tag next to those approved by the NMPA. Similarly, searches of drug brand or generic names will yield their NMPA approval number, producer, description, and dosage (Qing, 2013). However, most rogue online pharmacy operators are skilled at resurfacing days or weeks after being closed by using obscure or unsuspecting domain names; therefore, public-private anticounterfeiting partnerships in China should be expanded into ongoing, long-term projects.

NOTABLE U.S. AND INTERNATIONAL ANTI-COUNTERFEITING INITIATIVES AND SHORTCOMINGS

In 2011, the Counterfeit Pharmaceutical Inter-Agency Working Group's report to the Vice President and Congress addressed the nascent but growing threat posed by rogue online pharmacies illegally distributing pharmaceuticals throughout the supply chain. Then White House Intellectual Property Enforcement Coordinator Victoria Espinosa encouraged private sector participation and resources in limiting the reach of these rogue websites. From this report came a number of recommendations, one of which is the adoption of a federally regulated Track-and-Trace System. This interoperable system allows for comprehensive tracking of a pharmaceutical drug at any point through the supply chain, identifies those responsible for unsafe products, and facilitates recall of those products.

Congress subsequently enacted the Drug Supply Chain Security Act (DSCSA) on November 27, 2013, establishing a track-and-trace system set to be fully implemented by 2023. A

10-year implementation is an obvious limitation, as other countries like China, Iran, the Philippines, and the EU have pledged to have comparable systems introduced by 2015, 2014, 2015, and 2019, respectively (World Health Organization, n.d., p. 25). Certain provisions under this law have put the FDA in charge of initiating preparatory pilot projects that coordinate multiple stakeholders throughout the supply chain such as manufacturers, re-packagers, wholesale distributors, and dispensers. The FDA's work throughout the last seven years has been nothing short of critical; it has explored key issues related to utilizing product identifiers for product tracing, parties' technical capabilities and data quality, investigation protocol for suspected or illegitimate products, and barcode readability (ECA Academy, 2019).

However, because the DSCSA Pilot Project Program must operationalize all supply chain security requirements, there have been numerous complications identified with such a large-scale project. These include, but are not limited to, processes related to the requirement for manufacturers to affix or imprint a product identifier to each package; readability of a barcode, including impact of environmental and human factors; interoperability issues relating to the type of database used and system architecture among trading partners; use of technical standards for defining data attributes. Multiple concerns have also been raised regarding the extent to which these pilot projects can effectively simulate the mix of products and packaging in the supply chain, target known weaknesses, simulate likely illegitimate products, and provide useful information to trading partners within a reasonable time frame (Federal Register, 2019).

Phase 1 Lot-level traceability was supposedly achieved in 2015. The real challenge has yet to come, however—unit-level traceability scheduled for 2023 requires that each item have a unique product identifier in addition to a lot identifier. This will put unprecedented strain on IT and documentation among different supply chain levels. One serialization software company noted

that the FDA's failure to standardize data formats has hindered anticounterfeiting efforts. According to them, "perhaps the greatest challenge has been the need for all companies in the chain to communicate with each other . . . a single 3PL, wholesale distributor or pharmacist may receive documentation in a variety of different formats. They [documentations] all have to be understood, they all have to be processed, they all have to be stored and they all have to be capable of production on request" (Souza, n.d.). A final weakness identified in the DSCSA Pilot Program is its voluntary participation. Although the FDA has ensured that those selected reflect diverse facets of the supply chain, fewer participants could mean less expertise to anticipate rogue online pharmacy trends and techniques.

A second initiative publicized in the CPIWG's report is the Center for Safe Internet Pharmacies, a nonprofit founded in December 2010 aimed at protecting consumers against illegitimate online pharmacies. It constitutes one of the first major anticounterfeiting measures from the private sector, coordinating efforts and funding from large companies like Google, GoDaddy, American Express, MasterCard, Microsoft, Neustar, PayPal, Visa, Network Solutions, and Yahoo. The CSIP is particularly promising in solving the illegitimate online pharmacy crisis as its approach targets both the domain and payment processing sides. Members have been able to share information about suspected rogue pharmacies, whitelist known legitimate sellers, create educational campaigns for the public, and work with law enforcement in investigating and prosecuting those running the sites (Higgins, 2010). The nonprofit has made critical advancements since its inception—between November 1, 2011 and December 1, 2012, its members took over 3 million collective actions in shutting down their websites, blocking advertisements, and blocking payments (U.S. Government Accountability Office, 2014, pp. 32-33).

The nonprofit is not without its criticisms, however. Gabriel Levitt, then Vice President of PharmacyChecker.com, a company that verifies online pharmacy credentials, ridiculed the CSIP as a profiteering scheme for Big Pharma. Companies such as PharmacyChecker.com aim to address the U.S. drug affordability issue by increasing public awareness of safe but less expensive alternatives; therefore, legitimate criticisms have been raised that CSIP is less concerned with consumer safety than it is with intellectual property rights of major pharmaceutical companies. Some evidence suggests that CSIP is the “brainchild” of the Alliance for Safe Online Pharmacies and has sponsored an information clearinghouse of reports and studies coming almost exclusively from ASOP and other partners like LegitScript and the National Association of Boards of Pharmacies. ASOP was founded in 2009 with the position that “Americans should only have access to U.S. online pharmacies, essentially only those approved under standards adopted by the National Association of Boards of Pharmacy (NABP) . . . NABP’s president-elect has worked for Walgreens, the biggest U.S. pharmacy chain, since 1977” (Levitt, 2014). As Levitt notes, this poses a potential conflict of interest: CSIP’s website has a search portal for consumers to identify “legitimate” online pharmacies, but this register relies on LegitScript’s NABP-approved database. Through this functionality, Levitt claims, Google and the other CSIP members are scaring Americans away from all non-U.S. online pharmacies even if these pharmacies are deemed safe by other international safety standards (Levitt, 2014).

A final initiative worth mentioning is Operation Pangea, an international effort coordinated by INTERPOL in 2008 to disrupt the online sale of counterfeit health products. Since its inception, Operation Pangea has seized over 105 million counterfeit pills, ampoules, sachets, and bottles from circulation and made over 3,000 arrests. The project has uncovered new trends such as sending medicines in smaller parcels and concealing them among other legitimate goods such as DVDs,

clothing, bedding, and food (“Operation Pangea,” 2019). Furthermore, because Operation Pangea is updated on a yearly basis, its member agencies have been able to compile best practices and lessons learned from previous years’ work to allow for a more robust COVID-19 response. Operation Pangea is worth noting here because it has been among the most responsive projects fighting counterfeit drugs relating to the COVID-19 pandemic. In its latest version launched March 2020, more than 90 member countries identified over 2,000 links to coronavirus products and seized unauthorized antiviral medications, chloroquine, vitamin C, painkillers, and antibiotics. Small parcel shipments were also less common, likely due to the global shutdown and shipping delays (Galletti, 2020).

However, Operation Pangea has also given stakeholders the ability to expose the sheer magnitude of the counterfeit drug problem, especially the extent to which it has infiltrated the Internet and public health response to the COVID-19 pandemic. The findings of Operation Pangea just within the last year have confirmed that earlier projections in EUROPOL’s March 2020 report are very real but that the rate at which they are unfolding is significantly quicker than predicted. In spite of all of its accomplishments, Operation Pangea is still a short-term fix—as long as the Internet and the global pandemic are a reality, illegal online pharmacies will reappear as quickly as they are shut down. INTERPOL’s work has shown that there is still much to be done and adapted if governments and firms are to fully comprehend the newly globalized counterfeit pharmaceutical supply chain, its inner workings, and the strategies employed by its major players.

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